WHITE PAPER

CONSIDERATIONS FOR CONNECTOR DESIGN IN MOBILE AND PATIENT-WORN MEDICAL DEVICES

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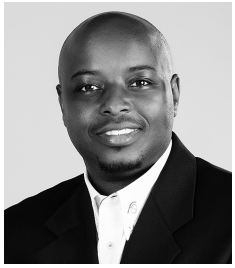
fischer® CONNECTORS

THE **RELIABLE** EXPERT

CONSIDERATIONS FOR CONNECTOR DESIGN IN MOBILE AND PATIENT-WORN MEDICAL DEVICES

CHALLENGES FACED BY DESIGNERS OF MEDICAL DEVICES ARE AMONG THE MOST STRINGENT IN THE WORLD. EVERYTHING DESIGNED AND MANUFACTURED MUST BE SAFE FOR THE PATIENT AND SAFE FOR THE OPERATOR.

Devices can be put through years of U.S. Food & Drug Administration (FDA) trials, with additional tests in Europe, so reducing the risks associated with any device is paramount in the designer's approach. This white paper takes a look at the increasing need for mobile and patient worn devices, and makes recommendations on proper approaches to designing interconnect solutions for those applications.



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Patrick Kinyanjui is a Senior Engineer at Fischer Connectors Inc., an ISO 13485:2016 certified supplier with a nearly 60-year history of working with medical product manufacturers to develop and produce innovative electronic connectors and cabling for use in medical applications. He has extensive experience in electro-mechanical design and manufacturing. He has been in the connector and cable industry for over 10 years, working with a wide range of military and medical companies to determine the best connector and cable solution for their particular applications.

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INTRODUCTION

You have the biggest challenges. Medtech designers face some of the most stringent requirements in the world. Everything must be safe for the patient and safe for the operator. In addition, devices can be put through years of U.S. Food & Drug Administration (FDA) trials and trials in Europe, so reducing the risks associated with any device is paramount in the designer's approach.

Every device must satisfy a different set of parameters, because every detail is based on how the device will be used, who will be using it, and how long it will be used. The design team needs to know whether trained medical professionals will be operating devices now, or whether patients are the end users. Is it meant to be disposed of after a few uses, or is it expected to last for years? New in the question set: Will it be used in a dedicated clinical/hospital setting, or will it be carried from place to place? All these usability questions must be answered early in the design cycle, because you certainly don't want to start thinking about this just before trials.

Along with ensuring a device is low risk, reliable, and functions to the highest expectations of a diverse base of medical professionals and their patients, manufacturers must meet another level of design challenges. Devices must look modern, provide a positive patient experience, include more technology and functionality in a smaller space, and work in an increasingly global market.

Connectors and cable assemblies play an important role in all these trends, as they deliver power to hand tools and handheld diagnostic equipment, and return signals to mobile consoles and surgical systems. They work with sensors to keep warming blankets at the right temperatures and can even be part of vests, jackets and other clothing that is important to measuring and maintaining a person's health. Selecting the right connector and cable assembly solution can help build small, safe, stylish, and functional devices that hit the right price point to keep manufacturers competitive while keeping risk low for both the patient and the operator.

Because Class III medical devices (implantables) carry much more stringent FDA rules and oversight, this white paper addresses the challenges of designing Class I and Class II devices only.

MEETING FDA REQUIREMENTS

To meet FDA requirements, every medical device must first be classified according to its risk level. Class I devices are low-risk, like an external diagnostic device or control, and need very little in the way of government regulation to make it to market. Class II devices carry moderate risk, like electric wheelchairs or infusion devices, and therefore require more oversight to ensure they're as safe and effective as consumers would expect them to be. Class III devices have the highest risk, like replacement heart valves and other implanted devices, and thus are subject to the highest degree of regulatory control.[1]

This paper only deals with Class I and II devices, but the approval process for these devices is still sufficiently stringent. Most Class I devices and a few Class II devices are exempt from Premarket Notification 510(k), but for those that aren't, the manufacturers must prove to the FDA that the device is "substantially equivalent" to one that's already legally on the market. If it is not, the premarket approval (PMA) process must be followed, which includes clinical trials and other data to show there is sufficient scientific evidence that the device is safe, effective, and useful.[2] Every part of each device must pass the test, down to the connectors and cables.

CRITICAL CONSIDERATIONS

With some medical devices, unexpected failure can be a nuisance and an extra expense; with others, it can be the difference between life and death. It is important to know through how many mating cycles the connector will be expected to last, whether an untrained patient or a trained medical professional will be operating and sterilizing it, and what kinds of conditions the device will need to endure. The answers to questions like these will affect details like the material choice, the sealing level required, and what type of mating mechanism to use.

Sterilization is a vital aspect of protecting patients' health, but different devices will endure different sterilization methods. Some may be submerged in water or cleaned with liquid chemicals, while others may be subjected to a steam autoclave or irradiated. Depending on the situation, specially designed rugged connectors may be necessary. Some circumstances may call for cost-effective disposable connectors instead.

If the device will be cleaned with liquid or subjected to dusty environments, the IP rating will be critical. Described under IEC standard 60529, it rates the degree of protections against solid and liquid ingress, so it's possible to choose a connector based on a specific end-use environment rather than vague terms like “waterproof.” IP68 can be defined somewhat differently from one manufacturer to another, so when choosing a connector for a medical device, it's important to ensure that the particular manufacturer's IP68 rating matches or exceeds the conditions expected for the device. For Fischer Core Series connectors, tests for environmentally sealed products are standardized to IP68 at a depth of two meters and a duration of 24 hours.[3]

The need to shield connectors from environmental hazards also includes shielding them from electromagnetic interference (EMI/RFI), which can introduce anomalies into data, cause a device to move when it shouldn't, or prevent a device from operating. So many ordinary electronics emit EM energy that, depending on the medical device's end use, it's reasonable to plan on including EMI/RFI shielding to ensure reliable data transmission.

At-a-glance: Consideration for wearable, patient-worn connectors	
Connector Size	Take a close look at who will be managing the connection. A patient who is sick and self-managing will have different needs than a caregiver or medical professional. Make sure your connector is small enough to help keep design in line, but large enough for anyone to get a good grip on it. In addition, keep an eye on the profile of the connector. The lower, the better when it comes to wearables.
Connections for Patient Mobility	If you are looking at mobility, look at how and how much the patient will be moving. Lots of mobility will mean a different set of design considerations than if a person is bedridden. New options for the most mobile patients include connectors with concentric rings that allow movement of the cable, making it less likely to be damaged over time.
Connector Torque	Many connectors are purposely designed so that it is hard to connect or disconnect. Make sure that the connector is easy enough to connect and disconnect, but difficult to accidently disconnect.
Shape & Locking Types	We admit to bias here, but we think circular push-pull connectors are perfect for wearables, with no little tabs to break off, rectangles to challenge your spatial awareness, or USB-type hassles when you can’t find the right way to place the connector into the receptacle no matter how many times you turn it over. Circular connectors also have quick-release/no lock solutions or if you need it to stay in place in high vibrations, look for a screw lock.

Cable Management	Wearables and devices that move around a lot require pre-planning for cable length and how the cables need to move with the person or the device. Think about sewing cables into clothing to minimize a patent's ability to damage or tangle them. Make sure there is enough (but not too much) cable. You may want to consider offering different lengths of cable. Robotic devices and exoskeletons with embedded sensors also need protected cable systems.
EMI Shielding	The more technology in the area, the more you need EMI shielding to protect the system from the noise. But you can't skip EMI protections just because a product will have in-home use. Medical devices are critical, and you can't predict electrical interference on that alone.
Color	The more connectors, the more color-coding you want to consider. Minimize the number of colors needed with multi-use connectors for signal and power or air and signal. Look at materials that can be ordered in different colors, or rings that match connector or cable colors.

THE PATIENT EXPERIENCE

Over time, there has been a shift toward self-care and collaborative care. Lifespans have continued to increase, care for chronic conditions has become more important, consumers have been seeking ways to lower medical expenses, medical devices have become smaller and cheaper, and consumer-level health trackers have shifted expectations toward a more democratic approach to healthcare.

The global market for wearable medical devices is projected to approach US $10 billion by the year 2023, with wearable heart rate monitors and electrocardiographs projected to do especially well.[4] The U.S. Bureau of Labor Statistics has projected that home healthcare services will be the industry with the largest wage and salary employment growth between 2014 and 2024, with a compound annual growth rate of 4.8%.[5] All this reflects the desire to put healthcare in the hands of patients, and creates additional pressures to ensure that interconnect solutions must perform perfectly in less-than-sterile conditions.

With more self-care comes a greater need for patient adherence, which is affected by the way the device is designed. A medical device for home use should be easy to use, easy to sterilize, and fit naturally into the patient's existing routines. If it's a wearable, it should be comfortable, and if it's handheld, it should be easy to hold and carry.

The connector design has its own specific challenges. How easy is it to use the connector? Can the youngest and oldest patients easily mate and unmate it? Investigate the torque required for mating and unmating your connectors. Are similarly shaped connectors color-coded or otherwise clearly distinguished? Plastic is most often color-coded, but you can also look for color coding in aluminum materials, or you can integrate colored rings in your design to make it easier on the user. Is it sturdy enough for minimally trained patients to use and clean without worry? Is it rugged enough for long-term use? Would a sturdy, cost-effective disposable make sense? Examining the full range of questions early in the design cycle help you determine whether your device can take advantage of the newest connector technology.

Some medical devices call for fluids or air to be carried through a connector and along a line. Engineers must choose early in the design process whether to use separate connectors for fluids and power, or to use a single hybrid connector. A hybrid connector is easier for a patient to use and less expensive in the long run, though it's trickier to design and costs more up front. This is another reason why you should never leave connector selection to the very last thing in your design process.

If a device will be operated by a medical professional in a doctor's office or hospital, the patient experience may still affect whether someone will come back for a procedure, or whether the office would purchase a different brand of device in the future.

APPEARANCE MATTERS

Patient experience isn't only about function. The look and feel of a device affects the overall experience, which, again, affects patient adherence. It has been shown that adolescents suffering from idiopathic scoliosis are more likely to wear an uncomfortable brace if it's aesthetically pleasing,[6] and patients are less likely to continue taking a drug if it looks different than it used to, even if it's medically necessary.[7]

As wearables begin to saturate the market, it will be necessary to design devices that look modern, sleek, and relatively fashion-friendly. It's easy for patients to feel self-conscious about having to wear a medical device like a hearing aid or a glucose monitor, so the more "normal" such devices look, the better patient adherence will be. Even for devices that won't be worn, people simply prefer to use objects that they enjoy looking at or that fit their expectations. Every aspect, down to the connector, should be as sleek and attractive as possible.

MINIATURIZATION IN MEDICAL

While non-medical applications have quickly adopted small, powerful connector solutions as they have been brought into the market, medical device manufacturers are often slower to adopt the newest connector technology. There are several reasons for this:

- The medical device market moves more slowly than consumer, military, and even industrial markets because of extensive FDA trials and regulations.
- Designers wait to see how connector solutions work in other markets before adopting them as low-risk alternatives to their existing solutions.
- Device size pressures may not be as urgent as in other markets, especially in mobile surgical equipment, and patient care situations where the patient experience requires aesthetically pleasing equipment sets.

Where miniaturization is succeeding is in medtech. The newest innovations that are revolutionizing healthcare and how it is delivered have successfully implemented designs that take advantage of the new rugged connectors that carry both signal and power. This movement continues to expand into some of the newest mobile devices, patient-worn devices that the patient monitors and manages, and new devices incorporating technology such as sensors that report back — sometimes wirelessly — to a station.

Designing tiny connectors comes with its own challenges. The choice of material, the number of pins, the size of each pin, and the amount of electricity each pin can handle will influence the creepage and air clearance needs, which affect how many pins can fit in a smaller space. A higher pin density allows a single small connector to do what would otherwise require multiple larger connectors, transmitting data and power together without interference.

Miniaturization of a connector solution depends not just on the connector, but also on the cable. It is imperative to test connector/cable pairs and match the connector with a cable that is the correct size, which may involve a custom cable to ensure it fits the small connector while remaining free of interference.

CHART: MINIATURIZATION APPLICATION EXAMPLES

Device type	Connector Consideration	Cable Consideration
Surgical hand tools	• Normally must handle up to 400 amps, so look at pin size and the number of pins needed. • Must be lightweight. Choose aluminum connectors if available. • Heavy-duty, high number of mating cycles • Must be sterilizable	Must be sterilizable. Consider high-heat silicone with a low friction coating.
Dental hand tools	• Normally use less power, so a miniature connector with pins that handle 20 – 40 amps may work well. • Lightweight connectors are a must. • Sterilizable or disposable, depending on the application.	Lightweight, but small and strong enough to handle the power required
Handheld diagnostic devices	• Select a connector that handles both power and signal to enhance ease-of-use. • Look for the newest connectors with a high pin density that allows for smaller spaces between pins without creating interference.	May be sterilizable. Color-code overmolding for ease of use Lightweight cable with high EMI protection
Patient Care and Monitoring (home or office care)	• Quick release circular connector • Small, dense connector for power and signal • High number of mating cycles	Color-coded cable and overmolds when multiple connectors are in use
Surgical robotics	• High speed, error-free data transfer is essential	High degree of flexibility
Portable medical consoles	• Signal + power to simplify console-to-console communications	Effective high-speed communication via required protocol
Imaging devices	• High speed, high data capability	High speed video data cables often required
Wearables	• Small connectors that can be easily handled • High number of mating cycles • Low profile • Lightweight, but rugged	Light, flexible cables. May consider a ribbon cable for a lower profile

COUNTING THE COST

Like shrinking devices, reducing costs is part of democratizing healthcare, and the choice of connector also affects the overall cost of the medical device. Sometimes lowering the cost per patient for short-term use means choosing a disposable option. Other times it makes sense to combine signal and power in one connector rather than using two separate ones. It's also important to choose the right material for the task, to ensure the connector lasts and doesn't have to be replaced, but isn't unnecessarily costly, either. Finally, getting the complete cable assembly from the same manufacturer at the same time can save money and streamline your purchasing efforts.

THE COMPLETE CABLE ASSEMBLY

In any device, the cable — which may carry power, data, or both — is as critical as the connector itself. Unless a device uses disposable batteries, and until wireless charging technology is the norm, each device will be plugged into an outlet either while it's running or to recharge batteries. For data transfer, though, the need for a cable depends on the end use.

For some mobile and wearable devices, a wireless data transfer solution is desirable, as it gives the user greater freedom of movement. However, a cable that uses protocols like USB, Ethernet, or HDMI will be more secure, often faster, and significantly more reliable for data transfer than technologies like Wi-Fi or Bluetooth, and when security, speed, and reliability are vital, designers must choose the best cable for the application.

Cable choice, like everything, is based on the end-use environment. A silicone overmold might be necessary if it will be subjected to high heat, like an autoclave. A low-friction coating might be helpful for preventing cable damage in the long run. Should it be safe to submerge in fluid? Does it need special EMI/RFI protection, based on where it will be used? Would a straight or right-angle overmold work better? It is also imperative to ensure the cable and connector are compatible with each other.

A GLOBAL APPROACH

Communications technology has caused the world in which we live to effectively shrink. Large companies often have offices across the globe. A company might design a device in the US, test it in Europe, and manufacture it in Asia. Additionally, though developed countries spend the most on health care, developing markets are expected to rise from spending 23% of the global total in 2014, to 32% by 2020.[8]

It is, therefore, increasingly important to consider markets and manufacturing in other nations, and to face the challenges associated with them. For manufacturers that choose to do so, each medical device must meet or exceed the legal, technical, economic, and cultural requirements for each country where the device is made or sold. It may be necessary to have a separate version of a device, or part of a device, for overseas use, depending on the circumstances.

CONCLUSION

As discussed in this paper, connectors and cable assemblies play an important role in all areas of mobile and patient-worn medical devices, whether it’s delivering power to handheld diagnostic equipment, or returning signals to mobile consoles and surgical systems. Selecting the right connector and cable assembly solution can help build safe, aesthetically pleasing, functional devices that keep manufacturers competitive while keeping risk low for both the patient and the operator.

With so many details to consider, it is useful for medical device engineers to work directly with an international connector manufacturer that understands how to navigate the FDA gauntlet in the US, how that work transfers to Europe, Asia and the rest of the world, and how to build the optimal solution for a given end-use environment, whether that's a hospital or a home.

FISCHER MINIMAX™ SERIES

The Fischer MiniMax™ Series provides a high density, low weight solution to wearable and mobile equipment challenges. Several configurations in two sizes provide four to 24 connections, including both power and signal into one quick push-pull locking device. Low-torque, quick-release non-locking, and screw locking options are also available.

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ABOUT FISCHER CONNECTORS

Fischer Connectors has been designing, manufacturing and distributing high-performance connectors and cable assembly solutions for more than 60 years. Known for their reliability, precision and resistance to demanding and harsh environments, Fischer Connectors' products are commonly used in fields requiring faultless quality, such as medical equipment, industrial instrumentation, measuring and testing devices, broadcast, telecommunication and military forces worldwide.

Primary design and manufacturing facilities are located in Saint-Prex, Switzerland, with subsidiaries and distributors located worldwide.

Fischer® CONNECTORS

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