We get technical

The best medical robotics reflect care providers' input

Five considerations when specifying connectors for medical applications

Electricity or ethereal fire considered

How to improve ultrasound system image quality using ultra-low-noise supplies

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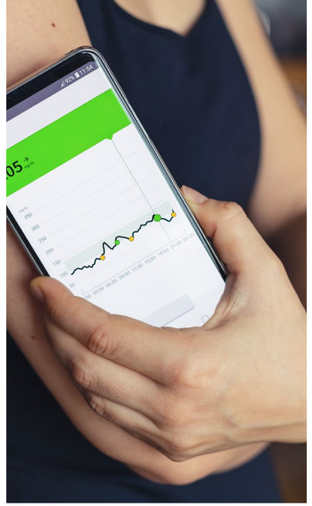


contents

Editor's note

The MedTech industry is at the forefront of a technological revolution, combining advances in electronics, software, and materials science to transform healthcare delivery. From wearable devices that monitor vital signs in real time to advanced imaging systems and robotic-assisted surgeries, MedTech has emerged as a key driver of innovation in the healthcare sector. For engineers, this field offers unparalleled opportunities to contribute to life-changing applications that improve patient outcomes and streamline medical processes.

At the heart of these innovations lies the integration of cutting-edge components, including microcontrollers, sensors, power management systems, and connectivity modules. As MedTech devices become smaller, smarter, and more connected, the challenges for engineers grow more complex. Regulatory compliance, ensuring device reliability, and meeting strict safety standards are just a few of the hurdles that must be navigated. For engineers working on MedTech projects, understanding these challenges and staying informed about the latest advancements in technology is crucial.

DigiKey is committed to empowering engineers to succeed in this demanding yet rewarding field. As a trusted partner, DigiKey offers access to an extensive range of components, development tools, and resources tailored to the needs of the MedTech industry. Whether you are prototyping a new device or optimizing an existing design, DigiKey provides the tools and support to accelerate your innovation.

This ebook is designed to provide engineers with the insights, knowledge, and inspiration needed to tackle the challenges of MedTech design. We will explore how to select and apply the right medical components, guidance for designing medical equipment alarms, and a close look at how medical robots are transforming the industry. Whether you are an experienced MedTech engineer or new to the field, this resource will guide you in navigating the complexities and seizing the opportunities of this transformative industry.

Together, let's shape the future of healthcare.

The best medical robotics reflect care providers' input

Written by Edward O'Brien

Popular interest in (and industrial adoption of) robotics has hastened since the COVID-19 pandemic and all the skilled-labor shortages it exposed. Now, robots are especially viable for medical applications of all types. Designs satisfying these uses take the form of professional-grade autonomous ground vehicles (AGVs), automated testing stations, and patient-support systems to compliment the most sophisticated surgery robotics in hospitals and other medical-treatment settings. Robotic designs to satisfy medical applications are also taking the form of household appliances designed to improve the quality of life for those who wish to maintain mobility and independence via age-in-place approaches despite medical issues.

Though beyond the focus of this article, it's worth noting that some robotics designs are adapting many of the technological advancements in home security (including video systems) and HVAC energy monitoring for household use for health-assist robotics that extend Internet of Things (IoT), home automation, and system interoperability. For example, some underlying IoT technologies are now being employed to help those aging in place to adhere to (sometimes complicated) medication schedules.

Another bourgeoning type of medical robotics – that of exoskeletons – has come to represent the convergence of prosthetics, orthotics, and wearables to help the elderly as well as warehouse and other plant personnel aiming to avoid injury during strenuous manual tasks. Many of the technologies here borrow from innovations first pursued for military applications. Nearly all include IoT connectivity and sensor arrays for feedback.

Dynamic market poised for growth

In hospitals and other medical facilities, robotics:

- Improve the repeatability of delicate procedures – as in minimally invasive surgical (MIS) procedures and other robot-assisted surgery
- Execute mundane tasks for periods longer than acceptable for medical staff – as in AGVs that shuttle bedding and other laundry around sprawling facilities
- Assist in jobs that are unsafe for caretakers – as in patient lifts and robotic beds to help the immobile from bed to chair or vice versa
- Complement automated systems employing data tracking. Watch the online video presentation How to use RFID to Increase Patient Safety and Protect Revenue for more on this topic
- Independently collect and deliver medications as well as lab specimens (leveraging secured patient data)

Figure 1: Medical robots take various forms. Some simply automate tasks that could be tedious or prone to increase the risk of human error. Image source: Getty Images

Such advancements can extend the capabilities of nurses, physicians, and hospital cleaning along with maintenance staff. They also present opportunities to pre-program predictable and repeatable tasks as well as leverage information from various hospital systems – to continually improve patient care and support medical-research efforts.

Surgical robotics continue to lead the increased automation of the medical field – for assisting surgeons as in the past and increasingly leveraging the benefits of artificial intelligence and machine learning. A report by Fortune Business Insights predicts the surgical-robot market will reach nearly $6.8B by 2026; it's no wonder, as computer-assist systems are well-proven to help surgeons enhance patient outcomes with magnified images and precise end-effector movements not subject to fatigue, tremors, or distractions.

Figure 2: FSR 400-series single-zone force sensing resistors are robust polymer thick film devices that exhibit a decrease in resistance with an increase in applied force. Sensitivity is suitable for use in human-machine interfaces, medical systems, and robotics. Image source: Interlink Electronics

Other medical-robot design considerations

The best medical-robotic designs are informed by experienced hospital personnel as well as other medical professionals and caretakers. This input and a thorough understanding of human anatomy can help robot designers deliver designs of sufficient accuracy and maneuverability, whether for goods transport,

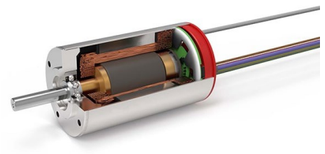


Figure 3: Electronically commutated or brushless DC (BLDC) motors are used in some medical robots to help retrain and condition arm and hand movements in patients with arm-mobility impairments. That's because such motors are particularly compact and efficient. Image: Portescap

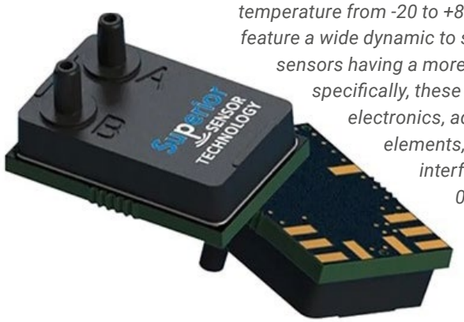


Figure 4: ND-series family extends the operating temperature from -20 to +85°C while pressure sensors feature a wide dynamic to serve the job of half a dozen sensors having a more traditional design. More specifically, these components include integrated electronics, advanced piezoresistive elements, an ADC, a DSP, and a digital interface to track pressures from 0.25 in. H2O to 5 psi for use in various designs – including automated eye-surgery equipment and autonomous vehicles. Image: Superior Sensor Technology Inc.

caregiving, drug delivery, or surgery. Where medical robots rely on IoT data systems for real time information, their compatibility with existing hospital networks is key.

Medical-robot supplier requirements

Medical-robotics engineers, software developers, and suppliers must have extensive knowledge of the best practices associated with the treatment or procedure being motorized or automated. Also required is a keen understanding of underlying business requirements and viable monetization approaches for the industry.

Any systems associated with the retention of patient information require secure data management. That applies to both structured data (as held in databases) and unstructured data in text-retaining systems. Excellent network integration and analytics capabilities are core to justifying the extra data-management design efforts with predictive and adaptive system behavior.

Medical-robot data considerations

Before full-scale adoption, medical robotics should be evaluated for how they affect patient safety, treatment comfort, and outcomes. Results from previous implementations should be studied to quantify patient-recovery improvements and cost reductions. Medical-robotics programs should also be assessed for how they free existing hospital staff to put more of their focus on patient care – whether in person or remote. Where robotics prove to support hospital systems' core missions related to quality care, patient satisfaction, and efficiency, hospital executives should be involved in communicating those benefits to staff and the local community.

Figure 5: Components such as tension load cells ensure patient lifts are operating correctly and within design specifications. Image: Loadstar Sensors

Training staff on medical-robot functions

Healthcare organizations adopting medical robotics should ensure the technologies are well aligned with caretaker expertise; for all hospital staff who will interface with the new robotics, upfront and continuing training programs should be implemented. Here, standard training standards can be lacking – so organizations should seek partners to recommend and craft training modules as needed. In addition to training on how to safely operate and maintain robotics (where applicable) such instruction should also include procedures for insurance documentation and billing – complemented by readily accessible manuals and digital refresher modules for hospital staff.

Data to support connected operations

Data visibility and AI can optimize control over equipment even while imparting deep insight into various roboticized procedures. Then equipment connectivity across networks can let hospitals analyze data to assess robot programs' effectiveness … which is especially useful where hospital systems aim to scale a given robotics program.

Figure 7: Medical-grade isolation transformers support the trouble-free operation of robotics and other equipment with continuous noise filtering and 100% isolation from input ac. UL 60601-1 medical-grade listing with hospital-grade plug and outlet receptacles render the transformers suitable for protecting electronic equipment in patient-care areas. Image: Tripp Lite

Data for satisfying regulatory requirements

Cohesive data-management systems can help multi-site hospital networks as well as standalone hospitals, clinics, and surgical centers more efficiently verify satisfaction of government and industry regulations. Sites employing medical robotics are more likely to have unified networks in place, or at least standard approaches to connect separate systems. The addition of robotic equipment for critical tasks also benefits from the way in which most healthcare facilities already have in place quick-response power and data backup systems.

Of course, medical robotics require stringent physical security and cybersecurity. This often necessitates tightly restricted and monitored access to robotic actuators, controllers, networks, and data storage. Adherence to industry, supplier, and government regulations must be strictly satisfied and documented.

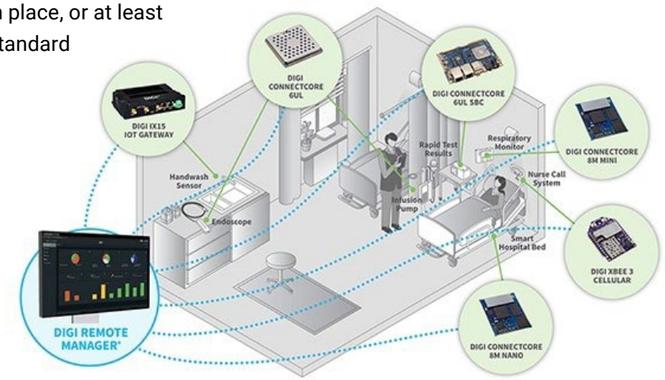


Figure 6: USB-to-serial and network-to-serial products can provide the interfaces between medical robotics and equipment not initially designed for connectivity. Data connectivity solutions can also monitor environments that must be tightly controlled – and keep mobile robotics securely and reliably connected. Image: Digi

Conclusion

In the U.S., the medical industry's adoption of robotics has continued unabated for the last decade. Those investments will likely continue as an aging populous relies more heavily on the industry – even while hospital budgets nationwide face serious challenges. After all, robotics can offer long-term operational savings for many routine healthcare functions … not to mention the most advanced options for surgeries and other treatments that are maximally precise and minimally invasive.

The caveats here are that adoption of robotics requires the clear mapping of hospital need and suitable robotics solutions; satisfying exceptionally stringent regulatory requirements; and sourcing from medical suppliers capable of long-term design support. At least for most larger hospital systems, robotics programs also require dedicated liaisons with automation expertise to coordinate continuous-improvement efforts.

Ultimately, medical-robot offerings should also be thoroughly evaluated through the lenses of patient safety and comfort as well as procedure or treatment efficiency and effectiveness.

How to select and apply the right components to protect medical devices, users, and patients

Written By Bill Schweber

The use of non-laboratory, patient-contact diagnostic and life-sustaining medical equipment such as ventilators, defibrillators, ultrasound scanners, and electrocardiogram (EKG) units continues to increase. Reasons include an aging population, heightened care expectations among patients, and improvements in medical electronics technology which make such systems more practical. Such equipment needs protection against multiple types of electrical issues that can harm the equipment, hospital staff, and patients.

However, full circuit protection takes much more than just a thermal fuse, and implementing protection is not a matter of finding the single best device for a given design and application. Instead, it involves first understanding which circuits need protection and then determining the best mode of protection. In general, multiple passive components are needed to provide protection, and a typical system may need a dozen or more of these specialized protection devices. Protection devices are like insurance: while the latter may only be rarely or never needed, the cost of not having it far exceeds the cost of having it.

This article looks at where protection is needed in such medical systems, including patient-facing signal/sensor I/O, power supply, communication ports, processing core, and user interfaces. It also discusses the various types of circuit and system protection components, using devices from Littelfuse, Inc. by way of example and examines the role and application of each.

The role of protection in medical systems

For most engineers the phrase “circuit protection” immediately brings to mind the classic thermal fuse, which has been in use for over 150 years. Its modern embodiment is largely due to the work of Edward V. Sundt, who in 1927 patented the first small, fast-acting protective fuse designed to prevent sensitive test meters from burning out (Reference 1). He then went on to found what eventually became Littelfuse, Inc.

Since then, circuit protection options have expanded significantly in recognition of the many potential circuit failure modes. These can be:

- Internal failures that may result in a cascade of damage to other components
- Internal failures that may put the operator or patient at risk
- Internal operational issues (voltage/current/thermal) that may stress other components and lead to their premature failure
- Voltage/current transients and spikes which are an inherent and unavoidable part of the circuit’s functionality and must be carefully managed

Many of these issues apply to battery-powered units, not just those that are AC line powered.

The function of many but not all protection devices is to suppress unacceptably large voltage transients. There are two major categories of transient suppressors: those that attenuate transients, thus preventing their propagation into the sensitive circuit; and those that divert transients away from sensitive loads and so limit the remaining voltage. It is critical to study device data sheets carefully for thermal and performance derating curves, as some are specified for transient protection of various durations bounded by defined voltage, current, and time limits rather than steady-state protection.

Among the many electrical parameters that must be considered are clamp voltage, maximum current, breakdown voltage, reverse working maximum or reverse stand-off voltage, peak pulse current, dynamic resistance, and capacitance. It is also important to understand under what conditions each of these is defined and specified. Device size and number of channels or lines protected are also considerations. The choice of the best protection device to use in a given part of a circuit is a function of these factors, and there are often the inevitable trade-offs among the various parameters. There will almost certainly be preferred or “standard” approaches, but there are also choices that must be judged, assessed, and made.

Circuit protection options are many: choose wisely

There are a variety of protection options. Each has a unique functionality and set of characteristics that makes it a suitable – or only – choice for implementing protection against specific classes of faults or unavoidable circuit characteristics. The main protection options are:

- The traditional thermal fuse
- Polymeric positive temperature coefficient (PPTC) devices
- Metal oxide varistors (MOVs)
- Multi-layer varistors (MLVs)
- Transient voltage suppression (TVS) diodes
- Diode arrays
- Solid state relays (SSRs)
- Temperature indicators
- Gas discharge tubes (GDTs)

The thermal fuse is simple in concept. It uses a conducting fusible link that is fabricated of carefully selected metals with precise dimensions. The flow of current beyond the design limit causes the link to heat up and melt, thus permanently breaking the current path. For standard fuses, the time to open circuit is on the order of several hundred milliseconds to several seconds, depending on the amount of overcurrent versus rated limit. In

many designs, it is a final line of protection, as it acts decisively and irrevocably.

Fuses are available for current values from under one ampere to hundreds of amperes or higher and can be designed to withstand hundreds or thousands of volts between their two terminals during fault-induced open-circuit conditions.

A typical fuse is the Littelfuse 0215.250TXP, a 250 milliampere (mA), 250 volt AC (VAC) fuse in a 5 x 20 millimeter (mm) ceramic enclosure (Figure 1). Like most fuses, it is a cylindrical or cartridge-shaped housing that is not soldered into the circuit but instead goes into a fuse holder for ease of replacement. Fuses are also available in rectangular and "blade" housings as well as those that can be soldered; note that the soldering profile must be carefully observed to avoid damaging the fuse element.

Despite their apparent simplicity, fuses have many variations, subtleties, and other factors that must be taken into account when selecting the appropriate one

Figure 1: The Littelfuse 0215.250TXP is a 250 mA 250 VAC fuse in a ceramic body with a 5mm diameter and a length of 20mm. Image source: Littelfuse, Inc.

Figure 2: The 2016L100/33DR 33 volt, 1.1 A PPTC device can be used in low voltage applications where resettable protection is needed; it reacts in under 0.5 s at an overcurrent of 8 A. Image source: Littelfuse, Inc.

for a circuit (References 2 and 3). Fuses are commonly used on input AC lines, output leads where a total short-circuit may occur, or internally where any overcurrent is a serious concern such that the current flow must be fully stopped, and the problem's source determined and fixed before operation can resume.

PPTC devices serve two main types of applications: safety regulation such as for a USB port, power supply, battery, or motor control; and risk prevention for an I/O port. During abnormal conditions such as overcurrent, overload, or overtemperature, the PPTC resistance will increase dramatically, which limits the power supply current in order to protect circuit components.

Once a PPTC device trips into a high resistance state, a small amount of current continues to flow through the device. PPTC devices require a low joule heating "leakage" current or external heat source in order to maintain their tripped condition. After the fault condition is removed and the power is cycled, this heat source is eliminated. The device can then return to a low resistance status and the circuit is restored to a normal operating condition. Although PPTC devices are sometimes described as "resettable fuses" they are, in fact, not fuses but nonlinear thermistors that limit current. Because all PPTC devices go into a high resistance state under a fault condition, normal operation can still result in hazardous voltage being present in parts of the circuit.

A good example of a PPTC is the Littelfuse 2016L100/33DR, a surface mount, 33 volt, 1.1 A PPTC device for low voltage (≤60 volts) applications where resettable protection is needed (Figure 2). It has a footprint of 4 x 5mm and will trip in under 0.5 seconds (s) at an overcurrent of 8 A.

In a typical ventilator, the 2016L100/33DR might be used to protect the battery management system's MOSFET from high currents due to external short circuits or provide overcurrent protection for USB chipsets (Figure 3).

MOVs are voltage dependent, nonlinear devices that have an electrical behavior similar to back-to-back Zener diodes. Their symmetrical and sharp breakdown characteristics enable them to provide excellent transient suppression performance.

When a high-voltage transient occurs, the varistor impedance decreases by many orders of magnitude from a near open circuit to a highly conductive level, clamping the transient voltage to a safe level in a few milliseconds (Figure 4).

As a result of this clamping action, the potentially destructive energy of the transient pulse is absorbed by the varistor (Figure 5).

MOVs are offered in a variety of packages such as the 390 volt, 1.75 kiloampere (kA) V07E250PL2T, which is a small disk with through-hole leads that measures just 7mm in diameter (Figure 6). They are often used on an input AC line to prevent damage due to AC line voltage transients (area 1 in Figure 3). Note that MOVs can be connected in parallel for improved peak current and energy handling capabilities, as well as in series to provide voltage ratings higher than those normally available, or ratings between the standard offerings.

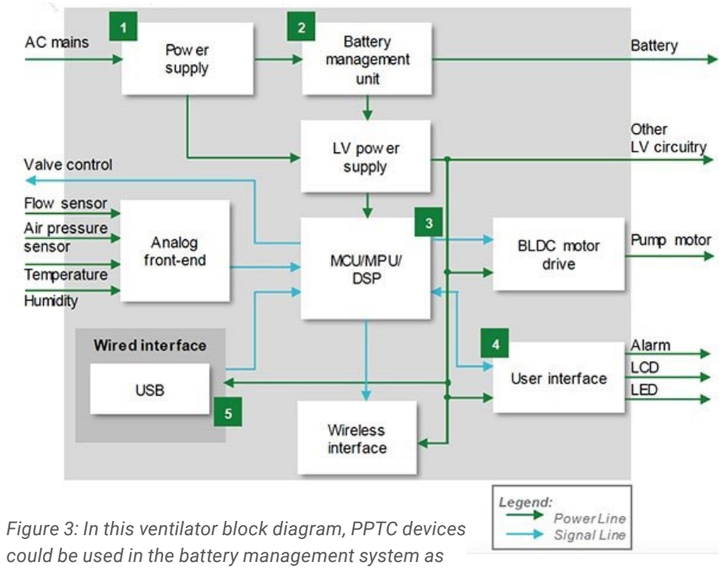


Figure 3: In this ventilator block diagram, PPTC devices could be used in the battery management system as well as the USB port sections (areas 2 and 5). Image source: Littelfuse, Inc.

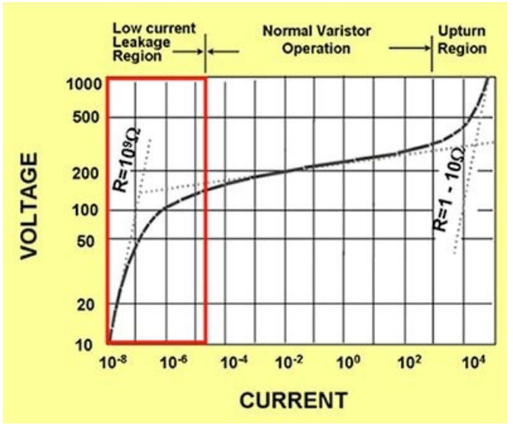
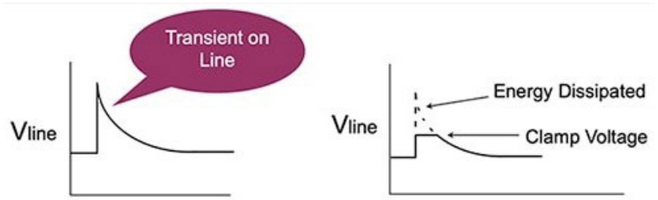


Figure 4: The voltage-current (V-I) curve of the MOV shows its normal high resistance region as well as its very low impedance region, which occurs when the voltage increases beyond a design threshold. Image source: Littelfuse, Inc.

MLVs are similar to MOVs and provide the same basic function but have different internal construction and thus somewhat different characteristics. MLVs are fabricated by wet stack printing layers of zinc oxide (ZnO) and metal inner electrodes, sintering, terminating, glassing, and finally plating. In general, for the same MOV voltage rating, smaller MLV parts have a higher clamp voltage at higher currents, while larger parts have a higher energy capability.

The V12MLA0805LNH MLV, for example, was tested with multiple pulses at its peak current rating (3 A, 8/20 microseconds (µs)). At the end of the test – 10,000 pulses later – the device voltage characteristics are still well within specification (Figure 7). This device should be considered for transient protection in the ventilator power supply and



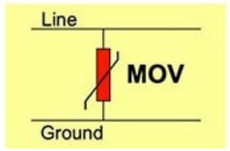


Figure 5: The abrupt switch of the MOV from high impedance to low impedance when a transient voltage occurs clamps that voltage to an acceptable level. Image source: Littelfuse, Inc.

USB port (areas 1 and 5 in Figure 3).

TVS diodes also protect sensitive electronics from high-voltage transients and can respond to overvoltage events faster than most other types of circuit protection devices. They clamp and thus limit voltage to a certain level using a p-n junction that has a larger cross-sectional area than that of a normal diode, allowing the TVS diode to conduct large currents to ground without sustaining damage.

TVS diodes are generally used to protect against electrical overstress such as those induced by lightning strikes, inductive load switching, and electrostatic discharge (ESD) associated with transmission or data lines and electronic circuits. Their response time is on the order of nanoseconds, which is advantageous for protecting relatively sensitive I/O interfaces in medical products, telecommunication and industrial equipment, computers, and consumer electronics. They have a defined clamping relationship between the transient voltage versus voltage across, and current through the TVS, with specifics defined by the TVS model under consideration (Figure 8).

The SMCJ33A is a unidirectional TVS diode with a 53 volt clamping voltage and 28 A peak current rating in a 5.6 x 6.6mm SMT package; a bidirectional version (B suffix) is also available for use when both positive and negative-going transients are anticipated. In a representative application such as a portable ultrasound scanner with a high voltage pulse generator to drive the piezoelectric transducers, TVS diodes could be used to protect the USB ports as well as the LCD/LED user interface display (areas 2 and 3 in Figure 9).

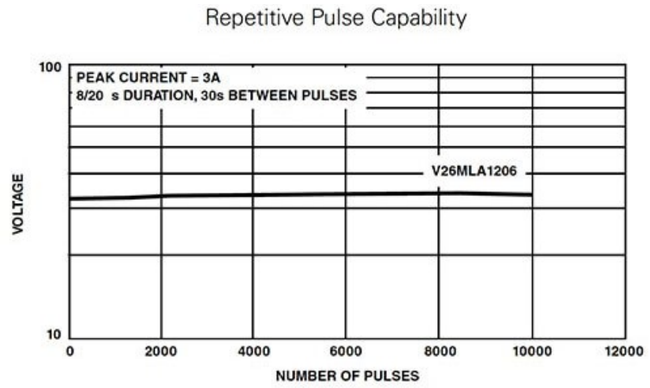
Diode arrays use steering diodes centered around a large TVS diode (such as a Zener diode) to help reduce the capacitance seen by I/O lines. These devices have a low off-state capacitance of 0.3 to 5 picofarads (pF) and are suitable for ESD levels from +/18 kilovolts (kV) to +/-30 kV. Applications include protection of USB 2.0, USB 3.0, HDMI, eSATA, and display port interfaces, to cite a few possibilities. Note that the similarly named TVS diode array provides the same basic functionality but has higher capacitance and thus is better suited for lower speed interfaces.

Figure 6: The V07E250PL2T MOV is a through-hole leaded, 7mm disk rated for operation to 390 volts and can handle transients up to 1,750 A. Image source: Littelfuse, Inc.

The SP3019-04HTG is an example of a such a diode array (Figure 10). It integrates four channels of ultra-low-capacitance (0.3 pF) asymmetrical ESD protection in a six-lead SOT23 package, and also features an extremely low typical leakage current of 10 nanoamperes (nA) at 5 volts. As with the TVS diode, typical applications are for protection of USB ports as well as the LCD/LED user interface display (again, areas 2 and 3 in Figure 9).

SSRs, also called optoisolators, allow one voltage to switch and control an independent, unrelated voltage with near-perfect galvanic isolation (no ohmic path) between input and output. They serve multiple broad objectives. One is functional: they can eliminate ground loops between separated sub-circuits or allow the high-side drivers of a half or H-bridge MOSFET configuration to “float” off ground. Another objective they serve is safety related and especially important for medical devices where their isolation provides an impassable barrier. This containment is needed where there are high internal voltages along with user or patient contact with instrumentation leads, knobs, probes, and enclosures.

Figure 7: MLVs such as the V12MLA0805LNH can withstand repeated transient pulses without performance deterioration. Image source: Littelfuse, Inc.



The CPC1017NTR is representative of a basic single-pole, normally open (1-Form-A) SSR. It is packaged in a diminutive 4mm2, four-lead housing while providing 1,500 volts RMS (VRMS) isolation between input and output. It’s extremely efficient, requiring just 1 mA of LED current to operate, can switch 100 mA/60 volts, and provides arc-free switching without the need for external snubbing circuits. Further, it does not generate EMI/RFI and is immune to external radiated electromagnetic fields – characteristics that are required in some medical instrumentation and systems. In an application such as a defibrillator, designers can use it to electrically separate the low-voltage circuitry from the high voltages of the bridge driving the unit’s paddles (Figure 11).

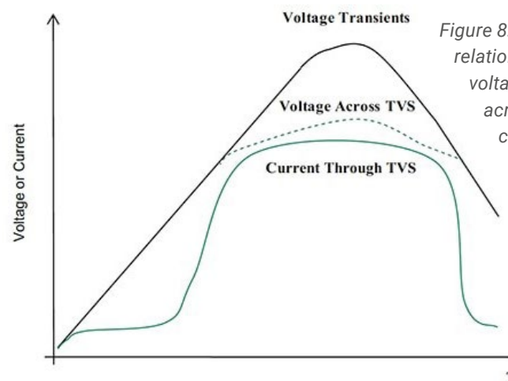


Figure 8: Shown is the general relationship for a TVS between voltage transients, voltage across the TVS, and current through the TVS, with specific values determined by the selected TVS diode model. Image source: Littelfuse, Inc.

Temperature indicators are specialized versions of temperature sensors such as thermistors. Although it may seem obvious that potentially hot areas such as power supplies or higher voltage sources need to be monitored for excess heating, even an I/O port such as USB-Type C can be handling significant current and thus overheat. This may be due to an internal failure or even a faulty load or shorted cable being plugged into it.

To manage this potential problem, a device such as the SETP0805-100-SE setP positive temperature coefficient (PTC) temperature indicator helps protect USB Type-C plugs from overheating. It has been designed to accommodate the unique specifications of this USB standard and is capable of helping to protect even the highest levels of USB Type-C power delivery. Available in an 0805 (2.0 x 1.2mm) package, it protects systems consuming 100 watts or higher, providing sensitive and reliable temperature indication as its resistance increases from a nominal 12 ohms (Ω) at 25°C to 35 kilohms (kΩ) at 100°C (typical values).

GDTs may conjure up images in engineers’ minds of large, bulky tubes with visible sparks, but they are in reality very different. These tubes are placed between a line or

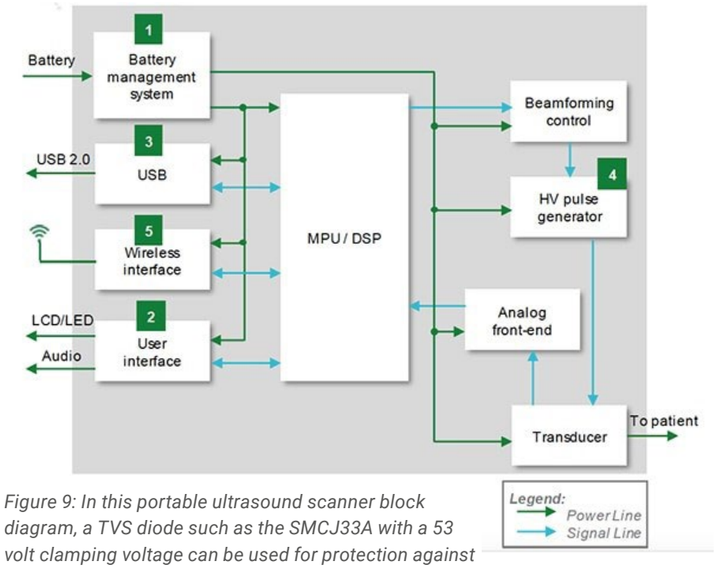


Figure 9: In this portable ultrasound scanner block diagram, a TVS diode such as the SMCJ33A with a 53 volt clamping voltage can be used for protection against transients at USB ports as well as at the LCD/LED display (areas 2 and 3). Image source: Littelfuse, Inc.

conductor to be protected – usually an AC power line or other "exposed" conductor and system ground – to provide a near-ideal mechanism for diverting higher overvoltages to ground.

Under normal operating conditions, the gas inside the device acts like an insulator and the GDT does not conduct current. When an overvoltage condition (called the sparkover voltage) occurs, gas inside the tube breaks down and conducts current. When the overvoltage condition exceeds the parameters of the sparkover voltage rating, the GDT turns on and discharges, diverting the damaging energy. GDTs are available as two-pole devices for ungrounded lines and three-pole devices for grounded lines, both in small SMT packages for ease of design-in and board assembly (Figure 12).

GDTs are available for sparkover values rated as low as 75 volts and can handle hundreds and even thousands of amperes. For example, the GTCS23-750M-R01-2 is a two-pole GDT with a 75 volt sparkover and a 1kA current rating, housed in an SMT package measuring 4.5mm long and 3mm in diameter, allowing it to be placed almost anywhere to provide protection (Figure 13).

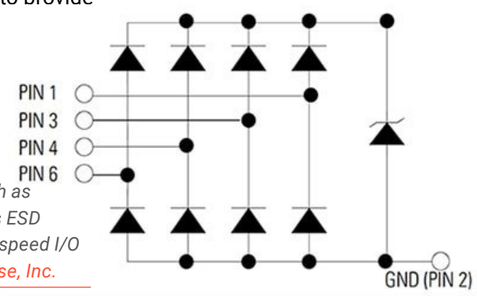


Figure 10: A diode array such as the SP3019-04HTG provides ESD protection for multiple high-speed I/O lines. Image source: Littelfuse, Inc.

Standards guide the design

Medical devices must meet multiple safety standards, some of which apply to all consumer and commercial products, and some of which are for medical devices only. Many of these standards are international in scope. Among the many standards and regulatory mandates are:

- IEC 60601-1-2, "Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests."
- IEC 60601-1-11, "Medical Electrical Equipment Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment."
- IEC 62311-2, "Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0Hz to 300GHz)."

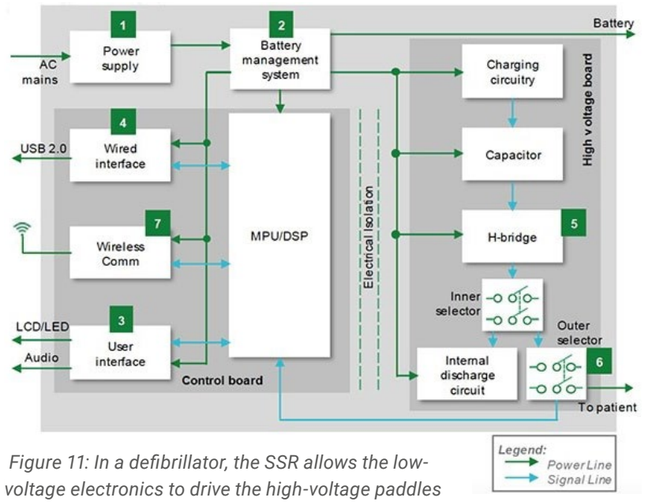


Figure 11: In a defibrillator, the SSR allows the low-voltage electronics to drive the high-voltage paddles while allowing the "floating" upper-side drivers of the H-bridge arrangement to remain isolated from system ground (area 5). Image source: Littelfuse, Inc.

- IEC 62133-2, "Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems."

Being careful about circuit protection device selection and how they are used goes a long way toward meeting these safety mandates. Using accepted, approved techniques and components can also speed up the approval process.

Conclusion

The requirements of where, why, what, and how to use circuit protection devices in general, and in medical units in particular, is a complicated design challenge. There are many suitable protection components, some specific to a given circuit function and others with more general applicability. Each component brings a set of attributes that makes it a best fit – or at least a better one – in the different circuit and system locations requiring such protection. No single device will fit the multiple diverse system requirements and so designers will end up using multiple protection approaches.

Figure 13: GDTs do not have to look like the big spark-gap devices seen in movies; the GTCS23-750M-R01-2 is a 75 volt, 1 kA GDT in an SMT package that measures just 4.5mm in length and 3mm in diameter. Image source: Littelfuse, Inc.

In most cases, the many decisions regarding which devices to use and how best to do so are inherently complicated and also subject to regulatory review. Designers should strongly consider asking for help from knowledgeable application engineers at the protection device vendor or their designated supplier (distributor). Their experience and expertise can reduce time to market, ensure a more thorough design, and ease the path to regulatory approval.

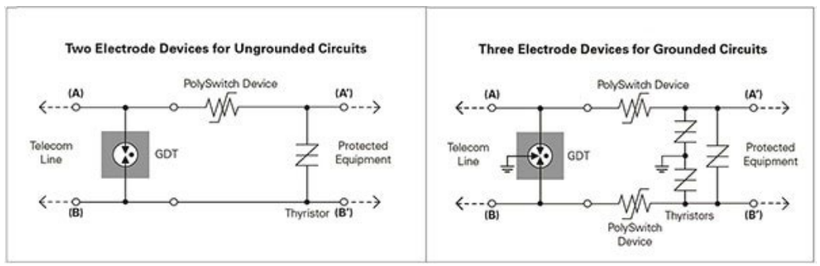


Figure 12: GDTs are offered as (left) two-pole devices for ungrounded circuits and (right) as three-pole devices for grounded circuits (the GDT symbol is the "Z-like" graphic to the right of each schematic diagram). Image source: Littelfuse, Inc.

Five considerations when specifying connectors for medical applications

Written by Jeff Shepard

Designers of medical devices and systems need connectors that will help them address increasing complexity and smaller form factors, while at the same time ensuring high levels of reliability and performance under various usage models. Some connectors are inaccessible within the system making reliability critical. Other connectors are regularly used by surgeons, physicians, nurses, or technicians, so ease of use, and a high number of mating cycles are also important.

Depending on the application, connectors for medical devices and systems must comply with standards such as IEC 60601, ISO 80369-1, and ISO 13485, and may require severe environmental testing beyond typical industry standards and specifications.

Along with a usable model and specific standards, designers need to consider technical tradeoffs between non-return-to-zero (NRZ), also called pulse amplitude modulation 2-level (PAM2), and pulse amplitude modulation 4-level (PAM4) connector technologies to arrive at the optimal cost and performance for a specific use case.

Designers have a broad range of connector types to consider when identifying the best solution. To assist in the process, this article begins by briefly reviewing five important factors to keep in mind when specifying connectors for medical devices. It then presents examples of connector options from Samtec and closes with an overview of application considerations when integrating connectors in high-speed systems.

NRZ versus PAM4

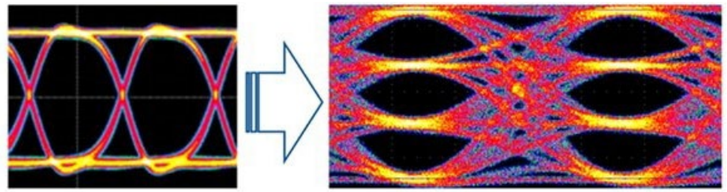
NRZ transmits 1 bit of information per signal interval. PAM4 is a multilevel signal modulation format with a throughput of 2 bits per interval. In the NRZ eye, the top represents “1” and the bottom represents “0”, while the PAM4 signal consists of three stacked eyes formed using four voltage levels; 00, 01, 10, and 11 (Figure 1). The height of the eyes is an important consideration. The greater eye height of the NRZ signal results in better signal quality. NRZ is simpler to implement, has lower reflections, a better signal-to-noise ratio (SNR), and is lower in cost compared with PAM4. However, PAM4 is inherently faster and used in high-speed links such as multi-gigabit communications.

Mechanical considerations

Mechanical considerations when selecting connectors include contact pitch, mating type, termination style, and size (Figure 2). Pitch measures the center-to-center spacing of the contacts. It can be more than one number; the pitch between contacts in each row and the pitch between rows can be the same or different. Connectors on printed circuit boards (pc boards) can use horizontal, vertical, or right-angle mating. Retention force is another consideration that measures how easily the connector can be removed.

Common termination styles include through-hole, surface-mount, paste-in-hole, and press fit. Through-hole contacts pass through a hole in the pc board and provide strong connections between the pc board layers. Surface-mount connectors mount on the surface of the pc board and don’t require holes to be drilled. They can have smaller pitch spacings compared with through-hole connectors. Though-hole

Figure 1: NRZ has a single eye (left) and transmits 1 bit of information per signal interval. PAM4 is a multilevel signal modulation format with three eyes (right) and has a throughput of 2 bits per interval. Image source: Samtec



terminations are being supplanted by surface mount terminations in a growing number of applications.

Paste-in-hole connectors are mounted in holes that do not completely penetrate the pc board. To be used for surface-mount or paste-in-hole designs, the connector body material must be able to withstand solder reflow temperatures, and they need to have horizontal and vertical clearance around the leads to accommodate the required quantity of solder paste.

Press fit terminations are solderless and lower in cost but require special tooling for installation. They are pressed into a hole on the pc board and held in place by compressive forces. Less common termination styles include land grid arrays, ball grid arrays, wire wrapping, crimping, and screw terminations.

Ease of use

Contact resistance, mating cycles, and mating/unmating force contribute to connector ease of use in applications where connectors need to be regularly mated and unmated. The lower the contact resistance, the less power that is lost through the connector. A low mating/unmating force can contribute to ease of use, as long as the contact resistance remains low enough to meet electrical requirements. Connectors have limited mating/unmating cycle specifications, ranging from tens of cycles to many thousands of cycles. The cycle life of the connector must be matched to the needs of the application.

When connector contacts are mated, the contact is displaced, and the metal is flexed. The flexing is important and determines the force needed to mate and unmate the connector, and the contact resistance. Flexing also causes stresses in the contacts that results in both the mating/unmating force decreasing and the contact resistance increasing over time. Replacing the brass base metal commonly used in connector contacts with more expensive phosphor bronze will increase the cycle life. Phosphor bronze is more elastic than brass and less susceptible to stresses that limit the cycle life of bronze contacts.

IEC 60601, ISO 80369-1, and ISO 13485

There are numerous application-specific industry standards for various medical systems and devices. Three of the more general standards that need to be considered in all designs are:

- ISO 80369-1: this focuses on the design methodology to reduce the risk of misconnections between medical devices, or between accessories for different applications
- IEC 60601 focuses on the general requirements for basic safety and essential performance including electromagnetic interference (EMI) and electromagnetic compatibility (EMC)
- ISO 13485 focuses on the quality systems needed for tracking the components and processes used in the manufacturing process. It is related to ISO-9001

Testing beyond industry standards

Severe Environment Testing (SET) is a suite of tests developed by Samtec that extend beyond typical industry standards and specifications and includes:

- 250 mating cycles with 100% humidity

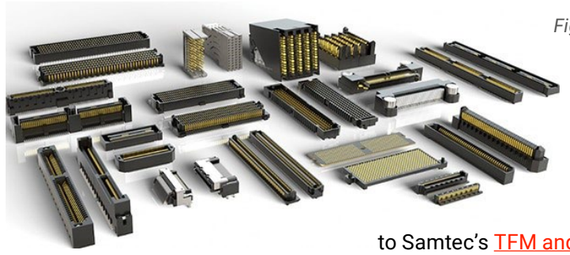


Figure 2: A small selection of the variety of available contact pitches, terminations, and sizes. Image source: Samtec

- Intense shock and vibration based on low-level contact resistance (LLCR) and event detection
- LLCR testing using 40 times the standard gravitational force (g) peak, 11 milliseconds (ms), half sine and 12g RMS, 5 – 2000 Hertz (Hz), 1 hour/axis
- Event detection according to EIA-364-87, EIA-364-27 and EIA-364-28 using the same test procedure as the LLCR testing
- 500 temperature cycles
- Non-operating-class temperature testing where the connector is LLCR tested, exposed to -55 to 105°C for 100 cycles, then tested for LLCR again; exposed to -65 to 125°C for 100 cycles, and tested for LLCR again; the connector must maintain a change of ≤5 milliohms (mΩ) in LLCR to pass
- Dielectric withstanding voltage at an altitude of 70,000 feet
- Electrostatic discharge (ESD) testing is not usually performed on connectors but is included in SET

Connectors that handle 10,000 mating cycles

Designers that need up to 10,000 mating cycles can turn to Samtec's TFM and SFM series, members of the company's Tiger Eye interconnect system. These connectors are designed for micro, rugged, high-reliability, high-cycle applications, and are available in three pitches; 0.80, 1.27, and 2.00 millimeters (mm). These connectors have heat-treated, beryllium copper (BeCu) multi-finger contacts optimized for high-cycle applications and are designed for rugged environments (Figure 3). For example, the model TFM-105-01-S-D-A is a 10-position header with 1.27mm pitch contacts.

The smooth contact mating surface does not stress the plating, providing lower contact resistance, longer plating life and longer cycle life. Solder can easily penetrate the micro slot on the tail providing greater solder joint strength. These connectors are polarized to guarantee proper mating, and optional friction locks improve connection security.

Figure 3: Tiger Eye interconnects (left) are available in a variety of formats and sizes and provide a rugged contact system rated to 10,000+ mating cycles. The TFM-105-01-S-D-A (right) is a 10-position header with 1.27mm pitch contacts. Image source: Samtec

High-density, high-speed connectors

Applications that need high speed and high density can use Samtec's SEARAY 1.27 mm open-pin field-press-fit arrays. These connectors have up to 500 contacts optimized for signal integrity and are available in vertical or right-angle mounting options (Figure 4). This system features up to 10 rows and 50 contacts per row to enable grounding and routing flexibility; a choice of 7mm, 8mm, 8.5mm, and 9.5mm stack heights; and can handle signals up to 28 gigabits per second (Gbits/s). For example, part number SEAFP-40-05.0-S-06 is a vertical mount design with 240 contacts and through-hole terminations.

Connectors for PAM4 or NRZ

Applications that need higher contact densities and more than 28Gbits/s speed can use the 56 Gbit/s SEARAY series. Their 0.8mm pitch delivers twice the contact density of connectors with 1.27 mm pitches, are available with 7mm and 10mm stack heights, and can handle PAM4 or NRZ communications. Configurations are available with up to 12 rows of 60 contacts for a total of 720. These open-pin-field arrays provide maximum grounding and routing flexibility including differential signal pairs, single-ended signal transmission and power delivery (Figure 5). Part number SEAF8-20-05.0-S-04-2-K features 80 gold-plated contacts and surface-mount terminations. These connectors are SET qualified.

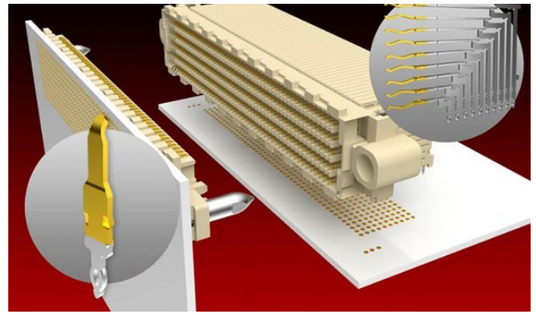


Figure 4: SEARAY 1.27mm high-density open-pin field-press-fit arrays are available in vertical and right-angle (shown above) options. Image source: Samtec

High-speed connector application considerations

When using high-speed connectors in medical applications, there are numerous factors that designers need to consider related to signal integrity and EMI, a few of these considerations include:

- Shorter is better. Shorter connectors deliver better signal quality. The shorter the connector, the shorter the time available for reflections and crosstalk to occur
- The signal-to-ground ratio is important. In most instances, a ratio of 1:1 is optimal, but for connectors with large pin counts, a ratio of less than 1:1 may be needed for reliable high-speed, single-ended operation
- Ground shielding of contact pairs is recommended for differential connectors carrying signals of 2.5Gbits/s or faster
- Misalignment can be a significant problem on pc boards with multiple connectors. Closely follow the manufacturer's recommended termination connection specifications and keep alignment pin hole diameter tolerances to ±0.002 inches (0.05mm)
- EMI is not just a pc board problem. Board-to-board connectors can contribute to EMI concerns and need to be considered from the beginning as part of the overall design

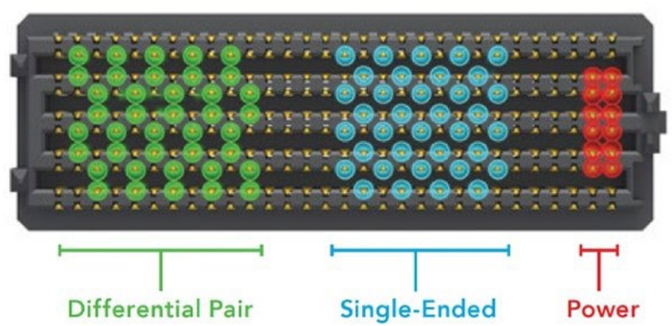


Figure 5: SEARAY high-density open-pin-field arrays provide maximum grounding and routing flexibility including differential signal pairs, single-ended signal transmission and power delivery. Image: Samtec

Conclusion

Selecting connectors for medical systems is an important and complex activity. Connectors need to be optimized to meet the mechanical durability, reliability, and ease of use requirements, in addition to meeting the electrical specifications and supporting communications protocols such as NRZ and PAM4. Adhering to relevant industry standards is important, but testing beyond the industry norms, such as with the Samtec devices mentioned here, is often needed to ensure the high levels of performance expected from connectors in medical devices and systems.

Select the right AC/DC power supply to meet unique medical requirements

Written by Bill Schweber

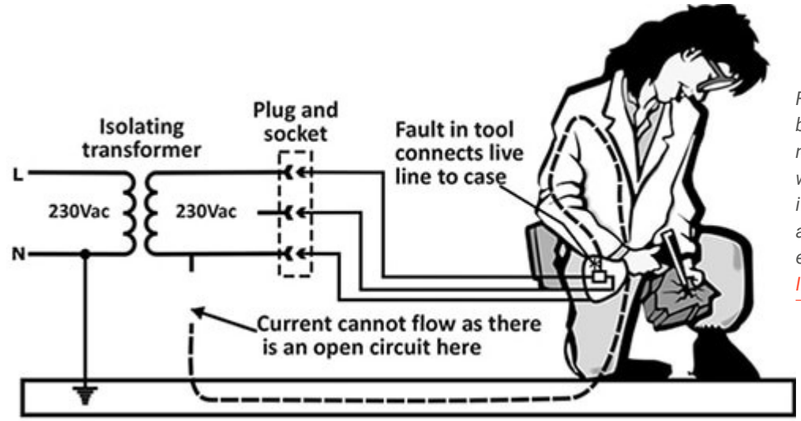


Figure 1: The isolation transformer breaks the current path from neutral to Earth, so the current will not flow through the user even if the user's device or system is accidentally connected to the exposed case.
Image source: Quora

Improvements in battery technology along with advances in low-power circuitry have made portable, battery-powered systems a viable option for many designs, but in applications such as medical and home healthcare, battery-only, untethered operation is not feasible, practical, or even desirable. Instead, the equipment must operate directly from an AC line or have access to an AC outlet to ensure reliable operation when the batteries are low. For these cases, the AC/DC supply must provide the usual power supply performance with respect to voltage and current output, static and dynamic regulation, as well as fault and other protection features.

In addition, basic power supply performance is not the only concern for medical systems designers. Various regulatory standards exist – and have recently been upgraded – which add additional mandates for less-obvious performance issues such as galvanic isolation voltage, leakage current, and two means of patient protection (2×MOPP). These are in place to ensure that the equipment which the supply is powering does not put the operator or patient at risk even if there is a failure in the supply or the equipment.

Various regulatory standards exist – and have recently been upgraded – which add additional mandates for less-obvious performance issues such as galvanic isolation voltage, leakage current, and two means of patient protection (2×MOPP).

The combination of performance, reliability, and standards requirements, as well as cost and time to market pressures, make designing a power supply from scratch a challenging proposition. Instead, designers need to sift carefully through an array of ready-made options for the optimum solution.

This article looks at applications for AC/DC supplies in medical-instrument environments, reviewing the critical regulatory standards for these supplies. It then introduces example supplies from CUI Inc. and discusses their respective characteristics and how they can help solve the medical system power supply challenge.

Use AC line or batteries?

Although untethered, battery-powered, and portable devices have become common and even preferred in many consumer and commercial products, there are still many situations where battery power is either impractical or undesirable. This is especially the case for medical instrumentation where consistent, reliable, and immediate availability is critical. Among the reasons medical systems may prefer or mandate AC line operation are:

- High power, voltage, or current requirements that may require a large, heavy, costly battery system along with recharge management circuitry
- Many medical sites run 12, 18, and even 24-hour daily shifts due to patient scheduling
- Even for those systems that can use rechargeable batteries for primary power or emergency backup, those batteries need to be charged while the system is in use, during which time the AC/DC supply must provide power

In principle, any properly sized, standard off-the-shelf (OTS) AC/DC supply with suitable voltage and current ratings should be a good fit for these systems. Yet while they are adequate in the basic sense, they do not meet the additional standards placed on medical supplies.

The rationale for these additional safety and performance mandates is the unique nature of medical applications and the very real possibility of component or system faults causing patient or operator harm. It's especially challenging since the patient is often in direct contact with sensors, probes, or other transducers that can conduct current directly into the body, thus posing a greater risk than casual contact.

Begin with safety basics

Although shock risk is normally associated with higher voltages, there is only an indirect correlation. Patient or user shock is due to current flowing through the body and back to its source. However, if that current has no return-flow path, then there is no risk, even if the person is touching a high-voltage line.

Except for very specialized exceptions, the line-operated AC/DC power supply has an input-side isolation transformer which can serve two roles:

- Provide voltage step up/down of the line voltage as needed before it is rectified to DC
- Provide input/output isolation so there is no path for the flow of current through the user and back to the neutral line. This is critical in the event of a fault that could put voltage and current on the surface of the unit, and thus to and through the operator or patient (Figure 1)

With the isolation transformer in place, this current flow cannot happen because the isolation transformer does not have a wire path from the AC-line neutral to Earth, so the current will not flow through the user.

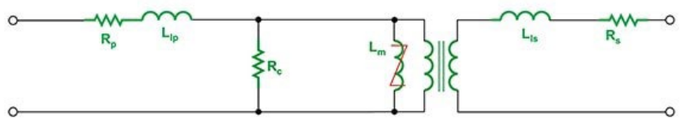


Figure 2: This basic model of a transformer shows there is no current path from primary side to secondary side.
Image source: Power Sources Manufacturers Association

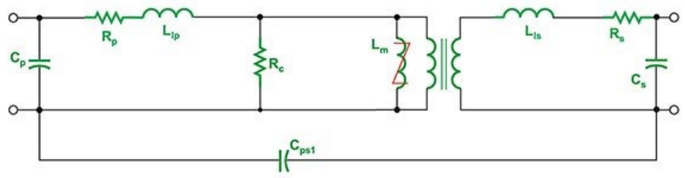


Figure 3: A more realistic model shows basic interwinding capacitance (Cps1) between primary and secondary sides.
Image source: Power Sources Manufacturers Association

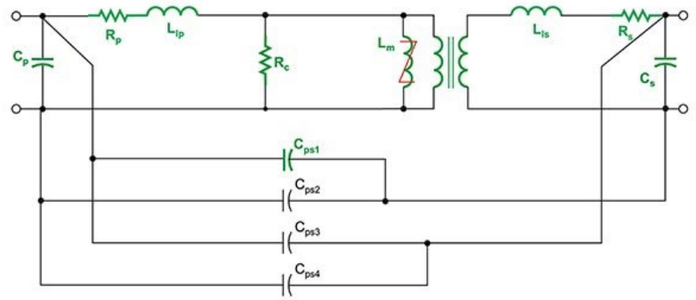


Figure 4: There are other transformer capacitances, in addition to Cps1.
Image source: Power Sources Manufacturers Association

Why worry about current?

Standard line voltage (110/230 volts; 50 or 60 hertz (Hz)) across the chest – even for a fraction of a second – may induce ventricular fibrillation at currents as low as 30 milliamperes (mA). If the current has a direct pathway to the heart such as via a cardiac catheter or other kind of electrode, a much-lower current of less than 1 mA (AC or DC) can cause fibrillation.

These are some standard thresholds which are often cited for current through the body via skin-surface contact:

- 1 mA: Barely perceptible
- 16 mA: Maximum current an average-size person can grasp and "let go"
- 20 mA: Paralysis of respiratory muscles
- 100 mA: Ventricular fibrillation threshold
- 2 A: Cardiac standstill and internal organ damage

The levels are also a function of the current-flow path, meaning where the two points of contact with the body are located, such as across or through the chest, from an arm down to the feet, or across the head.

Transformer isolation and leakage are critical

Leakage is current that passes through the dielectric insulation, whether due to physical "leaks" from the imperfect nature of the insulation, or due to capacitive currents that can cross even exceptionally good insulation. Although leakage current is never desirable, it's a much more serious concern for some medical applications.

A simplified model of a transformer shows perfect galvanic (ohmic) isolation between its primary and secondary sides in Figure 2.

No current can flow directly from the AC mains to the powered product – thus forming a complete current-flow loop back to the AC mains – even if a component or wiring failure provides a new current path on the secondary side. However, no transformer in the real world is perfect and there is always some primary-secondary interwinding capacitance (Figure 3).

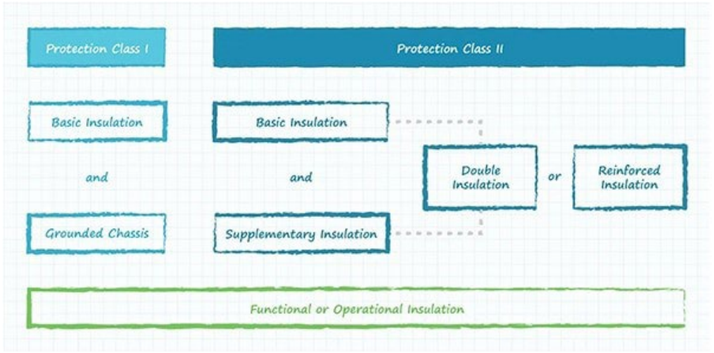
An even more sophisticated model adds additional sources of interwinding capacitance, shown in Figure 4.

This undesired capacitance which allows the flow of leakage current is a function of many variables such as wire size, winding pattern, and transformer geometry. The resultant value can range from as low as one picofarad (pF) to a few microfarads (µF). In addition to transformer capacitive leakage, other sources of unintentional capacitances are spacings on printed circuit boards, insulation between semiconductors and grounded heatsinks, and even parasitics between other components.

Transformer leakage current due to capacitance is not the only medical-standard power-supply concern. Obviously, basic AC safety and insulation are concerns. Depending on voltage and power levels, these supplies may need a second, independent insulation barrier in addition to the primary one.

Also, many medical products involve very low signal levels (millivolts or microvolts for

Figure 5: Class I devices require only basic insulation and a grounded chassis, while Class II devices require additional insulation modes. Image source: CUI Inc.



body sensors, for example), so generated electromagnetic interference (EMI) or radio-frequency interference (RFI) (broadly called electromagnetic compatibility, or EMC) are also concerns. The relevant standards call out the maximum allowed EMI/RFI generation, as well as their tolerance.

Standards and means of protection (MOP)

The primary standard governing medical electronics and safety is IEC 60601-1 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, along with its various associated standards. The 3rd edition of IEC 60601-1 extends the patient focus to require an overall MOP that combines one or more means of operator protection (MOOP) and means of patient protection (MOPP).

Thus, while the basic provisions of the 2nd edition, which guard against failure remain in place, the 3rd edition recognizes that the potential hazards seen by each user can be quite different; an operator has access to a control panel, for example, while the patient may be "connected" via probes.

The 3rd edition standard specifically calls out the Risk Management Process described in ISO 14971 that includes a risk management file where fault conditions are identified and assessed. The recently activated 4th edition of this standard goes even further. First, it has added updates to take technology changes into account. Second, it also expands on the risk analysis and addresses a reciprocal concern about EMC affecting both the medical device in question and other devices in the vicinity. In other words, the standard goes beyond saying, "You should do this" or "You should do it this way", but now requires assessment and even quantification of relevant risks and how to mitigate them.

Supplies and MOP

Regulatory standards have created protection classes of products that are characterized by the means of providing operator protection from hazardous voltages, designated as Class I and Class II.

Classification	Isolation	Creepage	Insulation
One MOOP	1500 Vac	2.5mm	Basic
Two MOOP	3000 Vac	5mm	Double/Reinforced
One MOOP	1500 Vac	4mm	Basic
Two MOOP	4000 Vac	8mm	Double/Reinforced

Figure 6: The different means of protection and levels have different mandates on isolation voltage rating, creepage and insulation. Image source: CUI Inc.

Figure 7: The SDM65-24-UD-P5 is a 24 V, 2.7 A, Class II AC/DC supply intended for external use with respect to the device it is powering. Image source: CUI Inc.

In a Class I product, there will be a conductive chassis which is connected to safety earth ground. Thus, an input power cord with a safety earth ground conductor is required in protection Class I products. In contrast, a Class II product will not have a safety earth ground conductor in the input power cord. Instead, a second layer of insulation is included for operator protection due to the absence of the grounded chassis (Figure 5).

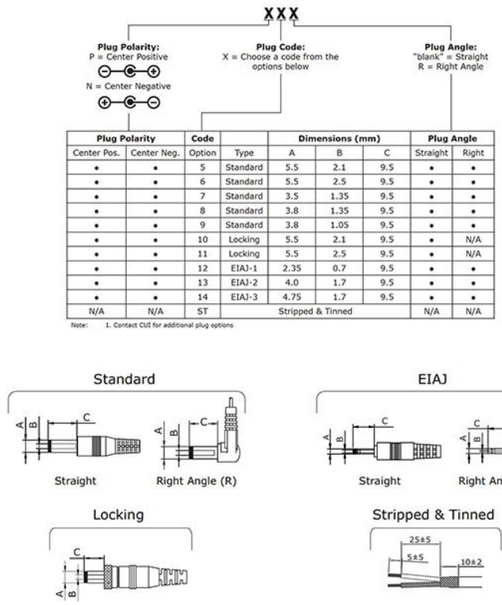
There are different requirements for MOP, such as isolation, creepage, and insulation in IEC 60601-1, including whether the requirement is for MOOP or the stricter MOPP (Figure 6).

The standard defines which classification is required in various application situations. For example, equipment that makes physical contact with a patient, such as a blood pressure monitor, will typically need to meet the requirements for both two MOOP and one MOPP.

There is no single number that can be placed up front on the value required on each parameter, as their maximum values are a function of many factors. They are also defined by whether the overall design uses single or dual MOPs, and whether that MOP is a MOPP or MOOP.

The IEC protection classes govern the construction and insulation of power supplies to protect the user from electrical shock. IEC protection Class II power supplies have a two-wire power cord, with two layers of insulation (or a single layer of reinforced insulation) between the user and the internal current-carrying conductors.

The first layer of insulation is typically referred to as "Basic Insulation" such as the insulation normally used on wires. Then, a second layer of insulation is often an insulating case enclosing the product (and may be labeled as "double insulated"), such as the plastic case used with wall-mount and desktop power supplies.



Plug Polarity		Code		Dimensions (mm)			Plug Angle	
Center Pos.	Center Neg.	Option	Type	A	B	C	Straight	Right
•	•	5	Standard	5.5	2.1	9.5	•	•
•	•	6	Standard	5.5	2.5	9.5	•	•
•	•	7	Standard	3.5	1.35	9.5	•	•
•	•	8	Standard	3.8	1.35	9.5	•	•
•	•	9	Standard	3.8	1.05	9.5	•	•
•	•	10	Locking	5.5	2.1	9.5	•	N/A
•	•	11	Locking	5.5	2.5	9.5	•	N/A
•	•	12	EIAJ-1	2.35	0.7	9.5	•	•
•	•	13	EIAJ-2	4.0	1.7	9.5	•	•
•	•	14	EIAJ-3	4.75	1.7	9.5	•	•
N/A	N/A	ST	Stripped & Tinned				N/A	N/A

Note: 1. Contact CUI for additional plug options

Figure 8: Supplies in the SDM65-UD series are offered with many standard barrel connector options for the DC output connector, as well as stripped & tinned leads. Image source: CUI Inc.

Make versus buy

Basic power supply design is supported by many available components, application notes, reference designs, and more. As a result, designers might be tempted to design and build their own,

Figure 9: The open-frame VMS-550-48 delivers 48 volts at 11.5 A and has a standard footprint of 3 × 5in. Image source: CUI Inc.

precisely tailored to the application requirements and its priorities. There is no doubt that in some cases, the supply requirements are so unusual or unique that there is no commercial supply available, so "make" is the only course.

Despite the feasibility of "make," the arguments against it are strong: "make" comes with high design and certification risk, plus lengthy time to market. In addition, the higher volume of supply vendors compared to "make" efforts results in a lower bill of materials (BOM) and assembly cost, so "make" is not even a cost saver, except perhaps at very low power levels (under about ten watts) where regulatory issues are less stringent.

OTS units: range of power levels, form factors

It's one thing to talk about certified, regulatory approved AC/DC power supplies for medical applications in the abstract, but looking at some of the versions available shows that meeting these mandates does not constrain use flexibility. Vendors offer different families of supplies with a range of voltage/current ratings within each family, and so can meet nearly all project requirements. Some examples show the breadth of what is available in external adapters, open-frame modules, and enclosed units.

Example #1

External desktop adapters such as the SDM65-UD series, include the 24 volt, 2.7 A SDM65-24-UD-P5 (Figure 7). This family of Class II supplies is often used for powering/charging laptops and similar devices and offers a universal input range of 90 to 264 volts and 47 to 63Hz.

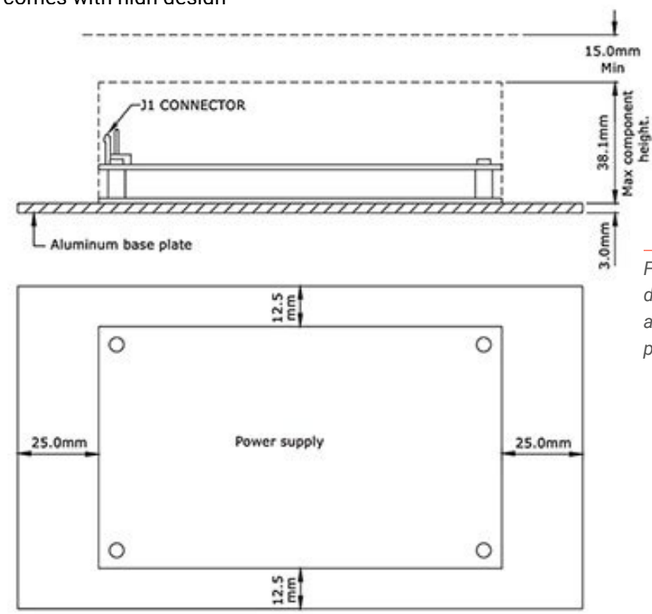


Figure 10: Mechanical drawing showing the dimensions and mounting arrangement for a suitable cooling plate for the VMS-550-48 power supply. Image source: CUI Inc.

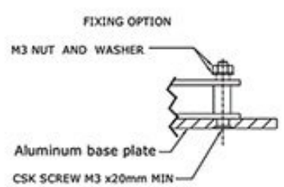


Figure 11: The 450-watt VMS-450B-24-CNF AC/DC supply series delivers 24 volts at 18.8 A and comes with a protective enclosure. Image source: CUI Inc.

These nominal 65-watt units have outputs that cover 12 volts at 5 A to 5 volts at 1.36 A, are housed in a fully enclosed insulating package measuring about 120 × 60 × 36 millimeters (mm) and include a user-convenient "power-on" indicator LED.

Supplies in this family operate from a user-supplied IEC320/C8 two-wire AC cord. The DC output comes with a 150 centimeter (cm) cord (16 or 18 gauge, depending on the supply's output current), can be ordered with either of two polarity orientations, and any one of a number of common "barrel" plug terminations or stripped/tinned wires (Figure 8).

Example #2

Open-frame (or tray) modules such as the VMS-550 series include the VMS-550-48, a 48 volt, 11.5 A unit.

Supplies in this family offer up to 550 watts of continuous power with outputs spanning 12 volts/42 A to 58 volts/9.5 A, with an industry standard 3 × 5 inch (in.) footprint and a low profile of 1.5in. (Figure 9).

These supplies include power factor correction (PFC), a regulatory requirement at this power level, and have a standby power dissipation of less than 0.5 watts, along with an efficiency up to 92%. They operate over a -40°C to 70°C temperature range and include a separate 12 volt/0.5 A output for a local cooling fan. AC connection for this Class II unit is via the male connector on the supply's circuit board using a two-wire cable terminated with a mating female connector.

The datasheet includes thermal derating curves along with a useful mechanical drawing showing an arrangement for a cooling baseplate with mounting standoffs and screws (Figure 10).

AC/DC supplies for medical applications must meet a large set of complex, stringent regulatory standards and mandates covering basic and additional safety requirements.

Example #3

Enclosed units such as the VMS-450B series, include the VMS-450B-24-CNF, a 450 watt supply that provides 24 volts at 18.8 A from inputs of 100 to 240 volts AC. The supply measures 127 × 86.6 × 50mm (approximately 5 × 3.4 × 2in.) and comes with a metal shield which allows for airflow while reducing EMI/RFI and providing some physical protection for both the supply and its users (Figure 11).

Supplies in this series can deliver from 12 volts at 37.5 A up to 56 volts at 8 A. They also include PFC and a 12 V, 600 mA drive for a fan, plus an additional 5 V, 1 A auxiliary DC output that eliminates the need for a separate small supply in many applications.

Conclusion

AC/DC supplies for medical applications must meet a large set of complex, stringent regulatory standards and mandates covering basic and additional safety requirements. Supplies which meet all relevant standards are available in a wide range of power ratings and come in form factors including external "desktop" style, as well as "drop-in" for incorporation into an end product. By selecting one of these standard units, system designers are relieved of all the issues associated with supply design, certification, final approval, and manufacturing.

Retro Electro: Electricity or Ethereal Fire Considered

The following article is not intended to be medical advice and should not be used as such. It explores post-Revolutionary War America, the innovations surrounding medical technology, and the misconceived concepts of electricity and medicine. The author or DigiKey does not endorse the ideas or opinions in the books covered in this article.

Written by David Ray, Cyber City Circuits

'Kind reader, I am determined to withhold nothing that shall be necessary to consummate your happiness and make you Master of the art of medical impractical electricity you shall reap the full harvest of all my labors for nearly 20 years on a subject that has engrossed my whole attention.'

T. Gale M.D. and his vision

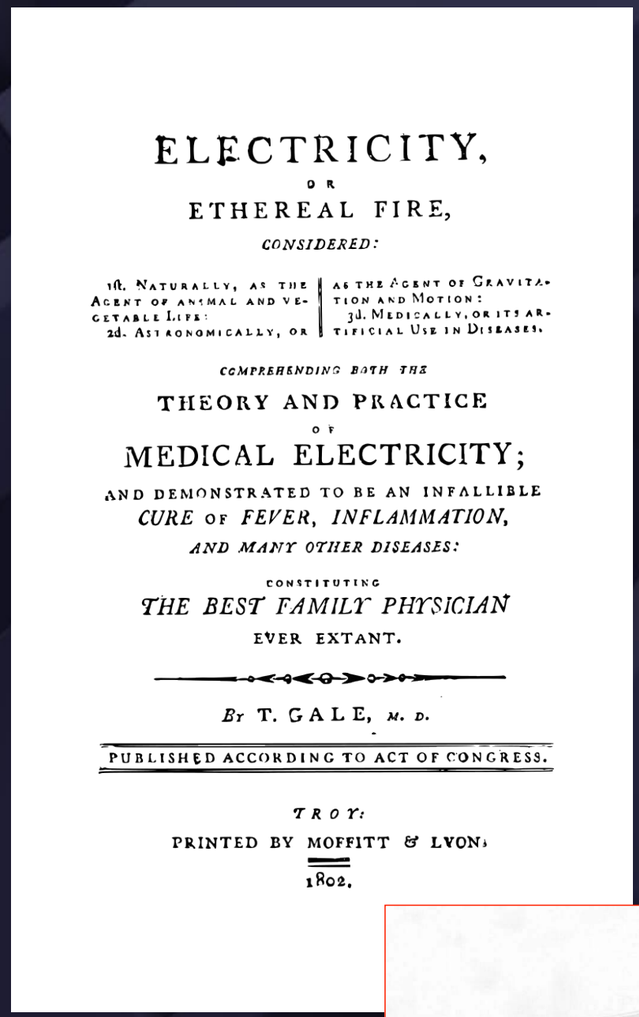
Modern medicine includes various applications for electricity, from pulse oximeters and blood pressure cuffs to MRI machines and CT scans. Civilization's ability to harness electricity revolutionized healthcare, curing diseases and extending lifespans.

The American Revolution bloodied the late 18th century, along with the plagues of pestilence, famine, and disease that always follow war. Diseases that are rarely treated today were very common. Medical training was sparse, and the frontiers were vast. Commonplace medicines like penicillin wouldn't be invented for over another hundred years.

Medicine in post-revolution America was a trial, with limited access to trained physicians and an increased need for self-care education. Itinerant physicians would journey through the countryside by horse and buggy, pitching elixirs to cure the loss of vigor and snake oil to treat consumption. By the late 1700s, with the invention of the Leyden Jar, electricity had been added to the mix of concoctions and cure-alls. Soon after, Luigi Galvani's writings introduced the concepts of 'animal electricity' and galvanism to the masses. For much of electricity's youth, it was wrapped in mysticism, superstition, and other controversies.

In 1802, Dr. T. Gale M.D. wrote an ambitious guidebook called 'Electricity or Ethereal Fire Considered.' It is thought by historians to be the very first electrotherapy or electrical medical guidebook published in the New World. In it, Dr. Gale makes a great effort to teach every man, from doctor to farmer, how to use electricity to heal themselves and their communities. He served in Saratoga County, New York. This was a real frontier at the time, as the county had only been established ten years earlier.

Very little is known about Dr. Gale himself, including his first name. All of this, it does seem, is lost to history, making this book the entirety of his surviving legacy. In the book, he alludes that he started practicing medicine as a traveling doctor in the 1780s, just as the American Revolution ended. In the book, Dr. Gale explains his views on electricity and how to build a machine to offer treatments for only two dollars in cost.



ELECTRICITY,
OR
ETHEREAL FIRE,
CONSIDERED:

1st. Naturally, as the Agent of animal and vegetable Life:
2d. Astronomically, or as the Agent of Gravitation and Motion:
3d. Medically, or its artificial Use in Diseases.

COMPREHENDING BOTH THE
THEORY AND PRACTICE
OF
MEDICAL ELECTRICITY;
AND DEMONSTRATED TO BE AN INFALLIBLE
CURE OF FEVER, INFLAMMATION,
AND MANY OTHER DISEASES:
CONSTITUTING
THE BEST FAMILY PHYSICIAN
EVER EXTANT.

By T. GALE, M. D.

PUBLISHED ACCORDING TO ACT OF CONGRESS.

TROY:
PRINTED BY MOFFITT & LYON.
1802.

Electricity: the soul of the universe

"This ethereal element, which I think is deservedly called the soul of the universe, assumes a variety of states and powers. I call it fire because when it expands, it is capable of giving flame to combustibles, as lightning will fire a tree, building, and many bodies. The spark from an electrical machine will give flame to spirit, and if the spark were sufficiently copious, it would produce all the effects of lightning."

Figure 1. Itinerant Physician

Figure 2. Saratoga County 1793

Electrical effluvia

During this time, the concept of electricity was very abstract and poorly understood. Benjamin Franklin's famous kite experiment was just fifty years prior. It was generally thought that electricity was a fluid called 'effluvia,' which pervades all substances. If you have ever been around a highly charged device, like a transformer, you might have witnessed the phenomenon known today as 'corona discharge.' When the electric field becomes strong enough, it ionizes the surrounding air, causing a visible glow, and you may even feel the hair on your arms stand up. In the late 18th century, this was thought to be caused by the conductor building a charge and interacting with an unseen effluvia field.

When researching ideas surrounding electricity in this era, some describe effluvia as akin to the 'Holy Spirit' of the Christian Trinity. They saw the mysterious power of electricity as an expression of divine force, with electrical sparks or lightning often interpreted as physical manifestations of God's presence or a sign from the heavens. In many societies of the day, suggesting that electricity could be anything less than divine was considered heresy and punished accordingly.

The four fundamental elements

Natural philosophers and scientists commonly thought that all matter was composed of a combination of four fundamental elements: Fire, Earth, Air, and Water, which create the balance to the universe. The Greek philosopher Empedocles created this theory of matter in the fifth century BCE. These teachings lasted for over two thousand years and are mostly found in mysticism and the occult today. This teaching was so prolific that it is what Aristotle and Socrates would have learned when they were in school.

'I call it fire because when it expands, it is capable of giving flame to combustibles as lightning will fire a tree, buildings, and many bodies. The spark from an electrical machine will give flame to spirits, and if the spark were sufficiently copious, it would produce all the

Figure 3. Empedocles

effects of lightning. I call it frost because according to the existing degree of its density, so is the degree of cold.'

Frost, lightning, and elementary fire

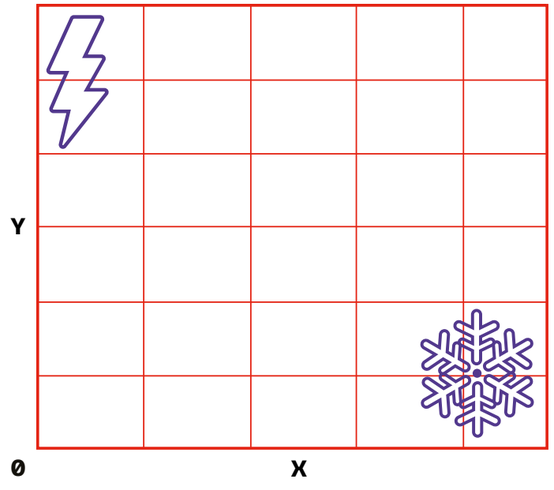
Elementary fire has a spectrum of electrical power that depends on the density of the fire element within an item. Highly conductive items contained less dense elementary fire and thus conducted very well, while things with a highly dense elementary fire could not conduct well. The book outlines a list and grade of conductors for the reader:

- **First class** – quality, metallic substances
- **Second class** – water, blood, or liquids
- **Third class** – animal bodies
- **Fourth class** – green wood
- **Fifth class** – dry wood, earth, and the like

Dr. Gale believed that electrical effluvia and elementary fire were the same. This also explains how lightning can create fire when it strikes the earth. Prior to the invention of the Leyden Jar, electricity was primarily only found in lightning and static shocks.

On one end of the spectrum, you find lightning, a high-powered, low-density manifestation of elementary fire. This is why lightning starts fires. On the other end of the spectrum, you'll find frost. The same frost you'll find on a window on a winter morning is made up of the exact same stuff as lightning but in a much denser form.

Figure 4. Elementary fire chart



Medical electricity

Disclaimer: The following is not intended to be medical advice and should not be used as such. It explores post-Revolutionary War America, the innovations surrounding medical technology, and the very poorly understood concepts of electricity and medicine. The author or DigiKey does not endorse the ideas or opinions in the books covered in this article.

"Every consideration that hath induced me to publish this treatise, stands opposed to that idea: I know that medical electricity hath never been understood and the subject is very occult…"

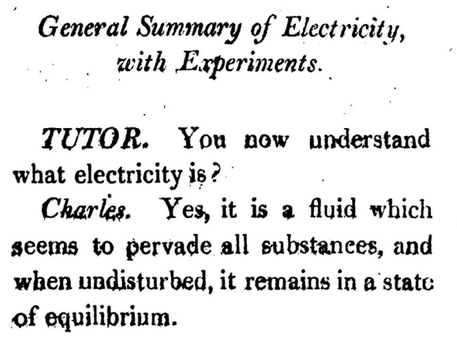
Another belief that survived from Aristotle's time was the theory of the four humors: blood, phlegm, yellow bile, and black bile. This doctrine originated from the Hippocratic medicine of ancient Greece and was further developed by people like Aristotle. It taught that health relies on maintaining a balance among these four bodily fluids, with each humor associated with specific qualities, like hot, cold, wet, and dry, and affects physical and mental well-being.

In this framework, diseases result from imbalances in these humors, leading to treatments designed to restore balance. For instance, if a patient has a fever, it was believed that there was an excess of blood, characterized as being *"hot and wet."* Bloodletting was used to reduce the excess and restore balance using tools like leeches.

"…electricity is a peculiar and an infallible remedy for fever and inflammation."

While this approach lacked any true scientific basis as we understand it today, it was influential. It formed the foundation for much Western medical practice until the 19th century.

Figure 5. What is electricity



General Summary of Electricity, with Experiments.

TUTOR. You now understand what electricity is?

Charles. Yes, it is a fluid which seems to pervade all substances, and when undisturbed, it remains in a state of equilibrium.

An excessive action of the shock described

Early in the book, it describes electrocution. Using the theory of 'electrical effluvia,' he reasons that when an excessive shock is given, the blood vessels burst only because they aren't strong enough to embrace the increased electrical effluvia, causing instant death.

Asthma

When talking about asthma, he says that he is not sure if it can be cured with electric shocks, but he is certain it could 'throw off' an active asthma attack.

Arthritis

Electricity was a common treatment for rheumatoid arthritis. It claimed that it can treat inflammation in 'such a manner as no other medicine on earth can possibly do.' The treatment removes tension, offering relief.

Consumption

During this time, consumption was the leading cause of death. Known today as tuberculosis, it starts in the lungs and spreads throughout the body. It was characterized by severe coughing fits, followed by quick and significant weight loss, leading to the appearance of a body that was 'consumed' from within. This disease was highly contagious and did not have a proper treatment until the invention of antibiotics.

At the time, the most common treatment for consumption was insolation. For many hours a day, every day for months, the patients would be left outside to sunbathe. This was used to treat many chronic diseases. Modern medicine shows that sun exposure allows the body to develop vitamin D. The symptoms of vitamin D deficiency include fatigue, back pain, weakness, depression, hair loss, muscle cramps, etc. With a modern eye, it is easy to see why insolation was considered an effective treatment.

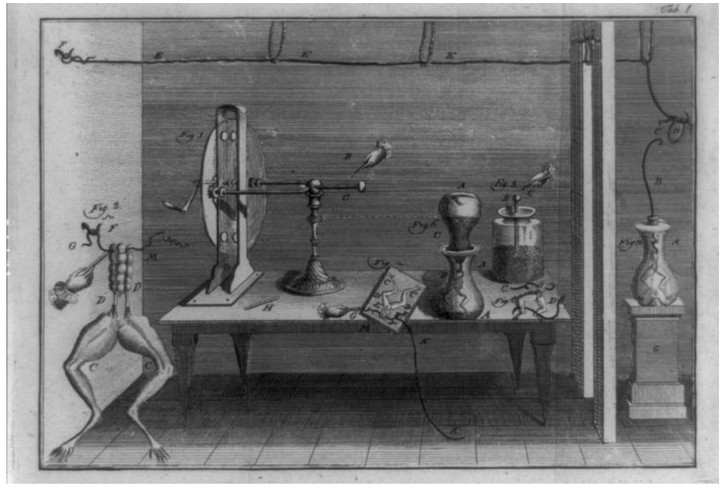


Figure 6. Galvani

'The patient must be made warm with little temperature variation in combination with insolation. Then, proceed to electrify the patient, but very lightly. A stronger shock would dilate the blood vessels and further weaken the patient. At the first electrification, as many as twenty shocks may be given, with the last few shocks being from the forehead to the feet. In the following three or four days, the patient may receive the same number of shocks, which must be reduced afterward.'

He tells of elixirs, teas, and tallows that he has heard of from other doctors. He gives the recipe for a tea made from the roots of a bayberry bush. He tells of how someone could only take one tablespoon twice a day without food, or else they would 'offend their stomachs.'

The book claims that not many cases of consumption would fail to be cured by electrical shocks alone, but when it is paired with the elixir paregoric, the cases that could resist his treatments would be very few, if any at all. The elixir paregoric was a common over-the-counter opiate treatment for many things, from cough and diarrhea to tuberculosis and pain relief.

Dysentery

Dr. Gale concedes that it sounds ludicrous to treat dysentery with electrification, and he says that he would never have suggested it if it wasn't for a patient a few years earlier, a man named Mr. Huntington. He arrived at Dr. Gale's office one day with 'vehement dysentery,' begging for relief. At first, he refused treatment to the man, but after days of seeing the man in great pain, he decided to treat the man. Dr. Gale gave him twenty very light shocks through the inside of his bowels to his back, and this eased his pain. Within a few hours, the pain came back, and he treated him the same as he did before, but there was less blood at that time. He did these three or four more times and was cured within 30 hours.

He continues the story that the following summer, there was an epidemic of dysentery. It claimed a lot of lives in Saratoga County. Nearly two-thirds of the people, particularly infants, did not survive. He was told that no children younger than two survived the disease except for two. The two surviving children were also the only two he treated with his electric machine.

He published these findings in a newspaper, but it didn't get the attention he thought he would. He later heard of Dr. Lyon in Lebanon, New York. Dr. Lyon found his article and was able to cure everyone in his community with the disease that had survived to that point.

He says treating dysentery was his 'only inconvenience to be regretted' while using medical electricity. While it is a miserable treatment, he tells of curing a four-month-old baby in an instant with half a dozen electric shocks.

Epilepsy

'This disease may sometimes be cured, but may always be relieved by electrifying… the gentle electrifications go the farthest in relieving persons who are so unhappy as to be subject to it.''

At the time, the most common treatment for epilepsy was insolation, but when insolation didn't work, Dr. Gale suggested artificial insolation by way of electric shocks. He states that if done correctly, a few light shocks from hand to hand will delay an oncoming seizure. If it does not, however, pass a shock from the top of the head to the feet, and they will immediately recover their senses.

After the series of shocks, the operator should prepare the patient a drink made of valerian root. Sometimes, it is helpful to alternate with opiates. It is important to keep the patient warm, as one slight chill can bring on a seizure.

Fever

The common treatment for fever was bloodletting. It worked by releasing tension on the blood vessels, allowing the patient to bleed out some amount, lessening a fever, by decreasing the blood pressure. Dr. Gale continues to explain that bloodletting is often a temporary measure.

Figure 7. 1880s Therapy

"I know of no fever without tension and retension; in short, this is what constitutes a fever, and to remove these is to cure a fever."

However, Dr. Gale was convinced that electric shock is useful to enlarge or dilate blood vessels. In his instructions, he explains that diaphoresis (when someone is sweating but not from outside heat or exercise, a.k.a. fever sweats) is needed before treatment. He states that 'to begin the electric shock before perspiration is established would be to leave the cause of heat unremoved' and would result in the same temporary effects of bloodletting.

Sore throat

The book says to treat sore throat

in the same way you would treat a fever, but not before the patient experiences diaporetics or fever sweats. The operator is to give shocks from shoulder to shoulder and then from underneath the chin to the feet, with the neck covered with a warm compress. This should be followed by a warm drink that includes white oak bark.

Gout

When discussing gout, Dr. Gail mentions that it used to be common practice to treat gout with strong shocks of electricity, but since that practice has been universally discarded, it discredited the use of electricity in medical treatment. He claims that relief should be the target of treatment, not cure. He begs instead to use several light shocks at a time.

Madness

In an example of early electro-shock therapy, Dr. Gale describes how to use electric shocks to treat insanity. He describes madness as a redundancy of blood in the head causing compression and irritation of the brain. Treatment includes keeping the patient warm and placing shocks of varying degrees on the patient.

He tells the story of one summer when a young man came to him to inform him that his father was crazy and to ask for his help. The son tells the story of his father selling his large farm to move to Galway and purchase two other smaller farms. Through deception and chicanery, he lost big in the deal, and this had a profound effect on his mental health. His family was already concerned about him, chaining him to the bed at night.

The next day, the father's family brought him up in a wagon. It took several people to move him as he constantly tried to remove his clothes and strip naked. He says that the man was violent and that he was scared that his very costly machine would be smashed and broken by him. He says it took twenty men to help him chain the man down. He says that he charged his machine as high as he thought that the man could live through, and then he passed a shock through him so strong that it knocked him to the floor. He continued to give six or seven lighter shocks to the patient, and the patient's behavior changed immediately. He was able to leave under his own strength. They returned the next day for a second treatment, and it was not long before he had the right use of his mind.

Palsy

In the section on treating palsy, Dr. Gale explains that palsy is caused by an insufficient flow of the muscle's own elementary fire, leading to weakened or paralyzed limbs. Remember, Gale thought that elementary fire and electricity were the same thing, and by providing shocks, the operator would inject elementary fire into the patient's body through the electric shocks.

Gale emphasizes that the electrical current works by stimulating the nervous system and improving circulation, which, in turn, helps revive muscle function. A partial palsy hardly ever fails a speedy cure by giving thirty or forty light shocks during the course of each day.

Smallpox

'Here, kind reader, is an infallible remedy in smallpox or measles'

Smallpox was a global plague of this time. It wasn't properly treatable until the invention and propagation of vaccines in the early nineteenth century. Dr. Gale developed a treatment using electricity and says that he proved this treatment with his own nine-year-old son when he contracted smallpox. The treatment consisted of pacing light shocks through each part of the body, avoiding the blisters caused by the disease.

Vertigo

In a short note, Dr. Gale lists how to treat vertigo or 'swimming in the head.' It is caused by too much blood being created by an overactive aorta. To treat this disorder, the operator should give 'six or eight pretty strong shocks' from the sides of the neck to the feet.

The legacy of medical electricity

It is remarkable how far civilization has come in the past 225 years. Dr. Gale's book represents an early and ambitious attempt to introduce medical electricity to a broader audience. He challenged the conventional boundaries of medical practice, aiming to empower individuals with the knowledge and tools to take control of their health. This book fosters a self-reliance spirit that deeply represents early America's ideals. Although Dr. Gale's understanding of electricity and his medical applications seem primitive today, his pioneer spirit and desire to democratize healthcare were ahead of their time.

Today, electronic medical devices are everywhere. You may interact with dozens of them daily. From smart watches to pacemakers, they are integral to twenty-first-century life.

"Every consideration that hath induced me to publish this treatise, stands opposed to that idea: I know that medical electricity hath never been understood and the subject is very occult..."

1752
Benjamin Franklin conducts his famous kite experiment.

1775
The Battle of Lexington and Concord formally begins the American Revolution

1783
American Revolution comes to an end.

1785
Dr. T. Gale starts treating patients as an 'itinerant physician' or traveling doctor.

1783
American Revolution comes to an end.

John Adams is named as the nation's first ambassador to Great Britain.

1788
The United States Constitution is ratified.

The United States Dollar is chosen as the nation's unit of currency and trade.

George Washington was elected to be the first President of the United States.

1789
The French Revolution begins.

1802
'Electricity or Ethereal Fire Considered' is published.

1821
'The Galvanic Circuit Investigated Mathematically' is published Georg Ohm.

How to use high accuracy digital temperature sensors in health monitoring wearables

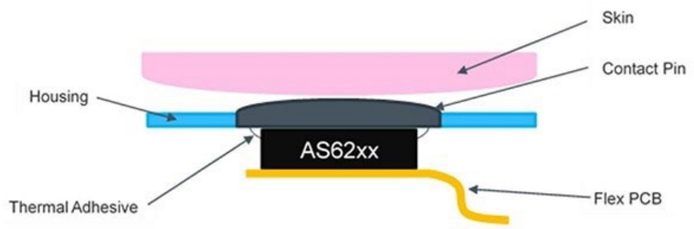
Written by Jeff Shepard

Accurate digital temperature measurements are important in a range of applications including wearables, medical monitoring devices, health and fitness trackers, cold chain and environmental monitoring, and industrial computing systems. While widely applied, the implementation of highly accurate digital temperature measurements frequently involves temperature sensor calibration or linearization, as well as higher power consumption which can be an issue for compact, ultra-low power applications with multiple acquisition modes. The design challenges can quickly mount, causing cost overruns and delayed schedules.

Complicating the matter, some applications involve multiple temperature sensors sharing a single communication bus. In addition, some production test setups need to be calibrated according to the U.S. National Institute of Standards and Technology (NIST), while verification equipment needs to be calibrated by an ISO/IEC-17025 accredited laboratory. Suddenly, what seemed a straightforward function becomes both intimidating and costly.

This article briefly describes the requirements for high-accuracy temperature measurements in mobile and battery-powered

Figure 1: A flex PCB and thermal adhesive can be used to provide a low thermal impedance path between the skin and the sensor. Image source: ams OSRAM



health monitoring applications. It then introduces a low-power, high-accuracy digital temperature sensor IC from ams OSRAM that doesn't require calibration or linearization. It finishes with integration recommendations, an evaluation board, and a Bluetooth-enabled demo kit with a companion app that makes it possible to modify sensor settings and observe the impact on power consumption.

Requirements for high-accuracy temperature monitoring

Accuracy is mandatory in health monitoring applications. As manufactured, digital temperature sensors exhibit part-to-part variations in performance that need to be addressed. As in-house calibration is expensive and using uncalibrated sensors increases the cost of achieving the desired accuracy, designers should consider sensors that are fully calibrated and linearized. It is, however, important to ensure that the sensor maker uses calibration instruments traceable to NIST standards. Using instruments with traceable calibration ensures an unbroken chain back to the basic NIST standards, with the uncertainties at each link in the chain identified and documented so they can be addressed in the device maker's quality assurance system.

The primary standard for testing and calibration laboratories is ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories." ISO/IEC 17025 is based on technical principles focused specifically on calibration and testing laboratories, is used for their accreditation, and provides the basis for developing continuous improvement plans.

Digital temperature sensor with NIST-traceable production testing

To meet the many design and certification requirements, designers can turn to the AS6211 digital temperature sensor from ams OSRAM that provides accuracy up to ±0.09°C and requires no calibration or linearization. Designed for use in healthcare devices, wearables and other applications that require high-performance thermal information, the AS6211's production testing is calibrated by an ISO/IEC-17025 accredited laboratory according to NIST standards. The calibrated production testing speeds the process of gaining certification to EN 12470-3, which is required for medical thermometers in the European Union.

The AS6211 is a complete digital temperature sensor in a six-pin, 1.5 x 1.0-millimeter (mm) wafer level chip scale package (WLCSP), ready for system integration. An orderable part number example, the AS6221-AWLT-S, is delivered in lots of 500 pieces on tape & reel. The AS6211's measurements are delivered through a standard I²C interface, and it supports eight I²C addresses, thereby eliminating concerns about bus conflicts in multi-sensor designs.

Figure 2: When the sensor is mounted on the bottom of a PCB, thermal vias and a contact spring can be used to connect to the contact pin. Image source: ams OSRAM

High accuracy plus low power

The AS6221 delivers high accuracy with low power consumption over its full supply range from 1.71 to 3.6 volts DC, which is especially important in applications powered by a single battery cell. It includes a sensitive and accurate silicon (Si) bandgap temperature sensor, an analog-to-digital converter, and a digital signal processor with associated registers and control logic. The integrated alert function can trigger an interrupt at a specific temperature threshold, which is programmed by setting a register value.

The AS6221 consumes 6 microamperes (µA) when making four measurements per second, and in standby mode, power consumption is only 0.1 µA. The use of the integrated alarm function to wake up the application processor only when a temperature threshold has been reached can reduce system power consumption even more.

Wearables integration options

In wearable applications, the better the thermal connection between the sensor and the skin, the more accurate the temperature measurement. Designers have several options for optimizing the thermal connection. One way is to put a thermally conductive pin between the skin and the sensor (Figure 1). To achieve reliable results, the pin needs to be isolated from any external sources of thermal energy, such as the device case, and a thermal paste or adhesive should be used between the pin and the AS6211. This approach benefits from using a flexible (flex) printed circuit board (PCB) to carry the AS6221, enabling more freedom in locating the sensor.

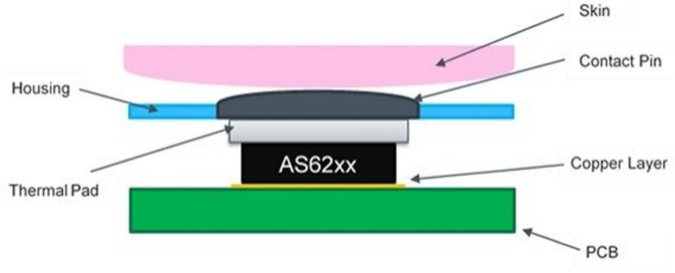


Figure 3: A thermal pad can connect a top-mounted sensor to the contact pin. This provides simpler assembly, while still delivering high performance. Image source: ams OSRAM

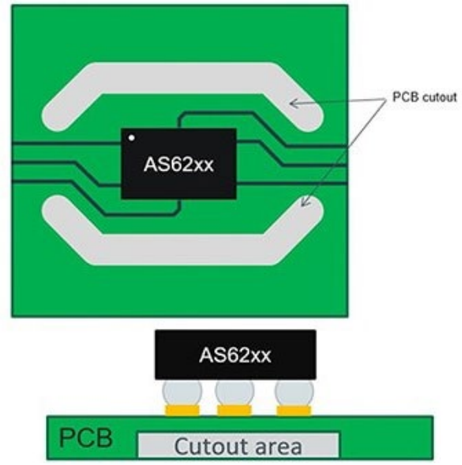


Figure 4: Cutouts on the top and bottom of the PCB can minimize the PCB mass around the sensor and improve its response time. Image source: ams OSRAM

In designs that benefit from having the sensor on the main PCB, the thermal connection can be made using a contact spring or a thermal pad. If the sensor is mounted on the bottom of the PCB, a contact

spring can be used to make a thermal connection between the contact pin and thermal vias on the PCB that are connected to the sensor (Figure 2). This approach can result in a cost-effective device that supports longer distances between the sensor and the skin, but it requires careful consideration of the several thermal interfaces to achieve high levels of sensitivity.

A third option is to use a thermal pad to connect the pin to a sensor mounted on the top of the PCB (Figure 3). Compared with using a spring contact or flex PCB, this approach requires a pad with high thermal conductivity and careful mechanical design to ensure minimum thermal impedance between the contact pin and the sensor. This can result in a simpler assembly while still delivering high levels of performance.

Improving thermal response time

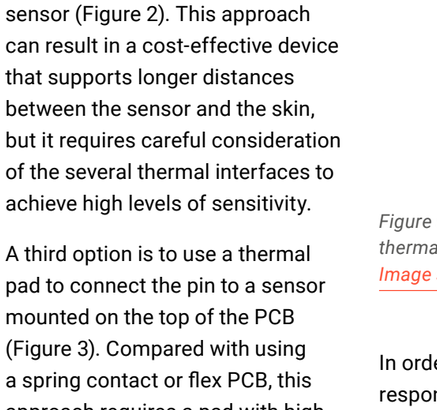


Figure 6: The AS62xx eval kit can be used to set up and evaluate the AS6221.
Image source: ams OSRAM

In order to obtain fast thermal response times, it's important to minimize the external influences on the measurement, especially by the portion of PCB directly adjacent to the sensor. Two viable design suggestions are to use cutouts to minimize any copper planes in the vicinity of the sensor on the top of the PCB (Figure 4, top), and to reduce thermal loading from the bottom of the PCB by using a cutout area below the sensor to reduce overall PCB mass (Figure 4, bottom).

In addition to minimizing PCB effects, other techniques that can help improve measurement speed and performance include:

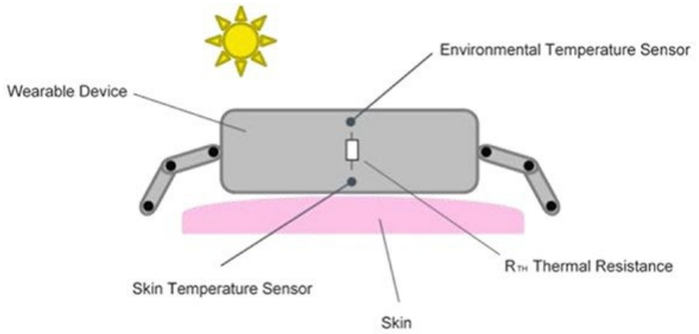


Figure 5: For accurate environmental temperature sensing, there should be a high thermal resistance between the skin and environmental temperature sensors.
Image source: ams OSRAM

- Maximizing the contact area with the skin to increase the heat available to the sensor
- Using thin copper traces and minimizing the size of power and ground planes
- Using batteries and other components such as displays that are as small as possible to achieve the device performance requirements
- Designing the package to thermally isolate the sensor on the PCB from the surrounding components and the outside environment

Sensing environmental temperature

Additional considerations apply when using multiple temperature sensors, such as in designs that use both skin temperature and the temperature of the surrounding environment. A separate sensor should be used for each measurement. The thermal design of the device should maximize the thermal impedance between the two sensors (Figure 5). A higher intervening thermal impedance provides better isolation between the sensors and ensures that the measurements will not interfere with one another. The device package should be fabricated with materials that have low thermal conductivities, and a thermal isolation barrier should be inserted between the two sensor sections.

Eval kit kickstarts AS6221 development

To speed application development and time to market, ams OSRAM offers designers both an eval kit and a demo kit. The AS62xx Eval Kit can be used to quickly set up the AS6221 digital temperature sensor, enabling a quick evaluation of its capabilities. This eval kit connects directly to an external microcontroller (MCU) that can be used to access temperature measurements.

Demo kit for the AS6221

Once the basic evaluation is completed, designers can turn to the AS6221 demo kit as an application development platform. The demo kit includes an AS6221 temperature button and a CR2023 coin cell battery. Downloading the companion app from the App Store or Google Play Store supports connection to up to three sensor buttons at one time (Figure 7). The app communicates with the sensor buttons over Bluetooth, making it possible to modify all of the sensor settings, including the measurement frequency, and observe the impact on power consumption. The app can record measurement sequences, thereby enabling comparisons of the performance of various temperature sensor settings.

Figure 7: The AS6221 demo kit serves as a temperature sensor application development platform for the AS6221.
Image source: ams OSRAM

Designers can also use the demo kit to experiment with the alert mode and learn how it can be used to improve solution performance.

Conclusion

Designing high-accuracy digital temperature sensing systems for healthcare, fitness, and other wearables is a complex process with respect to design, test, and certification. To simplify the process, lower cost, and get to market more quickly, designers can use highly integrated, low-power, high-accuracy sensors.

As shown, the AS6221 is one such device. It does not require calibration or linearization, and the production testing equipment is calibrated according to NIST standards by an ISO/IEC-17025 accredited laboratory, speeding the design and approval process for medical devices.

IEC 60601-1-8 guidance for designing medical equipment alarms

Written by Jeff Smoot, VP of Apps Engineering and Motion Control at Same Sky

One aspect of medical equipment that is often overlooked is the way the equipment communicates with its users. Visual indicators are incredibly useful, vital even, and can convey a significant amount of information in moments.

There are many challenges to designing medical equipment above and beyond the design of consumer equipment. In addition to higher reliability standards, medical equipment has more stringent and specific requirements. This makes sense as the stakes are much higher than with consumer electronics, where equipment failure is literally a life-or-death difference.

One aspect of medical equipment that is often overlooked is the way the equipment communicates with its users. Visual indicators are incredibly useful, vital even, and can convey a significant amount of information in moments. However, they require the user to pay specific attention to the equipment. Audible signals, however, can catch the attention of people in and out of a room, leading them to come and review the situation and gain information.

However, one of the challenges is that if there is a large variety of different medical equipment, which is more than likely in hospital settings, there could be a cacophony of confusing and conflicting audible tones. Different frequencies, loudness, and patterns would require rote memorization of a large variety of signals, which would almost certainly add to confusion instead of clarifying. Thus, the IEC 60601-1-8 standard was created to provide guidelines to designers on how to create medical equipment that quickly and clearly communicates the intended message to doctors, nurses, and other attendants. This article will review this standard in more depth and help to decipher a few of the nuances involved.

What is the IEC 60601-1-8?

As we start getting into IEC 60601-1-8, we should note where this actually comes from and the authority by which it is created and implemented. This was created by the International Electrotechnical Commission (IEC), a European-based standards organization that created the IEC 60601 technical standard that addresses all medical equipment. IEC 60601-1-8 is a subset that specifically addresses medical alarm systems. The verbose title of this subsection is: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

Like nearly every technical standard, this is a long and detailed document that provides explicit instructions on nearly every conceivable alarm. It includes instructions on when alarms should be triggered, how their priority is classified, and perhaps most importantly, provides the different patterns that define exactly what the alarm will sound like. Signal burst pattern, pulse shape, pulse frequency, rise/fall time, and amplitude are all given. There are regulations given to separate alarms from technical issues where there are potential faults with the equipment itself versus problems with the patient. While these alarms are all well-regulated, it also explicitly allows for more sounds to be used, like music or voices.

Outside of the more general guidelines, the IEC 60601-1-8 standard also outlines important technical metrics pertaining to medical alarms, such as:

- The alarm frequency must be between 150Hz to 1,000Hz and must be one of four harmonics with the greatest sound level.
- There must be a minimum of four frequency peaks between 150Hz and 4,000Hz.
- The sound level of the greatest four frequency peaks between 150Hz and 4,000Hz must be within 15 dB of each other.

Figure 1: Same Sky buzzer designed for medical applications. Image source: Same Sky

While this standard originated in the European Union, it is mandatory not only in the EU but also in the US and Canada. This is hugely beneficial for product designers to promote simpler compliance in multiple major locations and improves device safety and performance across the globe.

Medical alarm systems part selection

There are many components that can be used for the audio portions of a medical device. Sirens, buzzers, and even bells can be used, though other transducers are very common as well. These components are not equal and vary significantly ir the difficulty of implementation, cost, power consumption, and flexibility. Electrical buzzers chec the boxes in terms of cost, ease of implementation, flexibility, and power efficiency. Buzzers are unique because they either use electromechanical drivers, sometimes referred to as magnetic buzzers, or piezoelectric drivers, using a ceramic piezo driver. Because of these options, you can get different voltages, frequency ranges, sound pressure levels, footprints, and more, making buzzers the ideal choice for many alarms. In particular, Piezo buzzers are known for creating a louder signal (larger sound pressure level) than their electromechanical counterparts for the power consumed.

With buzzers, you also have the possibility to customize their output so that a buzzer can, without any special driver, create the precise tone required by IEC 60601-1-8. Same Sky has created an array of medical buzzers that not only meet the audio requirements set out by the guidelines but also meet the robustness requirements outlined. The tones available are identified in IEC 60601-1-8 and correspond to the more common concerns found in the medical industry (click the links below to listen to the specific tones):

- Cardiovascular, which sounds somewhat like a heart beating
- Oxygen, which sounds similar to a dripping noise
- Ventilation, which sounds like someone breathing
- General, which is a more generic sound

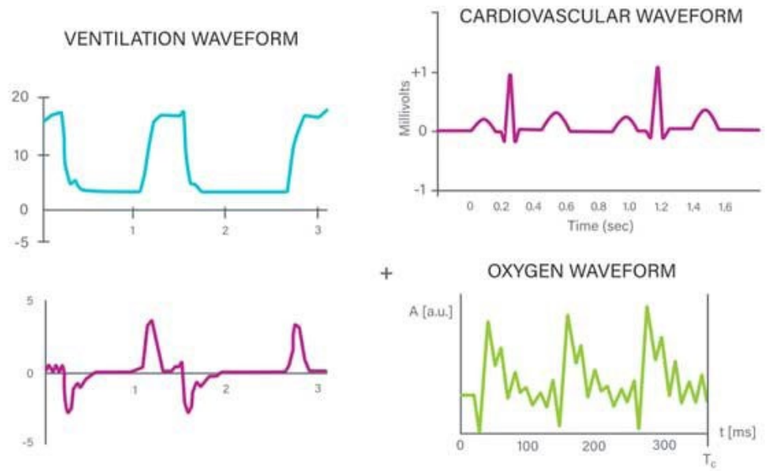


Figure 2: Sample waveforms of specific medical device tones. Image source: Same Sky

Medical equipment is and will continue to be in great demand and expectations will also continue to rise. Fortunately, with clear and detailed instructions, the IEC 60601-1-8 standard codifies and simplifies the alarm aspect of medical equipment.

Speakers versus buzzers in medical equipment

While IEC 60601-1-8 is focused on the sounds, the waveforms, and where the buzzers are used, it does not provide significant direction on what exactly should be used nor where it should be placed. While there are many benefits to buzzers, and they work in a wide range of applications, as mentioned earlier in this article, there are other options. While not as energy efficient as buzzers and more difficult to drive, speakers offer almost limitless flexibility in the sounds they make. Fully human voices, music, and any mixture of sounds, even at the same time, are all possible using a standard speaker.

There are directions in IEC 60601-1-8 about how speakers tend to make popping noises when there are sudden voltage changes, like when old headphones were plugged into a receiver or computer. While shaping the noise waveforms, you can avoid any sharp changes that would cause these noises, however, you will need to account for unexpected noise. Properly sized capacitors can absorb high frequency noises if they do not interfere with the intended signal. Physically protecting the connections from potentially coming into contact with outside electrical sources, including static electricity, will also help with this concern. Overall, while speakers are more of a challenge and require more thought in their implementation, they are an excellent choice when extra flexibility is needed. Same Sky has also developed specific medical speakers designed to meet the IEC 60601-1-8 guidelines.

Conclusion

Medical equipment is and will continue to be in great demand and expectations will also continue to rise. Fortunately, with clear and detailed instructions, the IEC 60601-1-8 standard codifies and simplifies the alarm aspect of medical equipment. While intense and potentially daunting, properly done, audible medical alarms can significantly increase the effectiveness of equipment and potentially save lives. To decrease the barrier to entry and any difficulty in implementing these guidelines, Same Sky has created medical buzzers and speakers that meet IEC 60601-1-8 requirements. For more explicit detail about IEC 60601-1-8, you can purchase the official document on the IEC website at www.iec.ch.

Keep biomedical sensors firmly in place and reduce errors with medical securement tape

Written by Bill Giovino

As the Internet of Things (IoT) expands into medical devices there has been an increase in the number and variety of biometric sensors that must be attached to human skin. The collected data is used to monitor and diagnose medical conditions, as well as study and improve the performance of professional athletes and commercial at-home personal exercise programs.

While specially manufactured medical securement tape is commonly used to secure the sensors, these tapes are not "one-size-fits-all". Instead, various factors must be considered such as comfort, air and moisture permeability, and resistance to fluids, all adding to the complexity of tape selection. In addition, for some applications, the tape must be quickly and easily removed and reattached to the skin to reposition the sensors, which can be important in emergency situations. What is needed is a variety of medical tapes that are easily differentiated so that they can be applied to the appropriate situation.

This article introduces a family of medical tapes from 3M designed for different human skin attachment situations. The article explains the uses of four 3M medical tapes and how they address specific medical securement applications. It also looks at the advantages of standardizing on one family of medical tape, which include simplifying purchasing, consistency of documentation, and ease of use.

The selection of backing and adhesive in the construction of a medical tape determines its use characteristics. Medical securement tape situations are not all the same, and the proper selection and use of the tape requires considering a number of ergonomic factors.

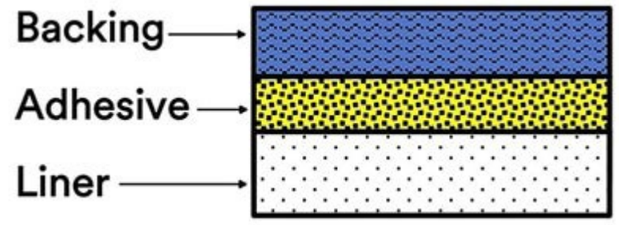


Figure 1: Medical securement tape is usually composed of a backing (top) and an adhesive (middle). A liner (bottom) protects the adhesive and is pulled away when ready for use. Image source: 3M Medical Materials

Medical securement tape applications

Just as the availability and wide selection of environmental sensors has spurred growth in commercial IoT as well as Industrial IoT (IIoT), the availability and variety of biometric sensors are encouraging new medical sensing devices, including medical IoT devices. Consumer biometric sensing products such as smart watches with heartbeat monitors can easily be strapped to a wrist, while consumer heart monitors can be strapped around a person's chest to provide even better-claimed accuracy. This improved accuracy is due not only to using a more precise sensor but also to the secure placement of the heart monitor over the heart. The accuracy of biometric sensor data is directly related to both sensor type and proper placement on the skin.

However, for medical-grade biometric sensing applications, many sensors must be attached to locations not amenable to a simple strap. In addition, they may also need to be more tightly and securely coupled to the skin surface for a reliable biometric reading. This requires the use of medical securement tape to keep the sensor in place. As seen in Figure 1, most medical securement tape is composed of a printable and writable backing that is the tape itself, an adhesive to affix the tape to skin, and a removable liner that is pulled away to expose the adhesive.

The selection of backing and adhesive in the construction of a medical tape determines its use characteristics. Medical securement tape situations are not all the same, and the proper selection and use of the tape requires considering a number of ergonomic factors. These combined factors dictate the construction of the tape's backing, and the choice of adhesive used.

Medical securement tape ergonomics

One important consideration is fluid resistance. For long-term use, a medical securement tape can become wet due to frequent washing of the area or during a shower, resulting in a lack of adhesion, leading to unreliable sensor readings. If fluid resistance is a requirement, that often involves a tape backing made of polyethylene with an acrylic-based medical adhesive. This construction is not only resistant to fluids but also prevents water vapor – such as in a hot shower or an area with high humidity – from permeating the tape.

A complementary requirement to fluid resistance is the typical moisture vapor transmission rate (MVTR) of the tape. MVTR is typically specified in grams per square meter (gm/m²) of moisture allowed through the material over a 24-hour period. While in some situations no fluids or water vapor at all may be allowed past the tape (MVTR = ~0), in others it may be necessary to allow moisture such as perspiration to pass through the tape. In the latter, a nonwoven fabric tape backing allows the skin to breathe and perspiration to evaporate.

There are some use cases where a tape must be easily repositionable so that the sensor can be quickly relocated or allow for limited multiple uses on the same patient. While a variety of adhesives are available for one-time-use tapes, silicone-based medical adhesives allow the sensor to be easily

Figure 2: The 3M 4077 medical securement tape is recommended for extended wear of up to 14 days. It ships in a convenient roll that is less than 8in. diameter. Image source: 3M Medical Materials

removed and securely attached again.

The comfort of the tape is always important, especially for extended-wear tapes. Nonwoven fiber tape with at least a moderate MVTR is usually the most comfortable, although polyethylene tape can be somewhat comfortable depending on the construction and placement. Tape comfort is also related to the thickness of the backing and the length of time a tape is used. Extended-wear tape needs to be comfortable for up to a week without causing patient discomfort, and thinner backing material can provide more flexibility and comfort.

3M medical securement tapes

To address these different applications, 3M Medical Materials manufactures a variety of different medical securement tapes. These securement tapes take into account the various ergonomic factors discussed above. In addition, because these tapes can be standardized and are available from one supplier, 3M simplifies inventory management and provides consistent documentation between products, which can simplify purchasing and reduce errors.

For extended wear applications, 3M manufactures their 3M-4077 extended wear nonwoven tape (Figure 2). The 3M 4077 4" X 10YD (Figure 1) is a popular size at 4 inches (in.) x 10 yards (yds) with a white nonwoven polyurethane backing that is 0.16 millimeter (mm) thick. It uses an extended wear acrylic adhesive, which makes it highly comfortable for extended use. Its MVTR is specified at ~185gm/m² and is somewhat fluid resistant, allowing skin to breathe for up to 14 days of recommended use.

The 3M 4077 medical securement tape is not repositionable and is recommended for one-time use only, making this tape applicable for extended wear biometric sensors that are discarded after one application.

Like all the tapes discussed here, the 3M 4077 ships in a roll for ease of use. The roll is less than 8 in. in diameter and is easily stored in a medical bay or emergency room.

For medical securement tape applications where the skin must be allowed to breathe, the tape must have a high MVTR. For these applications, 3M offers the 3M 1530 4" X 10YD. This tape measures 4 in. x 10 yds with a 0.14mm white nonwoven rayon backing material and comes with a surgical-grade acrylate medical adhesive. This construction results in a very high MVTR rate of 4200gm/m². It is not repositionable and has no resistance to fluids, making it unsuitable for most consumer biometric applications. With its high MVTR and good comfort level, the tape is specified for surgical applications and extended inpatient monitoring. It is easy to tear by hand – an advantage in emergency medical situations where events are progressing rapidly.

For applications where a high degree of comfort and flexibility is required, 3M provides the 3M 9836 4" X 10YD polyurethane film surgical tape with an acrylic medical adhesive. The tape is in the standard-sized 4 in x 10 yds. The backing is polyurethane film and at only 0.03mm thick is the thinnest tape here, providing flexibility and comfort. It is water resistant and reasonably breathable at ~450gm/m², providing a good compromise between breathability and water resistance. This tape's thin comfortable backing, flexibility, reasonable breathability, and water

For some sensor monitoring applications, the sensor must be repositionable for multiple uses and must also secure a medical instrument to the skin of the patient.

resistance can make it applicable for attaching sensors to a child where the sensor and securement tape must withstand some twisting – especially important with a patient that may not be able to provide effective verbal feedback as to the comfort of the sensor attachment.

For some sensor monitoring applications, the sensor must be repositionable for multiple uses and must also secure a medical instrument to the skin of the patient. In these applications, double-coated tape like the 3M 2477P 4" X 10YD is very useful (Figure 3). The tape measures 4in. x 10 yds with a very thin 0.04mm thermoplastic elastomer (TPE) backing, with adhesive on both sides (layer C). The TPE is translucent, allowing a convenient view of the sensor and skin to assist in proper placement. On one side is a silicone acrylate medical adhesive (layer B) that is designed to be gently removed and repositioned on the skin to secure a biometric sensor. On the reverse side of the TPE backing is an acrylic-based adhesive (layer D). This second adhesive can attach securely to a miniature medical biometric sensor device.

This unique medical securement tape can serve two purposes. First, it can serve as securement for both the sensor and the medical biometric recording device. This provides a compact biometric recording system without long wires. The biometric sensor device can be a very lightweight embedded computer powered by a CR2032 battery. It could record the sensor reading in flash memory or send the sensor readings via Bluetooth or Wi-Fi to a computer or mobile device. This is also useful for prototyping commercial biometric sensor devices based on postage stamp-sized single-board computers (SBCs).

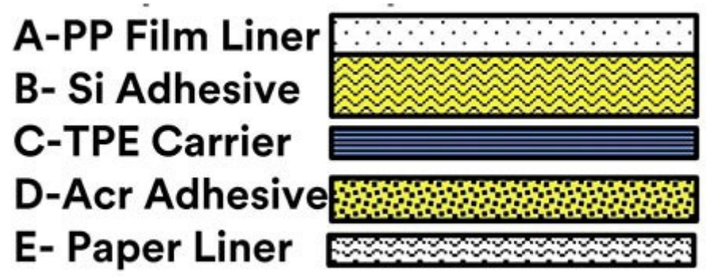


Figure 3: The layers of the double-sided 3M 2477P 4 x 10 YD medical securement tape includes a silicon acrylate adhesive on one side (layer B) and an acrylic-based adhesive (layer D) on the other. Image source: 3M medical Materials

Second, this tape can be used as a standalone medical tape. The silicone adhesive side can be used for repositionable or reusable biometric sensors. This allows biometric sensors for athletes to be used and reused on a daily basis. The tape has moderate resistance to fluids and has an MVTR of 400gm/m² – good for short-term use.

The 3M-2477P specifications do not recommend that the acrylic-based adhesive be used against the skin.

Conclusion

Not all biometric sensor securement applications are the same, so there exists a wide selection of medical securement tapes. The use conditions of medical tape, including the ergonomics of the situation, determines the materials used for the backing and adhesive. Standardizing on one supplier for medical tape simplifies purchasing and inventory, reduces errors, and provides consistency in documentation.

How to improve ultrasound system image quality using ultra-low-noise supplies

Written by Bill Schweber

Ultrasound technology, a widely used non-invasive tool in medical diagnostics and other applications, has shifted from static to dynamic images, and from black-and-white presentation to color Doppler images. These important enhancements are largely due to the introduction of digital ultrasound technology. While these advances have increased the effectiveness and versatility of ultrasound imaging, it is equally important for these systems to offer improved image quality via advances in the head-end ultrasound probe, and the analog front-end (AFE) that drives the probe and captures the return signals.

One of the impediments to achieving this improved image quality is noise, so the design goal is to increase the signal-to-noise ratio (SNR) of the system. This can be achieved in part by addressing noise due to the various power supply rails in the system. Note that such noise is not a single, simple entity. Instead, it has various characteristics and attributes which determine how it ultimately impacts system performance.

This article will look at the basic principle of ultrasound imaging, and then focus on different factors that affect image quality, primarily noise from the power supplies. It will use DC-DC regulator devices from Analog Devices as examples of power supply components that can greatly improve SNR and other aspects of ultrasound system performance.

Basics of ultrasound imaging

The concept is simple: generate a sharp acoustic pulse, then "listen" for its echo reflection as it encounters obstacles or various interfaces between organs and their differing acoustic impedances. By doing these impulse-return sequences repeatedly, the reflections can be used to create an image of the reflecting surfaces.

For most modes of ultrasound, the array of piezoelectric transducers sends a limited number of wave cycles (typically two to four) as a pulse. The frequency of these waves in each cycle is usually in the range of 2.5 to 14 megahertz (MHz). The array is controlled via beamforming techniques analogous to a phased-array RF antenna, so the overall ultrasound pulse can be focused and steered to create a scan. The transducer then switches to receive mode to sense the return of the reflected waves from within the body.

Note that the transmit/receive timing ratio is typically about 1%/99%, with a pulse repetition frequency usually between 1 and 10 kilohertz (kHz). By timing the pulse from its transmission to received echoes and knowing the speed at which the ultrasound energy propagates through body

tissue, it is possible to calculate the distance from the transducer to the organ or interface reflecting the wave. The amplitude of the returning waves determines the brightness of the pixels assigned to the reflection in the ultrasound image, after considerable digital post-processing.

Understanding system requirements

Despite the conceptual simplicity of the underlying principle, a complete, high-end ultrasound imaging system is a complicated device (Figure 1). The ultimate performance of the system is largely determined by the transducer and analog front-end (AFE), while post-processing of the digitized reflected signal allows algorithms to enhance the situation.

Not surprisingly, system noise of various types is one of the limiting factors in image quality and performance, again analogous to the consideration of bit error rate (BER) versus SNR in digital communication systems.

There is a transmit/receive (T/R) switch between the piezoelectric transducer array and the active electronics. The role of this switch is to prevent the high-voltage transmit signals driving the transducer from reaching and damaging the low-voltage receive-side AFE. After the reflection received is amplified and conditioned, it is passed to the analog-to-digital converter (ADC) of the AFE, where it is digitized and undergoes software-based image processing and enhancement.

Each of the different imaging modes of an ultrasound system has different requirements for the dynamic range – and thus SNR – or noise requirements:

- For black-and-white image mode, a dynamic range of 70 decibels (dB) is required; the noise floor is important as it impacts the maximum depth at which the smallest ultrasound echo can be seen in the far field. This is called penetration, one of the key features of black-and-white mode
- For pulse wave doppler (PWD) mode, a 130 dB dynamic range is required
- For continuous wave doppler (CWD) mode, 160 dB is needed. Note that the 1/f noise is particularly important for the PWD and CWD modes, as both of those images include the low-frequency spectrum element below 1kHz, and the phase noise impacts the Doppler frequency spectrum higher than 1kHz

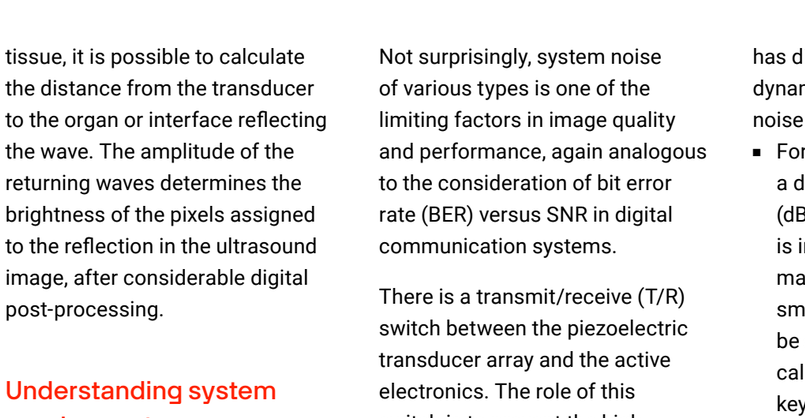


Figure 1: A complete ultrasound imaging system is a complex combination of a significant amount of analog, digital, power, and processing functionality; the AFE defines the bounds of system performance. Image source: Analog Devices

These requirements are not easy to meet. As the ultrasound transducer frequency is typically from 1MHz to 15MHz, it will be affected by any switching frequency noise within this range. If there are intermodulation frequencies within the PWD and CWD spectrums (from 100Hz to 200kHz), the obvious noise spectrums will appear in the Doppler images, which is unacceptable in the ultrasound system. For maximum system performance and image

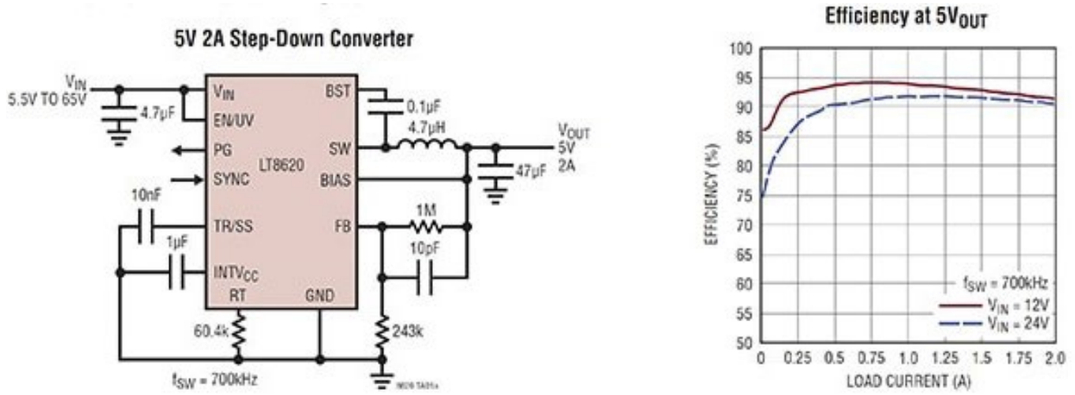


Figure 2: The highly efficient LT8620 step-down switching regulator includes a SYNC pin so its clocking can be synchronized with other system clocks, minimizing clock intermodulation effects. Image source: Analog Devices

quality (clarity, dynamic range, lack of image speckling, and other figures of merit), it's important to look at sources which cause loss of signal quality and degradation of SNR.

The first one is obvious: due to attenuation, the returns from tissues and organs deeper in the body (such as kidneys) are far weaker than those from those close to the transducer. Therefore, the reflected signal is "gained up" by the AFE so that it occupies as much of the AFE's input range as possible. For this, an automatic gain control (AGC) function is used. This AGC function is similar to the one used in wireless systems where the AGC assesses wireless RF received signal strength (RSS) and dynamically compensates for its random, unpredictable changes over a span of tens of decibels.

However, the situation is different in the ultrasound application than it is for a wireless link. Instead, the path attenuation is known approximately, as is the velocity of acoustic energy propagation velocity – 1540 meters per second (m/s) in soft tissue, or about five times faster than propagation in air at about 330m/s – and so the attenuation rate is also known.

Based on this knowledge, the AFE uses a variable-gain amplifier (VGA) which is arranged as a time-gain compensation (TGC) amplifier. The gain of this VGA is linear-in-dB and is configured such that a linear-versus-time ramping control voltage increases the gain-versus-time to compensate to a large extent for the attenuation. This maximizes SNR and the use of the dynamic range of the AFE.

Noise types and how to address them

Although in-body and patient-induced signal noise is beyond the control of the ultrasound system designer, internal system noise must be managed and controlled. For this, it's important to understand the noise types, their impact, and what can be done to reduce them. The primary areas of concern are switching regulator noise; white noise due to the signal chain, clock, and power; and layout related noise.

- **Switching regulator noise:** most switching regulators use a simple resistor to set the switching frequency. The unavoidable tolerance of the nominal value of this resistor introduces different switching frequencies and harmonics as the frequencies of different independent regulators mix and cross-modulate each other. Consider that even a tight-tolerance resistor with a 1% inaccuracy results in a 4kHz harmonic frequency in a 400kHz

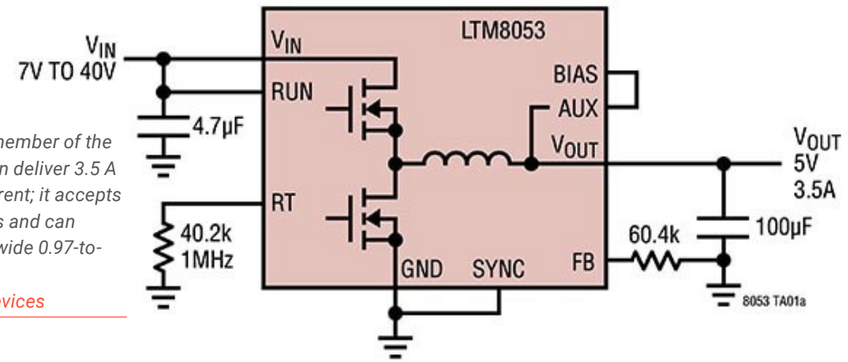


Figure 3: The LTM8053 member of the Silent Switcher family can deliver 3.5 A continuous/6 A peak current; it accepts an input of 3.4 to 40 volts and can provide output across a wide 0.97-to-15-volt range.
Image source: Analog Devices

DC-DC regulator, making the harmonics harder to control

A better solution is to select a switching regulator IC with a synchronization feature implemented via a SYNC connection on one of its package pins. Using this feature, an external clock can distribute a signal to the various regulators so that they all switch at the same frequency and phase. This eliminates the mixing of the nominal frequencies and associated harmonic products.

For example, the LT8620 is a high-efficiency, high-speed synchronous monolithic step-down switching regulator that accepts a wide input voltage range up to 65 volts, and consumes only 2.5 microamperes (µA) of quiescent current (Figure 2). Its low ripple "Burst Mode" operation enables high efficiency down to very low output currents while keeping the output ripple below 10 millivolts (mV) peak-to-peak. A SYNC pin allows for user-established synchronization to an external clock from 200kHz to 2.2MHz.

Another technique is to use a switching regulator that employs random spread-spectrum clocking to spread the generated electromagnetic interference (EMI) across a wider band, lowering its peak value at any specific frequency. While this is an attractive solution for some applications that are less SNR critical and more concerned with meeting EMI requirements, it introduces uncertainties in the resultant harmonics that will be created across a wider spectrum, making them harder to control. For example, a switching frequency spread of 20% for EMI consideration results in harmonic frequencies between zero and 80kHz in a 400kHz power supply. Thus, while this approach to lowering EMI "spikes" may help meet relevant regulatory mandates, it may be counterproductive for the special SNR needs of ultrasound designs.

Switching regulators with constant frequency help avoid this issue. ADI's family of Silent Switcher voltage regulators and µModule regulators feature constant-frequency switching. At the same time, they offer EMI performance with selectable spread spectrum techniques, to provide excellent transient response without introducing the uncertainties associated with spread spectrum.

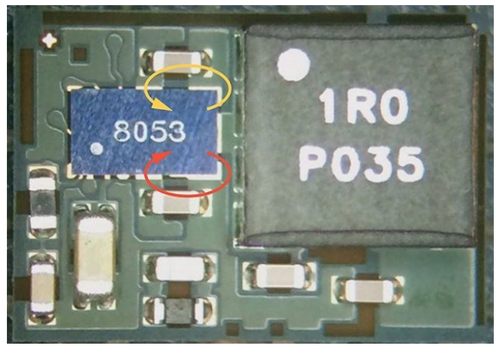


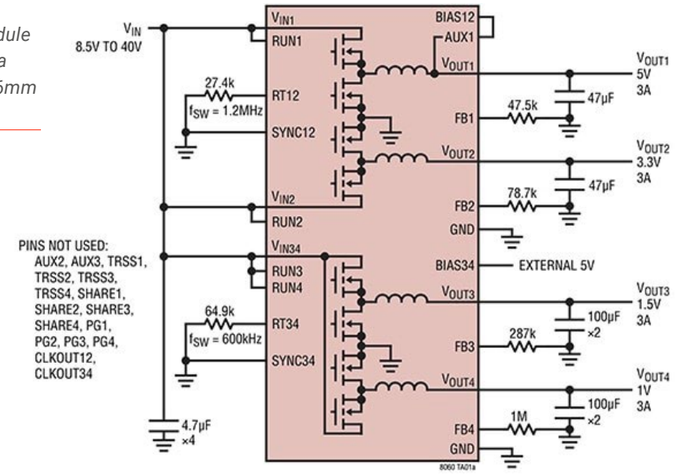
Figure 4: The LTM8053 (and other Silent Switcher devices) integrate a copper pillar flip-chip, enabling high-density design and large current capability in a small package while minimizing parasitic inductance.
Image source: Analog Devices

The Silent Switcher regulator family is not limited solely to lower power regulators, either. For example, the LTM8053 is a 40 VIN (maximum), 3.5 A continuous, 6 A peak, step-down regulator that includes a switching controller, power switches, an inductor, and all support components. Only input and output filter capacitors are needed to finish the design (Figure 3). It supports an output voltage range from 0.97 to 15 volts, and a switching frequency range of 200kHz to 3MHz, each set by a single resistor.

The LTM8053's unique packing helps maintain low EMI along with higher current output. A copper pillar flip-chip package in a Silent Switcher µModule regulator helps to reduce parasitic inductance and optimize spike and dead time, enabling high-density design and large current capability in a small package (Figure 4). If more current is needed, multiple LT8053 devices can be connected in parallel.

The Silent Switcher line's technology and topology are not limited to single-output regulators. The LTM8060 is a quad-channel, 40 VIN Silent Switcher µModule regulator with a configurable 3 A output array (Figure 5). It operates up to 3MHz and is packaged in a compact (11.9mm × 16mm × 3.32mm), over-molded ball grid array (BGA).

Figure 5: The LTM8060 is a four-channel µModule configurable array with 3 A/channel output in a compact package measuring just 11.9mm × 16mm × 3.32mm. Image source: Analog Devices



One of the interesting aspects of this quad-channel device is that its outputs can be paralleled in different configurations to match different load-current needs, up to a maximum of 12 A (Figure 6).

In summary, the Silent Switcher regulators offer many benefits with respect to noise, harmonics, and thermal performance (Figure 7).

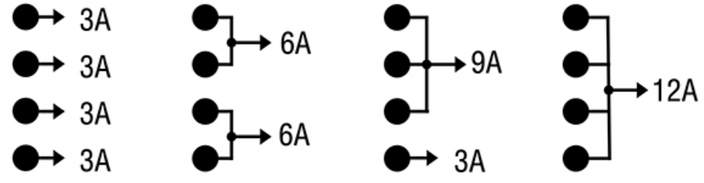


Figure 6: The four 3 A outputs of the LTM8060 can be arranged in different parallel configurations to match the application's DC rail requirements.
Image source: Analog Devices

- **White noise:** there are also many white noise sources in an ultrasound system, which leads to background noise and image "speckles." This noise comes primarily from the signal chain, clock, and power. Adding a low-dropout (LDO) regulator at the power pin of a sensitive analog

	Low Frequency Noise	Switching Noise Harmonics	High Thermal Performance
Architecture	Ultra-low noise reference in Silent Switcher 3 device	Silent Switcher technology plus Cu pillar package	Silent Switcher technology plus heatsink in package
Feature	Same performance as an LDO regulator in terms of low f noise	Low EMI, low switching noise	High power density Lower thermal resistance
Benefit in Application	Removes the need for post-LDO regulator while keeping the same image quality	High frequency with high efficiency	Minimize degrading for the same current level

Figure 7: Shown are the key attributes of the Silent Switcher family of regulators relative to important design perspectives. Image source: Analog Devices

component can resolve this

ADI's next-generation LDO regulators, such as the LT3045, feature an ultra-low noise level of around 1 microvolt (µV) rms (10Hz to 100kHz), and provide a current output of up to 500 mA at a typical dropout voltage of 260 mV (Figure 8). Operating quiescent current is nominally 2.3 mA and drops to much lower than 1 µA in shutdown mode. Other low-noise LDOs are available to cover current from 200 mA to 3 A.

- **Board layout**: in most PC board layouts, there is a conflict between high-current signal traces from the switching power supplies and the adjacent low-level signal traces, as noise from the former can couple into the latter. This switching noise is usually generated by the "hot loop" created by the input capacitor, top-side MOSFET, bottom-side MOSFET, and parasitic inductances due to wiring, routing, and bonding

The standard solution is to add a snubber circuit to reduce electromagnetic emission, but this decreases efficiency. The Silent Switcher architecture improves performance and maintains high efficiency even at a high switching frequency by creating an opposite hot loop (called "splitting") using bidirectional emissions, reducing EMI by about 20 dB (Figure 9).

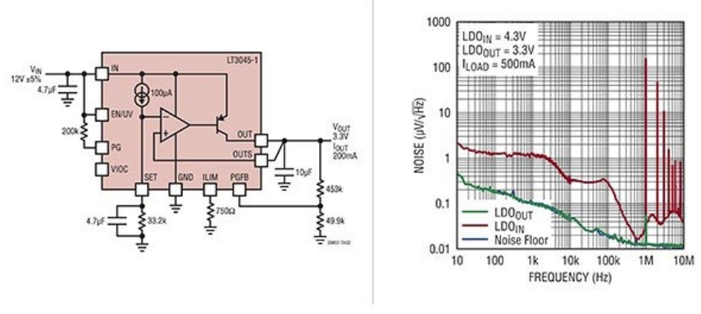


Figure 8: The LT3045 LDO regulators are noted for their ultra-low noise of around 1 µV rms over a current range from 200 mA to 3 A. Image source: Analog Devices

Efficiency versus noise

It may seem that if there is a tradeoff between power supply noise versus potential efficiency, the need for ultra-low noise in the ultrasound application should prevail. After all, a few more milliwatts of dissipation should not be that much of a burden at the "big-picture" system level. Further, why not increase the energy pulsed by the transducer to increase the pulse signal strength and thus the reflected SNR?

But this tradeoff has another complication: self-heating in the handheld digital probe that contains the transducer, piezoelectric element driver, AFE, and other electronic circuitry. Some of the probe's electrical energy is dissipated in the piezoelectric element, lens, and backing material, thus causing transducer heating. Along with wasted acoustic energy in the transducer head, this will result in heating and a temperature rise at the probe.

There is a limit on the maximum allowable transducer surface temperature. IEC standard 60601-2-37 (Rev 2007) restricts this temperature to 50°C when the transducer is transmitting into air, and 43°C when transmitting into a suitable phantom (a standard body simulator); the latter limit implies that skin (typically at 33°C) can be heated by 10°C at most. Thus, transducer heating is a significant design consideration in complex transducers. These temperature limits may effectively restrict the acoustic output that can be employed, independent of available DC power.

Conclusion

Ultrasound imaging is a widely used, invaluable, non-invasive, and risk-free medical imaging tool. Although the basic principle is conceptually simple, designing an effective imaging system requires a significant amount of complex circuitry, along with multiple DC regulators to power its various subcircuits. These regulators and associated power must be efficient, but also be very low noise due to the extreme SNR and dynamic range mandates on the reflected acoustic signal energy. As shown, LDOs and Silent Switcher ICs from Analog Devices meet these requirements without compromising space, EMI, or other key attributes.

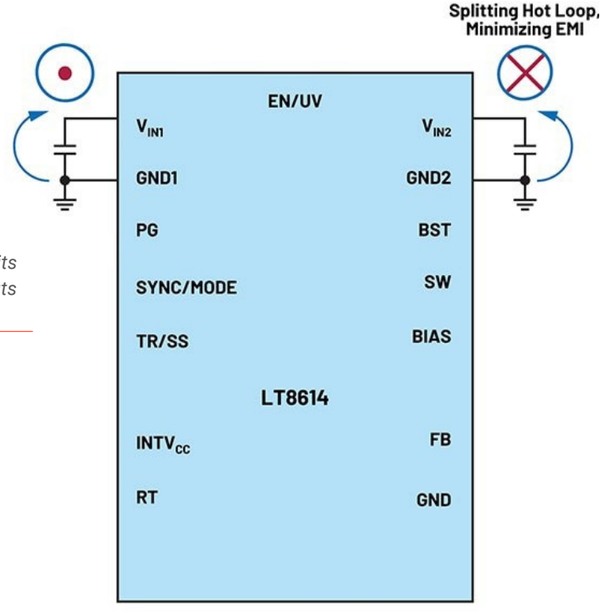


Figure 9: By establishing an opposing "hot loop" that splits the current-flow path, the Silent Switcher significantly cuts EMI by about 20 dB. Image source: Analog Devices

Tuning forks for medical applications

Written by David Meaney, Vice President of Global Technical Sales and Marketing at ECS Inc.

What is a tuning fork watch crystal

A tuning fork crystal, also known as a watch crystal, is a quartz crystal used to maintain accurate time in clocks, watches and modern electronics like real-time clocks (RTCs) in computers. Its design is inspired by a musical tuning fork, resonating at a precise frequency determined by the mass and dimensions of its two tangs.

There are multiple elements that bring together the functionality of a tuning fork crystal such as resonance, frequency control and application. When an electric current is applied, the crystal vibrates at a precise and stable frequency, typically 32.768kHz. This frequency is ideal because it is power-efficient and can easily be divided down to a one-second signal for timekeeping. The frequency is controlled by the size, shape and mass of the tuning fork's tangs. Achieving the 32.768kHz frequency in a compact quartz crystal is critical, as a crystal resonating directly at one hertz would need to be so large it would resemble a component for a grandfather clock, not a wristwatch. Obviously, that would be rather impractical in terms of production and use so there's a special trick.

Watch crystals are designed to resonate at a frequency of 32.768kHz, chosen specifically because it can be easily deduced to one hertz. By passing the 32.768kHz signal through 15 consecutive flip-flops in series, the frequency is halved with each stage, eventually producing a precise one hertz output, or one-second interval. This allows accurate tracking of time, including day, date and seconds. The compact and easy-to-manufactured tuning fork crystal achieves this frequency through a combination of simple arithmetic and the physical dimensions of the quartz blank.

Choosing the right tuning fork crystal

Although all tuning forks resonate at the same 32.768kHz frequency, selecting the right one isn't as straightforward as it seems. As mentioned earlier, several factors come into play. In your design, you need to consider board space, required accuracy and power consumption. Each of these involves trade-offs that must be carefully balanced. Below are some areas to consider when evaluating tuning fork crystals for your design system:

- **Small form factor** – smaller crystals typically have higher ESR, which can impact power consumption
- **Tolerance and stability** – the tighter the required stability, the narrower the operating temperature range. Enhancing one aspect will impact the other
- **Power considerations** – lower ESR and load capacitance options add significant complexity to the oscillator design. Achieving reliable crystal startup and continuous oscillation will require precise design accuracy
- **Load capacitance** – load capacitance (CL) refers to the external capacitance in parallel with the crystal, as determined by the combined capacitances of the circuit, including input, output, and stray capacitances. It plays a critical role in the accuracy and functionality of a quartz crystal. For the circuit to resonate at the correct frequency, the circuit's capacitance must match the crystal.
- **Equivalent Series Resistance (ESR)** – Equivalent Series Resistance (ESR) is the electrical resistance of a quartz crystal in series resonance, measured in kilo-ohms (KΩ). It's a crucial factor when selecting a crystal, as it impacts the crystal's ability to start and maintain oscillation. A higher ESR requires more current for startup, while a lower ESR reduces power consumption during oscillation.
- **Performance and parabolic temperature curve** – due to their unique shape, tuning fork crystals are not highly accurate over a wide temperature range. Stability follows a parabolic curve as temperatures deviate from room temperature, with accuracy significantly worsening at extreme highs and lows. A common parabolic coefficient for a 32.768kHz tuning fork crystal is 0.04 ppm/°C².

If you need assistance choosing an appropriate tuning fork crystal for your design system, ECS Inc.'s dedicated engineering team can help you find a solution.

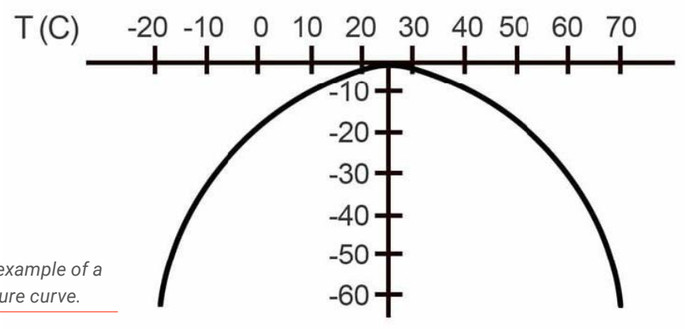


Figure 1 shows an example of a parabolic temperature curve.

Applications of tuning forks in medical technology

Tuning fork crystals are used in applications requiring a stable frequency reference, such as processor control and time management. Over the past decade, healthcare technology has advanced significantly, with innovations like artificial intelligence (AI), increased connectivity via the Internet of Medical Things (IoMT), robotic surgery, minimally invasive procedures, personalized medicine and the integration of augmented and virtual reality. These developments have led to more precise diagnostics, improved treatment options and enhanced patient care.

Some of the broad areas that have seen significant growth would include:

- Diagnostic Equipment
- Therapeutic Devices
- Patient Monitoring
- Home Healthcare

Here are some examples of medical designs driving advancements in medical technology:

- **Glucose monitors** – these devices depend on precision to accurately report blood sugar levels and deliver insulin when needed
- **Wearables** – allow people to keep track of heart rates and blood pressure in real-time, a common requirement in these applications are compact form factor components and low power capabilities
- **Remote monitoring** – allows physicians and nurses to monitor patients as they convalesce at home
- **Sterilizers** – this includes all manner of keeping areas and people clean and germ-free – these applications may have requirements to withstand high-temperature ranges
- **Ventilators** – these are products that help maintain oxygen levels such as CPAP machines or non-invasive oxygen support machines
- **Readers and tools** – these include temperature, blood pressure, heart rate or other equipment that allows medical staff to gather and analyze medical conditions
- **Exercise equipment** – many of today's standard gym equipment incorporate intelligence, tracking and monitoring for a holistic exercise experience

The future of timing devices in medical technology will continue to play a pivotal role in advancing healthcare innovations.

The future of timing devices in medical technology

The future of timing devices in medical technology will continue to play a pivotal role in advancing healthcare innovations. Precise timing is critical for devices like glucometers, sphygmomanometers, wearable health monitors and diagnostic equipment, ensuring accurate measurements and synchronized data transmission. As medical devices become smaller, more integrated and wireless, timing components will need to evolve with enhanced miniaturization, ultra-low power consumption and improved reliability.

ECS Inc. offers comprehensive engineering support, and an extensive portfolio of tuning fork crystals designed to meet the demanding specifications of today's medical applications. With a wide range of technical options – including precision frequency control, low power consumption, and robust temperature stability – ECS Inc. ensures that our solutions align with the evolving needs of medical technology. Whether for wearable devices, diagnostic equipment or implantable systems, our tuning fork crystals are engineered for reliability and accuracy, making them ideal for the healthcare innovations of today and the future.

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