

## The Future of Safety Isolation in Home Healthcare Electronics

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### IDEA IN BRIEF

*The defibrillator illustrates the direction of the future of healthcare. They are an amazing life saving technology that, only a few years ago, existed only in ambulances and hospitals where they required specialized training and a team of dedicated healthcare professionals to use. Some people eye defibrillators with suspicion. Imagine what an untrained employee might do if a colleague suddenly clutched his chest and fell to the floor: run up to the box, break the glass, grab the Quick Start Guide, quickly scan the literature to learn the connections, controls, and precautions. Meanwhile, the victim is on the floor turning five shades of blue. At the same time, every dramatic scene from a medical drama goes through his head, where the doctor defibrillates himself or the nurse, instead of the patient. The reality is much less dramatic and illustrates how medical technology is following us out of the hospital and into the workplace and the home.*

### DEFIBRILLATORS IN THE WORKPLACE

These defibrillators actually offer instructions, verbally and through diagrams, for a person who has never used the machine before, on exactly how to apply the monitors and paddles. The machine then makes the decision on how much energy to apply to the person in distress, while keeping the novice operator from doing damage to himself or the unfortunate victim. When the EMT arrives, he can plug into the defibrillator and download the stored data to take back to the hospital for a doctor to review.

### WHERE HEALTHCARE IS HEADED

This story illustrates the promise of technology, as well as the challenges. Medical devices will be moving out of clinically based settings and become increasingly integrated into people's lives. These devices will range from helpful health aids such as a calorie counter app on a phone or a heart rate monitor on a treadmill, to life sustaining drug

infusion pumps, long term monitors for vital sign logging, to emergency intervention devices such as the defibrillator. To support the move of medical monitoring and dispensing into the home setting, these devices are en route to becoming more

1. Mobile: they have smaller and lower power so that they do not encumber even an elderly patient.
2. Smart: with the available monitoring information, they're able to make sure that they are properly configured to do their intended job or call for immediate attention.
3. Safe: they must be designed to provide all of the electrical and operational safety of their older hospital based versions while being used by someone without any training.
4. Connected: they can easily be programmed, updated, and read out. This function will increasingly have to interface with nonmedical devices such as commercial networked computers to allow communications with a distant medical facility.

### SAFETY

The revolution in healthcare devices demands as much, if not more, attention to safety as the current generation of hospital based electronics. There are many aspects to safety; devices must self diagnose for proper connection or patient condition. Devices must not allow misuse or malicious tampering. Due to privacy requirements, they must preserve and transfer patient data in a secure manner. They require electrical safety so that connections to nonmedical communications devices or other appliances in the home will not create unintended paths for high voltage or leakage currents through the patient. The electrical safety is largely guaranteed by isolation. Isolation breaks electrical paths to the power from electrical mains, or from other medical devices, such as defibrillators that generate high voltage. In the remainder of this article, how safety isolation is applied to connectivity in medical devices will be examined, particularly those intended for nonclinical environments.

Medical applications leave patients particularly vulnerable to electrical devices. The human body is mostly made up of salt water, consisting of blood and cytoplasm inside a protective covering—the skin. Salt water is a fairly good conductor of electricity, while the skin, when it is dry, is a fairly good insulator. Medical devices trying to monitor what is going on inside the body reduce the impedance of the skin with large area electrodes and conductive gel. This means that any unintended signals on these electrical devices can easily

cause currents to flow through the patient, disrupting the nervous system and interfering with muscles such as the heart. These critical electrical safety requirements that build electrically safe electronics are part of the medical safety standard, IEC60601. Even the seemingly innocuous applications like heart rate meters on exercise equipment must follow the isolation rules in order to maintain safety. Life critical devices need to follow increasingly stringent standards.

## PROTECTION FROM DIRTY POWER AND CONTROL OF GROUNDING

The primary source of unintended signals in electronics is the power grid. The medical application must block ac leakage from the 50 Hz to 60 Hz line, as well as transients due to lightning strikes, switching noise or line fault conditions. This is not a requirement specific to medical devices; however, the requirements for medical devices are more stringent, and leakage levels are determined by the way that a device is connected to the patient.

Connections to the patient must also be isolated to prevent multiple medical devices connected to the patient from using the other connections as an alternative return path causing current to flow where it is not intended. In addition, if the patient can touch anything that is connected to the building's safety ground, such as home electronics or a metal framed bed, currents must not be able to flow through that path either. Insulation to the patient requires two independent insulation systems, or one system that has been demonstrated to be equivalent to two systems. This is called isolation through two means of patient protection, or 2MOPP.

The challenge is to provide safety for the communications and power of a home based medical device. Communications interfaces will be the focus for the remainder of this article.

## HOW ELECTRONICS WILL SUPPORT THE ISOLATION DEMANDS

A typical home healthcare electronic device will need to communicate with either other medical devices or existing home electronics infrastructure. It will need to support the privacy and security requirements so that information can't be intercepted or corrupted. It will need to meet the leakage and safety requirements of IEC60601. Typically, electrical connections need to have two means of patient protection rated for 4 kV to withstand voltage, as well as very low capacitive leakage and a defibrillation proof rating.

## METHODS

There are several approaches to meeting the electrical safety requirements.

### *RF Communications*

The first approach is to avoid electrical connections completely by making the communications via an RF link, such as low power Bluetooth or the ZigBee standard. A battery operated medical device with a nonconductive case would provide all of the electrical isolation required. Bluetooth has the advantage of being present in most laptops and smart phones, so devices could interface for either data logging or remote control. ZigBee interfaces would require extra interface hardware to interact with nonmedical networking devices such as laptops in the home. This is ideal for monitors where data rates are low and wires are inconvenient.

The downside of RF communications is that this type of link is prone to interference from RF sources. It could also be vulnerable to malicious tampering. Since this signal is available over the air, the medical privacy laws require encryption of data so that it can't be intercepted. For simple devices, this can consume a significant portion of the applications resources. These connections also require some knowledge to set up the connection, a task not always simple for an elderly patient. Although RF communications meet all of the safety requirements, its robustness makes it more challenging to use for life critical applications. However, the mobility achieved through the use of wireless technology makes it the preferred communications method going forward.

Some applications for this approach include adhesive patches with monitors built in or blood glucose meters that automatically log results. The functioning of the link at all times is not required to guarantee the safety of the user.

### *Mechanical Interlocks*

In cases where data integrity and robustness is required, wired interfaces perform best. Data can be transferred at high speeds while errors are nearly nonexistent. Power can be supplied through the connection as well. The interfaces that are commonly used are a USB, RS-232, or RS-485. A wired interface is reliable enough to be used for data logging, critical control information for life sustaining applications, and for device program updates. Only the USB remains as a standard interface in home electronics such as PCs and cell phones. However, this interface must meet the stringent isolation requirements of IEC60601. An approach that is widely used is to design the device such that a nonisolated interface can only be used when the device is not in contact with a patient. For example, a USB port can be positioned under a cover that blocks the USB connector when the

device is being used. This type of arrangement has the advantage of being inexpensive, but it is limiting for real-time monitoring or in applications where the connections to the patient can't be readily removed. So, it would be great for a device that does not need to be continuously connected to the patient, but it would not be very good for a device, such as an infusion pump, where a patient connection is invasive and must be done in a clinical setting.

Another type of mechanical interlock is used in field deployed defibrillators. These can have direct network connections built into their housing so that when the defibrillator is in its wall housing, it is connected to the network and charging power. The device will perform periodic self diagnostics and battery health checks and report its status over the network. When the defibrillator is used, it must be removed from its wall mount which disables the network and power connections.

The last type of mechanical interlock is the removable memory element. Similar to an SD card in a digital camera, data is written to a memory card, then the card is removed and placed in a separate reader. The data is then transferred where it needs to go. This is the most labor intensive method since it is likely that the patient will not be asked to do this himself.

### **Isolated Interface**

The most reliable option for communications is the wired isolated interface. It has the robustness of a wired interface; power can also be provided with the inclusion of an isolated dc-to-dc converter. It can support high upload and download speeds and be used while the device has active patient connections. Data encryption is not required on a wired interface, reducing the processor overhead. Software maintenance can also be performed on the device while it is in use. This interface can also be set up to allow real-time remote monitoring at high data rates so, for example, a doctor could get a remote ECG if the patient needed a routine follow-up. The isolation in these interfaces has traditionally relied on devices like optocouplers which have speed limitations and poor integration capabilities. Medical grade digital isolators, which do not suffer from these limitations are replacing optocouplers in new applications.

The same communications interfaces mentioned in the Mechanical Interlocks section can be isolated with appropriate digital isolators. RS-232 and RS-485 have been the backbone of isolated medical communications for many years. They can use devices such as the Analog Devices [ADuM2201](#) with a 2MOPP medical rating under IEC60601. Unfortunately, these interfaces have all but vanished in nonmedical electronics. That leaves the USB as the most widely used and available interface. This can now be isolated with the [ADuM4160](#) to again achieve 2MOPP of defibrillation proof protection. It is being designed into infusion pumps, defibrillators, noninvasive glucose meters, and a wide variety of clinical patient monitors. It can interface directly to a nonmedical grade PC so that real-time monitoring can be implemented, and the link will still be fully defibrillation proof and meet the appropriate leakage requirements. Even in systems where wireless communications is used, a USB port is provided for critical operations like software maintenance and battery charging. Since there are always situations where the USB might be connected, the ports are isolated for safety. The downside of wired interfaces is that they do not allow great mobility.

### **Defibrillator Isolation**

The defibrillator shown in Figure 1 provides a good example for examining isolated communications interfaces since it has several different interfaces and a variety of isolation techniques. The unit must use an ECG to monitor a victim's heart activity to decide if defibrillation is warranted. The ECG data path must be isolated from the high voltage section of the defibrillator so that the sensitive ECG electronics are not blown out when a shock is applied to the victim. This may be accomplished internally through isolated gate drivers and digital isolators. The unit can also contain an Ethernet interface for device health monitoring while the unit sits idle in its wall mount. The Ethernet is mechanically interlocked so it can't be used if the defibrillator is removed from its wall mount. The battery charging system is similarly connected to the wall mount and interlocked. The final function that requires isolation is the communications port that allows the ECG and defibrillation data to be downloaded for a doctor to review. This connection commonly isolates the USB so that the data can be retrieved without disconnecting the victim.

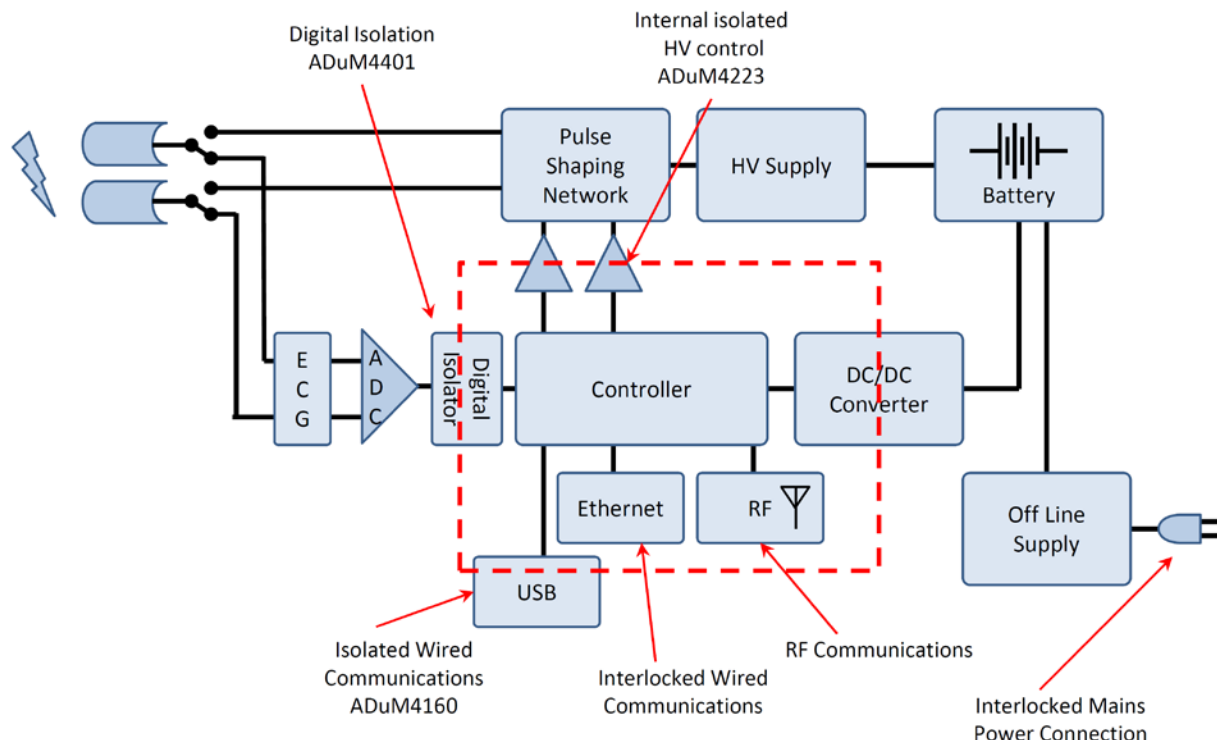


Figure 1. Typical Emergency Defibrillator

## CONCLUSION

Medical monitors and treatment delivery devices are cutting the tether between the clinical setting and the delivery of healthcare. These devices allow dramatic improvements in the quality of life, allowing people to remain in their homes while receiving quality treatment and monitoring. Complete mobile monitoring and treatment dispensing systems allow real-time analysis of the body's needs and precise real-time dosing of medications. For example, insulin infusion pumps can mimic the body's insulin response making disease management better for an ambulatory patient than ever before. The new technologies also allow patients without ready access to hospitals and clinics to upload their monitored signs to a hospital that may be hours away. Cardiac monitors can detect the onset of problems before the patient is symptomatic.

Information must flow in both directions between the medical device, the physician, and the company that maintains the device. Operational parameters, such as dosing, must be transferred to the device. The device firmware must be maintained to the latest revisions at all times. Several methods of maintaining electrical safety are used. All methods discussed here are effective in providing highly safe and reliable healthcare devices for use in the home, as well as clinical settings. The choice depends on the requirements of the particular application.

## RESOURCES

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