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Isolation in Medical Applications

Various standards and regulations govern medical product development. In particular, IEC60601-1 defines important parameters for electronic circuits used in medical devices. Until recently, optocouplers were the obvious choice for transferring signals across the isolation boundary. A new family of 4-channel digital isolators directly addresses the shortcomings of optocouplers. **Rich Ghiorse and Steve Ranta, Analog Devices, USA**

FRANCAIS

Le développement de produits médicaux est régi par diverses normes et réglementations. La norme CEI60601-1, en particulier, définit des paramètres importants pour les circuits électroniques utilisés dans les dispositifs médicaux. Jusque récemment les optocoupleurs étaient les appareils de choix pour le transfert des signaux à travers les limites d'isolation. Une nouvelle famille d'isolateurs numériques à 4 canaux règle directement les problèmes associés aux optocoupleurs. **Rich Ghiorse et Steve Ranta, Analog Devices, USA**

DEUTSCH

Viele Standards und Regulierungen beeinflussen die Entwicklung medizintechnischer Produkte. Im besonderen definiert die IEC60601-1 wichtige Parameter für elektronische Schaltungen in medizinischen Geräten. Bisher waren Optokoppler die offensichtliche Wahl für die isolierte Signalübertragung. Eine neue Familie von 4-kanaligen digitaen Isolatoren adressiert nun direkt die Einschränkungen der Optokoppler. **Rich Ghiorse and Steve Ranta, Analog Devices, USA**

Circuit design is increasingly being driven by people who are not doing the design. Purchasing, marketing, and others not involved with the subtleties of design think that the product should take less time to develop, cost less than previous versions, and have higher performance. This places significant demands on the designer to juggle opposing requirements to come up with a product that meets all of the goals. This scenario is very common across all segments of electronic product development, including medical product design. If these challenges weren't enough, add strict medical regulations, adverse operating conditions, and, above all, patient safety.

Various standards and regulations govern medical product development. One of the most widely used standards for medical equipment is IEC60601-1, which contains a wealth of information and requirements relating to the safe design of medical devices. In particular, IEC60601-1 defines expectations for leakage current, dielectric-withstand voltage, and creepage and clearance distances for circuits used in medical devices. Creepage can be defined as the shortest surface path over a solid (not through air) dielectric between two galvanically isolated metallic conductors. Clearance is the shortest distance through air between two galvanically isolated metallic conductors. The working voltage of the equipment specifies what the minimum creepage and clearance distances can be. Fault conditions in patient-connected equipment must not cause significant current flow through the patient, so creepage and clearance also applies to battery-powered equipment.

OPTOCOUPLERS VERSUS DIGITAL ISOLATION

Until recently, optocouplers were the obvious choice for transferring signals across the isolation boundary. They are relatively low cost and satisfy regulatory requirements when applied properly. But optocouplers require interfacing electronics on both the sending and receiving sides, they need significant amounts of current when transmitting, they have a wear out mechanism, and they are suited mostly for lower data rate applications (<5Mbit/s).

Interfacing to optocouplers is not rocket science, but there are a few caveats. Due to logic family output current limitations, it may not be possible to directly drive the LED from the digital signal source on the transmit side. Thus, the digital output may require a buffer device with enough current drive to illuminate the LED sufficiently. Optocouplers with integrated output conditioning circuits are typically designed to run on 5V supplies, so another power supply rail is required to interface with digital circuits running on 3.3V supplies. The optocoupler outputs are usually open-collector, so passive pull-up resistors are also required. The optocoupler wear out mechanism is typically detrimental only in analog

Figure 1 (right). Cross-sectional view of digital isolator AduM1100 in an 8-lead SOIC package a) and cross-sectional view of top coil and polyimide layers

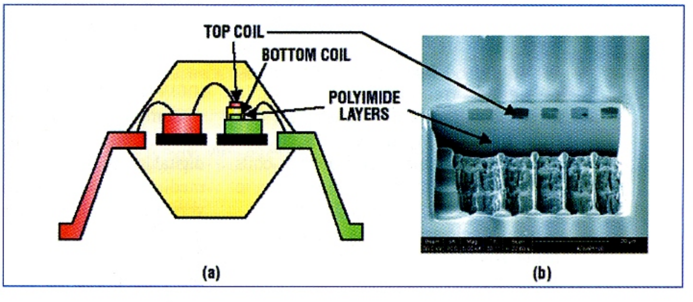
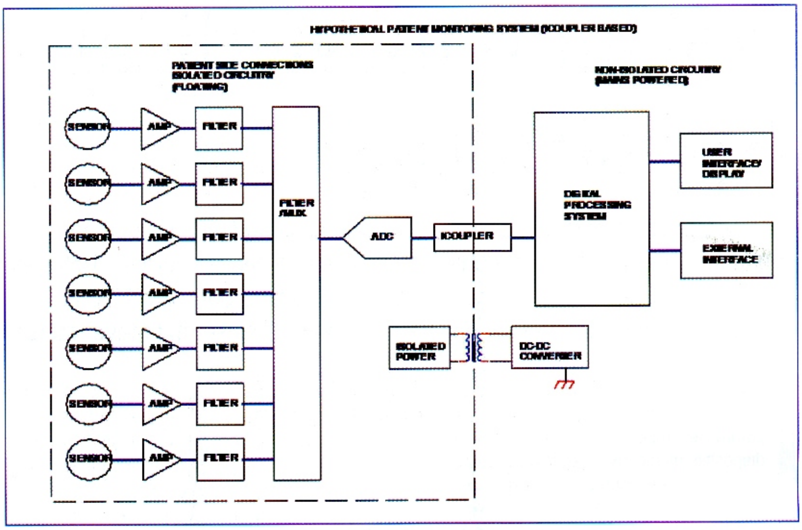


Figure 2 (right). Block diagram of a typical patient monitoring system using an iCoupler as the digital isolation device



signaling, and is likely not to affect digital signaling for the life of the unit. The data-rate limitation is significant, however, and can limit the partitioning of isolated and non-isolated circuits based on the speed that data must pass over the isolated boundary. The system partitioning could thus have significant impacts on both the system costs and the performance of the design.

The ADuM240x family of 4-channel iCoupler digital isolators directly addresses the shortcomings of optocouplers and helps to achieve the electrical safety standards set forth in IEC60601-1. With their 5kV isolation-voltage rating, these devices are suitable for use in medical products that are designed to general safety requirements with a working voltage rating of up to $250V_{rms}$ as specified in IEC60601-1.

iCoupler isolation technology is based on chip-scale transformers rather than the LEDs and photodiodes used in optocouplers. Fabricating the transformers directly on chip using wafer-level processing allows low-cost integration of iCoupler channels with other semiconductor functions. iCoupler transformers are planar structures built using CMOS metal layers plus a gold layer fabricated on top of the wafer passivation. A high-breakdown voltage polyimide layer underneath the gold layer insulates the top transformer coil from the bottom one. CMOS circuits connected to the top and bottom coils provide the interface between the transformers and external signals.

Input logic transitions are encoded using 1ns pulses routed to the primary side of a given transformer. These pulses couple across the transformer and are detected by the circuitry on the secondary side. This circuitry then recreates the digital input signal at the output. In addition, a refresh circuit is included at the input side to ensure that the output state matches the input state even if no input transitions are present. This is important in power-up situations and with input waveforms having low data rates or long periods with constant inputs.

Isolation is required, so the circuitry on one side of the transformers must be separated from the circuitry on the second side of the transformers. The transformers themselves can be placed on either input chip or output chip - or even on a third chip. The entire chip set is assembled within a standard plastic package similar to that used for a wide variety of semiconductor devices.

A novel feature of iCoupler devices is their ability to combine both transmit and receive channels in the same package. Since the iCoupler transformers are inherently bidirectional, signals can pass in either direction as long as the appropriate circuitry is present on either side of the transformers. In this manner, multi-channel isolators are offered with a variety of transmit/receive channel configurations.

ICOUPLERS IN MEDICAL APPLICATIONS

Compliance to IEC60601-1 now brings iCouplers into the spotlight as the digital isolation component of choice for medical applications. The iCoupler has very high transient immunity of 25kV/μs minimum, a key specification in the real world of noisy electrical signals. A higher transient immunity in the presence of common-mode transients results in a lower probability of false outputs, and therefore in higher data reliability.

The design shown in Figure 2 details a possible scenario where a single iCoupler can displace several optocouplers. It is unlikely that a single low-cost optocoupler would be able to handle the high speed digital serial stream required by a multiplexed application. Multiple optocouplers and ADCs would thus be required to partition the digital data, reducing the number of bits per second that must be transmitted over each optoisolated link. The design becomes greatly simplified by the use of a single ADuM240X iCoupler and a single ADC with a higher throughput rate. Other benefits that can be realised through an iCoupler approach are reduced power requirements of the patient side circuitry and lower component count. In additional to performance advantages mentioned earlier, this design also benefits from improved system cost, size, and reliability.

Several options for interfacing to the ADC's digital output, including SPI or bit banging from the digital controller, are available to the designer. In medical applications, the ADuM240x is directly suitable as an isolation alternative in products seeking IEC60601-1 compliance. Low power requirements, high data rates, high transient immunity, low component count makes the ADuM240x family the choice for digital isolation in medical applications.

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