CMOS Advanced Galvanic Isolators for Medical Electronics

SILICON LABS

Introduction

Safety standards for ac line-powered medical electronic systems require galvanic isolation to protect patients and operators from electrically-induced trauma. The direct connection between machine and patient together with the presence of conductive body fluids and gels increase the risk of injury; thus isolators used in these systems must be robust and reliable.

Optocouplers and transformers are commonly used within medical system isolation circuits, and their deficiencies well known to the design community. Optocouplers are notoriously slow and exhibit wide performance variations over temperature and device age. They are single-ended devices, and consequently exhibit poor common mode transient immunity (CMTI). In addition, optocouplers are fabricated in Gallium Arsenide (GaAs) processes, with intrinsic wear out mechanisms that cause permanent reductions in LED emission at elevated temperature and/or LED current. This degradation reduces optocoupler reliability, performance and service life. While transformers offer higher speed and better reliability than optocouplers, they cannot pass dc and low-frequency signals, thereby imposing limits on system timing (e.g. ON-time and duty cycle). Transformers also tend to be large and power-inefficient, and often require additional external components for core reset.

CMOS Isolator Overview

Unlike optocouplers, complementary metallic oxide semiconductor (CMOS) isolators offer substantial gains in performance, reliability, operating stability, power savings, and functional integration. Unlike transformers, CMOS isolators operate from DC to 150 Mbps, and consume less space (up to six isolation channels per package) and are more power efficient. These attributes are made possible by fundamental technologies underlying CMOS isolators; specifically:

- Mainstream, low-power CMOS instead of GaAs process technology: CMOS is the most mature, widely sourced process technology in the world. Advanced circuit design techniques and CMOS technology enable isolators having fast 150 Mbps data rate, short 10ns propagation delay, low 5.6 mW/channel power consumption, and many other industry-leading performance specifications. CMOS also enables an isolator mean time-to-failure (MTTF) of more than 1000 years at maximum operating voltage and temperature; more than 10 times higher than optocouplers.

- RF carrier instead of light: RF technology further reduces isolator operating power and adds the benefits of precise frequency discrimination for superior noise rejection. Device packaging is also simpler compared to optocouplers.

- Fully differential instead of single-ended isolation path: The differential signal path and high receiver selectivity enables CMTI above 60 kV/us, excellent external RF field immunity to 300V/m, and magnetic field immunity greater than 1000 A/m for error-free operation. These attributes make CMOS isolators well-suited for deployment in harsh operating environments where strong electric and magnetic fields are present.

- Proprietary EMI suppression techniques: CMOS isolators meet the emission standards of FCC Part B, and tested to automotive J1750 (CISPR) test methods.

For more information on CMOS isolator emissions, susceptibility, and reliability vs. optocouplers, please see the Si86xx Digital Isolator data sheets, available at www.silabs.com.

Safety Certifications
From a system point-of-view, medical equipment is divided into individual classes, according to operating voltage. Class I equipment operates from 70 V or less, and requires only basic insulation and protective grounding for all accessible parts. Class II equipment operates from voltages above 70 V, and requires reinforced or double insulation. Class III equipment is operated from voltage levels below 25 V ac or 60 V dc, and is referred to as Safety Extra Low Voltage (SELV). Class III equipment does not require isolation.

From a component perspective, isolator package geometry is important in the prevention of electrical arcing across package surfaces. Safety agencies therefore specify package *creepage* and *clearance* dimensions as a function of test voltage. As shown in Figure 1, creepage is the distance along the insulating surface an arc may travel, and clearance is the shortest path through air an arc may travel.

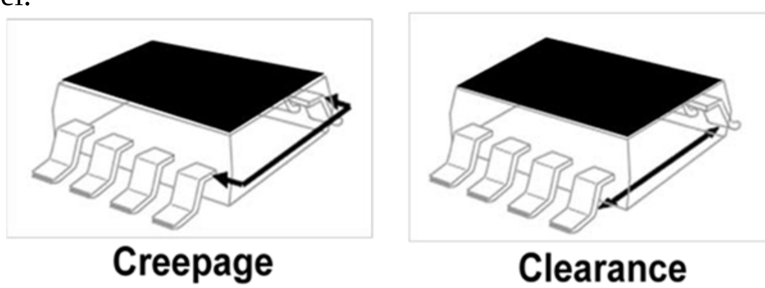

FIGURE 1: Creepage and Clearance Distances

The heart of the isolator is the *insulator,* the dielectric strength of which determines the isolator's voltage rating. Isolation classifications include "Basic" and "Reinforced". Basic isolation provides a single-level of protection against electrical shock, and cannot be considered *failsafe* (i.e. a failure does not cause the system to automatically retreat to a safe, secure state). Devices with Basic isolation can be accessible to the user, but must be contained within the system. Certification testing for Basic isolation devices consists of applying a stress voltage of 1.6 kV_{RMS} for a period of 1 minute, with a minimum creepage of 4mm. Reinforced isolation provides two levels of protection for failsafe operation, and allows for user access. Certification testing of Reinforced isolation devices consists of applying a stress voltage of 4.8 kV_{RMS} for a period of 1 minute, with a minimum creepage of 8 mm. Medical electronic systems almost always require Reinforced isolation because of its failsafe protection attribute.

Reinforced CMOS isolators are certified under international standard IEC/EN/DIN (Deutsches Institut für Normung) EN 60747. CMOS isolators are also certified to IEC-60601-1 medical standards' insulation requirements, which requires UL (Underwriters Laboratories) 1577 or IEC 60747 certification as a prerequisite. IEC-60601-1 specifies dielectric strength test certification criterion for Basic and Reinforced isolation, which includes creepage and clearance limits, and stress voltage and duration, as summarized in Table 1.

Working Voltage		Insulation	Creepage	Clearance	Test Voltage
V_{DC}	V_{RMS}	Type	(mm)	(mm)	V_{RMS} for 1 Minute
17	12	Basic	1.7	0.8	1,600
		Reinforced	3.4	1.6	3,200
34	30	Basic	2	1	1,600
		Reinforced	4	2	3,200
85	60	Basic	2.3	1.2	1,600
		Reinforced	4.6	2.4	3,200
177	125	Basic	3	1.6	1,600
		Reinforced	6	3.2	3,200
354	250	Basic	4	2.5	1,600
		Reinforced	8	5	3,200

Table 1: IEC60601-1 Safety Standard Requirements for CMOS Isolators

Optocouplers use plastic mold compound as their primary insulator, and must therefore meet an internal mechanical distance specification referred to as "Distance Through Insulation" (DTI), as referenced in IEC 60601-1. For optocouplers, DTI is the distance between the LED and optical receiver die, typically 0.4mm minimum. CMOS isolators utilize semiconductor oxides as their primary insulator, which have greater dielectric strength and uniformity than package mold compound, and therefore occupy less space. To certify to IEC 60601-1, safety regulating agencies perform test for DTI equivalence by thermally cycling CMOS isolators at 125 °C for 10 weeks with an applied stress voltage of 250 V_{ACRMS}, then post-testing the isolators at 4.8 KV_{ACRMS} for 1 minute. Note the DTI evaluation for CMOS isolators is far more stringent than that of the optocoupler.

Medical electronic systems must be immune to external interference caused by localized fields, static electricity, and by power line perturbations such as line voltage dips, surges and transients. As a result, both optocouplers and CMOS isolators are safety tested to a number IEC-61000 standards, using test limits specified by IEC 60601-1-2 as shown in Table 2. For example, electrostatic discharge (ESD) is tested to IEC 61000-4-2, and uses the test limits specified by IEC 60101-1-2. RF emissions and power line perturbations are tested using methods from CISPR11 test methodology, a subset of automotive specification J1750. (CISPR does not specify test limits - it is a test methodology standard.) Limits for emissions and power line sensitivities are specified in IEC 60601-1-2.

Immunity Test	Standard	IEC 60601 Test Level
Electrostatic Discharge (ESD)	IEC 61000-4-2	±6kV contact, ±8kV air
Electrical Fast Transient/Burst	IEC 61000-4-4	±2kV (power supply lines), ±1kV (I/O lines)
Surge	IEC 61000-4-5	±1kV lines-to-lines (Basic), ±2kV lines-to-lines (Reinforced)
Brownouts, voltage dips, interruptions and voltage variations on power supply lines	IEC 61000-4-11	Less than 5% **U** (> 95% dip in **U** for 0.5 cycle) 40% **U** (60% dip in **U** for 5 cycles) 70% **U** (30% dip in **U** for 25 cycles) < 5% **U** (>95% dip in **U** for 5 sec)
Power Frequency (50/60 Hz) Magnetic Field	IEC 61000-4-8	3A/m

Table 2: IEC 60601-1-2 Immunity Requirements

Note: Variable **U** is the ac mains voltage prior to the application of the test level.

The criteria for passing these tests are very stringent: the system cannot exhibit any component failures, parametric changes, configuration errors, or false positives. In addition to external field immunity, the system under test cannot generate significant radiated or conducted emissions of its own.

Typical Applications

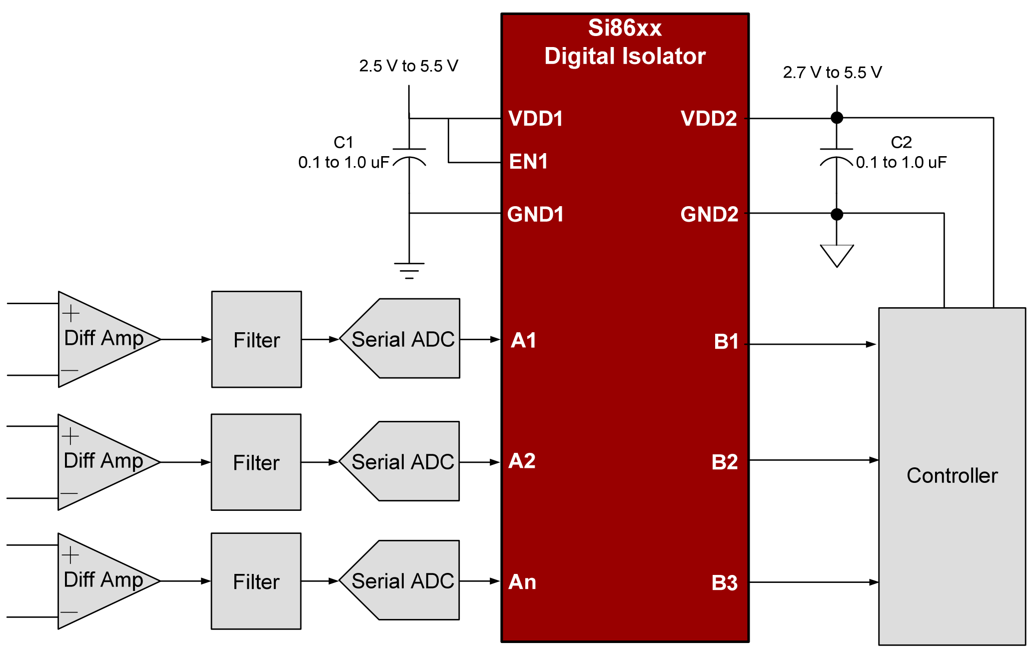

Figure 2: ECG Front End

ECG Application

Figure 2 shows a block diagram of an electrocardiogram (ECG) front end where analog output from the instrumentation amplifiers are high-pass filtered, then converted to digital format by the serial ADCs. Converted data is transmitted through the Si86xx reinforced (5 kV) digital isolator to the controller for processing. The Si86xx digital isolator can operate at throughput rates as high as 150 Mbps per channel for "bottleneck free" data transfer. If parallel output ADCs were used, isolation can be implemented using as few as four Si8660 six-channel isolators (assuming 16-bit ADCs).

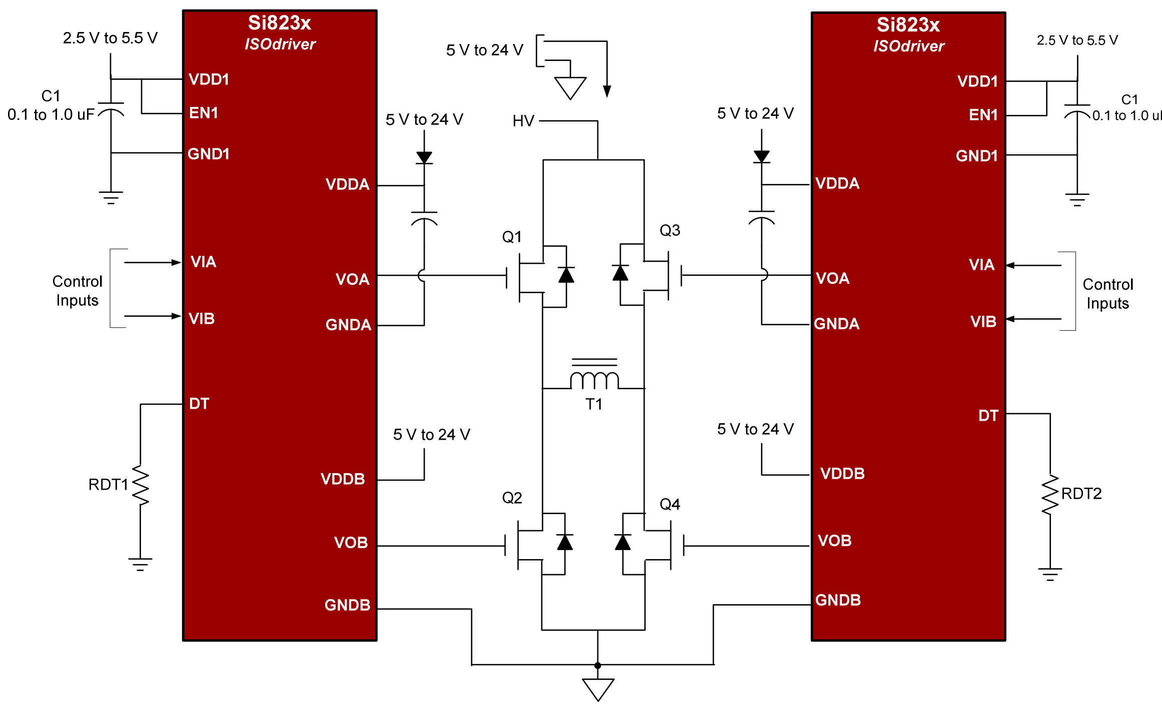

Figure 3: ISOdriver-Based Defibrillator Power Stage

Defibrillator Application

Figure 3 shows the power stage for a defibrillator where two high-side/low-side isolated drivers (*ISOdrivers*) drive a full-bridge circuit. Note this circuit requires only two ISOdrivers with standard high-side bootstrap circuits to implement a full-bridge drive solution. Each ISOdriver has an on-chip input signal conditioning circuit consisting of Schmitt-trigger inputs, input UVLO protection, output overlap protection, and dead time generator. These features are critical for reliable operation of safety-critical medical systems.

The input stage is followed by a reinforced two-channel isolator, the outputs of which connect to the gate drivers, each isolated from the other as well as from the input. Resistors RDT1 and RDT2 determine the amount dead time added within each cycle. If dead time is not required, the DT inputs should be tied to the local source of VDD.

In addition to logic input ISOdrivers, Silicon Labs also offers the Si826x series of enhanced, function-compatible replacements for optically-coupled drivers. The Si826x series have an input stage that mimics the behavior of an optocoupler LED, allowing direct replacement gate drivers products such as the HCPL-3120, yet offer lower power operation, better performance across temperature, and higher reliability. For more information, please see the "*Si826x ISOdriver Data Sheet*" available for down load at www.silabs.com.

Medical Power Supply Application

The examples above illustrate how CMOS isolators can be used in electronic medical systems at the circuit level. Other systems may use CMOS isolators for different circuit functions, such as voltage level-shifting or eliminating noise-causing ground loops. Table 3 shows a partial list of medical electronic systems that can benefit from the use of CMOS isolation technology. Isolation requirements in these and other applications result in a virtually open-ended number of CMOS isolator use cases, and CMOS isolator technology will ultimately supplant legacy isolation technologies as the medical electronics market continues to expand.

Equipment Category	System Examples
Cardiology Systems	Blood pressure, ECG, Defibrillator
Fluid Pumps	IV pumps, Portable Drug Pumps, Fluid Evacuation Systems
Lab Equipment	Biomedical Test Systems, Centrifuges, Warming Cabinets
Ob/Gyn Equipment	Fetal Monitors, Suction Pumps, Surgical Hysteroscopes
Otoscopes/Opthalmascopes	Power Supplies and Interface Adaptors
Physical Therapy Equipment	Chilling Units, Ultrasound/EMS Units, Measurement Instruments
Radiology	Mamography, X-Ray Systems, MRI Systems, Motorized Viewers
Sterile Processing Equipment	Autoclaves, Automated Washers, Distillers, Ultrasonic Cleaners

Table 3: Example Applications for CMOS Isolation Products in Medical Systems

Summary

Electronic medical systems must have integrated robust isolation to ensure patient and operator safety. Stringent international safety regulatory agencies certify medical electronics systems to their specifications for uniform safety. Isolators play a key role in such these systems, and must be robust and reliable, yet consume minimum space and add negligible cost to the system. Optocouplers and transformers have been the favored solutions for medical system isolator circuits. However advances in technology have made possible smaller, more reliable and higher performance isolation devices including single-package multi-channel digital isolators, AC current sensors and gate drivers. These new isolation products are based on main-stream CMOS process technology and offer significant benefits over legacy solutions, including 10 times lower failure rates compared to optocouplers. CMOS isolation products are the ideal solution for many electronic medical systems.

References

- IEC 60601-1, "General Requirements for Basic Safety and Essential Performance", International Electrotechnical Commission.
- IEC 60601-1-2, "International Standard for Medical Equipment", International Electrotechnical Commission.
- Designing Medical Devices for Isolation and Safety, Avago Technologies, May 24, 2007 EDN Magazine

Related Documents

Silicon Labs “Si86xx Digital Isolator Data Sheet”
Silicon Labs “Si823x ISOdriver Data Sheet”
Silicon Labs “Si826x ISOdriver Data Sheet”