CMOS Advanced Galvanic Isolators for Medical Electronics

1. 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; therefore, isolators used in these systems must be robust and reliable.

Optocouplers and transformers are commonly used within medical system isolation circuits, and their deficiencies are well known to the design community. Optocouplers are notoriously slow and exhibit wide performance variations over temperature and device lifetime. They are single-ended devices, which 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 temperatures and/or LED currents. 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, thus 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.

2. CMOS Isolator Overview

Unlike optocouplers, complementary metal oxide semiconductor (CMOS) isolators offer substantial advantages in performance, reliability, operating stability, power savings, and functional integration. Unlike transformers, CMOS isolators operate from dc to 150 Mbps, require less space (up to six isolation channels per package), and are more power-efficient. These advantages are made possible by the following fundamental technologies underlying CMOS isolators.

- **Standard CMOS Process Technology Silicon Dioxide Based Capacitive Isolation Barrier instead of GaAs Process Technology**
  CMOS is a well understood process technology with 40+ years of learning and offers 5.5 times lower failures-in-time (FIT) rate than GaAs-based optocouplers. The silicon dioxide isolation barrier offers a time dependent dielectric breakdown (TDDB) of 60 years compared to less than 15 years in optocouplers. It also offers a mean time-to-failure (MTTF) of 87 years. The operating temperature range is –40 to +125 °C as compared to –40 to +85 °C for optocouplers. This wide operating temperature range leads to greater parametric stability over voltage and temperature, and lower operating power versus optocouplers.
- **Improved Performance**
- Shorter propagation delay time and PWD, wider operating temperature range and greater parametric operating permit greater system stability than when using optocouplers.
- **High Frequency 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 enable CMTI above 25 kV/µs, excellent external RF field immunity to 300 V/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, such as in motor-control circuits and medical MRI systems.
- **Proprietary EMI Suppression Techniques**
  CMOS isolators meet the emission standards of FCC Part B and are tested to automotive J1750 (CISPR) test standards.

For more information on CMOS isolators emissions, susceptibility, and reliability vs. optocouplers, see the Silicon Laboratories website at www.silabs.com/isolation.

3. 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 Vac or 60 Vdc 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. Therefore, safety agencies 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 that an arc may travel, and clearance is the shortest path through air that an arc may travel.

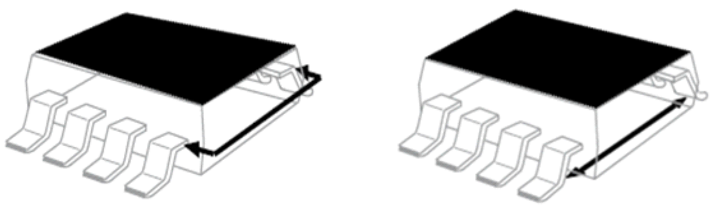

Figure 1. Creepage and Clearance Distances

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 in 250V_{RMS} systems that require 4mm of creepage, consists of applying a stress voltage of 1.6 kV_{RMS} for a period of 1 minute. Reinforced isolation provides two levels of protection for failsafe operation and allows user access. Certification testing of reinforced isolation devices in 250V_{RMS} systems that require 8 mm of creepage, consists of applying a stress voltage of 4.8 kV_{RMS} for a period of 1 minute. 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 60747-5-2. CMOS isolators are also certified to the IEC-60601-1 medical standards insulation requirements, which require UL (Underwriters Laboratories) 1577 or IEC 60747-5-2 certification as a prerequisite. IEC-60601-1 specifies dielectric strength test certification criteria for Basic and Reinforced isolation, which includes creepage and clearance limits and stress voltage and duration as summarized in Table 1.

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

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	1600
		Reinforced	3.4	1.6	3200
34	30	Basic	2	1	1600
		Reinforced	4	2	3200

Table 1. IEC60601-1 Safety Standard Requirements for CMOS Isolators (Continued)

Working Voltage		Insulation	Creepage	Clearance	Test Voltage
V_{DC}	V_{RMS}	Type	(mm)	(mm)	V_{RMS} for 1 Minute
85	60	Basic	2.3	1.2	1600
		Reinforced	4.6	2.4	3200
177	125	Basic	3	1.6	1600
		Reinforced	6	3.2	3200
354	250	Basic	4	2.5	1600
		Reinforced	8	5	3200

Optocouplers use a plastic mold compound as their primary insulator and must, therefore, meet an internal mechanical distance specification referred to as “Distance Through Insulation” (DTI), referenced in IEC 60601-1. For optocouplers, DTI is the distance between the LED and optical receiver die (typically 0.4 mm minimum). CMOS isolators utilize semiconductor oxides for their primary insulator, which offer greater dielectric strength and uniformity than package mold compounds and, therefore, occupy less space.

To certify to IEC 60601-1, safety regulating agencies perform tests for DTI equivalence by thermally cycling CMOS isolators at 125 °C for 10 weeks with an applied stress voltage of 250 VAC_{RMS} and post-testing the isolators at 4.8 $kVAC_{RMS}$ for one 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 power line anomalies, such as line voltage dips, surges, and transients. As a result, both optocouplers and CMOS isolators are safety tested to a number of 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.

Table 2. IEC 60601-1-2 Immunity Requirements

Immunity Test	Standard	IEC 60601 Test Level
Electrostatic Discharge (ESD)	IEC 61000-4-2	±6 kV contact, ±8 kV air
Electrical Fast Transient/Burst	IEC 61000-4-4	±2 kV (power supply lines), ±1 kV (I/O lines)
Surge	IEC 61000-4-5	±1 kV lines-to-lines (Basic), ±2 kV 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	3 A/m
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.

4. Typical Applications

4.1. ECG Application

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

In addition to logic input isolators, Silicon Labs also offers the Si87xx series of enhanced, function-compatible replacements for optocouplers. The Si87xx series has an input stage that mimics the behavior of an optocoupler LED, allowing functional replacement of optocouplers, yet offering lower power operation, better performance across temperature, and higher reliability. For more information, see the Si87xx series of isolator data sheets available at www.silabs.com.

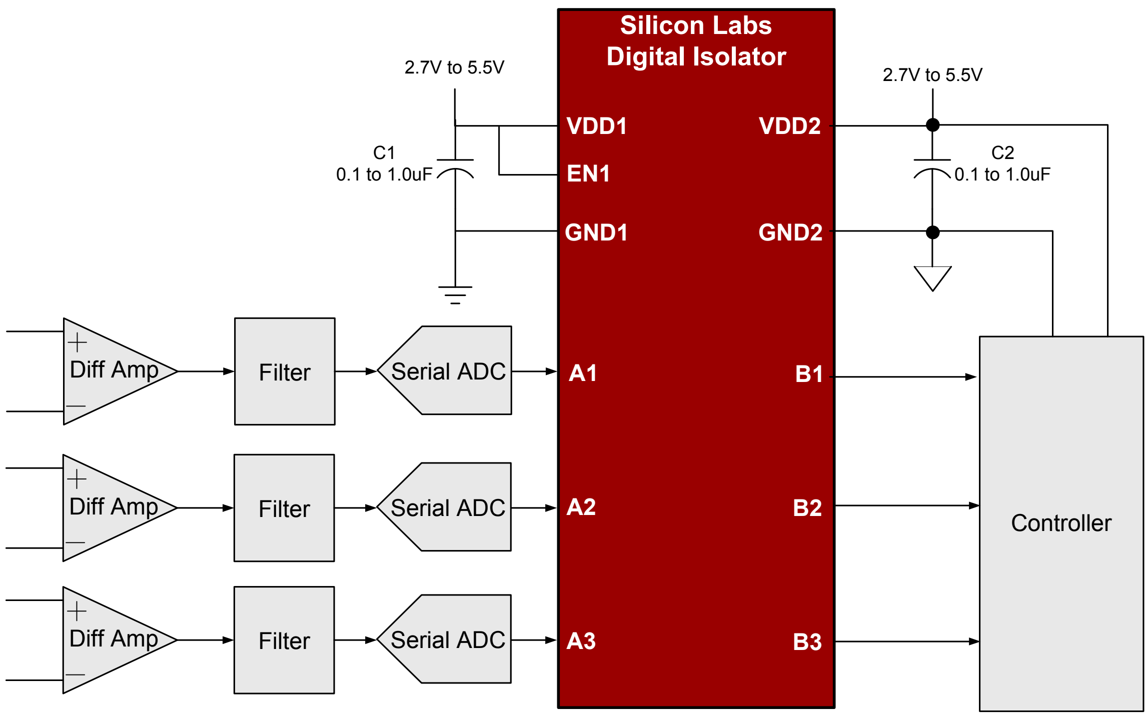

Figure 2. ECG Front End

4.2. 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 that 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 a dead time generator. These features are essential for the 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 of 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 Si822x/6x series of enhanced, function-compatible replacements for optically-coupled drivers. The Si822x/6x series has an input stage that mimics the behavior of an optocoupler LED, allowing functional replacement of gate driver products, such as the HCPL-3120, yet offering lower power operation, better performance across temperature, and higher reliability. For more information, see the Si822x/6x series of ISOdriver data sheets available at www.silabs.com.

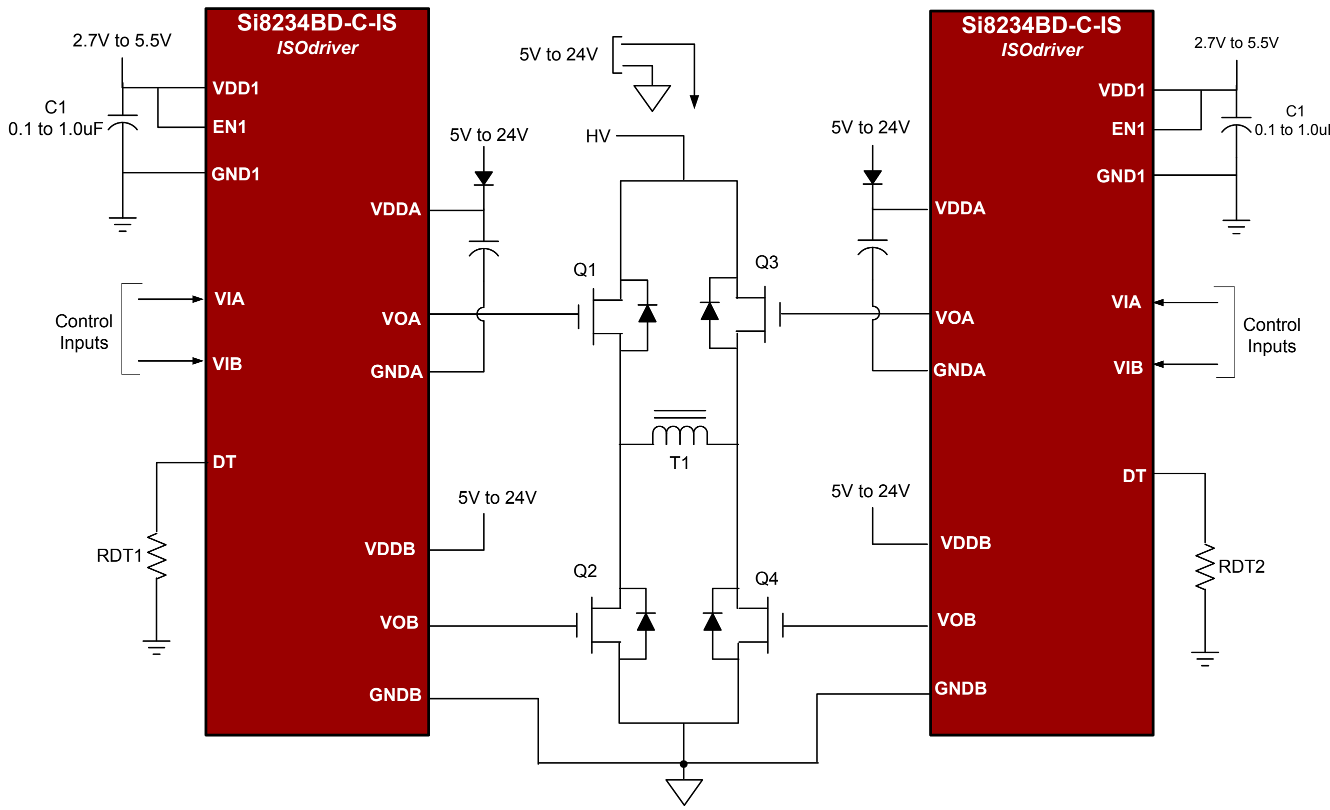

Figure 3. ISOdriver-Based Defibrillator Power Stage

4.3. Medical Power Supply Application

Figure 4 shows a phase-shift-modulated full-bridge application typical of power supplies used in large medical systems, such as clinical MRIs. These systems commonly use current-sense transformers, which require external discrete circuits for core reset and special layout considerations. They also tend to have low-amplitude output waveforms and often exhibit problematic EMI performance.

The Si850x/1x series of isolated ac current sensors offers integrated reset circuits, high 2 Vp-p full-scale output signals, 5% measurement accuracy, small size, and low-power operation. They operate over a frequency range of 50 kHz to 1 MHz (full-scale measurement ranges of 5, 10, and 20 A) and available isolation ratings of 1 kV and 5 kV (reinforced). These devices have an input resistance of 1.3 mΩ for low power loss and a series inductance of 2 nH for reduced ringing. The current sensor in Figure 4 has a “Ping-Pong” output mode that routes current signals from each leg of the bridge to separate output pins for transformer flux balance monitoring.

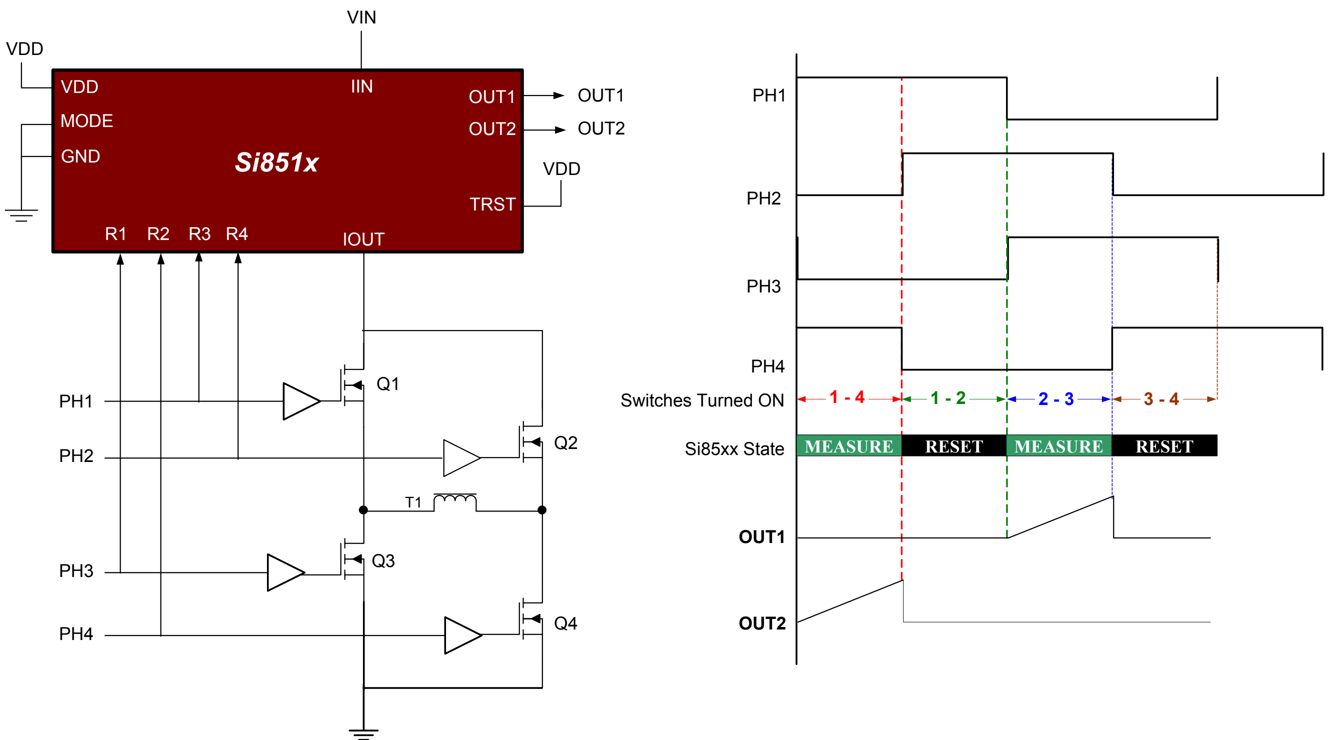

Figure 4. Si851x (Ping-Pong Mode) in a Phase-Shifted Full Bridge Application

Measured current flowing when Q1 and Q4 are on appears on OUT2, and current flowing when Q2 and Q3 are on appears on OUT1. Integrator reset occurs during the current circulation phase (i.e. when Q1 and Q2 are on or Q3 and Q4 are on). For more information, see “AN398: Using the Si85xx Current Sensors in Switch Mode Power Supplies”.

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.

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

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	Mammography, X-Ray Systems, MRI Systems, Motorized Viewers
Sterile Processing Equipment	Autoclaves, Automated Washers, Distillers, Ultrasonic Cleaners

Table 4 is a summary of Silicon Laboratories isolation products compliant to medical specification IEC 60601.

Table 4. Silicon Laboratories Isolation Products Summary*

Silicon Labs Product	Isolation Rating (kV_{RMS})	Max Working Voltage (V_{RMS})	Package	Creepage (mm)	Clearance (mm)	IEC 60601 Compliant
Si822x	5	125	WB SOIC-16	8*	8*	Yes
Si823x	5	125	WB SOIC-16	8*	8*	Yes
Si826x	5	125	DIP8	7	7	Yes
Si826x	5	250	SDIP6	8.3	8.3	Yes
Si826x	5	250	LGA8	10	10	Yes
Si841x/2x	5	125	WB SOIC-16	8*	8*	Yes
Si850x/1x	5	125	WB SOIC-20	8*	8*	Yes
Si86xx	5	125	WB SOIC-16	8*	8*	Yes
Si87xx	5	125	DIP8	7	7	Yes
Si87xx	5	250	SDIP6	8.3	8.3	Yes
Si87xx	5	250	LGA8	10	10	Yes
***Note:** 8 mm creepage and clearance assumes conformal coating is used. Creepage in air is 7.6 mm.						

5. Summary

Electronic medical systems must have robust integrated 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 these systems and must be robust and reliable while requiring minimum space and adding negligible cost to the system. Optocouplers and transformers have been the preferred 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 mainstream CMOS process technology. CMOS is a well understood process technology with 40+ years of learning and offers 5.5 times lower failures-in-time (FIT) rate than GaAs-based optocouplers. CMOS isolation products are the ideal solution for many electronic medical systems. When combined with Silicon Laboratories mixed-signal MCUs, ISOdrivers, and Si85xx-series current sensors, CMOS isolators enable highly-integrated, power-efficient designs that comply with critical safety specifications for medical systems.

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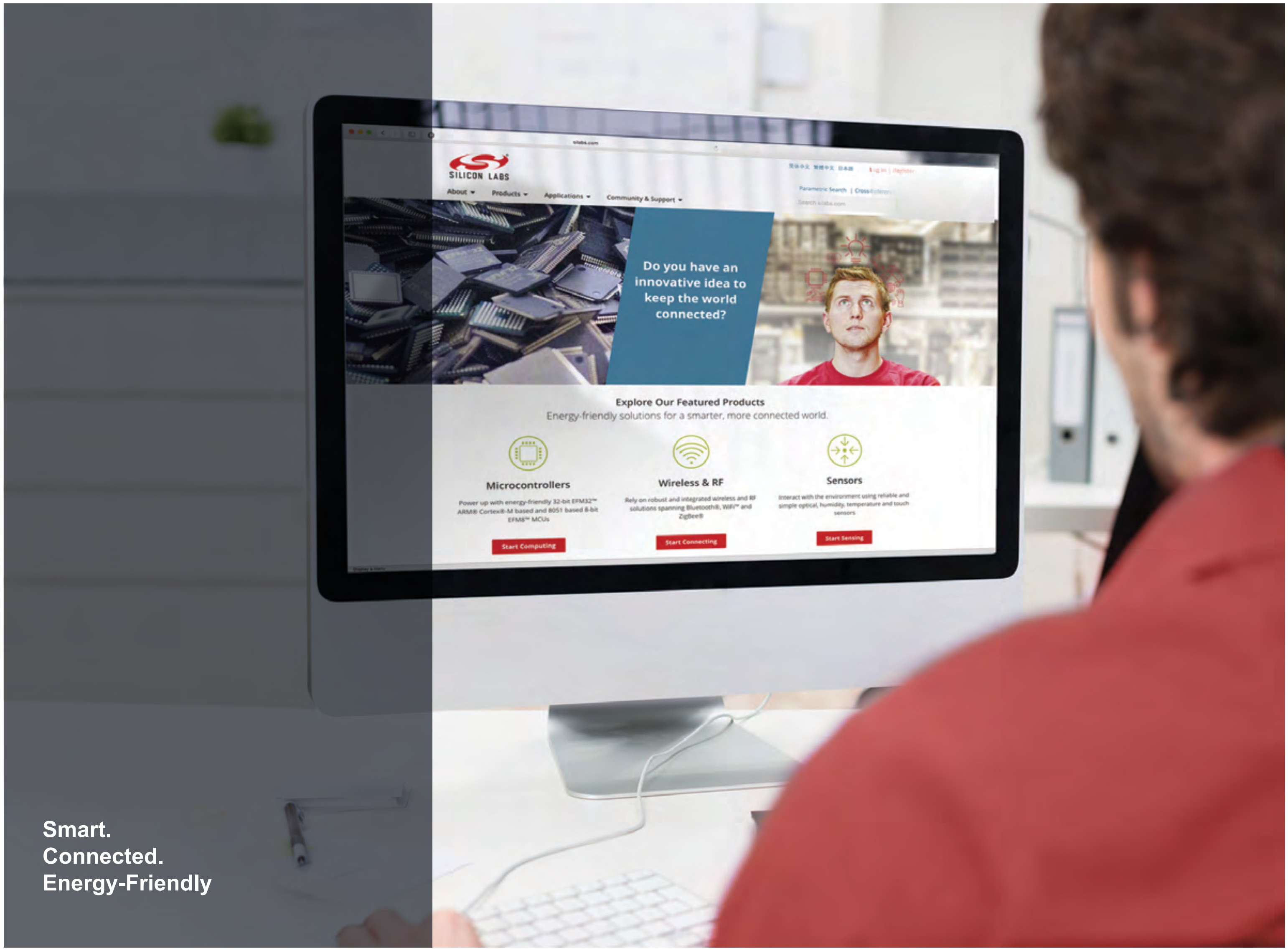

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