Design and Evaluation of a USB Isolator for Medical Instrumentation

Gaspar González-Briceño, *Student Member, IEEE*, Joshua E. Medow, Susana Ortega-Cisneros, Daniel Lorias-Espinoza, Arturo Minor-Martínez, and John G. Webster, *Life Fellow, IEEE*

***Abstract*— Design of medical equipment (ME) has benefitted from the use of personal computers (PCs). In order to integrate both technologies, important factors must be considered in the design of medical instrumentation, such as magnitude parameters and frequency range. Electrical protection is a fundamental characteristic in all MEs to guarantee electrical safety for both operator and patient. This paper describes the design and electrical considerations necessary to achieve galvanic isolation between ME and PC, through an isolated universal serial bus interface (IUSBI), an excellent alternative for achieving connectivity with different types of MEs and to guarantee the appropriate electric safety, according to the International Standard IEC 60601-1. The IUSBI integrates isolation technologies (energy and data transfer) into a printed circuit board (PCB), made of flamed-retardant # 4 (FR4) epoxy, with a 6.8 mm gap for air clearance and creepage distance capable of supporting a high-potential test of 3000 V ac with 125 V rms of working voltage, which provides the interface with a reinforced insulation.**

***Index Terms*— Dielectric strength, digital isolation, electrical safety, IEC 60601-1, isolated communication interface (ICI), medical instrumentation, reinforced insulation.**

I. Introduction

VENTRICULAR fibrillation is the leading cause of death due to electric shock. The threshold for ventricular fibrillation for an average-sized human varies from about 75–400 mA. A first attempt to provide electrical safety is to control the availability of electric power and the grounds in the patient's environment [1], such as the grounding placed in the medical equipment (ME) [2]. However, even with proper grounding, there is a risk of electric shock when the patient comes into contact with ME, giving rise to the effect known as Macroshock (where the flow path of the electric current passes through the body without going directly through the heart) or Microshock (where the electric current goes directly to the heart) [3], [4]. In order to minimize the risk of these two effects, a galvanic isolation is performed in the power supply integrated into the ME, protecting the ME, the operator, and the patient from an electric shock [5].

At present, the development and construction of ME have benefitted from the inclusion of personal computers (PCs). This approach reduces costs and development time, due to the versatility in performing analysis applications with the software [6] and the fact that many PC components are available at commodity prices [7]. Meanwhile, if the ME is connected to a PC, it must include another isolation media to provide the appropriate electrical protection to the patient.

Different isolation methods to provide electrical protection to the patient in those MEs integrated into the PCs have been applied. Some of these isolate the power supply stage of the PC [8]–[10], others isolate the signal acquisition stage in the ME [11]–[18], and others perform an isolation in the communication stage between the PC and the ME [19]–[27]. However, isolation in the PC's power supply could reduce the portability of the PC (e.g., medical transformers or medical uninterruptible power system) and if isolation in the acquisition stage is used as an alternative, there could be a risk of electric shock for the operator. Thus, isolating in the communication stage would be the most convenient in these cases.

Communication media between a PC and an ME varies depending on the necessity and the applications. However, the most popular standard technology for connecting hardware by cable is the universal serial bus (USB) [28], [29], which has some considerable advantages, such as being expandable to 127 peripherals, having plug and play features and compatibility with multiple platforms, operating at high data rates (1.5 Mbps, 12 Mbps, 480 Mbps, 4.8 Gbps, and 10 Gbps), having standard compatibility in the industry [30], and being able to work as a transport layer under the guidelines of the Continua Alliance that use the ISO/IEEE 11073 standard for communication between ME and external computer systems [31]. In addition to this, it has a power stage that helps to energize bus-powered devices (USB devices that rely on power totally from the cable) or self-powered devices (USB devices that have an alternative power source). Unfortunately, the USB was not made for medical applications when a PC is connected by this port to a ME. Because of this, the design of an electrically isolated USB interface (IUSBI) independent

Manuscript received February 7, 2018; revised May 3, 2018; accepted June 12, 2018. Date of publication August 1, 2018; date of current version February 8, 2019. The Associate Editor coordinating the review process was Subhas Mukhopadhyay. *(Corresponding author: Gaspar González-Briceño.)*

G. González-Briceño, D. Lorias-Espinoza, and A. Minor-Martínez are with the Department of Electrical Engineering, Bioelectronics Section, CINVESTAV, Mexico City 07360, Mexico (e-mail: ggonzalezb@cinvestav.mx; aminor@cinvestav.mx; dlorias@cinvestav.mx).

J. E. Medow is with the Department of Neurological Surgery, University of Wisconsin–Madison, Madison, WI 53792 USA (e-mail: medow@neurosurgery.wisc.edu).

S. Ortega-Cisneros is with the Department of Electrical Engineering, CINVESTAV Guadalajara, Zapopan 45019, Mexico (e-mail: sortega@gdl.cinvestav.mx).

J. G. Webster is with the Department of Biomedical Engineering, University of Wisconsin–Madison, Madison, WI 53706 USA (e-mail: john.webster@wisc.edu).

Color versions of one or more of the figures in this paper are available online at http://ieeexplore.ieee.org.

Digital Object Identifier 10.1109/TIM.2018.2853319

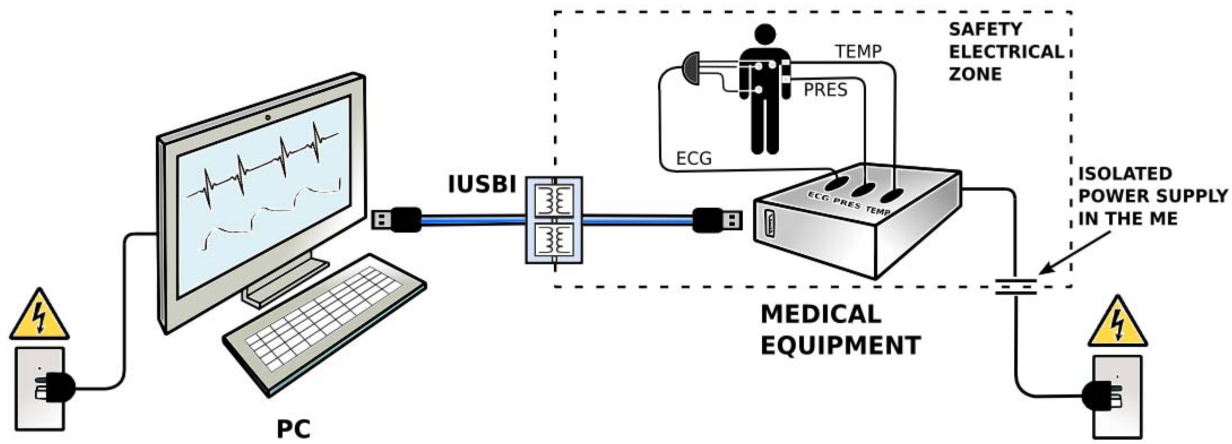

Fig. 1. Galvanic isolation via a USB cable between an ME and a computer.

of the ME is proposed, ensuring the electrical safety for both the operator and patient and complying with the IEC 60601-1 standard (Fig. 1).

IEC 60601-1 standard governs the electrical safety of a medical device and specifies requirements and test types used in protection against electric shock hazards [32]. This standard specifies three insulation levels for MEs: basic insulation, supplementary insulation, and reinforced insulation. This last level is the safest since it has two means of protection (MOP) in order to reduce the risk due to the electric shock of the patient. A MOP is categorized as a means of operator protection (MOOP) or a means of patient protection (MOPP). Moreover, it establishes the creepage distances and air clearances necessary to satisfy the reinforced insulation in an insulating material, helping the ME to contain accessible parts and applied parts.

There are three types of applied parts: types B, BF, and CF. Type CF applied parts providing the highest degree of patient protection and they are appropriate for a direct cardiac application. In this case, providing a reinforced insulation to the ME is the most effective solution to guarantee the electrical safety to the patient. For this reason, any isolated communication interface (ICI) as described in this paper must consider the type of applied parts to establish the proper use according to the level of protection against an electrical hazard.

The design of an IUSBI for medical instrumentation is described. This permits bidirectional data transfer and power exchange through galvanic isolation. The amount of dc isolated power is also measured, the signal delay of the prototype is measured, the electromagnetic amount radiated by the prototype at different frequencies is evaluated and the dielectric strength of solid insulation made by the flamed-retardant # 4 (FR4) between the primary and secondary sides of IUSBI is tested, thereby identifying whether the IUSBI can be used to interact with different MEs according to the frequency and electrical safety parameters.

II. Methods and Materials

A. Proposed Design

Some designs for medical and industrial applications have been developed to isolate the USB [21], [22], but the results do not prove the electrical safety in order to be used as a medical grade interface. In this paper, we introduce and demonstrate a simple, but robust digital isolation design that conforms to the international guidelines of electrical safety for ME (IEC 60601-1). The design proposed consists of three essential stages for the galvanic isolation between two devices connected via a USB port (Fig. 2). The first stage performs the isolation between D+ and D− data. However, it is necessary to supply both sides of the interface through an isolated power source to guarantee a complete electrical isolation. The second stage consists of a dc–dc converter with a voltage regulator. These two components have a reinforced insulation and comply with the IEC 60601-1 standard. The third stage consists of a gap between the primary side (upstream) and secondary side (downstream) necessary to reach a specific insulation level and determine the types of applied parts of an ME that can be used with the IUSBI.

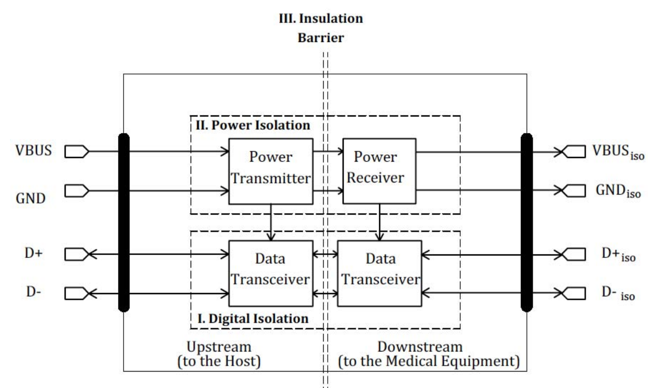

Fig. 2. IUSBI block diagram.

B. Data Isolation

Data transmissions, D+ and D−, are electrically isolated using the integrated circuit ADUM4160BRWZ, which is compatible with the USB 2 port and manages low- and full-speed data rates (1.5 and 12 Mbps, respectively) [33].

In the data isolator, the pin connection 5 (SPU) can be connected in a high state for full speed and in a low state

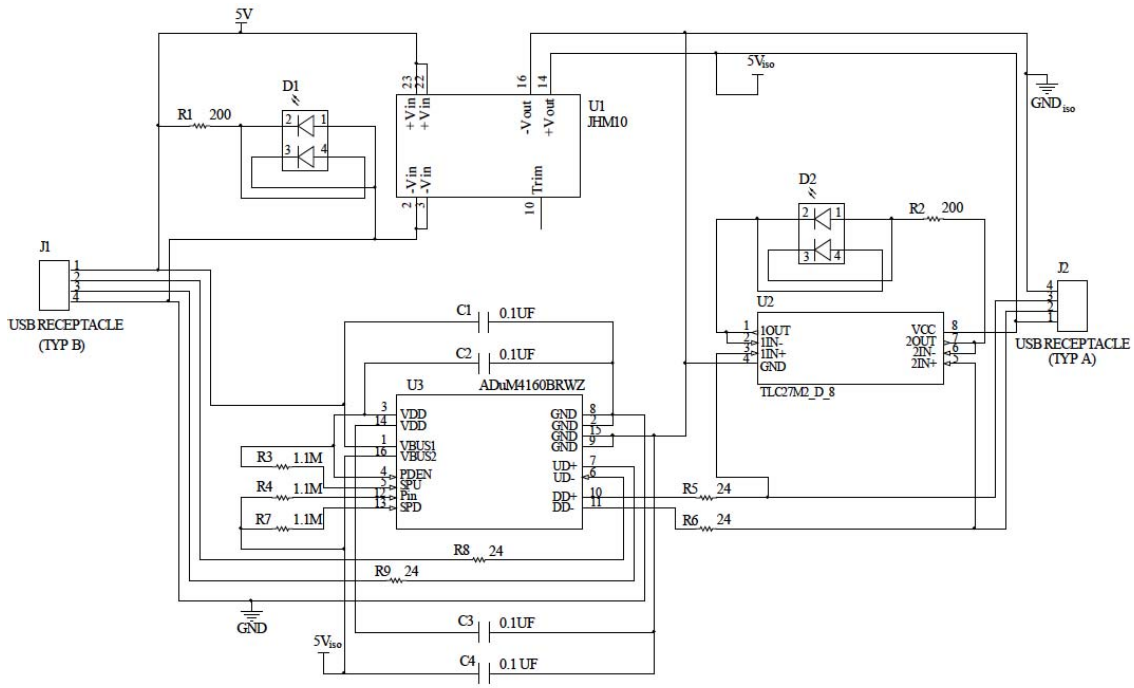

Fig. 3. Electric circuit for the IUSBI.

for low speed, performing the same operation with the pin of connection 13 (SPD) that acts in the same way for output data. If low-speed devices are connected, such as computer mouse or keyboard, these two pins must be connected in their low state (GND1 and GND2, respectively), and if a full-speed device is connected, they must be connected in a high state (VBUS1 and VBUS2, respectively). In our design, we connected SPU and SPD in a high state to perform a full-speed digital isolator. Fig. 3 shows an IUSBI electric circuit.

Even taking into account the above-mentioned considerations, 0.1 μF capacitors were set in order to work as a bypass, so the voltage is not affected by external conditions. These capacitors are placed between the power source and the ground of the data isolator.

C. Energy Transfer

As well as data transfer, isolated electronics must also have operating power. For this purpose, a dc–dc converter (JHM1005S05, XP POWER) is fed directly from the USB port on the host, which delivers a regulated output voltage of 5 V. In addition to this, the converter also has a reinforced insulation according to the IEC 60601-1 standard and has an efficiency of 83.5%.

To know the energy transfer of the IUSBI, we connected the downstream side to a resistive load and measured the output voltage and current versus input voltage and current. The input voltage and output voltage were measured with multimeters (GDM-8246, GW INSTEK), and both the input current and the output current were connected to an ammeter (B 4100, GW INSTEK). The resistive load connected to the output of the IUSBI was varied using resistances from 5 Ω of 3 W (53J5R0E, Ohmite) connected in series to the values from 5 to 100 Ω and two resistances connected in parallel to the load of 2.5 Ω.

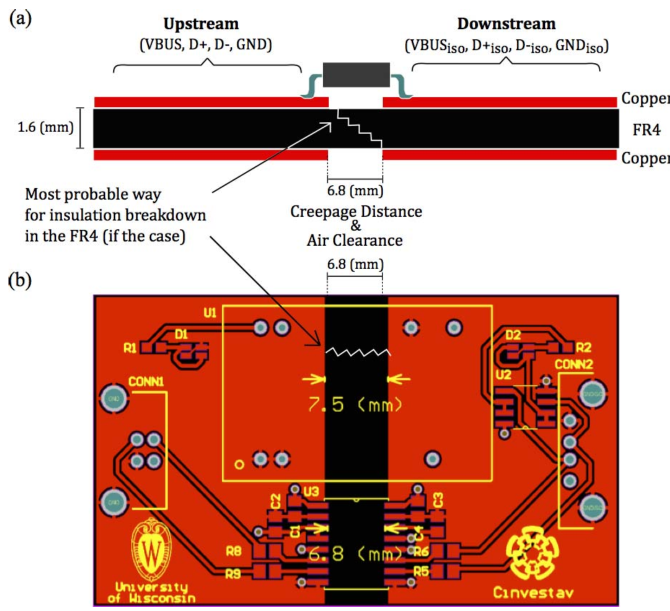

Fig. 4. Solid insulation barrier in the PCB between the input stage (upstream) and the isolated stage (downstream). The creepage distance and the minimum air clearance are provided by the 6.8 mm gap. (a) PCB transversal view. (b) PCB superior view.

D. PCB Specifications and Design

The printed circuit board (PCB) (manufactured by Advanced Circuits) was performed on a two-layer board with ground planes on both sides to reduce parasitic capacitances and electrical noise interference. In the design, a 6.8 mm gap was created on an FR4 dielectric with a thickness of 1.6 mm

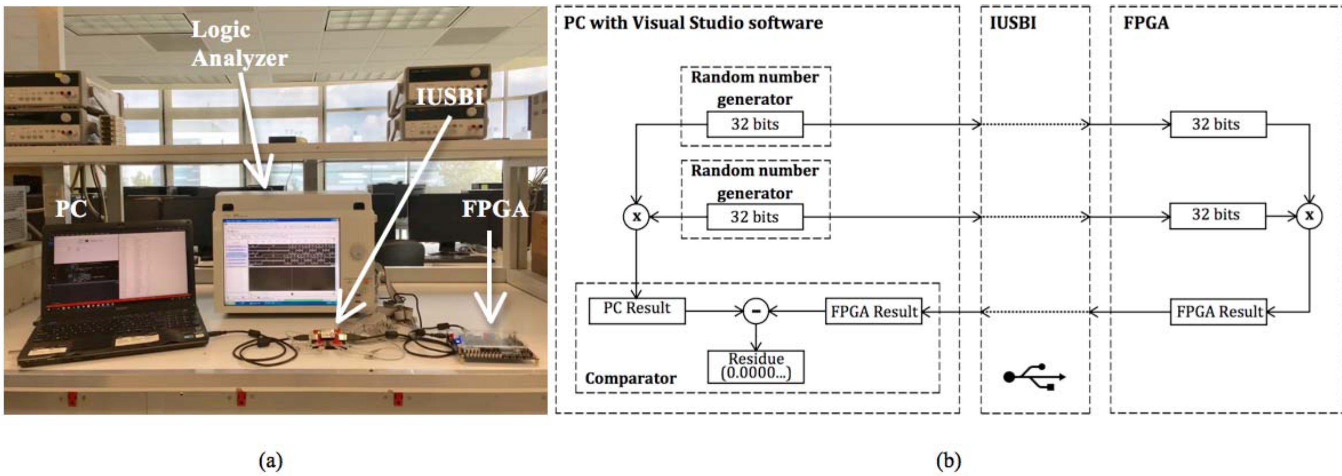

Fig. 5. Setup for data transmission test to prove the effectiveness of the USB communication. (a) Physical connection. (b) Data test block diagram.

separating the primary side from the secondary side. This FR4 has a dielectric constant of 5.4.

Fig. 4 shows the creepage distances and air clearances used in the PCB to perform a solid insulation with two MOPPs necessary to provide a reinforced insulation. The standard specifies a minimum creepage distance of 6 mm and a minimum air clearance of 3.2 mm in relation to a working voltage of 125 V rms (working voltage that powers the PC).

E. Data Transmission Test

In order to prove the effectiveness of the USB communication between two devices, while IUSBI connected between them, a digital test was developed. For this test, two floating point single precision numbers (32 bits) were generated randomly in the Visual Studio software and transmitted at full speed from the PC (VPCF120FL, Sony VAIO) to a field-programmable gate array (FPGA) (Cyclone V GX, Altera) connected through the IUSBI. Both numbers were multiplied on each device and each result was compared by doing a subtraction on the PC. Obtaining a residue equal to zero between both results, we could assume that all the data go across successfully through the IUSBI [Fig. 5(b)]. To prove the efficacy, we ran the test continuously until we got 100 000 comparisons. The FPGA uses a USB to serial universal asynchronous receiver-transmitter (UART) interface (FT232R, FTDI), which works with the bulk endpoint type for data exchange. USB cables (102-1030-BL-F0100, CNC Tech) used for the communication with the IUSBI complies with USB protocol.

While the test was running, two of the digital probes of the logic analyzer (16901A, Agilent Technologies) were connected to the input pins of the data isolator (D+ and D–) and the other two probes to the output pins of the data isolator ($D+_{iso}$ and $D–_{iso}$) [Fig. 5(a)]. Then, we captured a communication raster to check any difference between the bits in the input stage (upstream) versus the bits in the output stage (downstream) of the IUSBI. Finally, we analyzed if there was a delay in the digital signal. The sampling rate was 1 ms and 2 ns, for the FPGA and for the logic analyzer, respectively.

F. Dielectric Strength Test

This test was to determine whether the dielectric strength of the solid insulation performed between the primary and secondary sides of IUSBI, formed in a two-layer PCB and using the FR4 material as dielectric [Fig. 4(a)], was enough to reach the level of medical protection according to the IEC 60601-1 standard. In the case that a breakdown occurs, the current produced by the 125 V rms that powers the PC, could pass through the USB and produce an electrical hazard to the ME, the operator, and the patient. Because of this, we considered the working voltage that powers the PC as the peak working voltage for the dielectric strength test.

First, two cut end and prepared termination USB cables (102-1030-BL-00100, CNC Tech) with stripped wires were connected to each of the IUSBI sides. Second, the probe (GHT-205) of the high-potential tester (GPT-815, GW INSTEK) was connected with an alligator clip to each of the stripped wires from the USB cable connected to the upstream side of the IUSBI. Finally, the return terminal cable of the high-potential tester was connected to each of the stripped wires from the USB cable connected to the downstream side of the IUSBI. In this way, four tests were performed in order to test the individual insulation, in VBUS with $VBUS_{iso}$, D+ with $D+_{iso}$, D– with $D–_{iso}$, and GND with GND_{iso}. Then, a reading of the arc current (electric current produced by the high-potential test voltage that passes through the IUSBI's FR4) was taken, and we tested the voltage value supported by the IUSBI according to IEC 60601-1 standard. An additional test was performed by short-circuiting the stripped wires in conjunction with the shield of USB cables, and the procedure was repeated to test the complete insulation between the input stage and the output stage of the IUSBI. Tests were performed under room temperature, 25 °C, and 62% of relative humidity.

G. EMC Test

To know the electromagnetic amount radiated by the IUSBI, an electromagnetic compatibility (EMC) test was developed.

The test was performed with a spectrum analyzer (N9010A, Agilent Technologies) connected to a semianechoic chamber (Gtem 750 cell, Teseq), where the IUSBI was placed, for

TABLE I
TECHNICAL DATA FOR THE ME

Medical equipment characteristics	
Medical equipent class	Class I
ME working voltage[1]	125 V rms
PC working voltage[2]	125 V rms
Type BF applied parts	Temperature sensor
Type CF applied parts[3]	Electrodes-ECG lead wires and Pressure sensor
Biosignals	Pressure, temperature, heart rate (ECG)

[1] Working voltage acording to the medical grade supply.
[2]Working voltage considered for the IUSBI dielectric strength test.
[3] Because patient connections associated with the ECG and with the preassure transducer are not electrically separated, these are treated as two functions of the same applied part.

isolating external emissions from the measurement. Two USB cables were used for interconnecting a PC and an FPGA through the IUSBI, these cables crossed from the inside to the outside of the chamber through an orifice. Then, a single precision number was sent from the PC to the FPGA and vice versa for activating the IUSBI. The frequency range of interest for the test goes from dc to 10 kHz, which is the frequency range used in the design for different MEs, according to various medical and physiological parameters. However, because the frequency range allowed by the spectrum analyzer starts at 10 Hz, the test was performed from 10 Hz to 15 kHz, with an attenuation of 10 dB.

H. IUSBI's Biovalidation

To prove the proper operation of the IUSBI with an ME, a medical device for a small mammal (mice) was developed. Guidelines contained in the Mexican Norm for Care and Use of Animals for Scientific Purposes [34], were strictly followed. The ME measure and record three vital signs: temperature, blood pressure, and heart rate derived from the electrocardiography (ECG) record. The biosignals are processed with a microcontroller (ATmega328P, Atmel) and displayed on the PC monitor using Visual Studio. Communication between the microcontroller and the computer is via USB port. Table I shows the characteristics of the ME designed.

Rectal temperature was taken with a temperature sensor (LM35, National Semiconductor), which provides a linear output voltage with a scale factor of +10 mV/°C. The LM35 can operate in a temperature range of −55 °C–150 °C, but for the required purpose, it was connected to operate in a reliable operating range of 2 °C–150 °C. Arterial blood pressure was monitored by means of cannula inserted in the carotid artery connected to a pressure transducer (P23Db, Statham)that is made of four strain gauges of approximately 350 Ω in a complete Wheatstone bridge arrangement and it has a sensitivity of 5 μV/mmHg/*Vs* (where *Vs* is the power supply voltage). The ECG was built to measure limb leads, and it was developed with instrumentation amplifiers for signal acquisition and amplification, with a bandwidth of 0.05–100 Hz. A dc–dc (ADUM6000, Analog Devices) was connected in the ECG's instrumentation amplifiers to avoid that they become saturated by the high-efficiency oscillations from the IUSBI's power supply, and digital filters were made to soft the signal. Finally, the circuit for the signal analog processing was built in a PCB connected to a power supply.

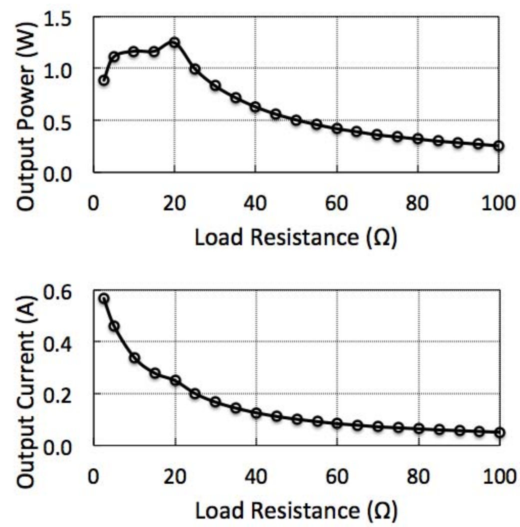

Fig. 6. IUSBI output power and current according to a load resistance.

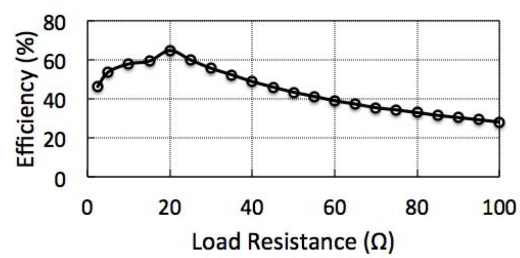

Fig. 7. Total efficiency of the IUSBI according to a load resistance.

A medical grade power supply (ECM40-100, XP Power) was used to power the circuits that perform the analog processing of the sensors. It has a 90–264 V ac input, an output of 5 V/8 A, 15 V/2.5 A, and 15 V/0.5 A, and it has medical approval, ensuring compliance with electrical safety standards for ME (EN60601-1).

III. RESULTS

A. Energy Transfer

The IUSBI energy output ($VBUS_{iso}$ and GND_{iso}) was connected to a load resistance (2.5–100 Ω) and the input power and output power were measured as a function of the voltage and the current. As shown in the power curve in Fig. 6, up to 1.25 W can be transferred to a device sourced by the USB port with a maximum output current of 250 mA, using a load resistance of 20 Ω.

Fig. 7 shows that the IUSBI maximum efficiency is 65%.

B. Data Transmission

First, the residue obtained in the 100 000 comparisons was equal to zero. Therefore, we could assume that the digital data

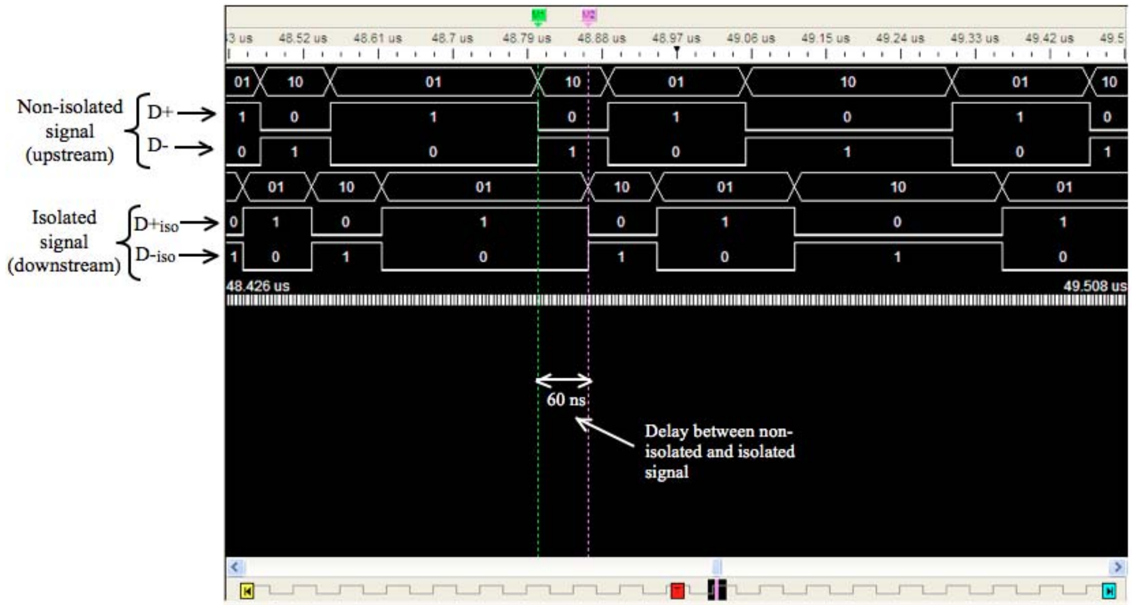

Fig. 8. One of the captured rasters of the non-isolated digital signal (upstream) and the isolated digital signal (downstream).

(32 bits word length) went across properly from the PC to the FPGA and vice versa, while IUSBI was connected.

Second, a delay of 60 ns was observed in the logic analyzer between non-isolated and isolated signals (Fig. 8). The delay was detected in both the upstream and downstream directions, due to the bidirectional transfer of the USB protocol. The maximum delay for each one of the two USB cables used for interconnecting two devices (PC and FPGA) with the IUSBI is 26 ns, which means that IUSBI's propagation delay, including both cables, is approximately 112 ns. On the other hand, the maximum delay of 3 ns is allowed from a host downstream port to its exterior downstream connector, while a maximum delay of 1 ns is allowed from the upstream connector to the upstream port of any device. Adding this 4 ns to the IUSBI's propagation delay, including both cables, yields a total delay of 116 ns, which is less than the worst case end-to-end signal delay allowed by the USB protocol (380 ns).

First, the result mentioned earlier shows the effectiveness of the USB communication between a host and a device, while connected through the IUSBI. Whereas, the second one shows that the end-to-end IUSBI's delay is allowed for the USB protocol at full-speed communication, including both USB cables. This enables the IUSBI to work properly between the PC and the ME, according to the USB protocol.

C. Dielectric Strength

A 1300 V ac voltage was applied to the IUSBI for each of the tests and was gradually increased during a 10 s period to reach 3000 V ac, which was maintained for 1 min. Finally, the voltage was gradually reduced to 1300 V ac in a 10 s period. Cut-off current (current provided by the high-potential tester that could produce a breakdown in the FR4) used for the test was 100 mA. Fig. 9 shows the mean arc current obtained for the five tests applied to the IUSBI with the high-potential tester during 80 s. The arc current started 0.12 mA, then it was increased to 0.31 mA within 60 s, and finished at 0.12 mA.

The maximum arc current according to the applied voltage was 0.31 mA, different values were recorded for each test. Fig. 10 shows the standard deviation arc current according to the applied voltage for the five tests at the increasing and decreasing voltage. As the arc current, which flows as a result, does not increase rapidly or uncontrollably to reach 100 mA, there is no insulation breakdown caused by the voltage applied between the input and output stages in the IUSBI. Thus, the dielectric strength test according to IEC 60601-1 standard is satisfactory, reaching an insulation level to protect from mains part, up to two MOPPs equivalent to 3 kV ac with a maximum working voltage of 125 V rms (176 V peak).

D. EMC Test Results

No emissions were observed in the frequency range from 10 Hz–15 kHz. However, the first component at 418 kHz was observed when the upstream side of the IUSBI was connected to the PC. Once the downstream side of the IUSBI was connected to the FPGA, the first component disappeared and a second one appeared at 355 kHz (Fig. 11). Results herein show that 0.5 pW (−73 dBm) approximately is radiated by the IUSBI at 355 and 418 kHz. Therefore, IUSBI emissions do not provide an interference to the MEs, which frequency range goes from dc–10 kHz. Allowed levels and specific tests for electromagnetic disturbances are described by the collateral standard IEC 60601-1-2.

E. Recording Biosignals

For the recording and visualization of the biosignals, a graphical user interface (GUI) was developed with Visual Studio, which shows the temperature, pressure, and heart rate (from the ECG signal) of the mice (Fig. 12). The GUI shows

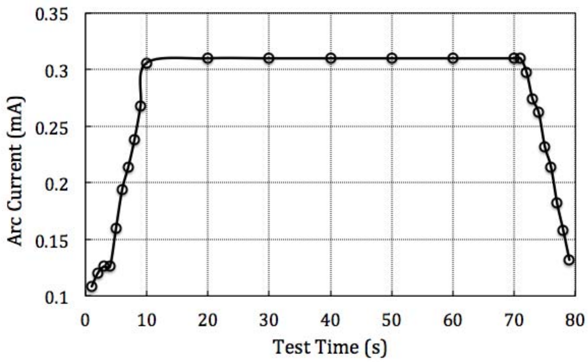

Fig. 9. Arc current obtained across the time.

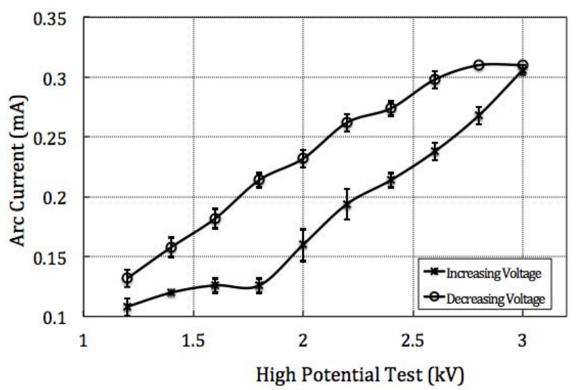

Fig. 10. Arc current obtained for the voltage.

the biosignals of the sensors, while the ME is connected to a PC through the IUSBI.

Table II shows the main characteristics of the IUSBI.

IV. Discussion

There is a potential for leakage current from PC to USB devices that connect to patients and vice versa. The former presents a direct risk to patient safety while the latter could pose a risk of damaging computer equipment. In order to integrate both technologies and to protect the patient, the operator and the USB devices from an electric shock an IUSBI was designed. Moreover, the IUSBI provides electrical safety to the PC if there is an electric risk coming from the USB devices or from the patient (e.g., when a monopolar electrocautery or a defibrillator are being used), due to its galvanic isolation.

The interface improves the cost-benefit ratio in the design of ME systems integrated into computer devices (PCs, tablets, smartphones, etc.), thanks to the great variety of USB connection devices on the market.

The development and construction of MEs require connection with a PC if there is interest in keeping biomedical records, performing data analysis, or using the PC as a monitor. In general, there are three stages that can be isolated in order to provide electrical protection to the patient while a PC is integrated into an ME. Some designs use batteries [8], [9] or medical grade isolation transformers [10]

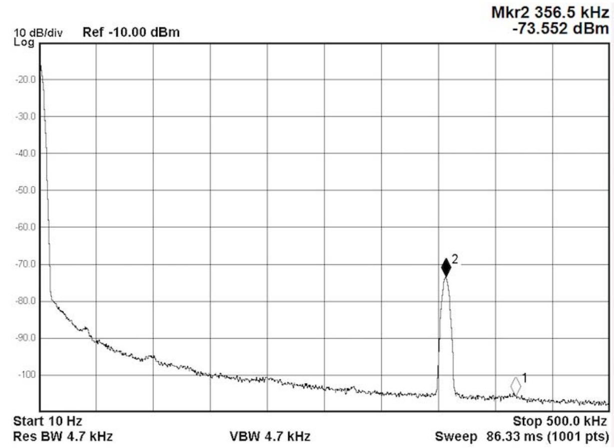

Fig. 11. Principal components found in the EMC test. Markers 1 and 2: frequencies where the components were found with a value of −73 dBm approximately for both cases.

TABLE II
TECHNICAL DATA FOR THE USB ISOLATOR

Parameter	Value	Unit
Dielectric strength	3000	V ac
Energy Transfer	65	%
Output current	25	mA
Coupling capacity for data transmission	25	pF
Coupling capacity for power distribution	45	pF
Maximum end-to-end delay	116	ns
Transmission	12	Mbps

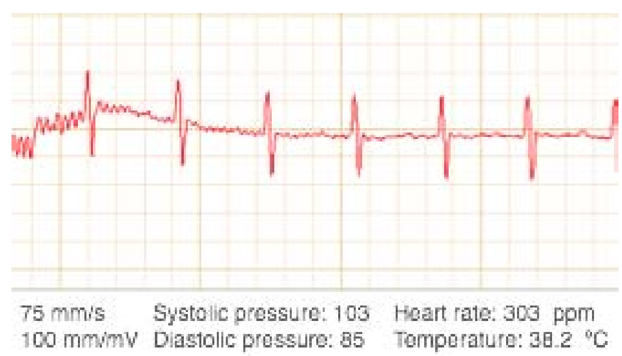

Fig. 12. GUI while a PC is connected to an ME through the IUSBI.

in the power supply stage of the PC. However, the usage of medical grade isolation transformers reduces the portability in the PC and the batteries limit the time of use of ME. Other designs use isolation amplifiers [11]–[13], isolation transformers [14], [15], or sensors that use insulating materials [16]–[18] in the signal acquisition stage of the ME. Although these provide electrical protection for the patient, the operator is at risk if there are no other isolation media to protect him/her from electric shock. In addition to this, the cost can be significantly increased if it is required to take various physiological signals. Because of this, isolation at the communication stage is very convenient.

TABLE III
USB ISOLATORS COMPARISON

Characteristic	Junnila et al.	Depari et al.	Cantrell	Our proposal
USB data isolation	✔	✔	✔	✔
USB power isolation	✘	✔	✔	✔
PCB design according IEC 60601-1	✘	✘	not specified	✔
Energy transfer	✘	not specified	not specified	65 %
Maximum end-to-end signal delay	not specified	not specified	not specified	116 ns
Dielectric strength	not specified	not specified	not specified	3000 V ac
Insulation level	not specified	not specified	not specified	Reinforced insulation
Acceptable applied parts	not specified	not specified	not specified	Type B, BF, and CF
Maximum data transfer	12 Mbps	12 Mbps	12 Mbps	12 Mbps

Isolation methods in the communication stage have been developed, such as RS232 [19], [20]. However, the hardware for this communication protocol has been decreasing in the PC ports every day. Isolation through a USB cable has also been worked and although some designs work properly, the results do not prove electrical safety in order to be used as a medical grade interface [22], [23]. Moreover, they do not specify the type of applied parts that can be used according to the dielectric strength. The interface shown in this paper simplifies the design and offers special attention in the dimensions, thickness, and type of insulating material that constitute the gap on which the isolated components are mounted for the interface design, since these can limit the IUSBI to be used with different types of ME (class I or class II), according to the insulation level required by the IEC 60601-1 standard. On the other hand, the electrical design described in this paper is similar to a previous one proposed by Cantrell [35], who describes three ways for using the data isolator (ADUM4160) to isolate the USB port and, although his designs are good proposals, the considerations in our design mentioned earlier are indispensable characteristics for enabling any of his three configurations to work in medical applications, according to the electrical safety. Table III shows a comparison between different USB isolators and our proposal.

An important advantage of the IUSBI over other electrical isolation methods in the communication stage, such as Bluetooth [24], ZigBee [25], or Wi-Fi [26], is that the data transfer is less susceptible to external interference, due to the controlled environment through which data travels (USB cable). In addition to this, with isolated power exchange, it is possible to energize embedded systems such as arduinos, raspberrys, beagle boards, digital signal processors (DSPs), FPGAs, and so on, which may be used in the design of MEs. Because of this, it is important to know the IUSBI's efficiency, if there is interest in knowing what kind of USB devices could be powered totally from the USB cable or if the devices need an alternative power source. At present, there are some medical devices that rely totally on the USB port [36] and they could be powered by the IUSBI with the appropriate electrical protection.

IEC 60601-1 standard governs the electrical safety of an ME [32], whereas ISO/IEEE 11073 standard enables communication between MEs and external computer systems [37]. Development of an ICI according to both standards guarantee its use for medical applications. In this context, the use of the IUSBI for medical applications could be restricted, because ISO/IEEE 11073 standards family does not address USB protocol. Nevertheless, Continua Design Guidelines is an alternative for implementing the IUSBI between the ME and PC, because it uses the USB protocol as a transport layer, and it works with the ISO/IEEE 11073 standard as a bridge in the communication for personal health systems in a personal area network [31].

ECG signal quality could improve by changing the IUSBI's power source for another with less efficiency or with a lower switching frequency. However, our interest focused on getting a high-efficiency power source certified by IEC 60601-1 with a reinforced insulation, as the dc–dc converter used in our design. This converter provides the maximum patient leakage current of 2 μA, which is less than the value allowed by the standard in normal condition or in a single fault condition. A leakage current level like this allows us to include CF applied parts in the design of the medical instrumentation. However, to guarantee a total electrical safety all leakage currents (earth leakage current, touch current, patient auxiliary current, and total patient leakage current) must be measured and not exceed permitted values when the IUSBI is connected to a specific class of ME (containing basic insulation, supplementary insulation, or reinforced insulation).

At present, with the increasing use of the PC into the medical space, medical instrumentation designers seek for alternatives such as the ICI presented in this paper for providing electrical safety to the patient while a PC is connected to an ME and, although the medical instrumentation must meet the requirements and the test specified by the IEC 60601-1, the ICIs used between both devices (ME and PC) must also follow the guidelines of the standard. On the other hand, considering just the medical grade electrical safety components, without the proper considerations for the design and testing of the whole ICI, do not guarantee the medical grade electrical safety of the entire interface. This could represent a serious risk for the patient or the operator. Therefore, care is needed when designing or selecting isolated boards or devices, because they could not reach allowable levels for medical usage (e.g., a board containing reinforced insulation components but designed with basic insulation can only reach the maximum protection level of basic insulation).

There is a technical limitation with the digital test for knowing if data transfer is being corrupted by the IUSBI or not. This is because the bulk endpoint, used for the data transfer, works with error detection and if the data are corrupted, they are retransmitted. For this reason, the zero residue is always expected. Therefore, the zero residue that we obtained in the 100 000 comparisons helps us to check the effectiveness of the data transfer but without considering the fact that the data are being corrupted or not by the IUSBI.

The purpose of this state of the investigation, shown in this paper, corresponds to IUSBI development, including creepage distances, air clearances, and the dielectric strength test of solid insulation forming two MOPPs according to IEC 60601-1 standard. The interface could not be used with commercial MEs because even these have USB ports, and their connection and protocol are limited to performing software configurations. However, the results herein show that the IUSBI can be integrated into the design of different types of ME, due to its reinforced insulation.

V. Conclusion

The innovative design of an IUSBI for medical instrumentation was introduced in this paper, and related tests were performed to ensure reinforced insulation according to the IEC 60601-1 standard and compatibility with the USB protocol. The interface permits the use of any computer device with an ME. Interoperability and electrical protection of the IUSBI make this a versatile device and allow its use to be extended to different fields, such as industry, research, clinics, hospitals, and so on. The characteristics of Table II show that the IUSBI can be integrated naturally with any computer device with a USB port and an ME. In addition to this, the interface enables the ME to perform data analysis, idiopathic analysis, long-term biomedical records, and data transmission in real time through the network. These advantages allow remote diagnosis and eliminate the need to have inpatients for monitoring, which means a great benefit for both the doctor and patient.

References

[1] W. H. Olson, "Physiological effects of electricity," in *Medical Instrumentation: Application and Design*, J. G. Webster, Ed., 4th ed. Hoboken, NJ, USA: Wiley, 2009, pp. 639–641.

[2] D. S. Gazzana, A. S. Bretas, G. A. Dias, M. Telló, D. W. Thomas, and C. Christopoulos, "A study of human safety against lightning considering the grounding system and the evaluation of the associated parameters," *Electr. Power Syst. Res.*, vol. 113, pp. 88–94, Aug. 2014.

[3] F. Rosewame, "Electrocution," in *Anaesthesia: An Introduction*, I. Harley and P. Hore, Eds., 5th ed. East Hawthorn, VIC, Australia: IP Communications, 2012, pp. 357–358.

[4] W. H. Olson, "Important susceptibility parameters," in *Medical Instrumentation Application and Design*, J. G. Webster, Ed., 4th ed. Hoboken, NJ, USA: Wiley, 2009, pp. 641–646.

[5] D. Flynn, "Challenges for power supplies in medical equipment: Ensuring patient and operator safety," *IEEE Power Electron. Mag.*, vol. 2, no. 2, pp. 32–37, Jun. 2015.

[6] S. Balters and M. Steinert, "Capturing emotion reactivity through physiology measurement as a foundation for affective engineering in engineering design science and engineering practices," *J. Intell. Manuf.*, vol. 28, no. 7, pp. 1585–1607, 2015.

[7] C. A. Mack, "Fifty years of Moore's law," *IEEE Trans. Semicond. Manuf.*, vol. 24, no. 2, pp. 202–207, May 2011.

[8] H. Ayaz, B. Onaral, K. Izzetoglu, P. A. Shewokis, R. McKendrick, and R. Parasuraman, "Continuous monitoring of brain dynamics with functional near infrared spectroscopy as a tool for neuroergonomic research: Empirical examples and a technological development," *Frontiers Hum. Neurosci.*, vol. 7, p. 871, Dec. 2013.

[9] I. Mohino-Herranz, R. Gil-Pita, J. Ferreira, M. Rosa-Zurera, and F. Seoane, "Assessment of mental, emotional and physical stress through analysis of physiological signals using smartphones," *Sensors*, vol. 15, no. 10, pp. 25607–25627, 2015.

[10] *ISB-100W Datasheet*, Toroid Technol., Bolton, ON, Canada, 2003.

[11] B. Xu *et al.*, "Design and evaluation of a motor imagery electroencephalogram-controlled robot system," *Adv. Mech. Eng.*, vol. 7, no. 3, pp. 1–11, 2015.

[12] Q. Huang, S. Chang, J. Peng, X. Mao, Y. Zhou, and H. Wang, "An implementation of SOPC-based neural monitoring system," *IEEE Trans. Instrum. Meas.*, vol. 61, no. 9, pp. 2469–2475, Sep. 2012.

[13] Z. Huang, Z. Wang, X. Lv, Y. Zhou, H. Wang, and S. Zong, "A novel functional electrical stimulation-control system for restoring motor function of post-stroke hemiplegic patients," *Neural Regener. Res.*, vol. 9, no. 23, pp. 2102–2110, 2014.

[14] V. V. Popov *et al.*, "Hearing threshold shifts and recovery after noise exposure in beluga whales, Delphinapterus leucas," *J. Exp. Biol.*, vol. 216, no. 9, pp. 1587–1596, 2013.

[15] E. V. Sysueva, D. I. Nechaev, V. V. Popov, and A. Y. Supin, "Frequency tuning of hearing in the beluga whale: Discrimination of rippled spectra," *J. Acoust. Soc. Amer.*, vol. 135, no. 2, pp. 963–974, 2014.

[16] J. I. Peterson and G. G. Vurek, "Fiber-optic sensors for biomedical applications," *Science*, vol. 224, no. 4645, pp. 123–127, 1984.

[17] E. Suaste-Gómez, D. Hernández-Rivera, A. S. Sánchez-Sánchez, and E. Villarreal-Calva, "Electrically insulated sensing of respiratory rate and heartbeat using optical fibers," *Sensors*, vol. 14, no. 11, pp. 21523–21534, 2014.

[18] A. Tsyganov *et al.*, "Anatomical predictors for successful pulmonary vein isolation using balloon-based technologies in atrial fibrillation," *J. Interventional Cardiac Electrophysiol.*, vol. 44, no. 3, pp. 265–271, 2015.

[19] E. González, F. Cagnolo, C. Olmos, C. Centeno, G. Riva, and C. Zerbini, "Medical data transmission system for remote healthcare centres," *J. Phys., Conf. Ser.*, vol. 90, no. 1, p. 012029, 2007.

[20] C. Pokorny, C. Breitwieser, and G. R. Müller-Putz, "A tactile stimulation device for EEG measurements in clinical use," *IEEE Trans. Biomed. Circuits Syst.*, vol. 8, no. 3, pp. 305–312, Jun. 2014.

[21] S. Junnila, J. Ruoho, and J. Niittylahti, "Medical isolation of universal serial bus data signals," in *Proc. 9th Int. Conf. Electron., Circuits Syst.*, vol. 3, Sep. 2002, pp. 1215–1218.

[22] A. Depari, A. Flammini, D. Marioli, and A. Taroni, "USB sensor network for industrial applications," *IEEE Trans. Instrum. Meas.*, vol. 57, no. 7, pp. 1344–1349, Jul. 2008.

[23] H. C. Liu, Y. Hu, S. M. Ye, and Z. Xu, "A new design of pain monitoring system during general anesthesia operations based on pulse wave transfer function," *Adv. Mater. Res.*, vols. 753–755, pp. 2374–2378, Aug. 2013.

[24] M. F. A. Rasid and B. Woodward, "Bluetooth telemedicine processor for multichannel biomedical signal transmission via mobile cellular networks," *IEEE Trans. Inf. Technol. Biomed.*, vol. 9, no. 1, pp. 35–43, Mar. 2005.

[25] H. C. Tung *et al.*, "A mobility enabled inpatient monitoring system using a ZigBee medical sensor network," *Sensors*, vol. 14, no. 2, pp. 2397–2416, 2014.

[26] Y. Wang, Q. Wang, G. Zheng, Z. Zeng, R. Zheng, and Q. Zhang, "WiCop: Engineering WiFi temporal white-spaces for safe operations of wireless personal area networks in medical applications," *IEEE Trans. Mobile Comput.*, vol. 13, no. 5, pp. 1145–1158, May 2014.

[27] M. Forouzanfar, S. Ahmad, I. Batkin, H. R. Dajani, V. Z. Groza, and M. Bolic, "Model-based mean arterial pressure estimation using simultaneous electrocardiogram and oscillometric blood pressure measurements," *IEEE Trans. Instrum. Meas.*, vol. 64, no. 9, pp. 2443–2452, Sep. 2015.

[28] F.-Y. Yang, T.-D. Wu, and S.-H. Chiu, "A secure control protocol for USB mass storage devices," *IEEE Trans. Consum. Electron.*, vol. 56, no. 4, pp. 2239–2343, Nov. 2010.

[29] D. He, N. Kumar, J.-H. Lee, and R. S. Sherratt, "Enhanced three-factor security protocol for consumer USB mass storage devices," *IEEE Trans. Consum. Electron.*, vol. 60, no. 1, pp. 30–37, Feb. 2014.

[30] *Universal Serial Bus Specification*, 2nd ed., USB Implementers Forum, Inc., Portland, OR, USA, Apr. 2000.

[31] *Interoperability Design Guidelines for Personal Health Systems*, Continua Design Guidelines Standard H.810, Nov. 2017.

[32] *Medical Electrical Equipment—Part 1: General Requirements for Basic Safety and Essential Performance*, IEC Standard 60601-1, Aug. 2012.

[33] *ADuM4160 Datasheet*, Analog Devices, Norwood, MA, USA, 2009.

[34] *Technical Specifications for the Production, Care and use of Laboratory Animals*, Standard NOM-062-ZOO-1999, Aug. 2001.

[35] M. Cantrell, "Digital isolator simplifies USB isolation in medical and industrial applications," in *A Forum for the Exchange of Circuits, Systems, and Software for Real-World Signal Processing*, vol. 43, no. 2. Norwood, MA, USA: Analog Dialogue, 2009, pp. 15–18.

[36] *KT88-2400 Datasheet*, Contec Medical Systems, Qinhuangdao, China.

[37] *IEEE Health Informatics—Personal Health Device Communication—Part 20601: Application Profile-Optimized Exchange Protocol*, ISO/IEEE Standard 11073-20601, 2010.

Gaspar González-Briceño (S'17) received the B.S. degree in electronic engineering from the Instituto Politécnico de Morelia, Michoacán, México, in 2009, and the M.S. degree in electrical engineering from CINVESTAV, Mexico City, México, in 2016.

From 2009 to 2013, he was a Research Assistant with CINVESTAV Guadalajara, Zapopan, México. His current research interests include the design of medical instrumentation, electrical safety for medical equipment, and healthcare data analytics.

Joshua E. Medow received the B.S. degree in biomechanics/kinesiology from the University of Illinois Urbana–Champaign, Champaign, IL, USA, in 1995, the M.D. degree from the University of Illinois Chicago, Chicago, IL, USA, in 1999, and the M.S. degree in clinical research from the University of Wisconsin–Madison, Madison, WI, USA, in 2010. He completed his residency in neurosurgery, training in critical care medicine, and fellowship in endovascular neurosurgery from the University of Wisconsin School of Medicine and Public Health, Madison, WI, USA.

He was a Founder of the neurocritical care program, which includes a state of the art, 16-bed, dedicated Neuro ICU with multimodality monitoring. He is currently a Tenured Associate Professor of neurological surgery and biomedical engineering and the Director of Neurocritical Care with the University of Wisconsin Hospital, Madison, WI, USA. His clinical focus is on providing value in the care of neurologically ill patients by improving outcomes and reducing costs. Most recently, he presented a plenary session talk describing how best practices and common sense reduced mortality in the sickest Neuro ICU patients by 43% and costs by about $3 million. Selected projects in his engineering laboratory include an inductively powered intracranial pressure monitor, nonsiphoning shunt valve for hydrocephalus, sodium MRI multinuclear coil for stroke evaluation, and a new multimodality ventilator. His goals for neurocritical care and neurosurgery, in general, are to improve awareness of the value provided by neurocritical care physicians and multidisciplinary staff and also to advance the science and technology used to detect and correct severe medical and neurological derangements. His current research interests include imaging and device development.

Dr. Medow was a recipient of numerous awards for excellent patient care and for teaching.

Susana Ortega-Cisneros received the B.S. degree in communications and electronics from the University of Guadalajara, Guadalajara, Mexico, in 1990, the master's degree from the Center of Research and Advanced Studies, Zacatenco IPN, Mexico City, Mexico, and the Ph.D. degree in computer science and telecommunications from the Autonomous University of Madrid, Madrid, Spain.

She was involved in the design of digital architecture based on FPGAs, digital signal processors (DSPs), and Microprocessors. Her current research interests include digital control, self-timed synchronization, electronic systems applied to biomedicine, embedded microprocessor design, digital electronics, and custom DSPs in FPGAs.

Daniel Lorias-Espinoza was born in Guaymas Sonora, Mexico, in 1974. He received the M.S. and Ph.D. degrees in electrical engineering from CINVESTAV, Mexico City, México, in 2004 and 2008, respectively.

Since 2008, he has been a Research Professor with CINVESTAV, Mexico, México. His current research interests include percutaneous and minimally invasive technologies.

Arturo Minor-Martínez was born in Mexico City, Mexico, in 1960. He received the M.S. and the Ph.D. degrees from CINVESTAV, Mexico City, México, in 1992 and 1999, respectively.

He is currently an Associate Researcher in bioelectronics with the Center of Research and Advanced Studies, IPN, Mexico City, Mexico. He has authored or co-authored over 30 articles published in SCI. He holds 15 issued patents.

Dr. Minor-Martínez was a recipient of the Prize Alfonso Robinson Bourns awarded by the UNAM and the Secretariat of Health published in research in medical education, the Tecnos Prize awarded by the Government of Monterrey by technological innovation. He is a pioneer in the development of medical Robotics at Mexico, with the robot Tonatihu, and pioneer in biomechatronics the development of mechatronic for use in laparoscopic surgery. He is also a pioneer in the development of systems of evaluation of the training of surgeons and systems analysis and rehabilitation of vocal cords. Some of their technological developments have integrated into everyday life, through private initiative.

John G. Webster (M'61–SM'71–F'86–LF'97) received the B.E.E. degree from Cornell University, Ithaca, NY, USA, in 1953, and the M.S.E.E. and Ph.D. degrees from the University of Rochester, Rochester, NY, USA, in 1965 and 1967, respectively.

He is currently a Professor with the Emeritus of Biomedical Engineering, University of Wisconsin–Madison, Madison, WI, USA. He was involved in implantable intracranial pressure sensor and a comfortable sleep apnea device that has no added pressure. He has edited *Medical Instrumentation: Application and Design* (Fourth Edition, New York, NY, USA: John Wiley & Sons, 2009). He has authored or co-authored over 22 other books including the *Encyclopedia of medical devices and instrumentation*, (Second Edition, New York, NY, USA: John Wiley & Sons, 2006) and 200 research papers.

Dr. Webster is a Fellow of the Institute of Electrical and Electronics Engineers, Instrument Society of America, American Institute of Medical and Biological Engineering, and Institute of Physics. He has been a member of the IEEE-EMBS Administrative Committee and the NIH Surgery and Bioengineering Study Section. He was a recipient of the 2001 IEEE-EMBS Career Achievement Award.