Powering IoT in medical applications with safety

The age of Internet of Things in medical
Technology presented at recent events, Medica, Embedded World and Mobile World congress, confirmed that our society has definitely entered the age of Internet of Things (IoT) and the medical industry quickly modernizing to improve patients' comfort and wellbeing.

Connected Devices and IoT are everywhere and we see them gradually changing our lives throughout; the development of new innovative products/applications able to communicate information that could have vital impact, saving lives and preventing diseases.

According to PwC's Health Research Institute's annual report, in 2016, 32 percent of U.S. consumers have at least one health app on their mobile devices (up 16 percent since 2013) and the Makovsky/Kelton "Pulse of Online Health" survey indicated that 66% of Americans would use a mobile app to manage health-related issues in next coming future.

As applications and services reaching the market at fast pace, questions about security and safety are becoming an important topic for all of us, which regulatory bodies are addressing by standardization.

In the medical segment, safety is the most important parameter we have to consider and the growing numbers of connected devices in medical equipment operated within controlled environment (i.e. hospital) and non-controlled environment (i.e. home healthcare) are changing the way power designers are developing new power solutions. Beside electrical safety, which Power Designers are used to deal with, the proliferation

of connected devices and IoT in medical environment requires to consider a new dimension: "Electromagnetic Coexistence" motivating regulators to align standardization to new market conditions.

From 1977 to 2017 40 years of IEC 60601 paving the way to safety in medical IoT

Published in 1977; the IEC 60601 standard is internationally adopted (Table 01) and continuously updated to improve patient safety and comfort. Since it has been released, the standard has been through three major editions and is evolving to a fourth one, which we will present later in the article. As power designer, it is interesting to take a step-back to understand how major modifications influenced the way we develop power supplies for medical applications to guarantee the highest level of safety for patient and operators.

Country	Standard connected to IEC 60601
European Union	EN 60601-1 (identical to IEC 60601-1)
United States	UL 60601-1
Canada	CAN/CSA C22.2 No. 606.1
Japan	JIS T 0601-1
Australia & New Zealand	AS/NZ 3200.1.0

Table 01 - IEC 60601-1 national standards adapted by countries or regions.

In 1988 the second edition introduced three categories specifying specific conditions under which the medical equipment, including the power supplies, are operated in patient vicinity:

Type "B" (Body) no electrical contact with Patient

Type "BF" (Body Floating) electrically connected to Patient but not directly to heart

Type "CF" (Cardiac Floating) electrically connected to the heart of the Patient.

Strengthening patient protection against electrical shock and effects of current leakage, December 2005 the regulation bodies released the 3rd edition. This new revision introduced a more stringent requirement; defining the meaning of different protections for patient and operators. Means of protection (MOP) describes the isolation protection between the electrically charged circuitry and any equipment that may come in contact with the device.

The isolation protection includes the creepage/clearance distances, insulation and protective earth connections. The means of protection is further separated into two categories (Means of operator protection MOOP and Means of patient protection MOPP) implying specific isolation test voltage and creepage distance, as presented in Table 02.

Classifications	Isolation	Insulation	Creepage	Clearance
One MOOP	1 500 Vac	Basic	2.5 mm	2 mm
Two MOOP	3 000 Vac	Double	5 mm	4 mm
One MOPP	1 500 Vac	Basic	4 mm	2.5 mm
Two MOPP	4 000 Vac	Double	8 mm	5 mm

Table 02 - IEC 60601-1 third edition, Means of Protection (MOP) classifications in two categories means of operator protection (MOOP) and means of patient protection (MOPP).

The third revision requires from power supply designers to perform a risk assessment analysis in accordance with the ISO 14971:2000 (Application of risk management to medical devices) to ensure that hazards are identified and mitigated to guarantee that the appropriate level of safety provided to the final application.

For example in a medical equipment not in contact with patient, a power supply complying with 2 x MOOP is normally acceptable though the outcomes from the risk assessment could steer the designer to increase the creepage distance to guarantee higher level of safety for the patients and the operators.

IEC60601-1 third revision has also introduced a new way of working, combining power design, risk assessment but as well motivated higher level of cooperation with equipment manufacturer to guarantee the final equipment has the proper level of safety to protect patients and operators.

In the case of external power supplies, considered as stand-alone medical devices, it requires from the power supply manufacturer a full risk assessment and documentation according ISO 14971. On the contrary for built-in power supplies the medical device manufacturer is fully responsible for the risk analysis, however medical equipment manufacturers are requiring very close cooperation with power supplies manufacturers to secure their equipment will not only meet safety standards but guarantee the highest level of safety in case of "unpredictable event."

When radio coexistence matters

As the medical industry entered into the Internet era, starting in 2010, the number of cases of medical equipment reporting false or random alarms, has grown significantly, warning the medical community about the coexistence of multiple radio transmitting equipment that patients' lives might depend upon. In many cases of faults reported, it was very difficult to pinpoint the exact cause, until in-depth investigations revealed that potential radio interferences were the root cause of the problem. In the US, the Food and Drug Administration (FDA) records malfunctions in a central database "MAUDE", which reflects the growing number of EMC problems.

Taking in consideration the rapid expansion of connected devices and new technologies medical equipment will be connected (today known as 5G, WiFi-LTE and others), in cooperation with the industry, which included power supplies manufacturers, regulatory bodies worked on a new revision of the IEC 60601 standard, with focus on radio coexistence.

In 2014 the International Electro technical Commission (IEC) published a new revision of the electromagnetic compatibility (EMC) requirements for medical devices, the IEC 60601-1-2 in 2014 (so called 4th edition). This revision contained a number of changes, including new immunity and more robust risk analysis performed during the design and qualification of medical equipment.

Taking in consideration the changing market, new operated radio frequency bands and the risk of interferences between the different pieces of medical equipment, the revised standards included; increased immunity test levels, with the range for radiated immunity, magnetic-immunity, conducted-immunity, significant increases in electrostatic discharge (ESD) levels and voltage dips and interruption phase angles.

In addition, immunity testing has been added which follows the rationale of 60601-1-11 (Collateral standard for Home Healthcare) in the form of immunity to proximity fields from RF wireless communications equipment at significantly higher levels than have been used for radiated RF immunity testing in the past; some examples of the changes from the third edition are presented in Table 03.

	IEC 60601-1-2 3rd Edition	IEC 60601-1-2 4th Edition	
		Professional Healthcare	Home Healthcare
ESD IEC 61000-4-2	8 KV Air Discharge (Max.) 6 KV Contact Discharge	15 KV Air Discharge (Max.) 8 KV Contact Discharge	
Radiated Immunity IEC 61000-4-3	3 V/m – Non Life Support 10 V/m – Life Support 80 MHz – 2.5 GHz 80% @ 2Hz (or 1 KHz) AM Modulation	3 V/m 80 MHz – 2.7 GHz 80% @ 1 KHz AM Modulation	10 V/m 80 MHz – 2.7 GHz 80% @ 1 KHz AM Modulation
Proximity Field from Wireless Transmitters (NEW TEST)		9 V/m to 28 V/m 15 specific frequencies	
EFT/Burst IEC 61000-4-4	±2 KV, 5KHz – AC Mains ±1 KV, 5KHz – I/O Ports 5 KHz or 100 KHz PRR	±2 KV – AC Mains ±1 KV – I/O Ports 100 KHz PRR	
Conducted Immunity IEC 61000-4-6	3 V (0.15 – 80 MHz) 10 V ISM Bands (Life Support)	3 V (0.15 – 80 MHz) 6 V ISM Bands	3 V (0.15 – 80 MHz) 6 V ISM Bands + Amateurs
Magnetic Immunity IEC 61000-4-8	3 A/m – 50 and 60 Hz	30 A/m – 50 and 60 Hz	

Table 03 - IEC 60601-1 third edition, Means of Protection (MOP) classifications in two categories means of operator protection (MOOP) and means of patient protection (MOPP).

The main goal of the 4th edition is to ensure that the medical practices aimed at saving lives are not disturbed by common EMC phenomena. By testing, verifying and certifying units according to the new standards, including collateral, products will become safer and secured to operate in harmony with others equipment.

The fourth edition also included a new definition "Used environments" in which equipment, including power supplies, will be used - requiring power designers to integrate the application segment when developing products. Each of those environments might require different specifications (i.e. higher isolation or immunity to different frequencies).

The three categories are:

- Professional healthcare facility environment (Hospital, Physician offices...)
- Home healthcare environment (Homes, Nursing Home, Public places...)
- Special Environment (Military areas, Heavy Industrial areas, High Power Medical Equipment)

In addition, the 4th edition introduces new definitions:

- Intended use (medical purpose only)
- Normal use (including medical use and transport, maintenance, standby)

Implementation and consequences
The fourth edition of the IEC 60601-1-2:2014 standard is now published and implementation in progress. Facing arise of faults reports, late 2014 the FDA issued a letter recommending that devices undergo EMC testing to the 4th standard as soon as possible. Starting on April 1, 2017 the FDA will no longer accept declarations of conformity in support of either IEC 60601-1-2 Edition 3:2007 or ANSI/AAMI/IEC 60601-1-2:2007. In Europe and rest of the world, the date for implementation will depend on local organizations but considering the extreme pressure from the market and exponential development of connected devices in the medical industry, the power supplies industry is already offering solutions meeting the 4th edition and working on new technologies to lower EMI to an unprecedented level.

For many of us “Powering IoT in medical applications with safety” is a very exciting area, especially when considering sensors that will be powered by harvesting energy and the increase of inter-operations between power supplies and medical applications.

About Powerbox
Founded in 1974, with headquarters in Sweden and operations in 15 countries across four continents, Powerbox serves customers all around the globe. The company focuses on four major markets - industrial, medical, transportation/railway and defense - for which it designs and markets premium quality power conversion systems for demanding applications. Powerbox's mission is to use its expertise to increase customers' competitiveness by meeting all of their power needs. Every aspect of the company's business is focused on that goal, from the design of advanced components that go into products, through to high levels of customer service. Powerbox is recognized for technical innovations that reduce energy consumption and its ability to manage full product lifecycles while minimizing environmental impact.

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