Power to Home Healthcare in safety

Introduction
With a global population that is both living longer and experiencing an increasing rate of chronic disease, combined with economic factors that are driving the increased of healthcare in the home, there is a growing demand for medical electrical equipment designed for use in home environment, requiring from power supplies manufacturers to not only consider standards and regulations but as well Patient Comfort and Patient Environment.

Some may question; what Patient Comfort has to do with a power supply? Recent study published by Madalena Cunha & Nélio Silva form Superior School of Health, Polytechnic Institute of Viseu, Portugal investigated noise impact on patient wellbeing in hospital environment. The report confirmed that subjective wellbeing is influenced by the hospital noise in general and, more specifically, the noise from clinical sources (e.g. monitors, infusion pumps and other equipment).

Reducing noise in medical equipment, especially when those equipment installed in non-clinic environment becomes a must and manufacturers are now building their equipment to reduce the level of noise clause to inaudible, limiting forced ventilation to extraordinary condition.

For power supplies manufacturers that implies that power supplies will be operated with cooling limited to conduction and convection, requiring power designers to optimize performances while keeping in mind reliability in such environment (we all know that MTBF decreases with temperature)!

Patient Safety is also a very important aspect power supplies designers have to consider and knowing that studies revealed that 60% of the homes in Europe and 40% of those in the U.S. have no reliable ground wires, it is very important to protect users of home medical devices from electrical shock. Powering Home Healthcare equipment with safety is what standards and regulations are for sure addressing but as well something all power designers have in mind when developing power solutions for medical applications and especially home healthcare.

Power to Home Healthcare with safety IEC 60601
Safety is a very important concern and medical power supplies must comply with the standard IEC 60601 published in 1977; standard that is internationally adopted (see figure 01) and continuously updated to improve patient safety and comfort. More detailed information can be found from the different standardization organizations but it is interesting to quick look at the two revisions that impacted on the implementation of new technologies power designers have to consider 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

Figure 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 (1.83 m (6 feet) beyond the perimeter of the intended locations, e.g. bed, treatment-area):

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, the third 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 (figure 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

Figure 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 introduced a new way of working, combining power design, risk assessment but as well an extreme level of cooperation with equipment manufacturer to guarantee the proper level of safety to patient and operators.

This new approach becomes tangible in connection with the form factors of medical power supplies. Since the 3rd. Edition external power supplies are considered as

stand-alone medical devices, which 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, for which a close cooperation with the power supply manufacturer is needed.

Power to Home Healthcare with safety IEC 60601-1-11
Collateral standard from the IEC 60601-1, the IEC 60601-1-11 was introduced in 2010 and covers the basic safety and essential performance of medical electrical equipment and systems manufactured for use in the home healthcare environment. Considering the new standard includes a number of major changes compared to previous, manufacturer were given three years to comply. June 30, 2013, the IEC 60601-1-11 went into effect in European markets and by the end of the year in U.S.A and is now empowered internationally.

Among many, the latest issue of the IEC 60601-1-11 includes changes in the safety class of medical devices not being installed permanently by an accredited electrician (requirement of Class I products). As the study revealed and despite significant improvements, EU and US homes have no reliable earth ground wires. In consequence of that, the latest revision requires that all medical devices for home fall under the Class II designation, which does not rely upon earth ground for protection.

As well, the latest edition addressed the definition of "Nursing Home" by region, which differs between US and Europe. In US nursing home are considered as operated in "Professional" environment (product must meet Class I) when in Europe it's considered as "Home" environment requiring Class II equipment. This definition is important in case equipment manufactured in USA might not comply with European regulations.

With the protection class alone, not all possibilities are exploited in terms of increased safety. Power supplies for use in IEC 60601-1-11 environment have to be protected against intrusion of dust and drop water, which means to comply to protection grade IP21. Furthermore in contrast to the main norm possible openings of the housing need be kept such small, that also children can not touch electical parts inside. This needs to be proven by test with the so called "child-finger".

IEC 60601-1-11 includes as well additional requirements for interruption of the power supplied to the Life-supporting ME Equipment or ME Systems and to secure the power source (e.g. battery backup) maintains Essential Performance for sufficient time or number of procedures, to allow for alternate methods to be employed in such case.

As collateral to IEC 60601-1 Third revision, the IEC 60601-1-11 requires power designers to consider Usability Engineering process and File when manufacturing medical products for home use (Clause 9). Not all may apply to power supplies though when performing the risk assessment it is important to consider all and potential impacts. The following hazards must now be considered: Changes of Controls - Confusion in Operation Modes - Unexpected Movement - Transfer of Energy/Substances - Potential of Disconnection - Exposure to Biological Materials - Improper/Unsafe Operation - Parts Inhaled/Swallowed

Power to Home Healthcare challenges and solutions
Topology and Optimization - Taking in consideration standards and regulations, patient comfort and safety, power supply designers are facing a number of challenges, which can all be solved by using proper technologies but as well requiring a significant level of innovation to package always more power in a confined spaced with limited, or no ventilation. Adding to that MTBF and low EMI complying with IEC60601-1-2 and ITE requirements a must, designers' challenges are becoming very exciting!

Choosing the right technology at very early stage of the project is a key to success! In the case of external power supplies for medical equipment the topology is an important factor when considering space, cost and performance. Conventional topologies are usually using around to 200 components. Considering an innovative approach, similar to One Step Conversion combined with passive Power Factor Corrector (PFC) will result in reducing count parts by about 40% with a total of 120 components (figure 03) which will directly benefit to the MTBF but also to make the power supply more compact.

If in theory reducing the number of components to such low number seems to be easy, in practice it is much more complicated and with a goal to exceed 90% efficiency, a power factor correction >0.90, to meet IEC60601-1-11 requirements, able to operate in free air convection

or in sealed box and to reduce the zero-load power consumption to a level close to 0.3W, power designers have to be very innovative and creative, which is fun!

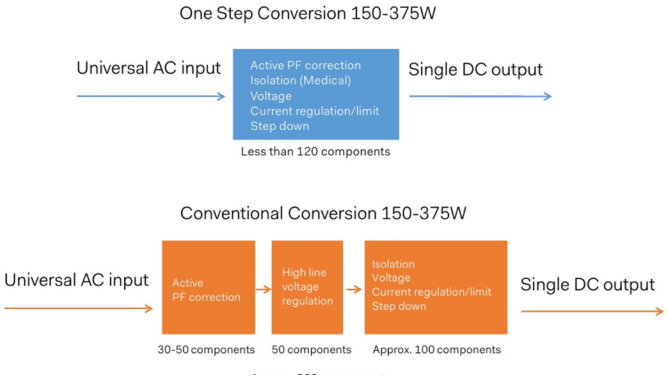

Figure 03 – One step conversion technology reduces total components count by 40%.

Developing One Step Conversion with limited number of components requires a very high knowledge in transformer and coupling to achieve high performance, low leakage current and EMC complying with IEC60601-1-2. One example of product based on this approach is showed in figure 04.

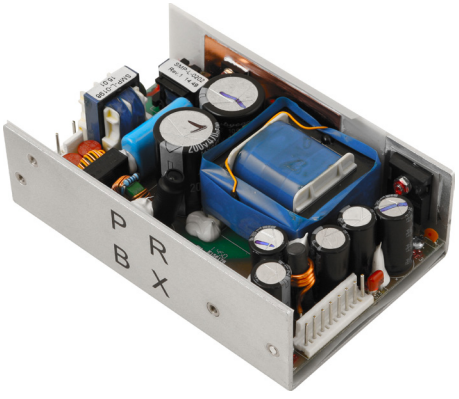

Figure 04 – One step conversion 225W power supply (Powerbox OFM 225) based on One Step Conversion technology.

→ **Mechanical with patient in mind** – As we introduced earlier in this article, designing external power supply for medical applications and especially for home healthcare requires power designers to work in very close cooperation with end-users; to not only secured the highest level of electrical safety but as well usability in patient environment.

One example of such cooperation is the development of a new generation of external power supplies for hospital and home healthcare, complying with the IEC60601-1-11 and designed with patient comfort in mind.

Conventionally housing for external power supplies for medical equipment over 150W are very similar to PC adapter, rectangular parallelepiped with sharp edges, which in case of homecare might create mobility problems, for example wheelchair blocking. Another parameter often not taken in consideration when designing such type of power supply is when housekeeping cleaning patient's room. The parallelepiped shapes is not easy cleanable at same time the operators cleaning the floor, requiring extra attention and time.

From a teamwork with a group of users resulted a concept based on a half lenticular shape, which will avoid wheelchair blocking, make the product easy to clean with conventional Sweepers but; as well conferring to the product a nice look and feel, which is also very important for patient when such product visible or place on a desk.

Once the shape approved by the user group, the next challenge for power designers was to integrate a 225W power supply in the center part of the half lenticular and to guarantee that product will operate at full power in patient's room conditions. With limited number of components and compact design, the One Step Conversion makes possible to room the power conversion, filtering and monitoring in the limited space and to operate safely without need for extra cooling (Figure 05).

Figure 05 – Home Healthcare external power supply (Powerbox EXM 225) designed in semi lenticular shape for homecare integration and patient comfort.

Another important safety aspect is to guarantee that input and output cables are secured by proper locks to avoid power supply disruption in case cables are pooled out accidentally. AC input connector must be protected and locked to sustain a traction of 100 Nm pull strength while the output connector secured by mechanical lock, requiring an action from the operator to unlock (Figure 06).

Figure 06 – Output connector equipped with lock to prevent accidental disconnection and power disruption to medical equipment.

Conclusion

As we presented in this article, designing a power supply for medical application, operated in home healthcare environment, requires from power designers to fully understand and apprehend how the final product will be operated. Taking in consideration end users and in this specific case the patient environment is business critical and if prior reading this article you questioned: "What Patient Comfort has to do with a power supply?" We wish this article gave you a better understanding of the exciting challenges faced by power designers when developing new generation of power supplies with Patient Comfort in mind.

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.

For more information

Visit www.prbx.com
Please contact Patrick Le Fèvre, CMCO
+46 (0)158 703 00

PRBX white paper 003 Rev A
2016.03.14