Points to consider when selecting external power supplies for home healthcare applications

With life expectancy rates rising and the associated costs of patient care soaring, medical providers are looking at ways of reducing costs while still maintaining a high level of treatment. With this, the solution of treating and monitoring patients in their homes is gaining prominence. Medical regulators recognise that there are implications and unique risks associated with these home devices but what point should we consider when selecting the external power supply?

This white paper is intended for electronics engineers and designers working with power systems for the industrial environment, and outlines the points to consider when selecting external power supplies for home healthcare applications.

References

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Andrew Skinner, CTO, TDK-Lambda EMEA

With life expectancy rates rising and the associated costs of patient care soaring, medical providers are looking at ways of reducing costs while still maintaining a high level of treatment. With this, the solution of treating and monitoring patients in their homes is gaining prominence. Secondly, due to medical advancements, many individuals with chronic diseases are living longer but are dependent on medical care. Lower costs for electronic equipment and a mainstream adoption of cellular and internet services now make moving healthcare from hospitals and clinics to the patient's home viable. Already, non-clinical treatment of respiratory ailments is common through the use of infusion pumps, oxygen concentrators and positive airway pressure machines.

Home healthcare offers additional benefits to the patient, who now can be treated in the comfort and familiarity of their homes, avoiding long, stressful hospital stays. In the example of kidney dialysis, treatment is more effective when performed over a longer period of time, rather than with short, multiple visits to the healthcare provider's facility. Haemodialysis, the cleaning and filtering blood, when performed daily for two to three hours, emulates the normal functions of healthy kidneys.

The medical regulators recognise that there are implications and unique risks associated with these home devices, and that these need to be assessed early in product development. In a hospital the environment is sterile and defined, with trained staff on hand during patient treatment. Once outside, potentially hazardous situations can arise. Inappropriate or incorrect use combined with the incompatibility of the environment can cause devices to malfunction, contributing to serious injury or even death. As a note, in the EU nursing homes are classed as "home", rather in the United States where they are considered as "clinical".

The international standard IEC 60601-1-11 - Part 1-11, lays down the general requirements for basic safety and essential performance of medical electrical equipment and medical electrical systems used in the home healthcare environment. This standard is also applicable to external AC-DC power supplies used to power those products.

Medically certified external AC-DC power supplies have been widely used for many years meeting relevant parts of the IEC 60601-1 standard. Their primary use though, has been inside hospitals and clinics. Certification for home use requires additional testing. This is primarily directed at the actual use of the product rather than electrical spacing, temperatures and identification of safety critical components.

In North America and Europe, it is estimated that less than half of the homes have reliable earth grounding. With a Class I product, an electrical fault would cause current to flow through a low impedance ground connection and trip a leakage breaker. With inadequate house wiring, this could lead to an electrical shock and have serious implications on a patient whose health could be in a weakened state. With a Class II, double insulated power supply; no ground connection is needed, eliminating the need for the equipment to be professionally, permanently installed.

Outside of a hospital environment, the external power supply could be subject to the ingress of water, either by rainfall or even a spilt drink. Two levels of ingress protection (IP) are considered for IEC 60601-1-11: IP21 (as a minimum) vertically dripping water, or IP22 (preferred) angled dripping water, equivalent to 3mm of rainfall a minute in accordance to IEC 60529. Dielectric voltage withstand tests are performed to ensure compliance. The IP rating is added to the power supply rating label.

Class B EMC is mandatory, avoiding interference to any household appliances. The tested AC input voltage is lower than regular power supply safety standards, down to -20%. Most external power supplies will meet this anyway as they will usually have wide range operability down to 90Vac.

Again due to home use, additional temperature and humidity testing is conducted. The mandated temperature range is -25 to +70 °C for storage, +5 to +40 °C for operating and 15 to 93% RH for humidity. Any deviation from this can be noted in the product installation manual.

The nature of using an external power supply in the home justifies the shock and vibration testing. Tests are conducted in accordance with IEC 60068-2-27:2008 and IEC 60068-2-64:2008. This is to ensure that the product will be reliable and basic safety and operational performance maintained.

10.1.2a	TABLE: Shock test (IEC 60068-2-27:2008), using the following conditions*:		Pass
	Peak acceleration ..... :	150 m/s^2 (15 g)	
	Duration ..... :	11 ms	
	Pulse shape ..... :	half-sine	
	Number of shocks ..... :	3 shocks per direction per axis (18 total)	

Direction Shock Applied	Axis Shock Applied	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
+	X	Yes	3 shocks
-	X	Yes	3 shocks
+	Y	Yes	3 shocks
-	Y	Yes	3 shocks
+	Z	Yes	3 shocks
-	Z	Yes	3 shocks

Supplementary information:

*(NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [6])

Clause	Requirement + Test	Result - Remark	Verdict
10.1.2b	TABLE: Broad-band random vibration test (IEC 60068-2-64:2008) using the following conditions*:		Pass
1	Acceleration amplitude ..... :	10 Hz to 100 Hz: 1,0 $(m/s^2)^2$/Hz	
2	Acceleration amplitude ..... :	100 Hz to 200 Hz: – 3 db per octave	
3	Acceleration amplitude ..... :	200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2$/Hz	
	Duration ..... :	30 min per perpendicular axis (3 total)	

Perpendicular axis subjected to broad-band random vibration test	Acceleration amplitude	BASIC SAFETY and ESSENTIAL PERFORMANCE maintained? Yes/No	Remarks
1	1	Yes	—
2	1	Yes	—
3	1	Yes	—
1	2	Yes	—
2	2	Yes	—
3	2	Yes	—
1	3	Yes	—
2	3	Yes	—
3	3	Yes	—

Supplementary information:

* (NOTE 2 This represents Class 7M1 and 7M2 as described in IEC TR 60721-4-7:2001)

Energy conservation standards are not covered by the IEC medical standard, and although regional regulation is in place for consumer equipment, medical power supplies have some degree of exemption. As of the publication of this article, it would be wise though to select a power supply with a level VI rating.

The additional testing and certification for IEC 60601-1-11 - Part 1-11 is not arduous. With the sometimes harsh nature of the home environment, coupled with the likelihood of physically weakened patients being at risk, compliance with the standard will become more common across the power supply industry.

For more information and to access our world-leading power supply experience and comprehensive product range, please visit:
www.uk.tdk-lambda.com/medical

You may also contact the author with any questions or comments at:
powersolutions@uk.tdk-lambda.com

TDK-Lambda UK Ltd
Kingsley Avenue
Ilfracombe
Devon EX34 8ES UK
+44 (0)1271 856600
powersolutions@uk.tdk-lambda.com
www.uk.tdk-lambda.com

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