Extending IEC 60601-1 Type Testing to Production

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Manufacturing tests can help OEMs to meet cost, quality, and delivery objectives. Rather than limiting certain tests to the design or initial stages of the product development process, conducting them throughout production can help to ensure a smooth approval process. Additionally, performance benchmarks that are obtained from the testing procedures can aid in monitoring product reliability.

Manufacturers can help prevent rework and possible recalls by continuing to test throughout the manufacturing phase of the product's lifecycle. Periodic hipot and surge testing can prove insulation systems are meeting requirements for operator and patient safety. IEC 60601-1 and ancillary IEC 60601-2-XX standards should be reviewed to determine exact ongoing test programs that will provide the most benefit for the amount of testing time available. As a minimum requirement, refer to safety agency requirements for production line testing, which will include basic insulation between live parts and ground. Reinforced insulation and insulation of patient parts should also be hipot tested periodically against the requirements of the applicable standard, and records kept. These tests can be supplemented with operational tests, which can be implemented either on the line or in the lab.

New requirements can cause problems as well, as test packages and procedures need to be put in place while there is still ambiguity surrounding the interpretation or implementation of the requirements. In most cases, these requirements are given time before they become effective. In some cases, new requirements are effective upon publication. Manufacturers of equipment covered by the requirements of IEC 60601-2-25 and -2-27, Electrocardiographs, now will use the 2011 editions of these Standards, as the old versions are withdrawn. These Standards were introduced to reference the 3rd Edition of IEC 60601-1, but new requirements were introduced in both Standards as well.

IEC 60601-1 Issue 3 will soon become effective in many countries. With it comes the Energy Measurement Test, adapted from IEC 60601-2-49, which is designed to ensure that a defibrillation pulse will not be absorbed by the equipment under test. The procedure used to conduct the Energy Measurement Test is not straightforward. It can be accomplished using either of the following methods, both of which are supported by YouTube videos.

Measurement of the energy of the pulse can be done directly using a Fluke 7000DP equipped with a Fluke 7010 Load Box set to 100 ohms. Some commercially available generators can be optionally configured to apply this method. If planning on using this method, contact the manufacturer of the Defibrillation Proof generator to get details on the option, as a standard generator must be reconfigured to use

this method. Please see the video for details [1].

The waveform can be captured on an oscilloscope and imported to a spreadsheet to calculate the energy over all the points. An Excel program [2], which calculates the energy after the digital oscilloscope output has been imported, and explanatory videos (video 1 [3] and video 2 [4]) are available.

A Note About Standards
Safety agencies all over the world have adopted IEC Standards, thereby facilitating access to world markets for manufacturers using a single design, but that has led to one unfortunate by-product: the standards themselves have become more complex. Many tests require application-specific equipment that outputs high voltages and can require extreme caution to operate safely. The test setups also can be challenging, as the figures in the standards are general in nature. It may be a challenge to determine exact test setups for all applicable equipment.

Conclusion
Product pretesting methods are invaluable in helping designers make sure the product will pass regulatory tests during the agency investigation. These methods can also be implemented as part of an ongoing production testing program. IEC tests can be used as they are convenient, and since the product has already passed them, provide a benchmark to compare ongoing results, and hopefully provide warning of long-term degradation failures, and also new, sudden changes in product behaviour. These problems can be addressed by a properly administered yet simple ongoing test program.

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