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edition of IEC 60601-1 was published. It was the result of a comprehensive review of the second edition (dating from 1988). Some key changes are: the outline and the numbering scheme of the clauses and subclauses were changed, risk management was made much more relevant

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and the concept of essential performance was added.

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manufacturer's EP requirements may vary from the standard's, depending on the proposed use of the device. For example, a laser device used for the removal of

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60601-1 applies to all electrical and electronic medical devices and their accessories. The 3rd edition is in the process of being adopted by global regulatory authorities. But on a national level, regulatory affectivity dates are not harmonized across global jurisdictions.

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THE BASICS OF IEC

60601-1. Depending on the country you are getting approval for, you'll be following either the 2nd, 3rd or 3.1 version. IEC 60601-1 is the basis for the whole series of collateral and particular IEC standards.

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Questions and answers  
on IEC 60601-1:2005  
3rd Edition

DISCLAIMER: Below is  
a list of the questions  
we received during our  
webinar ^Application  
of IEC 60601-1:2005 \_  
on 11th November 2015.  
Sometimes it cannot  
be ensured that the

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questions have been fully understood due to the lack of additional information such as pictures from the MEE,

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1 Application Note  
0004 Title : Symbols  
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and Markings of IEC  
60601-1 / IEC 62353  
The IEC 60601 has  
defined the  
requirements for  
information / data to be  
present on the medical  
equipment's nameplate,  
in order to form an  
unambiguous  
identification of the  
equipment. Information

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3rd edition is expected through 2012.

Major IEC 60601-1 3rd Ed changes 9-14-10 IEC 60601-1:2005+A1:2012(E) contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment. For certain

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types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard.

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requirements for an  
"adult" are below: ...

What is the Scope of  
IEC 60601-1:2005 (3rd  
edition)? Posted by Rob  
Packard on October 2,  
2013. This blog will

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help you determine if  
and how the IEC  
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applies to your medical  
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and lessens the potential for device misuse. A review of IEC 60601-1's global regulatory importance, "A Primer for IEC 60601-1," was presented in an earlier issue of this magazine, and the differences between national standards were discussed in "National Deviations to IEC

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out all French-language pages. Missing page numbers correspond to the French-language pages.

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Transition to 60601-1,  
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“Medical electrical equipment – General requirements for basic safety and essential performance.” Medical devices sold to the European Community and Canada must comply with the standard

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