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IEC 62366-1:2015 (Part 1) IEC/TR 62366-2:2016 (Part 2) Mainly focusing on the usability engineering as a design and development process for the medical device user interface to identify and reduce the possibility of use errors and use associated risks.

IEC 62366:2007+A1:2014 Specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use.

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Re: IEC 62366 vs. IEC 60601 - Has IEC 62366 now replaced IEC 60601? MMANTUNES, I know you've responded to posts in the past that Brazil requires conformance to the IEC standards (vs optional in EU). Do you know if Brazilian law includes IEC60601-1-6 or does Brazil only require conformance to the base IEC60601-1?

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The international standard IEC 62366 medical devices - Application of usability engineering to medical devices is a standard which specifies usability requirements for the development of medical devices.It is harmonized by the European Union (EU) and the United States (US), and therefore can be used as a benchmark to comply with regulatory requirements from both these markets

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IEC 60601-1-6, the usability collateral standard for medical electrical equipment, was the base for IEC 62366. In the future, IEC 62366 will completely replace IEC 60601-1-6. Likes: Ronen E , sagai , Jerome and 3 others

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