


American National Standard



ANSI/AAMI/ IEC 62366-1: 2015+ AMD1:2020

(Consolidated Text)

Medical devices—Part 1:
Application of usability
engineering to medical
devices, including
Amendment 1

Medical devices—Part 1: Application of usability engineering to medical devices—Amendment 1

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AAMI

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Abstract: The amendment included in this consolidated version of ANSI/AAMI/IEC 62366-1:2015 and ANSI/AAMI/IEC 62366-1:2015/A1:2020 corrects identified inaccuracies in ANSI/AAMI/IEC 62366-1:2015 while making no fundamental changes to the usability engineering process as originally conceived in that document.

Keywords: human factors, usability engineering, medical device design

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Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering

The adoption of IEC 62366-1:2015/Amendment 1 as an amendment to an American National Standard was initiated by the AAMI Human Factors Engineering Committee. AAMI HE provides input to the U.S. TAG to IEC/SC 62A which is the responsible group for providing the U.S. input to the relevant group in IEC/SC 62A/JWG 4. U.S. representatives from the AAMI Human Factors Engineering Committee and the TAG played an active part in developing the IEC document.

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