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IEC 62366-1:2015 specifies a PROCESS for a MANUFACTURER to analyse, specify, develop and evaluate the USABILITY of a MEDICAL DEVICE as it relates to SAFETY. This USABILITY ENGINEERING (HUMAN FACTORS ENGINEERING) PROCESS permits the MANUFACTURER to assess and mitigate RISKS associated with CORRECT USE and USE ERRORS, i.e., NORMAL USE.

ISO - IEC 62366-1:2015 - Medical devices — Part 1 ...

IEC 62366-1:2015/AMD1:2020 Amendment 1 - Medical devices - Part 1: Application of usability engineering to medical devices. TC 62/SC 62A; Additional information; Note: a

consolidated version of this publication exists IEC 62366-1:2015+AMD1:2020 CSV

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ISO - IEC 62366-1:2015/Amd 1 - Medical devices — Part 1 ...

– 6 – IEC 62366 -1:2015 IEC 2015 INTRODUCTION Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern.

Many of the MEDICAL DEVICES developed without applying a

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IEC 62366-1:2015 - Estonian Centre for Standardisation

IEC 62366-1 edition 1.1 contains the edition (first 2015-02) [documents 62A/977/FDIS and 62A/988/RVD] and its corrigendum (2016-07), and its amendment 1 2020-06) ([documents 62A/1386/FDIS and 62A/1397/RVD]. In this Redline version, a vertical line in the

margin shows where the technical content is modified by amendment 1.

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Abstract IEC 62366-1:2015 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use.

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PD IEC/TR 62366-2:2016 Medical devices. Guidance on the application of

usability engineering to medical devices 19/30357102 DC BS EN 60601-1-6 AMD2. Medical electrical equipment.

BS EN 62366-1:2015 Medical devices. Application of ...

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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.

IEC 62366 - Wikipedia

IEC 62366-1:2015+A1:2020 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use.

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IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices

[Including CORRIGENDUM 1 (2016)] U.S. Identical Adoption ANSI AAMI IEC 62366-1:2015

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This is the first edition of CAN/CSA-IEC 62366-1, Medical devices — Part 1: Application of usability engineering to medical devices, which is an adoption without modification of the identically titled IEC (International Electrotechnical Commission) Standard 62366-1 (first edition, 2015-02).

CAN/CSA-IEC 62366-1:15

IEC 62366-1:2015 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human

factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use.

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