

## SLOVENSKI STANDARD SIST EN IEC 80601-2-49:2019/oprA1:2023

01-januar-2023

Medicinska električna oprema - 2-49. del: Posebne zahteve za osnovno varnost in bistvene lastnosti večfunkcijske opreme za nadzor pacientov - Dopolnilo A1

Amendment 1 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitors

iTeh STANDARD PREVIEW

(standards.iteh.ai)

Appareils électromédicaux - Partie 2-49: Exigences particulières pour la sécurité de base et les performances essentielles des moniteurs multifonctions des patients

https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-9374-41f6-b7e2

Ta slovenski standard je istoveten z: EN IEC 80601-2-49:2019/prA1:2022

ICS:

11.040.55 Diagnostična oprema Diagnostic equipment

SIST EN IEC 80601-2- en 49:2019/oprA1:2023

SIST EN IEC 80601-2-49:2019/oprA1:2023

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<u>SIST EN IEC 80601-2-49:2019/oprA1:2023</u> https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-9374-41f6-b7e2-f2bb83adcd54/sist-en-iec-80601-2-49-2019-opra1-2023 PROJECT NUMBER:

2022-11-11

DATE OF CIRCULATION:

SUPERSEDES DOCUMENTS:

IEC 80601-2-49/AMD1 ED1



## 62D/1991/CDV

### COMMITTEE DRAFT FOR VOTE (CDV)

CLOSING DATE FOR VOTING:

2023-02-03

|   | 62D/1894/CD, 62                           | D/1923A/CC   |                           |  |
|---|---|--|---------------------------|--|
|   |   |  |                           |  |
| IEC SC 62D : ELECTROMEDICAL EQUIPME   | NT  |  |                           |  |
| SECRETARIAT:  |   | SECRETARY:   |                           |  |
| United States of America  |   | Ms Ladan Bulookbashi   |                           |  |
| OF INTEREST TO THE FOLLOWING COMMITTEES:  |   | PROPOSED HORIZONTAL STANDARD:  |                           |  |
|   |   | Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary. |                           |  |
| FUNCTIONS CONCERNED:  |   | DPREVIE  |                           |  |
| ☐ EMC ☐ ENVIRO  | ONMENT                                    | Quality assurance  | SAFETY                    |  |
| SUBMITTED FOR CENELEC PARALLEL  | VOTING                                    | ☐ NOT SUBMITTED FOR CENE   | LEC PARALLEL VOTING       |  |
| Attention IEC-CENELEC parallel voting The attention of IEC National Commit CENELEC, is drawn to the fact that this Vote (CDV) is submitted for parallel voting The CENELEC members are invited to CENELEC online voting system. | ttees, members of Committee Draft for ng. | 9:2019/oprA1:2023<br>ls/sist/1da1a3b8-9374-41<br>1-2-49-2019-opra1-2023                      |                           |  |
| This document is still under study and s Recipients of this document are invited they are aware and to provide supportin  | to submit, with their o                   |  |                           |  |
| TITLE:  |   |  |                           |  |
| Amendment 1 - Medical electrical and essential performance of mul   |   |  | ents for the basic safety |  |
|   |   |  |                           |  |
| PROPOSED STABILITY DATE: 2028   |   |  |                           |  |
| N T0/00   |   |  |                           |  |
| NOTE FROM TC/SC OFFICERS:   |   |  |                           |  |
|   |   |  |                           |  |

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62D/1991/CDV

- 2 - IEC/CD 80601-2-49:2018/AMD1:2022

#### FOREWORD

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- This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.
- 5 The text of this amendment is based on the following documents:

| Draft      | Report on voting |
|------------|------------------|
| XX/XX/FDIS | XX/XX/RVD        |

6

- 7 Full information on the voting for its approval can be found in the report on voting indicated in
- 8 the above table.
- 9 The committee has decided that the contents of this document will remain unchanged until the
- stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to
- the specific document. At this date, the document will be
- 12 reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- 15 amended.

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19 20 NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

21 22

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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#### **INTRODUCTION to Amendment 1**

- At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the
- amendments published in 2020.
- The full list of IEC SC 62D documents that will be amended or revised may be found within the
- 32 IEC document 62D/1792/DC. The results and comments on the DC may be found within
- 33 62D1808/INF. The review report for this amendment is 62D/1835A/RR.

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IEC CD 80601-2-49:2018/AMD1:2021

– 3 –

62D/1894/CDV

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Replace the text in footnote 1 with: 37

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- "The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-39
- 2:2005/AMD2:2020, Medical electrical equipment Part 1: General requirements for basic 40
- 41 safety and essential performance".

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#### 201.1.3 Collateral standards

- Replace the second paragraph with: 44
- IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-45
- 6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, as well as IEC 60601-1-8:2006, 46
- IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply as modified in 47
- Clauses 202, 206 and 208 respectively. IEC 60601-1-3 and IEC 60601-1-9 do not apply. All 48
- 49 other published collateral standards in the IEC 60601-1 series apply as published.

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#### 201.1.4 Particular standards

- Replace third paragraph with: 52
- IEC 60601-1:2005. IEC 60601-1:2005/AMD1:2012 53 For and
- IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general 54
- standard. Collateral standards are referred to by their document number. 55
- In the second sentence of the 8th paragraph replace "3.1 through 3.147" with "3.1 through 1.54" 56

#### 201.2 Normative references 57

- Replace existing text with: 58
- NOTE Informative references are listed in the Bibliography beginning on page 38. 59
- Clause 2 of the general standard applies, except as follows. 60
- Replacement: 61
- IEC 60601-1-2:2014, Medical electrical equipment Part 1-2: General requirements for basic 62
- safety and essential performance Collateral Standard: Electromagnetic disturbances -63
- Requirements and tests 64
- IEC 60601-1-2:2014/AMD1:2020 65
- IEC 60601-1-6:2010, Medical electrical equipment Part 1-6: General requirements for basic 66
- safety and essential performance Collateral standard: Usability 67
- IEC 60601-1-6:2010/AMD1:2013 68
- IEC 60601-1-6:2010/AMD2:2020 69
- IEC 60601-1-8:2006, Medical electrical equipment Part 1-8: General requirements for basic 70
- safety and essential performance Collateral standard: General requirements, tests and 71
- 72 quidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-8:2006/AMD1:2012 73
- IEC 60601-1-8:2006/AMD2:2020 74

62D/1991/CDV

- 4 - IEC/CD 80601-2-49:2018/AMD1:2022

|  | do |  |  |
|--|----|--|--|
|  |    |  |  |
|  |    |  |  |
|  |    |  |  |

- 76 IEC 60601-1:2005, Medical electrical equipment Part 1: General requirements for basic safety
- 77 and essential performance
- 78 IEC 60601-1:2005/AMD1:2012
- 79 IEC 60601-1:2005/AMD2:2020
- 80 IEC 60601-1-11:2015, Medical electrical equipment Part 1-11: General requirements for basic
- safety and essential performance Collateral Standard: Requirements for medical electrical
- 82 equipment and medical electrical systems used in the home healthcare environment
- 83 IEC 60601-1-11:2015/AMD1:2020
- IEC 60601-1-12:2014, Medical electrical equipment Part 1-12: General requirements for basic
- safety and essential performance Collateral Standard: Requirements for medical electrical
- 86 equipment and medical electrical systems intended for use in the emergency medical services
- 87 environment

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- 88 IEC 60601-1-12:2014/AMD1:2020
- 89 IEC 60601-2-2:2017, Medical electrical equipment Part 2-2: Particular requirements for the
- 90 basic safety and essential performance of high frequency surgical equipment and high
- 91 frequency surgical accessories
- 92 IEC 60601-2-27:2011, Medical electrical equipment Part 2-27, Particular requirements for the
- 93 basic safety and essential performance of electrocardiographic monitoring equipment
- 94 IEC 60601-2-34:2011, Medical electrical equipment Part 2-34, Particular requirements for the
- 95 basic safety and essential performance of invasive blood pressure monitoring equipment

#### SIST EN IEC 80601-2-49:2019/oprA1:2023

https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-93/4-41f6-b/e2-

#### 97 **201.3** Terms and definitions sist-en-iec-80601-2-49-2019-opra1-2023

- 98 Change first paragraph to:
- 99 For the purposes of this document, the terms and definitions given in IEC 60601-1,
- 100 IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-1-12,
- 101 IEC 60601-2-2, IEC 60601-2-27, IEC 60601-2-34 and the following apply.

#### 201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

104 Replace existing Table 201.101 with:

#### Table 201.101 - ESSENTIAL PERFORMANCE requirements

| Requirement  | Subclause     |
|--|---------------|
| Displaying data according PRIMARY OPERATING FUNCTIONS        | 206.101 c)    |
| Determination of ALARM CONDITIONS and assignment of priority | 208.6.1.2     |
| Indication of validity of measured values                    | 208.6.3.2.101 |
| or generating a TECHNICAL ALARM CONDITION                    | 208.6.1.2     |

|            | IEC CD 80601-2-49:2018/A                              | MD1:2021         | <b>- 5 -</b>   | 62D/1894/CDV         |
|------------|---|------------------|--|----------------------|
| 106        | 202 Electromagnetic di                                | sturbances –     | Requirements and tests   |                      |
| 107        | Replace existing text with:                           |                  |  |                      |
| 108        | IEC 60601-1-2:2014 and IE                             | C 60601-1-2:201  | 4/AMD1:2020 apply, except a  | as follows:          |
| 109        |   |                  |  |                      |
| 110        |   |                  |  |                      |
| 111        | 202.8.1 General                                       |                  |  |                      |
| 112        | In the second paragraph re                            | olace            |  |                      |
| 113<br>114 |   |                  | tic discharge, electrical fast to<br>supply lines and voltage inte |                      |
| 115        | with  |                  |  |                      |
| 116<br>117 |   |                  | tic discharge, electrical fast to<br>supply lines and proximity m  |                      |
| 118        | Add the following after the s                         | STAND            |  |                      |
| 119        | For requirements for voltage                          |                  |  |                      |
| 120        |   |                  |  |                      |
| 121        | 202.8.102 * Disturbance                               | s from HF SUR    |  |                      |
| 122<br>123 | In the second paragraph of t<br>300 kHz and 600 kHz": | he compliance c  | heck replace "of300 kHz to 60                                      | 0 kHz" with "between |
| 124        |   |                  |  |                      |
| 125        | 206 Usability   |                  |  |                      |
| 126        | Replace the first sentence v                          | vith:            |  |                      |
| 127<br>128 | IEC 60601-1-6:2010, IEC 6 apply, except as follows:   | 60601-1-6:2010// | AMD1:2013 and IEC 60601-   | 1-6:2010/AMD2:2020   |
| 129        |   |                  |  |                      |
| 130<br>131 | _   |                  | guidance for alarm syste   | ems in MEDICAL       |
| 132        | Replace the first sentence v                          | vith:            |  |                      |
| 133<br>134 | IEC 60601-1-8:2006, IEC 6 apply, except as follows:   | 60601-1-8:2006/  | AMD1:2012 and IEC 60601-   | 1-8:2006/AMD2:2020   |

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- 6 -

IEC/CD 80601-2-49:2018/AMD1:2022

62D/1991/CDV

208.6.3.2 **Visual ALARM SIGNALS** 136 Replace "sublcause" with "subclause". 137 138 208.6.8.1 General 139 In the second paragraph replace 140 "Symbols IEC 60417-5319:2002-11 or IEC 60417-5319:2002-11 (symbol 3 and 4 in Table C.1 141 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) or alternative marking 2 and 4 142 in Table C.2 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012," 143 with 144 Symbols IEC 60417-5319:2002-11 or IEC 60417-5319:2002-11 (symbol 3 and 4 in Table C.1 of 145 IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020) 146 or alternative marking 2 and 4 in Table C.2 of IEC 60601-1-8:2006, IEC 60601-1-147 8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 148 149 \* Non-latching and latching alarm signals 208.6.10 150 Delete existing text until "Additional sublause:" Salten all 151 152 208.6.11.1 Existence of DISTRIBUTED ALARM SYSTEM 2019-opral-2023 153 Change title to "Existence of a DIS or DAS" 154 155 156 208.6.12 \* ALARM SYSTEM logging Delete existing text. 157 Addition: 158 208.6.12.1 General 159 Replace first paragraph: 160 The ALARM SYSTEM of a MULTIFUNCTION PATIENT MONITOR shall be equipped with an OPERATOR 161 ALARM SYSTEM log and a RESPONSIBLE ORGANIZATION ALARM SYSTEM log. 162 163

62D/1894/CDV

IEC CD 80601-2-49:2018/AMD1:2021 - 7 -

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| 164   | 208.6.12.2  | OPERATOR ALARM SYSTEM logging  |
|---|---|--|
| 165   | Addition befo   | re the compliance statement:   |
| 166   | aa) the ALARM   | I SYSTEM log shall have a capacity of at least 1000 events.  |
| 167   |   |  |
| 168   | 208.6.12.3  | RESPONSIBLE ORGANIZATION ALARM SYSTEM logging  |
| 169   | Addition befo   | re the compliance statement:   |
|   |   |  |
| 170<br>171<br>172   | export the c  | CTION PATIENT MONITORS should be equipped with a FUNCTIONAL CONNECTION to ontents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as well as the of the PATIENT, MULTIFUNCTION PATIENT MONITOR or location.   |
| 173   |   |  |
| 174   | Annex AA  |  |
| 175   | Replace guid  | ance and rationale for Subclause 208.6.12 with:  |
| 176<br>177<br>178<br>179<br>180<br>181<br>182<br>183<br>184<br>185<br>186<br>187<br>188 | logs are part sustaining, Mito critical ALA ALARM SYSTEM complexity camonitoring diff.  To enable a capacity.  Index of define Replace  "DISTRIBUTED with | TIFUNCTION PATIENT MONITORS are used for vigilance monitoring, the ALARM SYSTEM icularly related to PATIENT safety. While not necessarily life-supporting or life-ULTIFUNCTION PATIENT MONITORS are often relied upon to provide timely responses ARM CONDITIONS. The typical use of MULTIFUNCTION PATIENT MONITORS make the M logs critical elements of ensuring their safe use. The associated ALARM SYSTEM an often make root cause analysis of adverse events occurring during or after ificult or impossible without detailed retrospective information.  The support of the provided HTML representation of the provided |
| 190<br>191<br>192<br>193  |   | NFORMATION SYSTEM ABOUT ALARM CONDITIONS IEC 60601-1-8:2006/AMD2:2020,   |
| 194<br>195  | <br>Delete:   |  |
| 196   |   | IETIC COMPATIBILITYIEC 60601-1-2:2014, 3.2   |

62D/1991/CDV - 8 - IEC/CD 80601-2-49:2018/AMD1:2022

| 198  | Replace   |   |
|--|---|---|
| 199  | HAZARDOUS SITUATION IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.4  | 40                                      |
| 200<br>201   | with HAZARDOUS SITUATIONIEC 60601-1:2005/AMD2:2020, 3.40  | 40                                      |
| 202<br>203<br>204  | Replace         HIGH PRIORITY       IEC 60601-1-8:2006, 3.2:  | 22                                      |
| 205<br>206   | with HIGH PRIORITYIEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.2  | 22                                      |
| 207  | HIGH PRIORITY   |   |
| 208<br>209   | Replace INFORMATION SIGNALIEC 60601-1-8:2006, 3.23  | 23                                      |
| 210<br>211   | with INFORMATION SIGNALIEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.23  | 23                                      |
| 212  |   |   |
| 213<br>214   | Replace INTENDED USE/INTENDED PURPOSE IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.4-   | 44                                      |
| 215<br>216   | with INTENDED USE/INTENDED PURPOSEIEC 60601-1:2005/AMD2:2020, 3.4-  | 44                                      |
| 217  |   | •                                       |
| 218<br>219   | Replace LOW PRIORITYIEC 60601-1-8:2006,3.2  | 27                                      |
| 220<br>221   | LOW PRIORITYIEC 60601-1-8:2006/AMD2:2020.3.2  |   |
| 222  | (standards.iten.ai)   |   |
|  |   |   |
| 223<br>224   |   |   |
|  | Replace https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-9374-41f6-b7e2-   |   |
| 224<br>225<br>226  | Replace https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-9374-41f6-b7e2-MANUFACTURER   | 55                                      |
| 224<br>225   | Replace https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-9374-41f6-b7e2-   |   |
| 224<br>225<br>226<br>227   | Replace https://standards.iteh.ai/catalog/standards/sist/1da1a3b8-9374-41f6-b7e2-MANUFACTURER   | 55                                      |
| 224<br>225<br>226<br>227<br>228<br>229<br>230  | Replace         MANUFACTURER       72 bb 83 adcd 54/2 IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.55         with         MANUFACTURER       IEC 60601-1:2005/AMD2:2020, 3.55         Replace  | 55<br>28                                |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234  | Replace         MANUFACTURER       12005/34         MEDIUM PRIORITY       12005/4         IEC 60601-1:2005/AMD1:2012, 3.5         With       12005/4         MEDIUM PRIORITY       12005/4         IEC 60601-1-8:2006, 3.2         With       12005/4         MEDIUM PRIORITY       12006/4   | 55<br>28                                |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233   | Replace         MANUFACTURER       MANUFACTURER         MEDIUM PRIORITY       IEC 60601-1:2005/AMD2:2020, 3.5         With       IEC 60601-1:2005/AMD2:2020, 3.5         Replace       MEDIUM PRIORITY         IEC 60601-1-8:2006, 3.2         With   | 55<br>28<br>28                          |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235   | Replace         MANUFACTURER       12005/34         MEDIUM PRIORITY       12005/4         IEC 60601-1:2005/AMD1:2012, 3.5         With       12005/4         MEDIUM PRIORITY       12005/4         MEDIUM PRIORITY       12006/4         Replace       12006/4         MEDIUM PRIORITY       12006/4         Replace       12006/4         Replace       12006/4         Replace       12006/4  | 55<br>28<br>28<br>89                    |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235<br>236<br>237<br>238  | Replace       https://standards.iteh.ai/catalog/standards/sist/Ida1a3b8-9374-41f6-b7e2-         MANUFACTURER       IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.5         with       IEC 60601-1:2005/AMD2:2020, 3.5         Replace       IEC 60601-1-8:2006, 3.2         with       IEC 60601-1-8:2006/AMD2:2020, 3.2         With       IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.2         Replace       PROCESS       IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.8         with       PROCESS       IEC 60601-1:2005/AMD2:2020, 3.8         with       PROCESS       IEC 60601-1:2005/AMD2:2020, 3.8  | 55<br>28<br>28<br>89                    |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235<br>236<br>237<br>238  | Replace       https://standards.iteh.al/catalog/standards/sisVIda1a3b8-9374-41f6-b7e2-         MANUFACTURER       1EC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.5         with       IEC 60601-1:2005/AMD2:2020, 3.5         Replace       IEC 60601-1-8:2006, 3.2         with       IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD2:2020, 3.2         Replace       PROCESS         IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.8         with       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       RISK MANAGEMENT   | 55<br>28<br>28<br>28<br>89              |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235<br>236<br>237<br>238<br>239<br>240                                    | Replace         MANUFACTURER       12005/AMD1:2012, 3.5         with       MANUFACTURER       IEC 60601-1:2005/AMD2:2020, 3.5         Replace       MEDIUM PRIORITY       IEC 60601-1-8:2006, 3.2         with       MEDIUM PRIORITY       IEC 60601-1-8:2006/AMD2:2020, 3.2         Replace       PROCESS       IEC 60601-1:2005/AMD1:2012, 3.8         with       PROCESS       IEC 60601-1:2005/AMD1:2012, 3.8         with       PROCESS       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       IEC 60601-1:2005/AMD2:2020, 3.8  | 55<br>28<br>28<br>89<br>89              |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235<br>236<br>237<br>238<br>239<br>240<br>241<br>242                      | Replace       120053adcd54/3 IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.5         with       MANUFACTURER       IEC 60601-1:2005/AMD2:2020, 3.5         Replace       MEDIUM PRIORITY       IEC 60601-1-8:2006, 3.2         with       MEDIUM PRIORITY       IEC 60601-1-8:2006/AMD2:2020, 3.2         Replace       PROCESS       IEC 60601-1:2005/AMD1:2012, 3.8         with       PROCESS       IEC 60601-1:2005/AMD2:2020, 3.8         With       PROCESS       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       RISK MANAGEMENT       IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.10         with       RISK MANAGEMENT       IEC 60601-1:2005/AMD2:2020, 3.10         with       RISK MANAGEMENT       IEC 60601-1:2005/AMD2:2020, 3.10                                  | 55<br>28<br>28<br>89<br>89              |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235<br>236<br>237<br>238<br>239<br>240<br>241<br>242<br>243<br>244        | Replace         MANUFACTURER  | 555<br>228<br>228<br>339<br>339<br>3707 |
| 224<br>225<br>226<br>227<br>228<br>229<br>230<br>231<br>232<br>233<br>234<br>235<br>236<br>237<br>238<br>239<br>240<br>241<br>242<br>243<br>244<br>245 | Replace       IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.5         with       IEC 60601-1:2005/AMD2:2020, 3.5         Replace       MEDIUM PRIORITY       IEC 60601-1-8:2006, 3.2         with       MEDIUM PRIORITY       IEC 60601-1-8:2006/AMD2:2020, 3.2         With       MEDIUM PRIORITY       IEC 60601-1-8:2006/AMD2:2020, 3.2         Replace       PROCESS       IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.8         with       PROCESS       IEC 60601-1:2005/AMD2:2020, 3.8         Replace       RISK MANAGEMENT       IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.10         with       RISK MANAGEMENT       IEC 60601-1:2005/AMD2:2020, 3.10         Replace       IEC 60601-1:2005/AMD2:2020, 3.10         Replace       IEC 60601-1:2005/AMD2:2020, 3.10 | 55<br>28<br>28<br>89<br>89<br>07<br>07  |