



**SLOVENSKI STANDARD**  
**oSIST prEN IEC 80601-2-86:2026**

**01-september-2026**

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**Medicinska električna oprema - 2-86. del: Posebne zahteve za osnovno varnost in bistvene lastnosti elektrokardiografov, vključno z diagnostično opremo, opremo za spremljanje, ambulantno opremo, elektrodami, kabli in priključnimi vodniki**

Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires

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**ICS:**

|           |                     |                      |
|-----------|---------------------|----------------------|
| 11.040.55 | Diagnostična oprema | Diagnostic equipment |
|-----------|---------------------|----------------------|

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# 62D/2310/CDV

## COMMITTEE DRAFT FOR VOTE (CDV)

|                                              |                                               |
|----------------------------------------------|-----------------------------------------------|
| PROJECT NUMBER:<br><b>IEC 80601-2-86 ED1</b> |                                               |
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|                                                                                                                                                                                                                                                                                                                                                                                             |                                                                    |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS                                                                                                                                                                                                                                                                                                                            |                                                                    |
| SECRETARIAT:<br>United States of America                                                                                                                                                                                                                                                                                                                                                    | SECRETARY:<br>Ms Ladan Bulookbashi                                 |
| OF INTEREST TO THE FOLLOWING COMMITTEES:                                                                                                                                                                                                                                                                                                                                                    | HORIZONTAL FUNCTION(S):                                            |
| ASPECTS CONCERNED:<br>Safety                                                                                                                                                                                                                                                                                                                                                                |                                                                    |
| <input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING<br><br><b>Attention IEC-CENELEC parallel voting</b><br><br>The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.<br><br>The CENELEC members are invited to vote through the CENELEC online voting system. | <input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING |

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TITLE:

**Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires**

PROPOSED STABILITY DATE: 2032

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# CONTENTS

|    |                                                                                                    |     |
|----|----------------------------------------------------------------------------------------------------|-----|
| 1  |                                                                                                    |     |
| 2  | FOREWORD .....                                                                                     | 4   |
| 3  | INTRODUCTION .....                                                                                 | 7   |
| 4  | 201.1 Scope, objective and related standards .....                                                 | 8   |
| 5  | 201.2 Normative references .....                                                                   | 11  |
| 6  | 201.3 *Terminology and definitions .....                                                           | 12  |
| 7  | 201.4 General requirements .....                                                                   | 16  |
| 8  | 201.5 General requirements for testing of ECG ME EQUIPMENT .....                                   | 17  |
| 9  | 201.6 Classification of ECG ME EQUIPMENT and ME SYSTEMS .....                                      | 18  |
| 10 | 201.7 ECG ME EQUIPMENT identification, marking and documents .....                                 | 19  |
| 11 | 201.8 Protection against electrical HAZARDS from ECG ME EQUIPMENT .....                            | 27  |
| 12 | 201.9 Protection against mechanical hazards of ECG ME EQUIPMENT and ME SYSTEMS .....               | 34  |
| 13 | 201.10 Protection against unwanted and excessive radiation HAZARDS .....                           | 34  |
| 14 | 201.11 Protection against excessive temperatures and other HAZARDS .....                           | 34  |
| 15 | 201.12 Accuracy of controls and instruments and protection against                                 |     |
| 16 | hazardous outputs .....                                                                            | 36  |
| 17 | 201.13 HAZARDOUS SITUATIONS and fault conditions .....                                             | 77  |
| 18 | 201.14 Programmable electrical medical systems (PEMS) .....                                        | 78  |
| 19 | 201.15 Construction of ME EQUIPMENT .....                                                          | 78  |
| 20 | 201.16 ME SYSTEMS .....                                                                            | 94  |
| 21 | 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....                          | 94  |
| 22 | 202 Electromagnetic disturbances – Requirements and tests .....                                    | 95  |
| 23 | 202.8 Electromagnetic immunity requirements for ecg me equipment and me                            |     |
| 24 | systems .....                                                                                      | 97  |
| 25 | 202.8.101 * Electrosurgery interference .....                                                      | 98  |
| 26 | 208 General requirements, tests and guidance for ALARM SYSTEMS in ME EQUIPMENT and                 |     |
| 27 | ME SYSTEMS .....                                                                                   | 101 |
| 28 | 208.6 Alarm systems .....                                                                          | 101 |
| 29 | Annex AA (informative) General guidance and rationale .....                                        | 107 |
| 30 | Annex BB (informative) Positions, identifications and colour codes of additional ECG               |     |
| 31 | ELECTRODES .....                                                                                   | 202 |
| 32 | Annex CC (informative) ECG clinical use cases .....                                                | 208 |
| 33 | Annex DD (informative) Definitions and rules for the measurement of                                |     |
| 34 | ELECTROCARDIOGRAMS .....                                                                           | 226 |
| 35 | Annex EE (informative) CTS test atlas .....                                                        | 232 |
| 36 | Annex GG (informative) Alarm diagrams of Clause 208/IEC 60601-1-8:2006 +A1:2012 .....              | 265 |
| 37 | <b>Bibliography</b> .....                                                                          | 268 |
| 38 |                                                                                                    |     |
| 39 | Figure 201.101 – Alternating QRS complexes and ventricular tachycardia waveforms for               |     |
| 40 | testing pattern recognition capability for 201.7.8.2 c) - 13) and 15) .....                        | 24  |
| 41 | Figure 201.102 – Test of protection against the effects of defibrillation (common mode) .....      | 29  |
| 42 | Figure 201.103 – Test of protection against the effects of defibrillation (differential mode) .... | 30  |
| 43 | Figure 201.104 – Application of the test voltage between LEAD WIRES to test the energy             |     |
| 44 | delivered by the defibrillator .....                                                               | 31  |
| 45 | Figure 201.105 – General test circuit .....                                                        | 35  |
| 46 | Figure 201.106 – Input impulse signal and electrocardiograph response .....                        | 37  |
| 47 | Figure 201.107 – Test circuit for common mode rejection .....                                      | 45  |
| 48 | Figure 201.108 – Pacemaker pulse .....                                                             | 47  |
| 49 | Figure 201.109 – Test waveforms for T-wave rejection .....                                         | 49  |
| 50 | Figure 201.110 – Normal paced rhythm .....                                                         | 50  |

|     |                                                                                                         |     |
|-----|---------------------------------------------------------------------------------------------------------|-----|
| 51  | – Ineffective pacing (heart rate at 30 complexes/min, pacemaker pulse at 80 complexes/min)              |     |
| 52  | 50                                                                                                      |     |
| 53  | Figure 201.112 – Simulated QRS complex .....                                                            | 50  |
| 54  | Figure 201.113 – Pacemaker test circuit .....                                                           | 51  |
| 55  | Figure 201.114: dielectric withstand test .....                                                         | 69  |
| 56  | Figure 201.115 – Test setup for cable noise measurement .....                                           | 70  |
| 57  | Figure 201.116 - Flex life test setup .....                                                             | 71  |
| 58  | Figure 201.117 – Test circuit for offset instability/internal noise determination .....                 | 76  |
| 59  | Figure 201.118 – Defibrillation overload test circuit ( <i>all capacitor and resistor values have a</i> |     |
| 60  | <i>tolerance of <math>\pm 10\%</math></i> ) .....                                                       | 77  |
| 61  | Figure 201.119 – Defibrillation overload test circuit for cables containing resistors .....             | 77  |
| 62  | Figure 202.101 – Test layout for radiated and conducted emission tests .....                            | 79  |
| 63  | Figure 202.102 – Set-up for immunity tests .....                                                        | 80  |
| 64  | Figure 202.103 – Test circuit for HF surgery protection measurement .....                               | 83  |
| 65  | Figure 202.104 – Test setup for HF surgery protection measurement .....                                 | 83  |
| 66  | Figure AA.1 – Applied part with multiple PATIENT connections .....                                      | 101 |
| 67  | Figure AA.2 – D-sub connector .....                                                                     | 101 |
| 68  | Figure AA.3 Simulation of a rectangular pulse filtered by 0,05 Hz causal highpass filter (right)        |     |
| 69  | and a 0,5 Hz non-causal highpass filter (left) .....                                                    | 109 |
| 70  | Figure AA.4 - Example of scatter plot of ST amplitude measurement .....                                 | 137 |
| 71  | Figure AA.5 - Example of scatter plot of ST amplitude error values for all measurements ...             | 137 |
| 72  | Figure AA.6 - Example of scatter plot of ST amplitude error values for ST reference values              |     |
| 73  | from -200 microvolt to + 200 microvolt .....                                                            | 138 |
| 74  | Figure AA.7 - Example of scatter plot of ST slope measurements .....                                    | 138 |
| 75  | Figure AA.8 - Example of scatter plot of all ST slope measurement errors .....                          | 139 |
| 76  | Figure AA.9—Example of scatter plot of all ST slope measurement errors for ST reference                 |     |
| 77  | values from -2.0 mV/sec to + 2.0 mV/sec .....                                                           | 140 |
| 78  |                                                                                                         |     |
| 79  | Figure BB.1 – LEADS and colours for fetal ecg .....                                                     | 4   |
| 80  | Figure BB.2 – Positions of the ECG ELECTRODES on the fetus for fetal ECG (see Table BB.2) ...           | 4   |
| 81  | Figure BB.3 – LEAD positions and colours for fetal scalp ECG (see Table BB.2) .....                     | 4   |
| 82  | Figure DD.1 – Normal electrocardiogram .....                                                            | 23  |
| 83  | Figure DD.2 – Determination of global intervals (example) .....                                         | 24  |
| 84  | Figure DD.3 – Waveform durations, isoelectric segments .....                                            | 25  |
| 85  | Figure DD.4 – QRS complex with small R-wave(s) (see Figure DD.5, DD.6) .....                            | 27  |
| 86  | Figure DD.5 – Detail of small accepted R-wave .....                                                     | 27  |
| 87  | Figure DD.6 – Detail of small rejected R-wave .....                                                     | 28  |
| 88  | Figure FF.1 – Nomenclature of CALIBRATION ECG S .....                                                   | 35  |
| 89  | Figure FF.2 – Nomenclature of analytical ECG s .....                                                    | 38  |
| 90  | Figure FF.3 – Noise Characteristics .....                                                               | 40  |
| 91  | Figure GG.1 – NON-LATCHING ALARM SIGNALS without ALARM RESET .....                                      | 2   |
| 92  | Figure GG.2 – NON-LATCHING ALARM SIGNALS with ALARM RESET .....                                         | 3   |
| 93  | Figure GG.3 – LATCHING ALARM SIGNALS with ALARM RESET .....                                             | 3   |
| 94  | Figure GG.4 – Two ALARM CONDITIONS with ALARM RESET .....                                               | 4   |
| 95  |                                                                                                         |     |
| 96  | Table 201.101 – ESSENTIAL PERFORMANCE requirements .....                                                | 17  |
| 97  | Table 201.102 – ECG ELECTRODE colour codes, identification codes, and position, for standard            |     |
| 98  | 12 LEAD & Frank ECG placement .....                                                                     | 20  |
| 99  | Table 201.103 – Identification and colour for AMBULATORY ECG placement .....                            | 21  |
| 100 | Table 201.104 – Protection against the effect of defibrillation (test conditions) .....                 | 28  |
| 101 | Table 201.105 – Frequency response by ECG category .....                                                | 35  |
| 102 | Table 201.106 – Electrode connection configurations for test of multichannel crosstalk .....            | 38  |
| 103 | Table 201.107 – Acceptable mean differences and standard deviations for global intervals and            |     |
| 104 | Q-, R-, S-durations on calibration and analytical ECGs .....                                            | 54  |
| 105 | Table 201.108 – Acceptable mean differences and standard deviations for global durations                |     |
| 106 | and intervals for biological ECGs .....                                                                 | 55  |
| 107 | Table 201.109 – Disclosed changes of measurements caused by NOISE on ECGs .....                         | 55  |
| 108 | Table 201.110 – Example for the documentation of accuracy measures for diagnostic                       |     |
| 109 | interpretative statements .....                                                                         | 57  |
| 110 | Table 201.111 – Example for the documentation of accuracy measures for rhythm                           |     |
| 111 | interpretative statements .....                                                                         | 58  |

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|     |                                                                                                                                                                                                                       |     |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|
| 112 | Table 201.112: Databases .....                                                                                                                                                                                        | 59  |
| 113 | Table 201.113 – Records to be included in a complete test .....                                                                                                                                                       | 60  |
| 114 | Table 201.114 – Requirements for all arrhythmia algorithms .....                                                                                                                                                      | 61  |
| 115 | Table 201.115: TRUNK CABLE and LEAD WIRE flex life .....                                                                                                                                                              | 70  |
| 116 | Table 201.116—Tensile strength of cable connections in N .....                                                                                                                                                        | 71  |
| 117 | Table 201.117 - Number of connector mating/unmating cycles .....                                                                                                                                                      | 72  |
| 118 | Table 201.118 - LEAD WIRE resistance ( $\Omega$ ) .....                                                                                                                                                               | 73  |
| 119 | Table 202.101 – Test signals and IMMUNITY Pass/Fail criteria .....                                                                                                                                                    | 81  |
| 120 | Table AA.1 – Summary of requirements for different types of ECG ME EQUIPMENT .....                                                                                                                                    | 95  |
| 121 | Table AA.2 – Summary of subclauses excluded in General Requirements .....                                                                                                                                             | 95  |
| 122 | Table AA.3 Summary of specific ME EQUIPMENT type applicability for subclauses excluded from General Requirements .....                                                                                                | 96  |
| 123 | Table AA.4 Prior definitions of ESSENTIAL PERFORMANCE .....                                                                                                                                                           | 98  |
| 124 | Table AA.5 – ECG ELECTRODE positions and electrical strength requirements .....                                                                                                                                       | 105 |
| 125 | Table AA.6 – Tabulation of test results .....                                                                                                                                                                         | 116 |
| 126 | Table AA.7—AHA and MIT–BIH database labels .....                                                                                                                                                                      | 121 |
| 127 | Table AA.8 – Beat label classifications .....                                                                                                                                                                         | 125 |
| 128 | Table AA.9 – Example of a line-format, beat-by-beat performance report .....                                                                                                                                          | 126 |
| 129 | Table AA.10 – Run sensitivity summary matrix .....                                                                                                                                                                    | 128 |
| 130 | Table AA.11 – Run positive predictivity summary matrix .....                                                                                                                                                          | 128 |
| 131 | Table AA.12 – Condensed beat-by-beat summary matrix containing 11 elements .....                                                                                                                                      | 129 |
| 132 | Table AA.13 – Summary table (matrix format) of beat-by-beat comparison .....                                                                                                                                          | 129 |
| 133 | Table AA.14 – Example of a line-format couplet and run performance report .....                                                                                                                                       | 130 |
| 134 | Table AA.15 – Example of a line-format shutdown report .....                                                                                                                                                          | 131 |
| 135 | Table AA.16 – Example of a line-format report .....                                                                                                                                                                   | 133 |
| 136 | Table AA.17 – Example of vf performance report .....                                                                                                                                                                  | 134 |
| 137 | Table AA.18 – Example of false vf false positive report .....                                                                                                                                                         | 134 |
| 138 | Table AA.19—Example of a line-format report .....                                                                                                                                                                     | 140 |
| 139 | Table AA.20 – Example of definitions for test patterns 2-5 .....                                                                                                                                                      | 143 |
| 140 | Table AA.21 – Example of choice of test patterns .....                                                                                                                                                                | 143 |
| 141 | Table AA.22 – Example of RMS interval differences .....                                                                                                                                                               | 146 |
| 142 | Table AA.23 – Example of summary of frequency components .....                                                                                                                                                        | 147 |
| 143 | Table AA.24 – Example of noise floor calculation results .....                                                                                                                                                        | 147 |
| 144 | Table AA.25 – Example of device measurements of synthetic test patterns .....                                                                                                                                         | 148 |
| 145 | Table BB.1 – LEADS and their identification (nomenclature and definition) .....                                                                                                                                       | 2   |
| 146 | Table BB.2 – Additional ECG ELECTRODES positions, identifiers and colour codes. ....                                                                                                                                  | 2   |
| 147 | Table BB.3 – ecg electrode polarities .....                                                                                                                                                                           | 5   |
| 148 | Table BB.4 – Recommended identification and colour code for a 14-wire TRUNK CABLE .....                                                                                                                               | 6   |
| 149 | Table EE.1 – Calibration and analytical ECGs .....                                                                                                                                                                    | 29  |
| 150 | Table EE.2 – Data set for testing of measurement and wave recognition accuracy of biological data – 100 selected ECGs of the CSE-study with their numbering in the CSE database, to be used in 201.12.1.101.3.2 ..... | 30  |
| 151 | Table EE.3 – Data set for testing NOISE stability .....                                                                                                                                                               | 30  |
| 152 | Table FF.1 – Naming of signals (calibration ECGs) .....                                                                                                                                                               | 36  |
| 153 | Table FF.2 – Naming of signals (analytical ECGs) .....                                                                                                                                                                | 37  |
| 154 |                                                                                                                                                                                                                       |     |
| 155 |                                                                                                                                                                                                                       |     |
| 156 |                                                                                                                                                                                                                       |     |
| 157 |                                                                                                                                                                                                                       |     |
| 158 |                                                                                                                                                                                                                       |     |

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-86: Particular requirements for the basic safety and essential  
performance of electrocardiographic equipment, including diagnostic  
equipment, monitoring equipment, ambulatory equipment, electrodes,  
cables and lead wires**

## FOREWORD

# Sample Document

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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199 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is  
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203 International standard IEC 80601-2-86 has been prepared by a Joint Working Group of IEC  
204 subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical  
205 committee 62: Medical equipment, software, and systems and ISO subcommittee SC 3:  
206 Respiratory devices and related equipment used for patient care, of ISO technical committee  
207 121: Anaesthetic and respiratory equipment.

208 This first edition cancels and replaces the second edition of IEC 60601-2-25 published in 2011;  
209 the third edition of IEC 60601-2-27 published in 2011; and the second edition of IEC 60601-2-  
210 47 published in 2012. This edition constitutes a technical revision to align with Amendment  
211 1:2012 of IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

212 The text of this particular standard is based on the following documents:

| FDIS         | Report on voting |
|--------------|------------------|
| 62D/XXX/FDIS | 62D/XXX/RVD      |

213  
214 Full information on the voting for the approval of this particular standard can be found in the  
215 report on voting indicated in the above Table.

216 This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

217 In this standard, the following print types are used:

218 – Requirements and definitions: roman type.

219 – *Test specifications: italic type.*

220 – Informative material appearing outside of Tables, such as notes, examples and references: in smaller type.  
221 Normative text of Tables is also in a smaller type.

222 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS  
223 NOTED: SMALL CAPITALS.

224 In referring to the structure of this standard, the term

225 – “clause” means one of the eighteen numbered divisions within the Table of contents,  
226 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

227 – “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all  
228 subclauses of Clause 7).

229 References to clauses within this standard are preceded by the term “Clause” followed by the  
230 clause number. References to subclauses within this particular standard are by number only.

231 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any  
232 combination of the conditions is true.

233 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC  
234 Directives, Part 2. For the purposes of this standard, the auxiliary verb:

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235 – “shall” means that compliance with a requirement or a test is mandatory for compliance with  
236 this standard.

237 – “should” means that compliance with a requirement or a test is recommended but is not  
238 mandatory for compliance with this standard.

239 – “may” is used to describe a permissible way to achieve compliance with a requirement or  
240 test.

241 An asterisk (\*) as the first character of a title or at the beginning of a paragraph or Table title  
242 indicates that there is guidance or rationale related to that item in Annex AA.

243 A list of all parts of the IEC 60601 series, published under the general title *Medical electrical*  
244 *equipment*, can be found on the IEC website.

245 The committee has decided that the contents of this publication will remain unchanged until the  
246 stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to  
247 the specific publication. At this date, the publication will be

248 • reconfirmed,

249 • withdrawn,

250 • replaced by a revised edition, or

251 • amended.

252 NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment  
253 MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended  
254 or revised IEC publication in which to make products in accordance with the new requirements and to equip  
255 themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this  
256 publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

257 The National Committees are requested to note that for this document the stability date  
258 is 20xx.

259 This text is included for the information of the national committees and will be deleted at the  
260 publication stage.

261

262

263

## INTRODUCTION

264 This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of  
 265 electrocardiographic equipment, including diagnostic equipment, monitoring equipment,  
 266 ambulatory equipment, electrodes, cables and LEAD WIRES. It amends and supplements  
 267 IEC 60601-1:2005 (third edition), IEC 60601-1:2005/AMD1:2012 and IEC 60601-  
 268 1:2005/AMD2:2020: *Medical electrical equipment – Part 1: General requirements for basic*  
 269 *safety and ESSENTIAL PERFORMANCE* hereinafter referred to as the general standard.

270 The aim of this first edition is to bring this particular standard up to date with reference to the  
 271 third edition of the general standard through reformatting and technical changes. Furthermore,  
 272 the purpose of this is to also accomplish the following additional goals:

273 1) To combine the three ECG particular standards into one particular standard, which will  
 274 cover general ECG requirements as well as specific requirements for monitoring,  
 275 diagnostic, and ambulatory ECG systems.

276 2) Inclusion of previously omitted requirements from 60601-2-51.

277 3) Addition of requirements for ECG TRUNK CABLES and patient LEAD WIRES (ANSI/AAMI  
 278 EC53), DISPOSABLE ECG ELECTRODES (ANSI/AAMI EC12), and cardiac rhythm and ST  
 279 segment measurement algorithms (ANSI/AAMI EC57).

280 The requirements of this particular standard take priority over those of the general standard.

281 A “General guidance and rationale” for the more important requirements of this particular  
 282 standard is included in Annex AA. It is considered that knowledge of the reasons for these  
 283 requirements will not only facilitate the proper application of the standard but will, in due course,  
 284 expedite any revision necessitated by changes in clinical practice or as a result of developments  
 285 in technology. However, Annex AA does not form part of the requirements of this standard.

286

## MEDICAL ELECTRICAL EQUIPMENT –

### **Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographic equipment, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and lead wires**

#### **201.1 Scope, objective and related standards**

Clause 1 of the general standard<sup>1)</sup> applies, except as follows:

##### **201.1.1 \* Scope**

##### *Replacement:*

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of ECG ME EQUIPMENT and ACCESSORIES (including ECG ELECTRODES, TRUNK CABLES, and LEAD WIRES) as defined in 201.3.211, 201.3.240, and 201.3.222, hereinafter also referred to as ECG ME EQUIPMENT. Additional specific requirements apply to the ECG ME EQUIPMENT based on the INTENDED USE claimed by the MANUFACTURER for equipment intended for ECG PATIENT monitoring, diagnostic, or ambulatory use as defined in 201.3.226, 201.3.207 and 201.3.202 respectively. This particular standard applies to ECG ME EQUIPMENT for use in professional healthcare facilities as well as in EMERGENCY MEDICAL SERVICE ENVIRONMENTS and HOME HEALTHCARE ENVIRONMENTS. In addition, clauses may be applied to ACCESSORIES (including ECG ELECTRODES, TRUNK CABLES, and LEAD WIRES) or a part or parts of an ECG system (e.g. AMBULATORY ECG RECORDER).

The scope for each of these types of ECG ME EQUIPMENT are described as follows:

ECG ME EQUIPMENT Any ECG device or system or part of a system, including ECG ELECTRODES, TRUNK CABLES, and LEAD WIRES and interconnecting means, that acquires an ECG signal from the body surface of one PATIENT and/or displays, records, analyses, or transmits the resultant data for the purpose of diagnosing, treating, or monitoring that PATIENT. This includes any device or system or part of a system that meets the definition of MONITORING, DIAGNOSTIC, or AMBULATORY ECG ME EQUIPMENT as well as any other device that acquires and/or processes an ECG signal for the purpose of diagnosing, treating or monitoring a PATIENT based on the acquired body surface ECG signal. This does not include devices that are used for diagnosing, treating or monitoring PATIENTS based only on other types of cardiac signals such as magnetocardiographic signals or derived from other cardiac signals such as heart rate monitors derived from a photo plethysmograph or phonocardiograph. In addition, ECG ME EQUIPMENT does not include devices that are solely used for health and wellness (e.g. fitness trackers measuring heart rate solely to improve general wellness or athletic performance). However, devices that are part of consumer devices (such as watches, patches, body-worn devices and similar devices) that acquired an ECG and displays, records, analyses, and/or transmits the ECG for the purpose of diagnosing, treating or monitoring the PATIENT are included in the scope of an ECG ME EQUIPMENT. This does not include external defibrillators unless they have an INTENDED USE for making a diagnosis, monitoring or treatment from the ECG waveform in addition to the function of delivering a defibrillation shock based on the ECG.

This does not include direct fetal ECG equipment and Fetal & Maternal MONITORING EQUIPMENT

328

329 Note: Fetal & Maternal Monitor: A Fetal-Maternal monitor that non-invasively measures and displays Fetal heart rate  
 330 (FHR), Maternal heart rate (MHR) and uterine activity (UA). The equipment acquires and displays the FHR & MHR  
 331 tracing from abdominal surface ELECTRODES that pick up the Fetal ECG (FECG) and Maternal ECG (MECG) signal.

332 Note: while this standard applies to certain EQUIPMENT, manufacturers may consider relevant requirements of this  
 333 standards for testing similar equipment not in scope.

#### 334 **DIAGNOSTIC ECG ME EQUIPMENT**

335 Any ECG ME EQUIPMENT that acquires and/or displays, records, analyzes, or transmits a 12 LEAD<sup>2</sup>  
 336 ECG signal for the purpose of diagnosis from the interpretation of the cardiac rhythm, conduction,  
 337 and waveform contour. This includes any device that acquires diagnostic resting ECG as well as  
 338 any other type of ECG ME EQUIPMENT that claims to have the capability of acquiring a diagnostic  
 339 12 LEAD ECG. Devices which have multiple purposes and include the DIAGNOSTIC ECG ME EQUIPMENT  
 340 definition in the INTENDED USE are included within this scope.

#### 341 **AMBULATORY ECG ME EQUIPMENT**

342 Any ECG ME EQUIPMENT that acquires and/or displays, records, analyzes, or transmits an ECG  
 343 signal from an ambulatory PATIENT. Examples of AMBULATORY ECG ME EQUIPMENT include Holter  
 344 systems and continuous long-term ambulatory full disclosure recording systems; Holter  
 345 recorders, mobile cardiac telemetry and long-term ambulatory patch recorders, event recorders,  
 346 and non-continuous loop recorders. Devices which have multiple purposes and include the  
 347 AMBULATORY ECG ME EQUIPMENT definition in the INTENDED USE are included within this scope.

#### 348 **MONITORING ECG ME EQUIPMENT**

349 Any ECG ME EQUIPMENT that acquires and/or displays, records, analyzes, or transmits an ECG for the  
 350 purpose of monitoring the cardiac activity of one PATIENT and devices used as part of an ALARM SYSTEM.  
 351 This includes displaying ECG, displaying measurements such as heart rate, and generating alarms based  
 352 on analysis of the ECG. It also includes devices where ECG or ECG-derived information device is  
 353 intended to be relied upon in deciding to take immediate clinical action. Examples of MONITORING ECG  
 354 EQUIPMENT include ECG and hardwired bedside patient monitors, telemetry systems, and other system  
 355 used to identify of patient conditions requiring intervention based on manual and/or automated analysis  
 356 of the ECG signal.

#### 357 **ECG TRUNK CABLES and PATIENT LEAD WIRES**

358 ECG TRUNK CABLES and PATIENT LEAD WIRES that are used in applications that require special  
 359 characteristics, such as a magnetic resonance imaging (MRI) suite, are excluded from this standard.  
 360 However, non-MRI ECG TRUNK CABLES and PATIENT LEAD WIRES must meet all of the requirements of this  
 361 standard, unless a requirement is specifically excluded.

#### 362 **ECG ELECTRODES**

363 This standard establishes minimum labeling, safety, and performance requirements for disposable ECG  
 364 ELECTRODES.

365 Included within the scope of this standard is any disposable ECG ELECTRODE SYSTEM

366 ELECTRODES excluded from the scope of this standard are active ELECTRODES, needle ELECTRODES,  
 367 reusable (non-disposable) ELECTRODES, ELECTRODES intended to deliver therapeutic energy, and  
 368 ELECTRODES intended solely for the measurement of physiologic signals other than the  
 369 ELECTROCARDIOGRAM (e.g., ELECTRODES used with apnea monitors, if the ELECTRODE is solely used for

<sup>2</sup> Unless otherwise specified, the term 12 LEAD indicates 12 or more LEADS, including at least the limb LEADS and precordial LEADS, as defined elsewhere in this document.

370 non-ECG purposes, e.g., impedance plethysmography). Also, requirements for electrolyte composition  
371 are not covered by this standard.

## 372 **201.1.2 Object**

373 *Replacement:*

374 The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE  
375 requirements for ECG ME EQUIPMENT.

### 376 **201.1.2.101 \* Organization of this particular standard**

377 The requirements in this particular standard are organized into the following types of  
378 requirements:

- 379 1) General requirements – all requirements are considered general requirements and apply  
380 to all types of ECG ME EQUIPMENT unless explicitly noted.
- 381 2) Diagnostic requirements specific to DIAGNOSTIC ECG ME EQUIPMENT will be explicitly  
382 identified as such.
- 383 3) Monitoring requirements specific to MONITORING ECG ME EQUIPMENT will be explicitly  
384 identified as such.
- 385 4) Ambulatory requirements specific to AMBULATORY ECG ME EQUIPMENT will be explicitly  
386 identified as such.

387 Additionally, the following requirements have been added to this particular standard:

- 388 • ECG TRUNK CABLE and LEAD WIRES, as in ANSI/AAMI EC53. These requirements apply  
389 to any ECG ME EQUIPMENT, including MONITORING, DIAGNOSTIC, AND AMBULATORY ECG  
390 ME EQUIPMENT.
- 391 • DISPOSABLE ECG ELECTRODE, as in ANSI/AAMI EC12. These requirements apply to  
392 any ECG ME EQUIPMENT that includes DISPOSABLE ECG ELECTRODES as an APPLIED PART.
- 393 • Requirements from the last edition of 60601-2-51 that were omitted when it was  
394 combined with 60601-2-25.

395 A summary of requirements for compliance to this standard for ECG ME EQUIPMENT are listed in  
396 Table AA.1 – AA.4 in Annex AA.

## 397 **201.1.3 Collateral standards**

398 *Addition:*

399 This particular standard refers to those applicable collateral standards that are listed in Clause  
400 2 of the general standard and Clause 201.2 of this particular standard.

401 IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, and IEC 60601-1-8:2006, IEC  
402 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020 apply as modified in Clauses  
403 202 and 208 respectively. All other published collateral standards in the IEC 60601-1 series  
404 apply as published.

#### 405 **201.1.4 Particular standards**

##### 406 *Replacement:*

407 In the IEC 60601 series, particular standards may modify, replace or delete requirements  
 408 contained in the general standard and collateral standards as appropriate for the particular ECG  
 409 ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL  
 410 PERFORMANCE requirements.

411 A requirement of a particular standard takes priority over the general standard.

412 For brevity, IEC 60601-1 is referred to in this particular standard as the general standard.  
 413 Collateral standards are referred to by their document number.

414 The numbering of clauses and subclauses of this particular standard corresponds to that of the  
 415 general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of  
 416 Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where  
 417 x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular  
 418 standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in  
 419 this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral  
 420 standard, etc.). The changes to the text of the general standard are specified by the use of the  
 421 following words:

422 “Replacement” means that the clause or subclause of the general standard or applicable  
 423 collateral standard is replaced completely by the text of this particular standard.

424 “Addition” means that the text of this particular standard is additional to the requirements of the  
 425 general standard or applicable collateral standard.

426 “Amendment” means that the clause or subclause of the general standard or applicable  
 427 collateral standard is amended as indicated by the text of this particular standard.

428 Subclauses, Figures or Tables which are additional to those of the general standard are  
 429 numbered starting from 201.101. However, because definitions in the general standard are  
 430 numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning  
 431 from 201.3.201. Additional Annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

432 Subclauses, Figures or Tables which are additional to those of a collateral standard are  
 433 numbered starting from 20x, where “x” is the final digit(s) of the collateral standard, e.g. 202 for  
 434 IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

435 The term “this standard” is used to reference to the general standard, any applicable collateral  
 436 standards and this particular standard taken together.

437 Where there is no corresponding clause or subclause in this particular standard, the clause or  
 438 subclause of the general standard or applicable collateral standard, although possibly not  
 439 relevant, applies without modification; where it is intended that any part of the general standard  
 440 or applicable collateral standard, although possibly relevant, is not to be applied, a statement  
 441 to that effect is given in this particular standard.

#### 442 **201.2 Normative references**

443 Clause 2 of the general standard applies, except as follows:

##### 444 *Replacement:*