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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

Appareils électromédicaux —

Partie 2-86: Exigences générales pour la sécurité de base et les performances essentielles des électrocardiographes, comprenant les appareils de diagnostic, les appareils de surveillance, les appareils à usage ambulatoire, les électrodes, les câbles et les câbles de dérivation

ICS: 11.040.55; 11.040.10

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This draft is submitted to a parallel vote in ISO and in IEC.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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International standard IEC 80601-2-86 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems and ISO subcommittee SC 3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment.

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

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

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

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

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

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

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

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

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

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

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

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees and Member Bodies 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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

The National Committees are requested to note that for this document the stability date is 20xx. This text is included for the information of the national committees and will be deleted at the publication stage.

INTRODUCTION

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

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

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

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

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

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

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

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[1)] 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

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

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

DIAGNOSTIC ECG ME EQUIPMENT

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

AMBULATORY ECG ME EQUIPMENT

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

MONITORING ECG ME EQUIPMENT

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

ECG TRUNK CABLES and PATIENT LEAD WIRES

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

ECG ELECTRODES

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

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

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

[2] 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.

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

201.1.2 Object

Replacement:

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

201.1.2.101 * Organization of this particular standard

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

1) General requirements – all requirements are considered general requirements and apply to all types of ECG ME EQUIPMENT unless explicitly noted.

2) Diagnostic requirements specific to DIAGNOSTIC ECG ME EQUIPMENT will be explicitly identified as such.

3) Monitoring requirements specific to MONITORING ECG ME EQUIPMENT will be explicitly identified as such.

4) Ambulatory requirements specific to AMBULATORY ECG ME EQUIPMENT will be explicitly identified as such.

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

- ECG TRUNK CABLE and LEAD WIREs, as in ANSI/AAMI EC53. These requirements apply to any ECG ME EQUIPMENT, including MONITORING, DIAGNOSTIC, AND AMBULATORY ECG ME EQUIPMENT.

- DISPOSABLE ECG ELECTRODE, as in ANSI/AAMI EC12. These requirements apply to any ECG ME EQUIPMENT that includes DISPOSABLE ECG ELECTRODES as an APPLIED PART.

- Requirements from the last edition of 60601-2-51 that were omitted when it was combined with 60601-2-25.

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

201.1.3 Collateral standards

Addition:

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

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

Replacement:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, *Medical electrical equipment – Part 1-2: General requirements for basic safety and ESSENTIAL PERFORMANCE – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, *Medical electrical equipment – Part 1-8: General requirements for basic safety and ESSENTIAL PERFORMANCE – Collateral standard: General requirements, tests and guidance for* ALARM SYSTEMS *in medical electrical equipment and medical electrical systems*

Addition:

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and ESSENTIAL PERFORMANCE of high frequency surgical equipment and high frequency surgical accessories*

201.3 *Terminology and definitions

For the purposes of this document, the terms and definitions given in the general standard apply, except as follows:

Addition:

201.3.1 AMBULATORY ECG ME EQUIPMENT

ANY ECG ME EQUIPMENT that acquires an ECG signal from an ambulatory PATIENT.

201.3.2 AMBULATORY ECG RECORDER

ECG ME EQUIPMENT connected to the PATIENT including associated ECG ELECTRODES and cables for recording an ECG signal from an ambulatory PATIENT.

Note to entry: An AMBULATORY ECG RECORDER may also analyze the heart action potentials. It may record selectively when significant events are detected, or continuously.

201.3.3 DC OFFSET VOLTAGE

Voltage across an ECG ELECTRODE pair due to the difference in their ECG ELECTRODE half-cell potentials.

201.3.4 DEFIBRILLATION PROOF

ECG ME EQUIPMENT and its APPLIED PARTS that are designed with protection against the effect of a discharge of a cardiac defibrillator to the PATIENT and recovers operation after a defibrillation discharge.

Note to entry: DEFIBRILLATION PROOF equipment also shall not shunt an excessive current from the defibrillation discharge.

201.3.5 DEFIBRILLATION SAFE

ECG ME EQUIPMENT and its APPLIED PARTS that are designed to not cause harm to the PATIENT if left applied during a discharge of an external cardiac defibrillator.

Note: In case of defibrillation, a DEFIBRILLATION SAFE equipment shall not shunt an excessive current from the defibrillation discharge shall not cause harm otherwise shall not cause harm otherwise (e.g., shall not explode, shall not fail in a way that causes electrocution to the PATIENT, etc.); however, a DEFIBRILLATION SAFE device does not need to recover after defibrillation and may be temporarily or permanently damaged by the defibrillation shock.

201.3.6 DIAGNOSTIC ECG ME EQUIPMENT

ANY ECG ME EQUIPMENT intended for the acquisition of 12 or more LEADs of ECG for the purpose of diagnosis from the interpretation of the cardiac rhythm, conduction, and waveform contour. This includes any device that acquires diagnostic resting ECG as well as any other type of ECG ME EQUIPMENT that claims to have the capability of acquiring a diagnostic 12 LEAD ECG.

Note **to entry**: electrode placements for the standard 12 LEAD ECG are described in Table 201.102 and the standard 12 LEAD ECG formation is described in Table BB.1

201.3.7 DISPOSABLE ECG ELECTRODE

AN ECG ELECTRODE designed for single application for a single PATIENT use that is adhered to the PATIENT body surface using adhesive and has a conductive interface based on electrolyte solution (electrolyte solution may be stabilized in gel/paste or sponge material and either included in the electrode assembly and/or intended to be added separately).

201.3.8 ELECTROCARDIOGRAM (ECG)

Voltage difference over time associated with cardiac activity, including its graphical representation or digital recording. ECG is acquired from the body surface by means of electrodes and usually displayed, stored, transmitted or reported as LEADs.

201.3.9 *ECG ELECTRODE

Sensor in contact with a specified part of the body to detect electrical cardiac activity.

201.3.10 ECG ELECTRODE IMPEDANCE

A combined measure of the opposition to current through the ECG ELECTRODE interface (resistance) and of the ability to store charge at the interface (capacitive reactance), in response to a current. An alternating current is used to measure both components of impedance.

201.3.11 ECG ELECTRODE SYSTEM

Device composed of two or more sensing elements and an electrolyte provided with the sensing elements by the MANUFACTURER or specified by the MANUFACTURER.

Note **to entry**: Conventional sensing elements may be PRE-GELLED ECG ELECTRODES or be a conductive semisolid, or it may require application of an electrolyte by the end user according to MANUFACTURER's instructions (non-PRE-GELLED ECG ELECTRODES). Alternatively, dry ECG ELECTRODE or new conductive interfaces technologies also exist that may be used as the sensing interface.

201.3.12 *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 displays, records, analyzes, 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 ECG ME EQUIPMENT, DIAGNOSTIC ECG ME EQUIPMENT, 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.

Note **to entry** : This includes both systems that process or display the ECG real time (i.e. as the data is acquired), near real-time (i.e. as the data is acquired but with a delay) and non-real time (i.e. after the data acquisition has

been completed), both continuous and non-continuous acquisition of the ECG signal, and both hardwire and telemetric acquisition of data.

201.3.13 ECG REPORT

Output data from a recorded ECG, which may be in the form of a PERMANENT DISPLAY output (hard copy), NON-PERMANENT DISPLAY output, or a stored digital record

Note 1 to entry: The output data may also include associated data such as the date and time that ECG was acquired, PATIENT identification, ECG acquisition parameters, computerized analysis results, etc.

Note 2 to entry: ECG ME EQUIPMENT may be recording-only devices and output ECG REPORT data in only the form of digital data record and do not have either a NON-PERMANENT DISPLAY or a PERMANENT DISPLAY.

201.3.14 * GAIN

The ratio of the amplitude of the displayed output signal to the amplitude of the input signal

Note to entry: GAIN is expressed in mm/mV.

201.3.15 GAIN INDICATOR

Graphical indication on a PERMANENT DISPLAY or NON-PERMANENT DISPLAY that allows the clinical OPERATOR to visually estimate the amplitude of the ECG input signal

201.3.16 HEARTRATE VARIABILITY (HRV)

Statistical results calculated from consecutive RR intervals

201.3.17 INSTRUMENT CONNECTOR

Connector that attaches the TRUNK CABLE to the receptacle on the ECG ME EQUIPMENT

201.3.18 LEAD

Voltage between ECG ELECTRODEs or between a combination of ECG ELECTRODEs

201.3.19 LEAD SELECTOR

System to select certain LEADs

201.3.20 LEAD WIRE

Individual wire connected between an ECG ELECTRODE and either a TRUNK CABLE YOKE or to the ECG ME EQUIPMENT

Note to entry: individual LEAD WIRES may be bonded together, for example as a ribbon cable, in which case the LEAD WIRES and TRUNK CABLE are one ASSEMBLY that does not have a TRUNK CABLE YOKE.

201.3.21 LEAD WIRE CONNECTOR

The connector that attaches the LEAD WIRE to the CABLE YOKE or to the ECG ME EQUIPMENT

201.3.22 MONITORING ECG ME EQUIPMENT

ECG ME EQUIPMENT that acquires and/or analyzes an ECG for the purpose of monitoring the cardiac activity of one PATIENT and devices used as part of an ALARM SYSTEM. This includes

displaying ECG, analyzing the ECG, displaying analysis results such as heart rate or measurements, and generating alarms based on the ECG analysis. It also includes devices where ECG or ECG-derived information device is intended to be relied upon in deciding to take immediate clinical action.

Note **to entry**: Examples of MONITORING ECG EQUIPMENT include ECG and hardwire bedside patient monitors, telemetry systems, and other system used to identify of patient conditions requiring intervention based on manual and/or automated analysis of the ECG signal. An ECG telemetry transmitter and receiver including its associated display of one PATIENT's data forms an ECG ME EQUIPMENT. ECG telemetry is typically used to display that data of a PATIENT at a remote location. Implementations of these remote displays frequently display data from several PATIENTS at the same time but logically separate the data of each PATIENT on such a display.

201.3.23 MULTI-PATIENT USE

Products specifically not labeled for SINGLE USE or SINGLE-PATIENT USE

201.3.24 NEUTRAL ECG ELECTRODE

Electrode used as reference point for differential amplifiers and/or interference suppression circuits, not intended to be used to calculate any LEAD, or alternatively, the neutral electrode may be defined as another electrical connection, in which case the manufacture shall specify what this connection is for testing purposes

Note **to entry**: A NEUTRAL ECG ELECTRODE is sometimes referred to as a reference ECG ELECTRODE. Some devices may not include a NEUTRAL ECG ELECTRODE and instead using internal circuitry not in contact with the PATIENT.

201.3.25 NOISE

Unwanted signals of any frequency present in the ELECTROCARDIOGRAM.

201.3.26 NON-PERMANENT DISPLAY

Non-persistent presentation of an ELECTROCARDIOGRAM.

Note **to entry**: examples of NON-PERMANENT DISPLAYS are a display screen across which an ECG WAVEFORM is moving; a display screen where a static ECG waveform is displayed. In case of ECG ME EQUIPMENT intended to use accessories (e.g., external display, mobile phones, etc.) for NON-PERMANENT DISPLAY, test shall be conducted using such accessories according to the intended use and instructions. A representative worst-case (or worst-cases) may be used for testing.

201.3.27 NORMAL GAIN

GAIN of 10 mm/mV.

201.3.28 * PERMANENT DISPLAY

Persistent presentation of an ELECTROCARDIOGRAM.

Note **to entry** Examples of PERMANENT DISPLAYS are hardcopy printouts of an ECG and electronic representation of such printout.

201.3.29 PRE-GELLED ECG ELECTRODE

ECG ELECTRODE in which the ELECTRODE MANUFACTURER has placed the electrolyte in contact with the sensing element.

201.3.30 RHYTHM EVENT

Any type of cardiac rhythm of clinical interest which is automatically detected by the device (e.g., pause, etc.).

201.3.31 * SHUTDOWN

Period of time when detection/classification functions are not performed by an ECG analysis program, or (if the system includes automate signal quality detector) periods of time when signal quality is detected as inadequate.

201.3.32 SINGLE USE

Products specifically labeled as being for a single use on a single PATIENT.

201.3.33 SINGLE-PATIENT USE

Products specifically labeled as being for longer term use on a single PATIENT only.

201.3.34 TECHNICAL FILE

Documents generated and maintained to demonstrate and support conformity with requirements of this or other International Standard and compliance with applicable regulatory requirements. The content of the file(s) include, but is not limited to:

a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
b) specifications for product;
c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
d) procedures for measuring and monitoring;
e) as appropriate, requirements for installation;
f) as appropriate, procedures for servicing.

201.3.35 TOTAL SHUTDOWN TIME

Amount of time during the test period for each record that the algorithm is not performing its detection/classification function, or (if the system includes automate signal quality detector) the amount of time the signal quality is detected as inadequate. For each record, it is expressed in minutes and seconds in the format MM:SS.

201.3.36 TRUNK CABLE

Portion of the cable and LEAD WIRE assembly within which all wires are bundled together in one jacket or are in some way bound permanently together and used to connect LEAD WIREs to ECG ME EQUIPMENT.

Note to entry: Individual LEAD WIREs may be bonded together, for example as a ribbon cable, in which case the LEAD WIREs and TRUNK CABLE are one ASSEMBLY that does not have a TRUNK CABLE YOKE.

201.3.37 TRUNK CABLE YOKE

End of the TRUNK CABLE into which all the LEAD WIREs plug.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE of ECG ME EQUIPMENT

Addition:

201.4.3.101 *Additional ESSENTIAL PERFORMANCE requirements