IEC 80601-2-26

Edition 1.1 2024-02
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

Appareils électromédicaux –
Partie 2-26: Exigences particulières pour la sécurité de base et les performances essentielles des électroencéphalographes



IEC 80601-2-26:2019-05+AMD1:2024-02 CSV(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8318-9

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IEC 80601-2-26

Edition 1.1 2024-02
CONSOLIDATED VERSION

REDLINE VERSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

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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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-26 edition 1.1 contains the first edition (2019-05) [documents 62D/1666/FDIS and 62D/1681/RVD] and its corrigendum 1 (2021-10), and its amendment 1 (2024-02) [documents 62D/2106/FDIS and 62D/2115/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 80601-2-26 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This publication is published as a double logo standard.

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.

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

In this document, 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 document, the term

– "clause" means one of the seventeen 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 80601 International Standard, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document and its amendment will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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 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.

IMPORTANT – The "colour inside" logo on the cover page of this document 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.

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS. It amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The aim of this document is to bring this particular standard up to date with reference to ~~the edition 3.1 of the general standard and new versions of collateral standards and amendments thereto~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020 and IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 through technical changes.

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 document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS as defined in 201.3.204, hereafter also referred to as ME EQUIPMENT or ME SYSTEM. This document is applicable to ELECTROENCEPHALOGRAPHS intended for use in professional healthcare facilities, the EMERGENCY MEDICAL SERVICES ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

This document does not cover requirements for other equipment used in electroencephalography such as:

– phono-photic stimulators;
– EEG data storage and retrieval;
– ME EQUIPMENT particularly intended for monitoring during electroconvulsive therapy.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title or content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as follows.

The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the corresponding safety measure or function not completely integrated into the ME EQUIPMENT but instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER specifies in the ACCOMPANYING DOCUMENTS which functionality and safety requirements are provided by the ME SYSTEM to comply with this document. The ME SYSTEM is verified accordingly.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROENCEPHALOGRAPHS as defined in 201.3.204.

1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601 1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:~~2013~~2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply as modified in Clause 202 and 206, respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 do not apply. 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 ME EQUIPMENT or ME SYSTEM under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular ~~standard~~ document 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 document 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, etc.). The changes to the text of the general standard and applicable collateral standards 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 due to the fact that definitions in the general standard are numbered 3.1 through ~~3.147~~ 3.154, additional definitions in this document 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 number of the collateral standard, e.g. 202 for IEC 60601-1-2, etc.

The term "this document" is used to make 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

NOTE Informative references are listed in the Bibliography.

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

Replacement:

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

IEC 60601-1-6:~~2013~~2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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 equipment and medical electrical systems used in the home healthcare environment*
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 equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

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 Terms and definitions

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:~~2013~~2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014, IEC 60601-1-12:2014/AMD1:2020, IEC 60601-2-2:2017 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 37.

Addition:

201.3.201
CHANNEL
hardware and/or software selection of a particular electroencephalographic voltage between ELECTRODES for purposes of display, recording, or transmission

201.3.202
ELECTRODE
sensor that is applied to the scalp, cerebral cortex, or subdural locations to detect electrical activity of the brain

201.3.203
ELECTROENCEPHALOGRAM
EEG
presentation (on screen or paper) of the variation with time of voltages taken from ELECTRODES, whose positions are specified

201.3.204
ELECTROENCEPHALOGRAPH
ME EQUIPMENT or ME SYSTEM to produce an ELECTROENCEPHALOGRAM

201.3.205
LEAD WIRE
cable connected between an ELECTRODE and either a PATIENT CABLE or the ELECTROENCEPHALOGRAPH

201.3.206
NEUTRAL ELECTRODE
reference point for differential amplifiers and/or interference suppression circuits

201.3.207
PATIENT CABLE
multiwire cable or junction box used to connect LEAD WIRES to the ELECTROENCEPHALOGRAPH

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of amplitude and rate of variation	201.12.1.102
Input dynamic range and differential offset voltage	201.12.1.103
Input noise	201.12.1.104
Frequency response	201.12.1.105
Common mode rejection	201.12.1.106
or	
Indication of invalid data	201.12.4.101

For ELECTROENCEPHALOGRAPHS having more than 10 identical EEG CHANNELS, testing 10 of these CHANNELS is sufficient to verify ESSENTIAL PERFORMANCE.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Addition:

aa) If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE may be replaced by an external battery or DC power supply to provide the necessary test voltage.

bb) The values used in test circuits, unless otherwise specified, shall have at least an accuracy as given below:

- resistors: ±1 %;
- capacitors: ±10 %;
- inductors: ±10 %;
- test voltages: ±1 %.

201.5.8 * Sequence of tests

Replacement:

Tests called for in 201.8.5.5.1 of this particular standard and in 8.5.5 of the general standard shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in 8.7 and 8.8 of the general standard and prior to the tests specified in 201.12.1.102 to 201.12.1.106 of this particular standard.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.6 Mode of operation

Replacement:

ELECTROENCEPHALOGRAPHS shall be classified for CONTINUOUS OPERATION.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.1 * Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

Addition:

If the ELECTROENCEPHALOGRAPH is specified as being protected against the effects of defibrillation:

Parts of the ELECTROENCEPHALOGRAPH (for example PATIENT CABLES) specified as being protected against the effects of defibrillation shall be marked with symbol 26 or 27 of Table D.1 of the general standard according to the classification as TYPE BF APPLIED PART or TYPE CF APPLIED PART.

201.7.9.2 Instructions for use

201.7.9.2.2 Warning and safety notices

Addition:

If protection against the effects of defibrillation is provided (see 201.8.5.5.1), the instructions for use shall include a warning that defibrillator protection requires the use of MANUFACTURER-specified ACCESSORIES, including PATIENT CABLES and LEAD WIRES.

Additional subclause:

201.7.9.2.101 Additional instructions for use

The instructions for use shall also include the following.

a) The INTENDED USE including environment of use.

   Likely misuse should be identified by RISK ANALYSIS and disclosed, if necessary (e.g. "not suitable for electro-cerebral inactivity (ECI) determination").

b) The procedures necessary for safe operation.

c) Conductive parts of ELECTRODES and associated connectors for APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth.

d) Information whether the ELECTROENCEPHALOGRAPH incorporates means to protect the PATIENT against burns when used with HF SURGICAL EQUIPMENT and advice regarding the location of ELECTRODES and LEAD WIRES etc., to reduce the HAZARD of burns in the event of a defect in the NEUTRAL ELECTRODE connection of the HF SURGICAL EQUIPMENT.

e) * The need for regular testing of the ELECTROENCEPHALOGRAPH and its ACCESSORIES.

f) Precautions to take when using a defibrillator on a PATIENT, if APPLIED PARTS not protected against the effects of defibrillation are being used; a description of how the discharge of a defibrillator affects the ELECTROENCEPHALOGRAPH.

g) The subsequent operation of the ELECTROENCEPHALOGRAPH after interruption of SUPPLY MAINS exceeding 30 s (see 201.11.8).

h) Any HAZARD due to simultaneous use of other PATIENT-connected ME EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators.

i) Technical specifications for the ELECTROENCEPHALOGRAPH of sufficient detail to allow the OPERATOR to understand what is being measured and any limitations. Minimally this shall include:

   – accuracy of signal reproduction;

- input dynamic range and maximum offset voltage;
- noise;
- frequency range and bandwidth;
- common mode rejection
- a description of all functions;
- a description of waveform displays (if applicable).

j) * Any known susceptibilities to electromagnetic phenomena.

k) If applicable, limitations of multipurpose CHANNELS (e.g. that these CHANNELS are not suitable for monitoring and of ECG or EMG) and to which clauses of applicable standards (e.g. IEC 80601-2-xx) they were tested, if any.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.1 Fundamental rule of protection against electrical shock

Additional subclause:

201.8.1.101 * Multipurpose CHANNEL(S)

If the ELECTROENCEPHALOGRAPH allows CHANNELS to be used for signals other than EEG, then this facility shall be tested to applicable clauses of relevant standards as specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection.

201.8.5.2.3 * PATIENT leads or PATIENT cables

Addition:

Any detachable ELECTRODE connector of a LEAD WIRE shall, when separated from the ELECTRODE, have an air clearance between connector pins and a flat surface of at least 0,5 mm.

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

201.8.5.5.1 * Defibrillation protection

Addition:

If protection against the effects of defibrillation is provided, the ELECTROENCEPHALOGRAPH shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as specified in this particular standard within 30 s after exposure to the defibrillation voltage.

For defibrillator testing, the ELECTROENCEPHALOGRAPH shall be operated using the PATIENT CABLES and LEAD WIRES specified by the MANUFACTURER.

- Common mode test

Addition:

Compliance is checked according to Figure 201.101.

For ELECTROENCEPHALOGRAPHS of CLASS I, apply the test voltage between all LEAD WIRES (E_1...E_x), including the NEUTRAL ELECTRODE E_N, connected together and the PROTECTIVE EARTH TERMINAL. Energize the ELECTROENCEPHALOGRAPH for these tests.

For ELECTROENCEPHALOGRAPHS of CLASS II and ELECTROENCEPHALOGRAPHS with an INTERNAL ELECTRICAL POWER SOURCE, apply the test voltage between all LEAD WIRES (E_1...E_x), including the NEUTRAL ELECTRODE E_N, connected together and the FUNCTIONAL EARTH TERMINAL or metal foil in close contact with the ENCLOSURE. Energize the ELECTROENCEPHALOGRAPH for these tests.

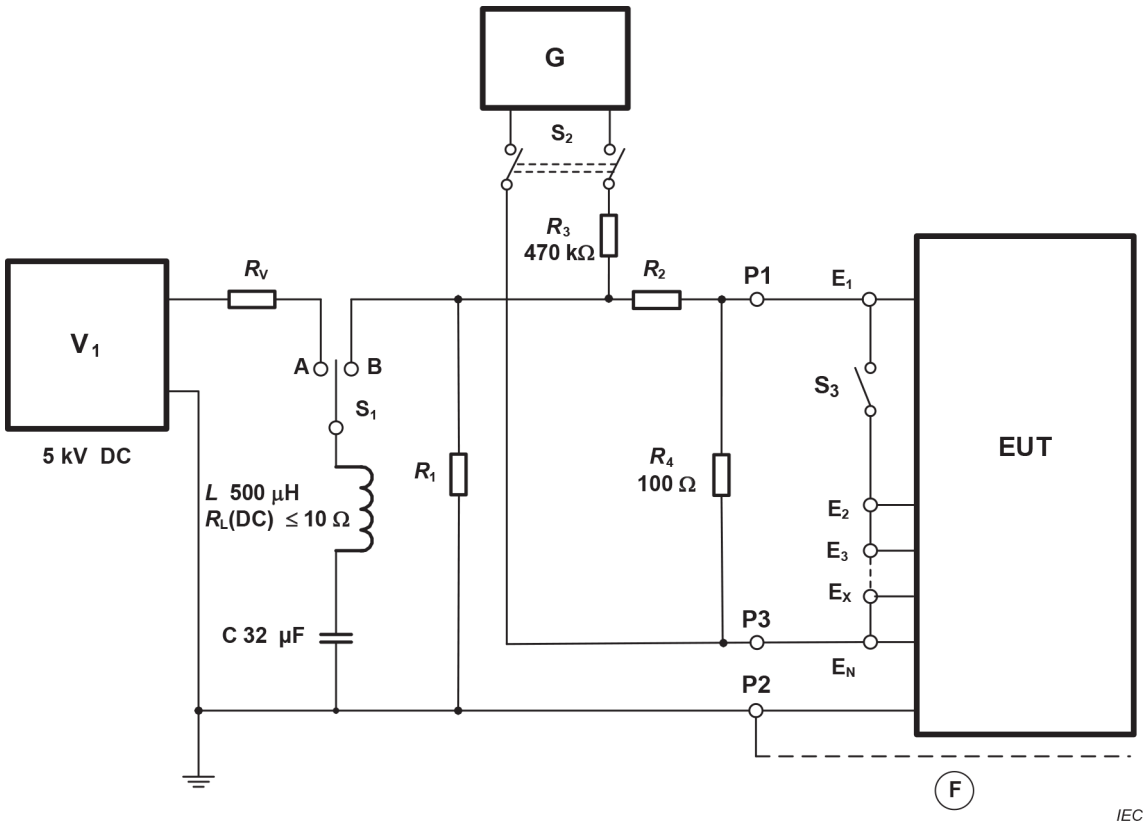
Test ELECTROENCEPHALOGRAPHS having an INTERNAL ELECTRICAL POWER SOURCE, which is rechargeable from the SUPPLY MAINS, with and without the SUPPLY MAINS connection, if the ELECTROENCEPHALOGRAPH is capable of operating while connected to SUPPLY MAINS.

Set the scale of the ELECTROENCEPHALOGRAPH such that a 0,5 mV peak-to-valley signal can be displayed without clipping. With S_2 closed and S_3 open, adjust the amplitude of the 10 Hz sine wave generator to produce a 0,25 mV peak-to-valley output signal. Open switch S_2 and close S_3.

Connect S_1 to position A and charge the capacitor C. After about 10 s, connect S_1 to position B for 200 ms ± 50 %. Open S_1 to remove residual voltages from the ELECTROENCEPHALOGRAPH.

Immediately close S_2 and open S_3. Verify that after 30 s the recorded test signal is within 0,2 mV to 0,3 mV peak-to-valley and the ELECTROENCEPHALOGRAPH resumed normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data.

Repeat the above test with the polarity of the high voltage source reversed. Repeat the tests with positive and negative polarities 5 times.



Components

G	sine wave generator 10 Hz
V_1	high voltage source 5 kV DC
Ⓕ	foil, simulating capacitance for CLASS II or INTERNALLY POWERED ELECTROENCEPHALOGRAPHS
S_1	switch; max. load 60 A, 5 kV
S_2	switch activating the signal source
S_3	switch connecting LEAD WIRE E_1 to remaining LEAD WIRES
R_1	100 Ω ±10 %, 5 kV dielectric strength, 400 J pulse energy dissipation capability, low inductance
R_2	50 Ω ±10 %, 5 kV dielectric strength, 400 J pulse energy dissipation capability, low inductance
R_L	DC resistance of inductance L
R_V	current limiting resistor
P1, P2, P3	connecting points for EUT (includes PATIENT CABLE and LEAD WIRES)

Figure 201.101 – Test of protection against the effects of defibrillation (common mode)

- Differential mode test

Addition:

Compliance is checked by the following test:

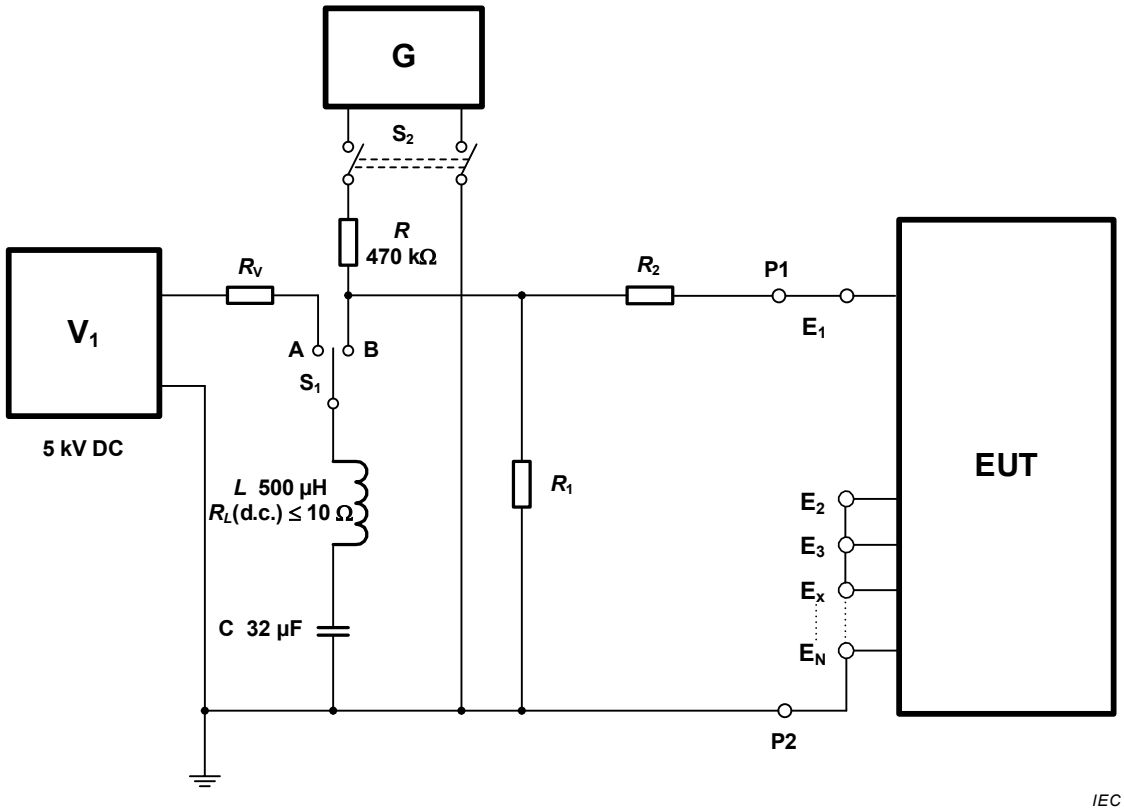
The ELECTROENCEPHALOGRAPH is connected to the test circuit shown in Figure 201.102. The test voltage is applied to each LEAD WIRE in turn with all the remaining LEAD WIRES being connected to earth. Initially, the test is conducted applying the test voltage between the E_1 LEAD WIRE and all remaining LEAD WIRES (E_2...E_x and E_N) connected to earth. The ELECTROENCEPHALOGRAPH shall be energized for these tests.

Set the scale of the ELECTROENCEPHALOGRAPH such that a 0,5 mV peak-to-valley signal can be displayed without clipping. With S_2 closed, adjust the amplitude of the 10 Hz sine wave generator to produce a 0,25 mV peak-to-valley output signal. Open switch S_2.

Connect S_1 to position A and charge the capacitor C. After about 10 s, connect S_1 to position B for 200 ms ± 50 %. Open S_1 to remove residual voltages from the ELECTROENCEPHALOGRAPH.

Immediately close S_2. Verify that after 30 s the recorded test signal is within 0,2 mV to 0,3 mV peak-to-valley and the ELECTROENCEPHALOGRAPH has resumed normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data.

Repeat the test for any other LEAD WIRE with all remaining LEAD WIRES connected to earth.



Components

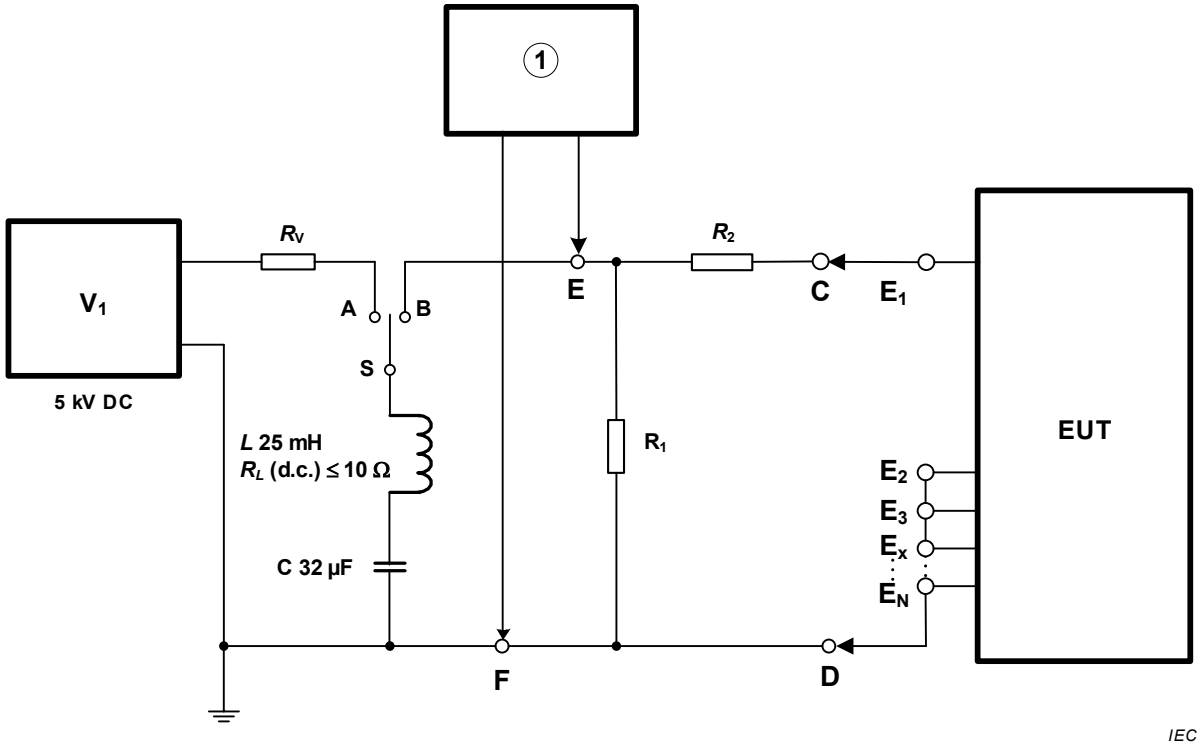
G	sine wave generator 10 Hz
V_1	high voltage source 5 kV DC
S_1	switch; max. load 60 A, 5 kV
S_2	switch activating the signal source
R_1	100 Ω ± 10 %, 5 kV dielectric strength, 400 J pulse energy dissipation capability, low inductance
R_2	50 Ω ± 10 %, 5 kV dielectric strength, 400 J pulse energy dissipation capability, low inductance
R_L	DC resistance of inductance *L*
R_V	current limiting resistor
P1, P2	connecting points for EUT (includes PATIENT CABLE and LEAD WIRES)

Figure 201.102 – Test of protection against the effects of defibrillation (differential mode)

201.8.5.5.2 Energy reduction test

Addition:

The test setup for the energy reduction test is shown in Figure 201.103.



Components

①	energy test equipment
V_1	high voltage source 5 kV DC
S	switch; max. load 60 A, 5 kV
R_1	100 Ω ± 10 %, 5 kV dielectric strength, 400 J pulse energy dissipation capability, low inductance
R_2	400 Ω ± 10 %, 5 kV dielectric strength, 400 J pulse energy dissipation capability, low inductance
R_L	DC resistance of inductance *L*
R_V	current limiting resistor
E, F	connecting points for energy test equipment
C, D	connecting points for EUT (includes PATIENT CABLE and LEAD WIRES; energy test equipment can be a defibrillator tester)

Figure 201.103 – Application of the test voltage between LEAD WIRES to test the energy delivered by the defibrillator

201.8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

201.8.7.1 General requirements

Amendment (add after the first three dashes of item b)):

– with any input selectors or montage selectors set so as to produce the worst-case conditions; the worst case shall be determined by inspection of the circuit diagram and/or the ELECTROENCEPHALOGRAPH and its associated ACCESSORIES;

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Amendment (add after the note):

If the SUPPLY MAINS to the ELECTROENCEPHALOGRAPH is interrupted for less than 30 s, no change of OPERATOR settings shall occur, including the mode of operation, and all stored PATIENT data shall remain available.

NOTE 101 The ELECTROENCEPHALOGRAPH does not have to remain in operation during the interruption of the SUPPLY MAINS.

Compliance is checked by observing the ELECTROENCEPHALOGRAPH operating mode, OPERATOR settings, and stored data and interrupting the SUPPLY MAINS for a period of between 25 s and 30 s by disconnecting the POWER SUPPLY CORD.

If the SUPPLY MAINS is interrupted for more than 30 s, the subsequent operation shall be one of the following:

– reversion to the MANUFACTURER'S default settings;
– reversion to previous RESPONSIBLE ORGANIZATION'S default settings; or
– reversion to the last settings used.

Means may be provided to the OPERATOR to select one or more than one of the above options.

Compliance shall be checked by functional testing.

If the ELECTROENCEPHALOGRAPH contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted, the ELECTROENCEPHALOGRAPH shall continue normal operation by switching automatically to operating from its INTERNAL ELECTRICAL POWER SOURCE, and the mode of operation, all OPERATOR settings and stored data shall not be changed. Power-saving measures may be taken provided the ELECTROENCEPHALOGRAPH continues to conform to this particular standard.

The ELECTROENCEPHALOGRAPH shall visually indicate the operation from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by interrupting the SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed, that normal operation continues, and that a visual indication is displayed that the ELECTROENCEPHALOGRAPH is operating from its INTERNAL ELECTRICAL POWER SOURCE. The 'on-off' switch shall remain in the 'on' position.

Additional subclause:

201.11.8.101 Protection against depletion of the INTERNAL ELECTRICAL POWER SOURCE

ELECTROENCEPHALOGRAPHS powered from an INTERNAL ELECTRICAL POWER SOURCE shall not cause a HAZARDOUS SITUATION to the PATIENT when the state of discharge can no longer maintain the NORMAL USE of the ELECTROENCEPHALOGRAPH (see 201.15.4.4.101):

When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the ELECTROENCEPHALOGRAPH can no longer function in accordance with the MANUFACTURER's specification, the ELECTROENCEPHALOGRAPH shall power down in a manner which causes no HAZARDOUS SITUATION to the PATIENT other than loss of function.

Compliance is checked by operating the ELECTROENCEPHALOGRAPH from the INTERNAL ELECTRICAL POWER SOURCE and by functional testing.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 Scale and calibration signal

The ELECTROENCEPHALOGRAM shall be displayed with a scale or calibration signal labelled in μV or mV.

Compliance is checked by visual inspection.

201.12.1.102 Accuracy of amplitude and rate of variation

Input voltages in the ranges and varying at rates selected from "Scalp" and/or "Cerebral cortex or subdural locations" according to Table 201.102 shall be reproduced on the output with an error of ≤ ±20 % of the nominal value of the output or ±10 μV, whichever is greater.

Table 201.102 – Input voltage ranges and rates of variation

EEG acquisition from	Input voltage range	Rate of variation
Scalp	1,0 mV peak-to-valley	12 mV/s
Cerebral cortex or subdural locations	20,0 mV peak-to-valley	240 mV/s

Compliance is checked using the test circuit of Figure 201.104.

Set the scale of the ELECTROENCEPHALOGRAPH such that the input signal according to Table 201.102 signal can be displayed without clipping. Set switch S_1 to position B. Adjust the signal generator to apply a triangular wave with a peak-to-valley amplitude according to Table 201.102 and a frequency of 6 Hz to any LEAD WIRE of a CHANNEL with all other LEAD WIRES connected to P2. Decrease the output of the signal generator by factors of 2, 5 and 10. The displayed peak-to-valley outputs shall be within ±20 % of the nominal values of the output. If necessary, the scale may be adjusted appropriately.

Repeat for each LEAD WIRE of the available CHANNELS until all combinations of LEAD WIRES have been tested.

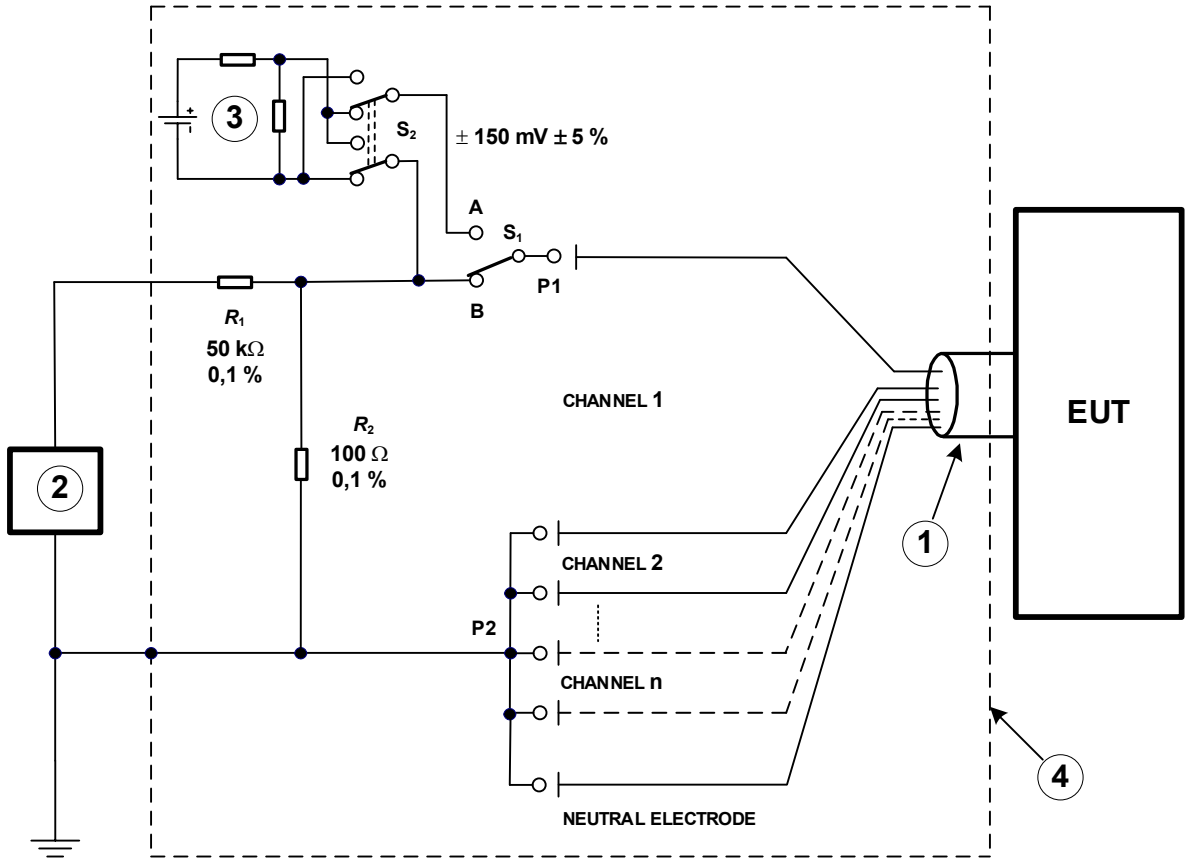
201.12.1.103 * Input dynamic range and differential offset voltage

With a DC offset voltage in the range of ±150 mV and differential input signal voltages of ±0,5 mV that vary at rates up to 12 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude shall not change by more than ±10 % of the peak-to-valley output without DC offset voltage.

Compliance is checked using the test circuit of Figure 201.104.

Set the scale of the ELECTROENCEPHALOGRAPH such that a 1 mV peak-to-valley signal can be displayed without clipping. Set switch S_1 to position B. Adjust the signal generator to apply a 6 Hz triangular signal with an amplitude of 1 mV peak-to-valley to any LEAD WIRE of a CHANNEL with all other LEAD WIRES connected to P2. Set switch S_1 to position A to apply a +150 mV DC offset voltage. Change switch S_2 to apply a –150 mV DC offset voltage. Verify that the peak-to-valley output with ±150 mV DC offset voltage is within ±10% of the peak-to-valley output without DC offset voltage.

Repeat for each LEAD WIRE until all CHANNELS have been tested.



Components

①	PATIENT CABLE
②	signal generator; minimum output range 0 V to 10 V, output impedance ≤1 kΩ and linearity ±1 %
③	DC offset voltage source; the voltage divider consisting of 2 resistors is used to adjust the DC output voltage to 150 mV ± 5 %
④	shield
S_1	switch, connects DC offset voltage source
S_2	switch, changes polarity of DC offset voltage source

The shield around the entire test configuration minimizes induction and capacitive coupling from mains voltage.

The figure illustrates the general test circuit for:

– 201.12.1.102 (accuracy of amplitude and rate of variation);

– 201.12.1.103 (input dynamic range and differential offset voltage);

– 201.12.1.105 (frequency response).

Figure 201.104 – General test circuit

201.12.1.104 Input noise

The signal noise at the bandwidth specified in 201.12.1.105 shall not exceed 6 μV peak to-valley referred to the input (RTI).

Compliance is checked using the test circuit of Figure 201.105. Set any adjustable filters of the ELECTROENCEPHALOGRAPH, if provided, such that the frequency response specified in 201.12.1.105 is obtained. Turn on the mains frequency notch filter of the ELECTROENCEPHALOGRAPH, if provided.

Open switch S_0, close switches S_1 to S_n and set switch S_{DC} to position B. When the PATIENT CABLE is motionless, the noise referred to the input shall not exceed 6 μV peak-to-valley referred to the input.

201.12.1.105 Frequency response

ELECTROENCEPHALOGRAPHS shall have a frequency response (bandwidth) of at least 0,5 Hz to 50 Hz when tested with sinusoidal input signals. The output at frequencies between 0,5 Hz and 50 Hz shall be within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal.

Compliance is checked by inspection of the filter frequency response characteristic documentation of the ELECTROENCEPHALOGRAPH and using the test circuit of Figure 201.104. The mains frequency notch filter and any other filter of the ELECTROENCEPHALOGRAPH, if provided, shall be switched off for this test.

Set the scale of the ELECTROENCEPHALOGRAPH such that a 100 μV peak-to-valley signal can be displayed without clipping. Set switch S_1 to position B. Use the signal generator to apply a 5 Hz, 50 μV peak-to-valley sine wave signal between any LEAD WIRE of a CHANNEL with all other LEAD WIRES connected to P2. Verify that, at 0,5 Hz and 50 Hz, the output signal amplitude remains within the range of 71 % to 110 % of the output signal amplitude at 5 Hz.

201.12.1.106 * Common mode rejection

A 1 V RMS signal at mains frequency (50 Hz/60 Hz) with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together shall not produce an output signal greater than 100 μV peak-to-valley over a period of not less than 10 s. In series with each ELECTRODE shall be a 10 kΩ resistor in parallel with a 47 nF capacitor. The PATIENT CABLE and LEAD WIRES specified by the MANUFACTURER shall be used.

Compliance is checked using the test circuit of Figure 201.105 with any mains frequency notch filter ~~(~~of the ELECTROENCEPHALOGRAPH, if provided~~)~~, turned off.

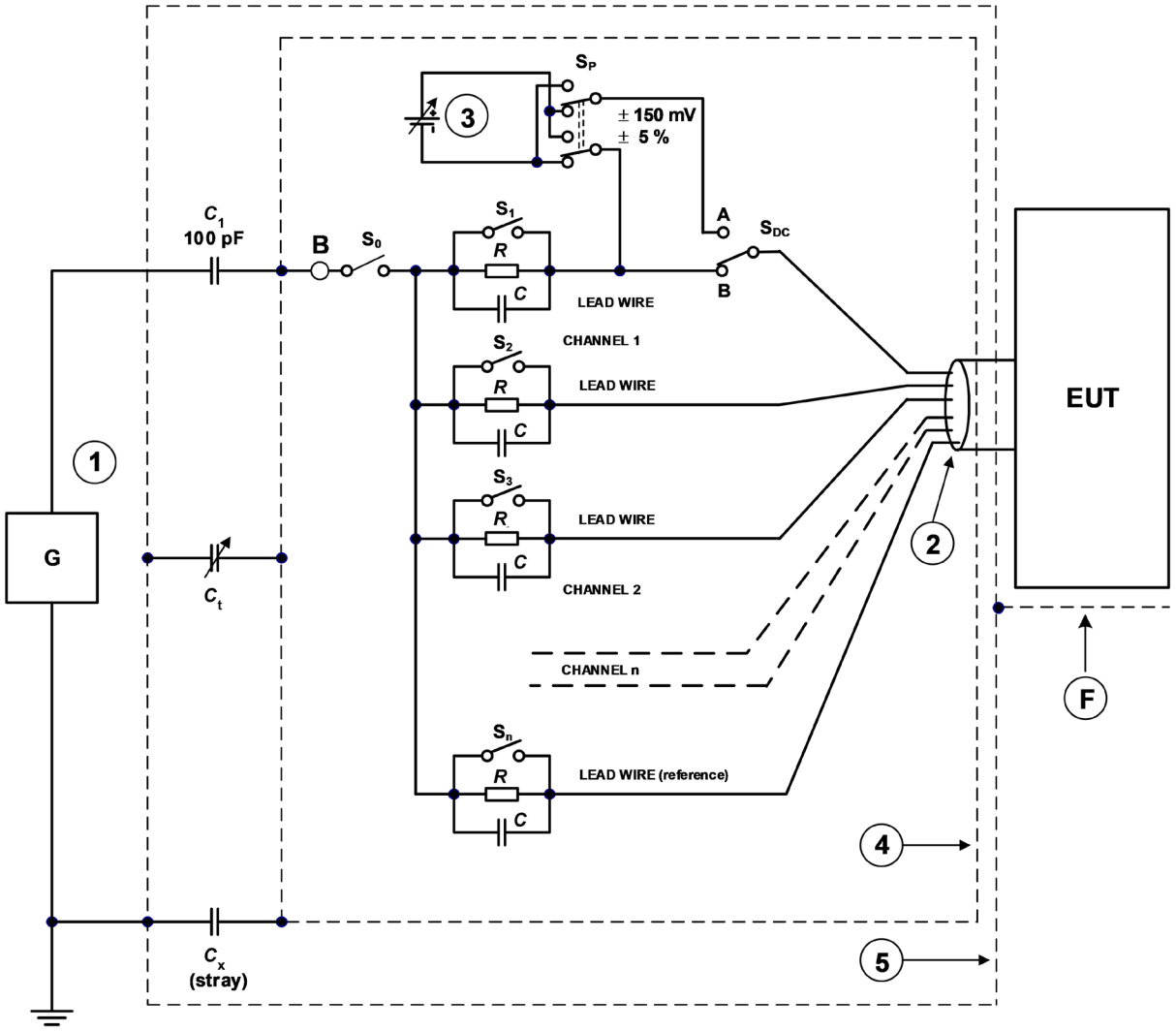
a) Adjust the sum of capacitance C_x and C_t to 100 pF, while no PATIENT CABLE is attached (S_0 open).

b) Set the signal generator to apply 2 V RMS sine wave signal at mains frequency. The common mode voltage applied to the ELECTROENCEPHALOGRAPH is then 1 V RMS.

c) Close switches S_0 and S_2 through S_n, open switch S_1 and set S_{DC} to position B. Measure the output over a period of not less than 10 s. Then open switch S_2 and close switch S_1. Repeat the amplitude measurement. Continue until the measurement has been made with all LEAD WIRES.

d) Repeat step c) with a +150 mV DC and –150 mV DC offset voltage in series with the imbalance impedance, by setting switch S_{DC} to position A and testing with the switch S_P in each of its two positions.

The measured output amplitude shall not be greater than 100 μV peak-to-valley.



Components

①	signal generator 2 V RMS mains frequency
②	PATIENT CABLE
③	DC offset source
④	inner shield
Ⓕ	foil, simulating capacitance for CLASS II or INTERNALLY POWERED ELECTROENCEPHALOGRAPHS
⑤	outer shield
B	common mode point
S_1 to S_n	switches; invoke unbalance circuit consisting of *C* and *R*
C	47 nF
R	10 kΩ

NOTE C_1, C_t and C_x simulate the PATIENT's capacitance to mains voltage and ground. The inner shield is used to reduce the pickup of unwanted extraneous signals and to eliminate the unbalance to ground. Since the capacitance C_x between the inner and external shields influences both the source capacitance and the common mode voltage, this capacitance is increased by trimmer capacity to 100 pF, equal to the generator capacitor C_1. The generator output is increased to 2 V RMS, thus providing 1 V RMS at the common mode point B with a source impedance equivalent to 200 pF when the PATIENT ~~cable~~ CABLE and LEAD WIRES are not connected to the test circuit.

Figure 201.105 – Test circuit for noise and common mode rejection
(see 201.12.1.104 and 201.12.1.106)

201.12.4 Protection against hazardous output

Additional subclause:

201.12.4.101 * Indication of invalid data

ELECTROENCEPHALOGRAPHS intended for unattended monitoring shall be provided with means to indicate overload, saturation of any part of the amplifier and disconnected LEAD WIRES.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.4.4 Indicators

Additional subclause:

201.15.4.4.101 Indicator of operation from the INTERNAL ELECTRICAL POWER SOURCE and the status of the INTERNAL ELECTRICAL POWER SOURCE

The ELECTROENCEPHALOGRAPH shall visually indicate when it is operating from its INTERNAL ELECTRICAL POWER SOURCE, unless it is only INTERNALLY POWERED.

The ELECTROENCEPHALOGRAPH shall visually indicate its remaining battery capacity when operating from its INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by functional testing.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 ~~applies~~ apply, except as follows:

202.4.3.1 Configurations

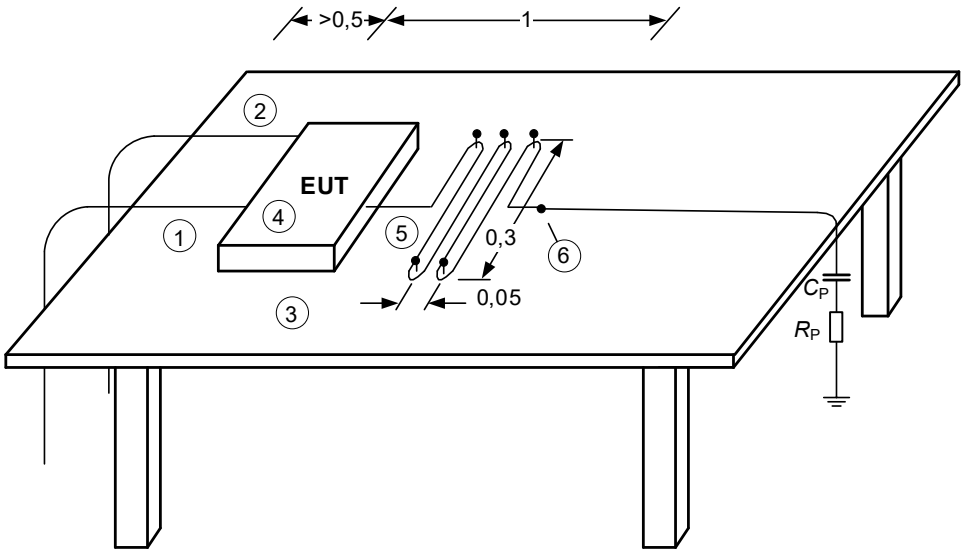
Addition:

ELECTROENCEPHALOGRAPHS shall be tested with the PATIENT CABLES and LEAD WIRES as specified by the MANUFACTURER. If the MANUFACTURER specifies different PATIENT CABLES or LEAD WIRES, only one representative sample of each length has to be tested.

If required to verify IMMUNITY pass/fail criteria determined by the MANUFACTURER, the LEAD WIRES may be connected to a PATIENT signal simulator instead of the common node (see Figure 202.101).

The RC-network (C_p, R_p) of Figure 202.101 shall be connected only if required by IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.

Dimensions in m



IEC

Components

①	POWER SUPPLY CORD
②	SIP/SOP cable
③	table made of insulating material
④	ELECTROENCEPHALOGRAPH under test (EUT)
⑤	PATIENT CABLE and LEAD WIRES
⑥	common node where all LEAD WIRES and the artificial hand, if required, are connected together
C_P	220 pF
R_P	510 Ω

NOTE C_P in series with R_P form the RC element of the artificial hand according 4.3.2 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.

Figure 202.101 – Test layout for radiated and conducted EMISSION test and radiated IMMUNITY test
(see 202.4.3.1)

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 * General

Amendment (replace paragraph below Note 5 by):

During and after non-transient electromagnetic phenomena (i.e. ~~radiated RF electromagnetic fields, proximity fields from RF wireless communications equipment, RATED power frequency magnetic fields, conducted disturbances induced by RF fields, and voltage dips~~ electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and proximity magnetic fields) the ELECTROENCEPHALOGRAPH:

– shall meet the IMMUNITY pass/fail criteria as determined by the MANUFACTURER for BASIC SAFETY and ESSENTIAL PERFORMANCE and shall not change operating modes, OPERATOR settings and any stored data. ELECTROENCEPHALOGRAPHS may exceed input noise level according subclause 201.12.1.104 during the test, if this does not result in unacceptable RISK.

During transient electromagnetic phenomena (i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and voltage interruptions) the ELECTROENCEPHALOGRAPH shall meet IMMUNITY pass/fail criteria for BASIC SAFETY as determined by the MANUFACTURER. Within 30 s after exposure to transient electromagnetic phenomena the ELECTROENCEPHALOGRAPH shall resume normal operation without loss of any OPERATOR settings or stored data and shall meet the input noise requirement in 201.12.1.104 and the IMMUNITY pass/fail criteria for BASIC SAFETY and ESSENTIAL PERFORMANCE as determined by the MANUFACTURER.

Requirements for voltage interruptions, see 201.11.8.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the test report for inclusion of the pass/fail criteria and by verification that the ELECTROENCEPHALOGRAPH meets specified IMMUNITY pass/fail criteria at the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Table 4 ~~through Table~~ to 9 and Table 11.

Maintenance of BASIC SAFETY shall be determined by inspection of the ELECTROENCEPHALOGRAPH after completion of the IMMUNITY tests and, if necessary, by performing the appropriate tests of the general standard.

202.8.9 IMMUNITY TEST LEVELS

Table 7 – PATIENT **coupling port**

Amendment:

Delete third row ("Conducted disturbances induced by RF fields").

Addition:

NOTE 101 PATIENT CABLES and LEAD WIRES are exempt from testing for conducted disturbances induced by RF fields.

Additional subclause:

202.8.101 * Disturbances from HF SURGICAL EQUIPMENT

If the intended environments of use as specified by the MANUFACTURER include environments where HF SURGICAL EQUIPMENT is used, the ELECTROENCEPHALOGRAPH shall return to its previous operating mode within 30 s after exposure to disturbances produced by HF SURGICAL EQUIPMENT, without any change in operating mode and OPERATOR settings and without loss of any stored data.

NOTE For example, ELECTROENCEPHALOGRAPHS intended solely for use in the HOME HEALTHCARE ENVIRONMENT are not intended to be used together with HF SURGICAL EQUIPMENT.

Compliance is checked according to Figures 202.102, and 202.103.

Use PATIENT CABLES, LEAD WIRES and settings recommended by the MANUFACTURER and HF SURGICAL EQUIPMENT which complies with IEC 60601-2-2:2017 and has a minimum power cut mode capability of 300 W, a minimum coagulation mode capability of 100 W and working frequency ~~of~~ between 300 kHz ~~to~~ and 600 kHz.

a) Test in pure cut mode:

Set the output power of the HF SURGICAL EQUIPMENT to the 300 W position.

Touch the metal plate in the test setup (see Figures 202.102 and 202.103) with the ACTIVE ELECTRODE and remove it to get an arc and maintain it for at least 1 s.

Confirm that the ELECTROENCEPHALOGRAPH returns within 30 s to the previous operating mode without change of any OPERATOR settings and without loss of any stored data.

Repeat the procedure five times.

b) Test in coagulation mode:

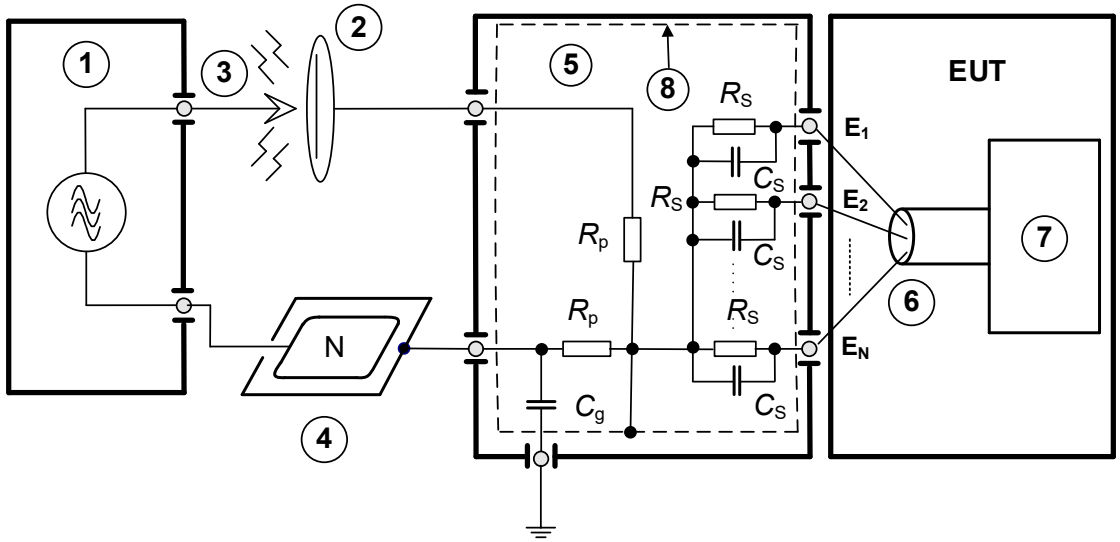
Set the output power of the HF SURGICAL EQUIPMENT to the 100 W position.

Touch the metal plate in the test setup (see Figures 202.102, and 202.103) with the ACTIVE ELECTRODE and remove it to get an arc and maintain it for at least 1 s.

Confirm that the ELECTROENCEPHALOGRAPH returns within 30 s to the previous operating mode without change of any OPERATOR settings and without loss of any stored data.

Repeat the procedure five times.

Test of other modes (e.g. spray coagulation) is not required.



IEC

Components

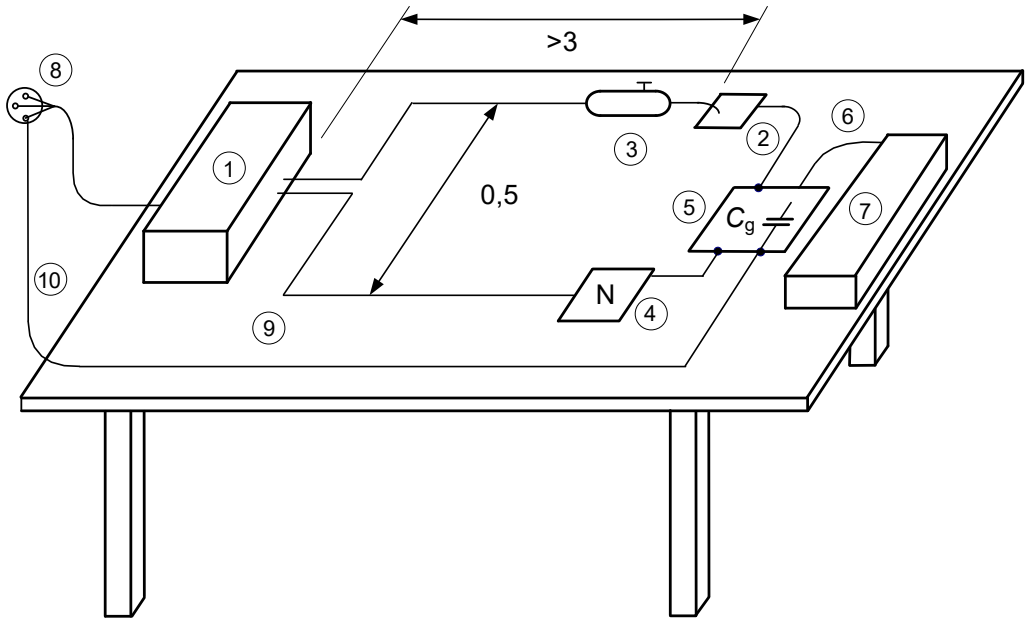
① HF SURGICAL EQUIPMENT
② metal plate
③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
④ metal plate/NEUTRAL ELECTRODE of HF SURGICAL EQUIPMENT
⑤ coupling network
⑥ PATIENT CABLE and LEAD WIRES
⑦ ELECTROENCEPHALOGRAPH
⑧ shielding

R_p 500 Ω ±10 %, 200 W, < 5 μH (simulates PATIENT impedance)
C_g 47 nF (to minimize the effect of different types of HF SURGICAL EQUIPMENT designs)
R_s 10 kΩ (R_s//C_s simulate the ELECTRODE to skin impedance)
C_s 47 nF
E_1, E_2, ...E_X, E_N PATIENT CONNECTIONS

The test report should identify the HF SURGICAL EQUIPMENT that was used.

Figure 202.102 –Test circuit for HF SURGICAL EQUIPMENT protection measurement according to 202.8.101

Dimensions in m



IEC

Components

① HF SURGICAL EQUIPMENT
② metal plate
③ ACTIVE ELECTRODE of the HF SURGICAL EQUIPMENT
④ NEUTRAL ELECTRODE of the HF SURGICAL EQUIPMENT
⑤ coupling network according to item 5 in Figure 202.102
⑥ PATIENT CABLE and LEAD WIRES
⑦ ELECTROENCEPHALOGRAPH under test
⑧ SUPPLY MAINS
⑨ table made of insulating material
⑩ connection to PROTECTIVE EARTH CONDUCTOR for grounding

Figure 202.103 – Test setup for HF SURGICAL EQUIPMENT measurement according to 202.8.101

206 USABILITY

IEC 60601-1-6:~~2013~~2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 ~~applies~~ apply, except as follows:

Additional subclause:

206.101 PRIMARY OPERATING FUNCTIONS

For ELECTROENCEPHALOGRAPHS, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) switching on/off;
b) connecting/disconnecting PATIENT CABLES and LEAD WIRES;
c) observing waveforms from display;
d) ELECTRODE impedance verification;
e) measuring amplitude and frequency of EEG signals, if such measurements are provided;

f) setting the OPERATOR-adjustable controls relevant for PATIENT safety.