INTERNATIONAL STANDARD

IEC 60601-2-25

1993

AMENDMENT 1
1999-05

Amendment 1

Medical electrical equipment –

Part 2-25: Particular requirements for the safety of electrocardiographs

Amendement 1

Appareils électromédicaux –

Partie 2-25: Règles particulières de sécurité pour les électrocardiographes

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PRICE CODE M

For price, see current catalogue

FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62D/309/FDIS	62D/314/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

_____

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CONTENTS

Replacement:

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1.3 Particular Standards

Replace the first paragraph of the Addition by the following:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995). The General Standard takes into account IEC 60601-1-2 (1993), *Medical electrical equipment – Part 1 General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests.*

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6 Identification, marking and documents

This clause of the Particular Standard applies except as follows:

6.1 Marking on the outside

Replace the existing title by the following:

Marking on the outside of EQUIPMENT or EQUIPMENT parts

Delete 6.1 l) and text.

6.8.2 Instructions for use

aa) Advice shall be given on the following:

In 1) replace the defined term TYPE B ELECTROCARDIOGRAPHS *by* TYPE B APPLIED PARTS.

In 3) replace the defined term TYPE BF OR CF ELECTROCARDIOGRAPHS *by* TYPE BF OR CF APPLIED PARTS.

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Addition:

13) Where relevant, a statement that the EQUIPMENT is protected against malfunction caused by electrosurgery.

17 Separation

Replacement:

This clause of the Particular Standard applies, except as follows:

17 h) second dash of the General Standard does not apply because it is covered by 51.101 and 51.102

Delete 17.101 and text.

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19.3 Allowable values

Delete 19.3 Item a), Additional item: 1) and Table 101, as they are covered by the General Standard.

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SECTION FIVE – PROTECTION AGAINST HAZARD
FROM UNWANTED OR EXCESSIVE RADIATION

36 Electromagnetic compatibility

Replacement:

IEC 60601-1-2 applies, except as follows:

36.201.1.1

Replacement:

The EQUIPMENT shall comply with the requirements of CISPR 11, group 1, class A or B depending on the environment of intended use.

36.201.1.7

Replacement:

The EQUIPMENT shall be tested with the PATIENT cables, leads and electrodes attached to the EQUIPMENT and terminated in a load simulating the PATIENT (see figure 108).

During the conductive emission test, the midpoint of the metal plate shall be connected to ground via 220 pF in series with 510 Ω (see figure 108).

Signal input/output cables (if applicable) shall be attached to the EQUIPMENT during the test (see 36.202.2.2 a).

36.202 IMMUNITY

Addition to paragraph 4:

Examples of SAFETY HAZARDS include failures involving changes in operating state, irrecoverable loss or change of stored data, errors in control software such as unintended changes in output or failure to meet the manufacturer's specification.

36.202.1 Electrostatic discharge

Replacement:

A level of 6 kV shall apply for contact discharge to conductive ACCESSIBLE PARTS and coupling planes.

Addition:

The EQUIPMENT shall return to the previous operating mode within 10 s without loss of any stored data.

36.202.2 Radiated radio-frequency electromagnetic fields

36.202.1 a)

Replacement:

The EQUIPMENT shall be tested in accordance with IEC 61000-4-3.

36.202.2.1 d)

Replacement:

The EQUIPMENT shall operate within the limits specified in this standard. (The field strength of 3 V/m applies.)

36.202.2.2 a)

Replacement:

The EQUIPMENT shall be exposed to an r.f. field amplitude modulated at 80 % with a modulation frequency of 10 Hz.

Any SIGNAL INPUT PART, SIGNAL OUTPUT PART cable and mains cable shall be arranged generally as in figure 109.

36.202.2.2 d)

Replacement:

See 36.201.1.7.

36.202.3 Transients

Addition:

The EQUIPMENT shall return to the previous operating mode within 10 s without loss of any stored data.

36.202.3.1 b)

Addition:

The patient cable shall be excluded from the test.

Compliance with the requirements is checked by verifying that the EQUIPMENT returns to the previous operating mode within 10 s.

36.202.5 Conducted disturbances, induced by radio-frequency fields above 9 kHz

Addition:

When exposed to a conducted radio-frequency voltage, via the POWER SUPPLY CORD, the EQUIPMENT shall operate within normal specifications.

The test methods and instruments shall be as described in IEC 61000-4-6.

The noise voltage that is injected into the mains power input shall be 3 V r.m.s. over the frequency range of 150 kHz to 80 MHz. It shall be amplitude modulated at 80 % with a modulation frequency of 10 Hz.

36.202.6 Magnetic fields

Addition:

The EQUIPMENT shall be exposed to an a.c. magnetic field at a frequency equal to the power line frequency. The EQUIPMENT shall operate within the NORMAL limits of this standard when exposed to this field.

Magnetic field intensity: 3 A/m

Frequency: SUPPLY MAINS

The test methods used shall be those of IEC 61000-4-8.

The ECG lead connector shall be shorted at the ECG unit. The ECG cable shall not be used.

Addition:

***36.202.101 Electrosurgery interference**

Where means are provided for protection against malfunction caused by electrosurgery, the test below, using any accessories or settings recommended by the manufacturer, applies.

When the EQUIPMENT has been used together with HIGH FREQUENCY SURGICAL EQUIPMENT it shall return to previous operating mode within 10 s after exposure to the field produced by the HIGH FREQUENCY SURGICAL EQUIPMENT, without loss of any stored data.

Compliance shall be tested according to figures 110 and 111.

The HIGH FREQUENCY SURGICAL EQUIPMENT which is used shall comply with IEC 60601-2-2, shall have a minimum power cut mode capability of 300 W, a minimum coag mode of 100 W and working frequency of 450 kHz ± 100 kHz.

a) Test in cut mode:

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

Touch the metal contact/block in the test set-up (see figures 110 and 111) with the active electrode and remove the electrode slowly to get an arc.

Repeat the procedure five times.

b) Test in coag mode:

Repeat the test in item a) except with a maximum output power of 100 W.

Test of the spray coagulation mode is excluded.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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44 *Modify the title to read:*

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

51.101* (Additional guidance and rationale text)

51.102* (Additional guidance and rationale text)

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

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56 Components and general assembly

This clause of the Particular Standard applies, except as follows:

56.3 Connection – General

aa) *Replacement:*

The ELECTRODES themselves, including re-usable wrist and leg plate ELECTRODES and suction chest ELECTRODES not having integral leads exceeding 100 mm in length and their associated connectors are exempt from this requirement. For ELECTRODES having an attached LEAD exceeding 100 mm in length, the EQUIPMENT end of the said LEAD is not exempt.

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56.7 INTERNAL ELECTRICAL POWER SOURCE

Replace the existing title by the following:

Batteries

aa) *Replace "aa)" with a title as follows:*

c) Battery state

Remark: The text of aa) remains.

57 MAINS PARTS, components and layout

This clause of the Particular Standard applies, except as follows:

57.5 *Replacement (clause title):*

MAINS TERMINAL DEVICES and wiring of MAINS PART

Delete the "additional item" and the associated guidance and rationale item because they are covered by the General Standard.

57.10 CREEPAGE DISTANCES and AIR CLEARANCES

Table XVI

Delete the "replacement" because it is covered by the General Standard.

FIGURES

Page 35

Delete figure 101 – Dynamic test for limitation of energy from different parts, because it is covered by the General Standard.

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Delete figure 102 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of CLASS I EQUIPMENT, caused by an external voltage on a FUNCTIONAL EARTH TERMINAL, because it is covered by the General Standard.

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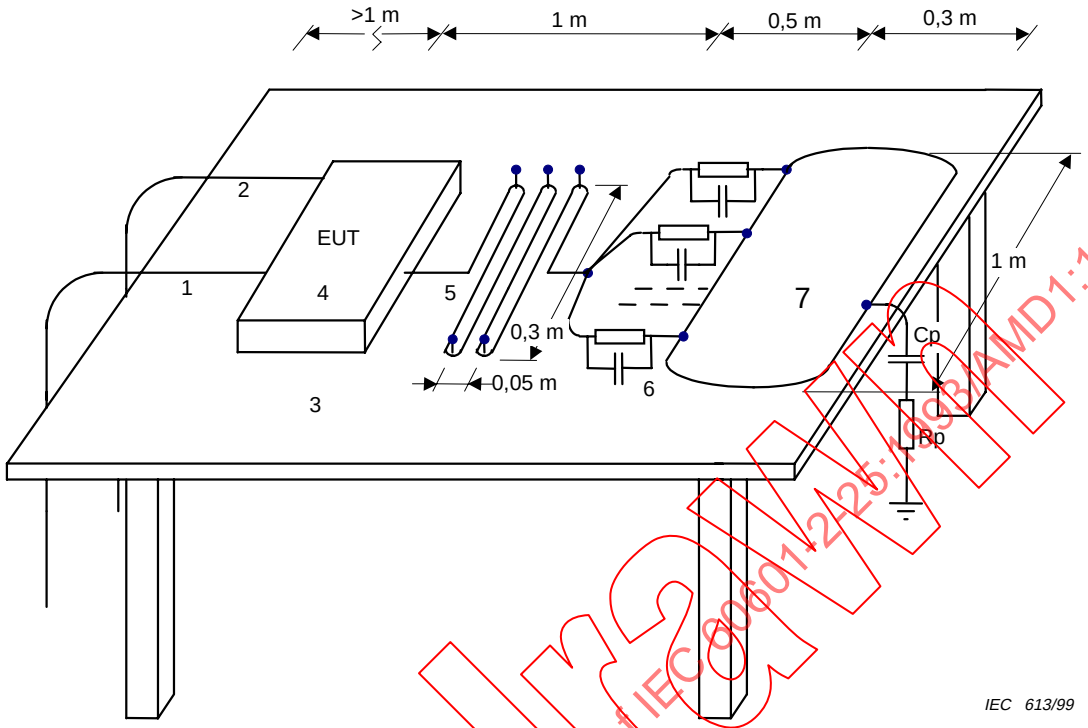
Delete figure 103 – Measuring circuit for the PATIENT LEAKAGE CURRENT from the APPLIED PART to earth of INTERNALLY POWERED EQUIPMENT, caused by an external voltage on a FUNCTIONAL EARTH TERMINAL, because it is covered by the General Standard.

Additions:



Key

1 Mains cable

2 Signal cable

3 Table made of insulating material

4 Equipment under test

5 PATIENT cable (only a representative number of pins shown)

6 Load simulating the PATIENT (51 kΩ in parallel with 47 nF)

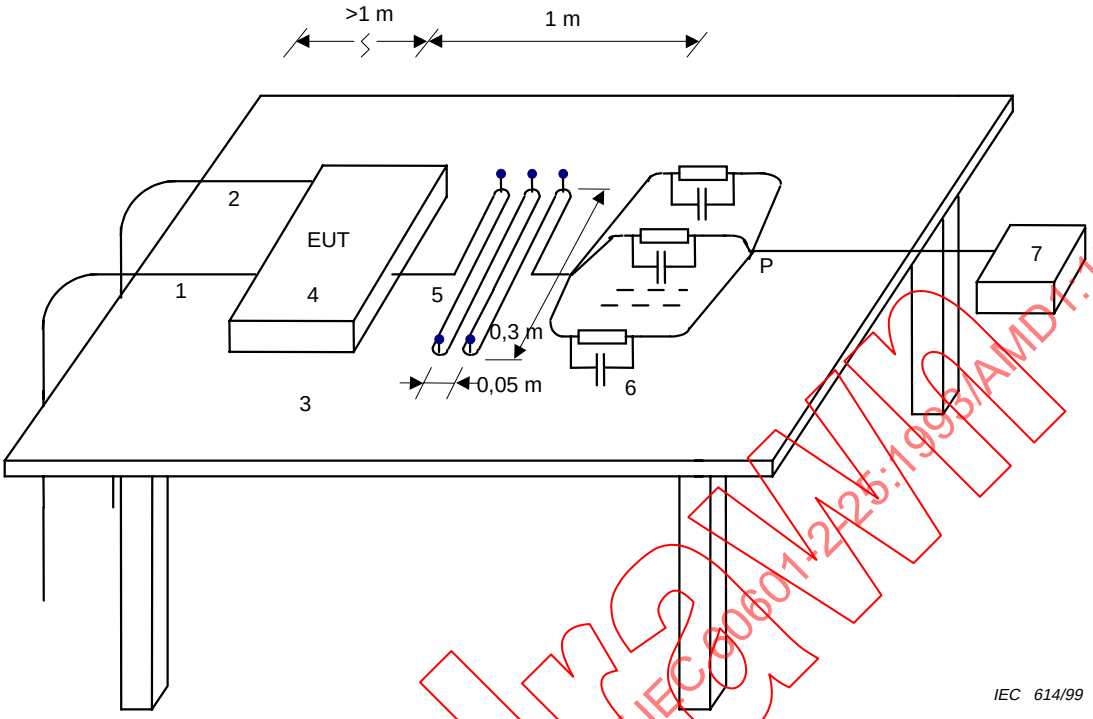
7 Metal plate

Components

Cp = 220 pF

Rp = 510 Ω (Cp in series with Rp simulate a PATIENT with respect to earth)

Figure 108 – Set-up for radiated and conducted emission test according to 36.201.1



Key

1 Mains cable

2 Signal cable

3 Table made of insulating material

4 Equipment under test

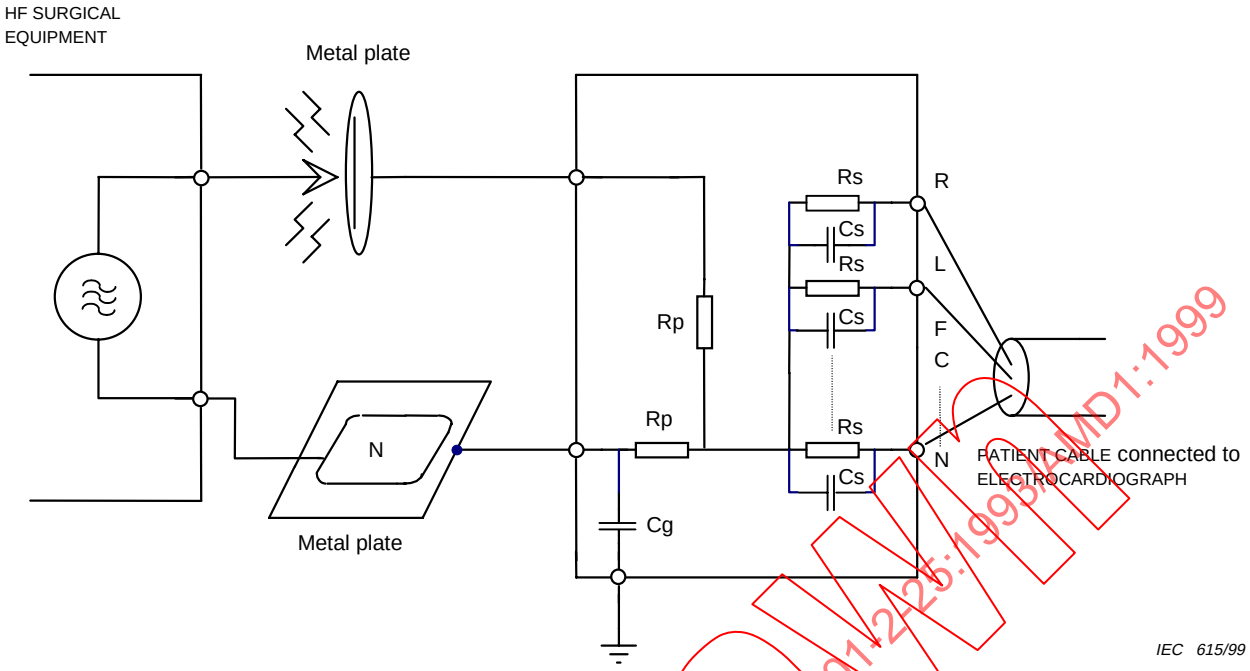
5 PATIENT cable (only a representative number of pins shown)

6 Load simulating the PATIENT (51 kΩ in parallel with 47 nF) (only needed if the simulator output impedance is not comparable with these values)

7 ECG simulator (shielded if susceptible to r.f. interference)

NOTE – As an alternative to the use of the simulator, the PATIENT cable may be shorted at point P and the simulator not used.

Figure 109 – Set-up for radiated immunity test according to 36.202.2



Components

Rp = 500 Ω, 200 W (low-inductive, <5 µH, simulates PATIENT impedance)

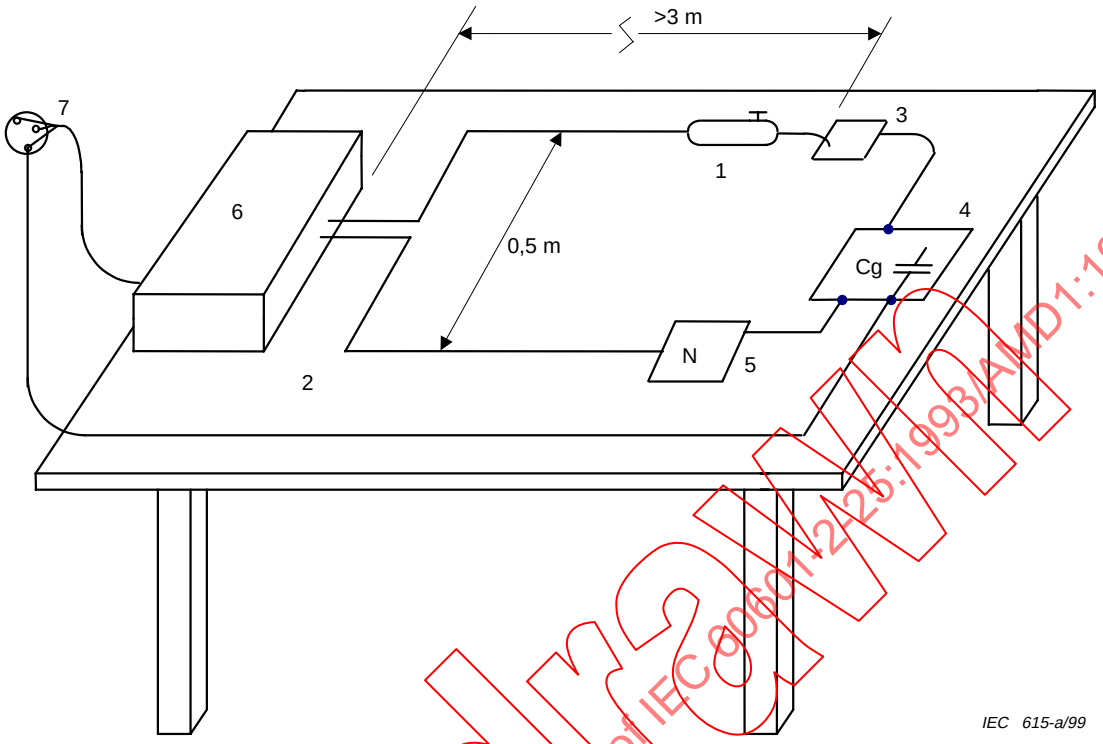
Cg = 47 nF (to minimise the effect of different types of HF surgery equipment designs)

Rs = 51 kΩ (Rs//Cs simulate the skin impedance)

Cs = 47 nF

NOTE – The HF SURGICAL EQUIPMENT used should be specified in the test report

Figure 110 – Test circuit for HF surgery interference measurement according to 36.202.101



Key

1 ACTIVE ELECTRODE

2 Table made of insulating material

3 Metal plate

4 Test set-up according to figure 110

5 NEUTRAL ELECTRODE, metallic or in contact with metal foil of the same size

6 HF SURGICAL EQUIPMENT

7 SUPPLY MAINS

Figure 111 – Test circuit for HF surgery interference measurement according to 36.202.101