

# INTERNATIONAL STANDARD

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## Medical electrical equipment –

### Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

#### *Appareils électromédicaux –*

#### *Partie 2-49: Règles particulières de sécurité des appareils de surveillance multifonction des patients*

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

Part 2-49: Particular requirements for the safety  
of multifunction patient monitoring equipment

## FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
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- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-49 has been prepared by subcommittee 62D: Electro-medical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based upon the following documents:

FDIS	Report on voting
62D/409/FDIS	62D/412/RVD

Full information on the voting for the approval of this 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 3.

Annexes AA, BB, EE and KK are for information only.

In this Particular Standard the following print types are used:

- requirements, compliance with which can be tested; and definitions: in **bold** type;
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type;
- *test specifications, headings of subclauses and headings of text in italics* type;
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD TEXT: in **bold** type, with CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2006. At this date, the publication will be:

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

A bilingual version of this publication may be issued at a later date.

## INTRODUCTION

This Particular Standard concerns the safety of multifunction patient monitoring equipment. It amends and supplements IEC 60601-1 (second edition 1988), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard, entitled "*Medical electrical equipment – Part 1: General requirements for safety*".

A "General guidance and rationale" for the 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, this annex does not form part of the requirements of this Standard.

An asterisk (\*) by a clause or subclause number indicates that some explanatory notes are given in Annex A of this Particular Standard.

At the time of the publication of this Particular Standard, work was in progress to create a joint ISO/IEC collateral standard addressing "General requirements and guidelines for the application of alarms in medical electrical equipment". It is intended to harmonize this standard with the above-mentioned collateral standard after its publication.



## MEDICAL ELECTRICAL EQUIPMENT -

### Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment

#### SECTION ONE - GENERAL

This section of the General Standard applies except as follows:

#### 1 Scope and object

##### \*1.1 Scope

This Particular Standard applies to the safety requirements of MULTIFUNCTION PATIENT MONITORING EQUIPMENT as defined in subclause 2.2 101.

The scope of this standard is restricted to EQUIPMENT having either more than one APPLIED PART or more than one SINGLE FUNCTION, intended for connection to a single PATIENT.

This standard does not specify requirements for individual monitoring functions.

##### 1.2 Object

The object of this Particular Standard is to specify requirements for the safety of MULTIFUNCTION PATIENT MONITORING EQUIPMENT.

##### 1.3 Particular Standards

###### *Addition.*

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).

For brevity, Part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. 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 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.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa)*, *bb)*, etc.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

The requirements of this Particular Standard take priority over those of the General Standard and Collateral Standard mentioned above.

### 1.5 Collateral standards

*Addition:*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2, Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4, Collateral standard: Programmable electric medical systems*  
Amendment 1 (1999)

## 2 Terminology and definitions

### \*2.1.5

#### APPLIED PART

*Delete second dash*

*Additional definitions:*

### 2.2. EQUIPMENT types (classification)

#### 2.2.101

**MULTIFUNCTION PATIENT MONITORING EQUIPMENT** (hereinafter referred to as **EQUIPMENT**)

modular or pre-configured device including more than one **PHYSIOLOGICAL MONITORING UNIT** designed to collect information from a single **PATIENT** and process it for monitoring purposes and to generate **ALARMS**

#### 2.2.102

**PHYSIOLOGICAL MONITORING UNIT**

a part of the **EQUIPMENT** whose purpose is to collect information relating to (a) physiological function(s) and to process it for monitoring and summary diagnostic purposes

### 2.5 Currents

#### 2.5.101

**MULTIPLE FUNCTION**

measurement of more than one physiological parameter



**\*2.5.102**

**PART LEAKAGE CURRENT**

current flowing from a SINGLE FUNCTION through the PATIENT to the remaining SINGLE FUNCTION(s) of the same APPLIED PART under NORMAL CONDITIONS

**2.5.103**

**SINGLE FUNCTION**

measurement of one physiological parameter

NOTE Examples of physiological functions are body temperature, ECG, invasive and non-invasive blood pressure etc.

**2.12 Miscellaneous**

**2.12.101**

**ALARM**

a signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

**2.12.102**

**INHIBITION**

disabling or SILENCING and disabling an ALARM until revoked intentionally

**2.12.103**

**LATCHED ALARM**

an ALARM, the visual and auditory manifestation of which does not stop when the ALARM condition no longer exists

**2.12.104**

**NON-LATCHED ALARM**

an ALARM, the auditory or visual and auditory manifestation of which stops when the ALARM condition no longer exists

**2.12.105**

**PHYSIOLOGICAL ALARM**

a signal which either indicates that a monitored physiological function is out of specified limits or indicates an abnormal PATIENT condition

**2.12.106**

**SILENCE**

the stopping of an auditory ALARM manifestation by OPERATOR action

**\*2.12.107**

**SILENCE/RESET**

the stopping of an auditory or auditory and visual ALARM manifestation and re-enabling system response to an ALARM condition

**2.12.108**

**SUSPENSION**

disabling or SILENCING and disabling an ALARM temporarily

**2.12.109**

**TECHNICAL ALARM**

a signal which indicates that the EQUIPMENT or part(s) of the EQUIPMENT is not capable of accurately monitoring the PATIENT'S condition



## 5 Classification

\*5.2 According to the degree of protection against electric shock:

*Amendment:* Delete TYPE B APPLIED PART.

5.6 According to the mode of operation:

*Amendment:*

Delete all but CONTINUOUS OPERATION.

## 5 Identification, marking and documents

### 6.1 Marking on the outside of the EQUIPMENT

*Addition:*

- aa) When detachable, each PHYSIOLOGICAL MONITORING UNIT shall be identified by the following markings and information:
  - 1) manufacturer's name or mark;
  - 2) designation of the model either by a name specific to the model or by reference number or reference letters;
  - 3) SERIAL NUMBER.
- bb) Each PATIENT input connection on the APPLIED PART shall be marked for the function.
- cc) Parts of an EQUIPMENT (for example, PATIENT CABLES or sensors) specified as not being protected against the effects of defibrillation shall be marked with symbol 14 of table DI in Appendix D of the General Standard.

### 6.8 ACCOMPANYING DOCUMENTS

#### 6.8.2 Instructions for use

*Addition:*

- aa) The instructions for use shall also include:
  - 1) the intended use of the equipment;
  - 2) that the use of the EQUIPMENT is restricted to one PATIENT at a time;
  - 3) the instructions for connection of any POTENTIAL EQUALIZATION CONDUCTOR;
  - 4) adequate information (and type number, if necessary) to identify the PATIENT CABLES which need to be used to provide protection against the effect of the discharge of a cardiac defibrillator and against burns;
  - 5) precautions specific to the EQUIPMENT to be taken when a defibrillator is used on a PATIENT, and effects on the EQUIPMENT of the discharge of a defibrillator;
  - 6) safety hazard due to simultaneous use of other PATIENT-connected MEDICAL ELECTRICAL EQUIPMENT, for example, a cardiac pacemaker or other electrical stimulators;

- 7) if the EQUIPMENT is provided with protective means against burns to the PATIENT when used with high-frequency (HF) surgical equipment, this shall be drawn to the attention of the OPERATOR; if no such means are incorporated, advice shall be given regarding the location of ELECTRODES and TRANSDUCERS to reduce the hazards of burns in the event of a defect in the HF surgical equipment NEUTRAL ELECTRODE connection;
- 8) the choice and application of the specified ACCESSORIES;
- 9) the procedure(s) for regular checks on the correct function of the EQUIPMENT and ACCESSORIES;
- 10) identification with which PHYSIOLOGICAL MONITORING UNIT/S the EQUIPMENT is intended to be used;
- 11) methods by which the visual and auditory ALARMS may be tested by the OPERATOR;
- 12) the default settings (e.g. ALARM settings, modes, and filter);
- 13) simple fault finding methods by which the OPERATOR can locate problems if the EQUIPMENT appears not to be functioning correctly;

NOTE This relates to simple OPERATOR difficulties, not to technical malfunctions.

- 14) the disclosure of the subsequent operation of the EQUIPMENT when the SUPPLY MAINS to the EQUIPMENT is interrupted for more than 30 seconds;
- 15) the disclosure how ALARM manifestations of TECHNICAL ALARMS may be disabled if sensors, probes, or modules are intentionally disconnected by the OPERATOR;
- 16) a statement indicating whether or not the EQUIPMENT is suitable for connection to public mains as defined in CISPR 11;
- 17) adjustment ranges of all PHYSIOLOGICAL ALARM limits (see 51.102.3).

## SECTION TWO – ENVIRONMENTAL CONDITIONS

This section of the General Standard applies.

## SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

This section of the General Standard applies except as follows:

### 14 Requirements related to classification

#### 14.6 TYPES B, BF AND CF APPLIED PARTS

*Addition:*

EQUIPMENT shall have TYPE BF and/or CF APPLIED PARTS.

### 17 Separation

This clause of the general standard applies with the following addition:

- aa) TYPE CF and TYPE BF APPLIED PARTS may consist of more than one SINGLE FUNCTION if the requirements of 19.1 and 56.3 for such EQUIPMENT have been met.



*\*17 h) Addition:*

1. DEFIBRILLATION-PROOF APPLIED PARTS and/or PATIENT CONNECTIONS shall incorporate a means so that the defibrillator energy delivered to a 100  $\Omega$  load is reduced by a maximum of 10 per cent relative to the energy delivered to this load with the EQUIPMENT disconnected.

*Compliance is checked by the following test:*

*The test circuit is shown in Fig. 101. The source generator shall have a minimum stored voltage of 5 kV, and the energy delivered to the test assembly shall be 360 J. For this test, the manufacturer's recommended ACCESSORIES such as cables, ELECTRODES and TRANSDUCERS shall be used. The test is applied to one APPLIED PART or PATIENT CONNECTION at a time). The procedure is as follows:*

- a. *Connect the APPLIED PART/PATIENT CONNECTION to the test circuit. For connection methods, follow the instructions for defibrillation tests described in particular standards where available and applicable.*
- b. *Charge the capacitor to 5 kV with switch S1 in position A.*
- c. *Discharge the test circuit by actuating the switch S1 to position B, and measure the energy E1 delivered to the defibrillator tester (i.e., 100  $\Omega$  load).*
- d. *Remove the EQUIPMENT under test from the test circuit and measure the energy E2 delivered to the 100  $\Omega$  load.*
- e. *Verify that the energy E1 is at least 90 per cent of E2.*

*Replacement 2<sup>nd</sup> dash:*

- *After defibrillation the EQUIPMENT shall return to the previous operating mode within 30 s (unless otherwise specified in the relevant Particular Standards) without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.*

*Replacement 3<sup>rd</sup> dash:*

- *(Common-mode test) The EQUIPMENT is connected to the test circuit shown in figure 50 of amendment 2 of the General Standard. The test voltage shall be applied to all PATIENT CONNECTIONS of an APPLIED PART connected together and isolated from earth. For EQUIPMENT having more than one APPLIED PART this test shall be repeated for the PATIENT CONNECTIONS of each APPLIED PART while the PATIENT CONNECTIONS of the remaining APPLIED PARTS are connected together and connected to earth.*

*Replacement 4<sup>th</sup> dash:*

- *(Differential-mode test) The EQUIPMENT is connected to the test circuit shown in figure 51 of amendment 2 of the General Standard. The test voltage is applied to each PATIENT CONNECTION in turn with all the remaining PATIENT CONNECTIONS of all APPLIED PARTS being connected to earth.*

*Replacement 6<sup>th</sup> dash:*

- *The EQUIPMENT shall be energized for this test.*

*Replacement last paragraph:*

*After 30 s recovery time, unless a shorter time is specified by an applicable particular standard, the EQUIPMENT 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 described in the ACCOMPANYING DOCUMENTS.*

## 19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

The clause of the General Standard applies, except as follows.

### 19.1 General requirements

*Replacement:*

- b) The specified values of the continuous earth leakage current, the enclosure leakage current, the patient leakage current, the patient auxiliary current, the part leakage current, and the total patient leakage current apply in any combination of the following conditions:

*Amendment:*

- e) The PATIENT LEAKAGE CURRENT shall be measured (see Annex KK):

*Delete: TYPE B APPLIED PARTS*

### \*19.3 Allowable values

*Addition*

- \*aa) PATIENT LEAKAGE CURRENT of TYPE BF APPLIED PARTS

PATIENT LEAKAGE CURRENT shall not exceed the values given in Table IV of the General Standard.

The PATIENT LEAKAGE CURRENT of a TYPE BF APPLIED PART shall be measured from and to all PATIENT CONNECTIONS of an APPLIED PART connected together. The measurement shall be carried out with all other PATIENT CONNECTIONS of the remaining APPLIED PARTS:

- 1) connected together, but not to earth, and
- 2) connected to earth

*Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figure KK.101 and verifying that the measured currents are below the limits given in Table IV of the General Standard.*

- \*bb) PATIENT LEAKAGE CURRENT of TYPE CF APPLIED PARTS

PATIENT LEAKAGE CURRENT shall not exceed the values given in Table IV of the General Standard.

The PATIENT LEAKAGE CURRENT of TYPE CF APPLIED PARTS shall be measured from and to each PATIENT CONNECTION in turn. The measurement shall be carried out with all other PATIENT CONNECTIONS of the remaining APPLIED PARTS:

- 1) connected together, but not to earth, and
- 2) connected to earth

*Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figure KK.102 and verifying that the measured currents are below the limits given in Table IV of the General Standard.*

- \*co) Total PATIENT LEAKAGE CURRENT of TYPE BF AND CF APPLIED PARTS

Total PATIENT LEAKAGE CURRENT shall not exceed the values given in table 101.



Table 101 – Maximum total PATIENT LEAKAGE CURRENT

Current mA	TYPE BF APPLIED PARTS		TYPE CF APPLIED PARTS	
	N.C.	S.F.C.	N.C.	S.F.C.
Total PATIENT LEAKAGE CURRENT (d.c.)	0,05	0,1	0,05	0,1
Total PATIENT LEAKAGE CURRENT (a.c.)	0,5	1	0,05	0,1
Total PATIENT LEAKAGE CURRENT (MAINS VOLTAGE on the APPLIED PART) (a.c.)	—	5	—	0,1
N.C.: normal condition				
S.F.C.: single fault condition				

Total PATIENT LEAKAGE CURRENT shall be measured by connecting all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE BF or TYPE CF) together and to

- 1) earth (NORMAL CONDITION), and to
- 2) MAINS VOLTAGE (SINGLE FAULT CONDITION)

SINGLE FAULT CONDITION other than compliance for cc) is checked according to 19.2 of the General Standard.

NOTE Figure KK.103 illustrates the compliance test of EQUIPMENT having only APPLIED PARTS of the same type (TYPE BF or TYPE CF). Figure KK.104 illustrates the compliance test of EQUIPMENT having TYPE BF and TYPE CF APPLIED PARTS.

*Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figures KK.103 and KK.104 (TYPE BF/CF APPLIED PARTS) and verifying that the measured current(s) is(are) below the limits given above.*

\*dd) PART LEAKAGE CURRENT of TYPE BF APPLIED PARTS

Total PART LEAKAGE CURRENT shall not exceed 0,01 mA d.c. or 0,1 mA a.c.

The PART LEAKAGE CURRENT of TYPE BF APPLIED PARTS shall be measured between any SINGLE FUNCTION and the remaining SINGLE FUNCTIONS of the same APPLIED PART in turn. The PATIENT CONNECTIONS shall be connected together.

*Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figure KK.105 and verifying that the measured currents are below the limits given above.*

\*ee) PART LEAKAGE CURRENT of TYPE CF APPLIED PARTS

Total PART LEAKAGE CURRENT shall not exceed 0,01 mA d.c. or 0,01 mA a.c.

In TYPE CF APPLIED PARTS, the PART LEAKAGE CURRENT shall be measured in turn between each PATIENT CONNECTION of the same SINGLE FUNCTION and the remaining SINGLE FUNCTIONS connected together.

*Compliance is checked by connecting the EQUIPMENT as shown in Annex KK Figure KK.106 and verifying that the measured currents are below the limits given above.*

ff) Total PATIENT LEAKAGE CURRENT for patient connectors

Any connector in a LEAD having a conductive connection to the equipment, which does not pass the test of 56.3 (aa) first dash shall meet the following requirements:

Total PATIENT LEAKAGE CURRENT for patient connectors shall not exceed the values given in table 102.

Table 102 – Maximum TOTAL PATIENT LEAKAGE CURRENTS for patient connectors

Current mA	TYPE BF APPLIED PARTS		TYPE CF APPLIED PARTS	
	N.C.	S.F.C.	N.C.	S.F.C.
Total PATIENT LEAKAGE CURRENT (MAINS VOLTAGE ON THE APPLIED PART)	–	5	–	0,1
N.C.: normal condition S.F.C.: single fault condition				

Total PATIENT LEAKAGE CURRENT shall be measured by applying the EQUIPMENT connector(s) of the same APPLIED PART connected to earth and connecting all remaining PATIENT CONNECTIONS of that APPLIED PART together and to mains voltage (SINGLE FAULT CONDITION).

Compliance is checked by connecting the EQUIPMENT as shown in Figure KK.107 of Annex KK and verifying that the measured current is below the limits given above.

## 20 Dielectric strength

The clause of the General Standard applies, except as follows.

### \*20.2 Requirements for EQUIPMENT with an APPLIED PART

*Replacement:*

- B-b Insulation between the APPLIED PARTS shall be at least BASIC INSULATION. The reference voltage shall be not less than the highest RATED supply voltage or for INTERNALLY POWERED EQUIPMENT 250 V. If voltages exist within the APPLIED PARTS, the insulation shall be in addition DOUBLE or REINFORCED INSULATION applicable to these voltages.

### 20.4 Tests

*Replacement:*

- c) For EQUIPMENT having more than one APPLIED PART the dielectric strength between APPLIED PARTS shall be tested as follows:
- the test voltage shall be applied between the PATIENT CONNECTIONS of one APPLIED PART and all remaining APPLIED PARTS whose PATIENT CONNECTIONS are connected to earth.
  - the test shall be repeated for each APPLIED PART.

See Figure EE.101 in Appendix EE for illustration.

## SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

This section of the General Standard applies.

## SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

This section of the General Standard applies except as follows:



### \*36 Electromagnetic compatibility

#### *Addition:*

Modular and preconfigured EQUIPMENT shall be tested configured with the maximum number of PHYSIOLOGICAL MONITORING UNITS. All specified PHYSIOLOGICAL MONITORING UNITS shall be tested. Representative samples from each family of PATIENT CABLES and/or TRANSDUCERS with similar construction listed in the ACCOMPANYING DOCUMENTS shall be tested with the corresponding PHYSIOLOGICAL MONITORING UNIT.

#### *Replacement:*

36.201.1.1 The EQUIPMENT shall comply with the requirements of CISPR 11, Group 1, Class A or B depending on its intended use as specified by the manufacturer.

## SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

This section of the General Standard applies.

## SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

This section of the General Standard applies except as follows:

### 44.3 Spillage

#### *Replacement:*

The EQUIPMENT shall be so constructed that, in the event of spillage of liquids (accidental wetting), no safety hazard shall result.

The EQUIPMENT shall not be subjected to the following test, unless the EQUIPMENT is PORTABLE/TRANSPORTABLE or part of the EQUIPMENT is separable while remaining functioning, in which case the said EQUIPMENT, or parts of the EQUIPMENT, shall be subjected to the following test.

*Compliance is checked by the following test:*

*The EQUIPMENT shall be placed in the least favourable position of NORMAL USE. The EQUIPMENT is then subjected for 30 seconds to an artificial rainfall of 3 mm/min falling vertically from a height of 0,5 m above the top of the EQUIPMENT.*

*A test apparatus is shown in figure 3 of IEC 60529.*

*An intercepting device may be used to determine the duration of the test.*

*Immediately after 30 seconds exposure, visible moisture on the ENCLOSURE shall be removed.*

*Immediately after the above test, check that any water which may have entered the EQUIPMENT cannot adversely affect the safety of the EQUIPMENT. In particular, the EQUIPMENT shall be capable of meeting the relevant dielectric strength test.*

## 49 Interruption of the power supply

### 49.2

*Addition:*

- a) When the SUPPLY MAINS to the EQUIPMENT is interrupted for less than 30 seconds, all OPERATOR settings, including the mode of operation, and all stored PATIENT data shall not be changed. However, the EQUIPMENT does not have to be operating during the interruption of the SUPPLY MAINS.

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

- b) When the SUPPLY MAINS is interrupted for more than 30 seconds:

The subsequent operation shall be one of the following: reversion to the manufacturer's default settings, to a previous USER's default settings or to the last settings used.

NOTE There may be provisions for the OPERATOR to select one or more than one of the above options.

*Compliance shall be checked by inspection.*

- c) When the EQUIPMENT contains an INTERNAL ELECTRICAL POWER SOURCE and the SUPPLY MAINS is interrupted the EQUIPMENT shall continue normal operation by switching automatically to operation from its INTERNAL ELECTRICAL POWER SOURCE and the mode of operation, all OPERATOR settings, and stored data shall not be changed.

EQUIPMENT shall be equipped with a device that visually indicates the operation from its INTERNAL ELECTRICAL POWER SOURCE.

*Compliance is checked by interrupting SUPPLY MAINS and observing that OPERATOR settings and stored data are not changed. The 'on-off' switch shall remain in the 'on' position.*

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

This section of the General Standard applies except as follows:

### 50 Accuracy of operating data

*Addition:*

#### 50.101 Software

Collateral Standard IEC 60601-1-4: Medical Electrical EQUIPMENT Incorporating Programmable Electronic Systems, shall be applied.

NOTE While performing the HAZARD ANALYSIS, special emphasis should be given to the HAZARDS associated with the ALARM system of the EQUIPMENT.

### 51 Protection against hazardous output

*Addition:*

#### 51.101 ALARMS (see also ALARM diagrams in annex BB)



**51.101.1 PHYSIOLOGICAL ALARM device**

EQUIPMENT shall be provided with at least one auditory and one visual PHYSIOLOGICAL ALARM device.

*Compliance is checked by inspection.*

**51.101.2 TECHNICAL ALARM device**

EQUIPMENT shall be provided with at least one auditory and one visual TECHNICAL ALARM device.

*Compliance is checked by inspection.*

**\*51.101.3 SUSPENSION or INHIBITION of all PHYSIOLOGICAL ALARMS and TECHNICAL ALARMS**

- a) EQUIPMENT may be provided with means to suspend or inhibit all PHYSIOLOGICAL ALARM(S) and all TECHNICAL ALARM(S) in NORMAL USE. The said means shall inhibit or suspend

– the auditory

or

– the auditory and visual

manifestations of all PHYSIOLOGICAL ALARMS and the auditory manifestations of all TECHNICAL ALARMS. The selection (configuration) of either SUSPENSION or INHIBITION function shall be protected to prevent that the OPERATOR may change the configuration in NORMAL USE. ACCOMPANYING DOCUMENTS (preferably in the technical documentation) shall describe the selection procedure.

*Compliance testing of INHIBITION: The PHYSIOLOGICAL ALARM(S) is/are simulated. As soon as the visual and auditory ALARM devices indicate the ALARMS, the function INHIBITION is activated. The function INHIBITION must disable the auditory or the auditory and visual ALARM manifestations permanently depending on the configuration.*

*Compliance testing of SUSPENSION: The PHYSIOLOGICAL ALARM(S) is/are simulated. As soon as the visual and auditory ALARM devices indicate the ALARMS, the function SUSPENSION is activated. The function SUSPENSION must disable the auditory or the auditory and visual ALARM manifestations temporarily depending on the configuration. After exceeding the pre-adjusted SUSPENSION time, the previously disabled auditory or visual and auditory ALARM manifestations shall be restored automatically.*

*Both tests are repeated with simulated TECHNICAL ALARM(S). The functions SUSPENSION and INHIBITION shall only disable the auditory ALARM manifestation.*

ACCOMPANYING DOCUMENTS are checked by inspection.

- b) If an EQUIPMENT is provided with means to suspend or inhibit the PHYSIOLOGICAL ALARM(S) and TECHNICAL ALARM(S) only one of the functions SUSPENSION and INHIBITION shall be selectable at a time.

*Compliance is checked by inspection.*

- c) The duration of SUSPENSION may be adjustable. Said means shall not be adjustable by the OPERATOR in NORMAL USE. The duration and/or the adjustment range of the duration shall be specified in the ACCOMPANYING DOCUMENTS.

*Compliance is checked by inspection.*

- d) If global SUSPENSION or INHIBITION of ALARM(S) is activated by the OPERATOR in NORMAL USE it shall be visually indicated.

*Compliance is checked by inspection.*

#### **51.101.4 SILENCE/RESET of ALARMS**

EQUIPMENT shall be equipped with means to SILENCE/RESET ALARMS.

*Compliance is checked by inspection.*

#### **51.101.5 Selection of NON-LATCHED ALARM(S) and LATCHED ALARM(S)**

EQUIPMENT shall be equipped with NON-LATCHED ALARM(S) and/or LATCHED ALARM(S). Only one of the modes shall be selectable for PHYSIOLOGICAL ALARMS.

*Compliance is checked by inspection.*

#### **51.101.6 NON-LATCHED ALARM(S)**

If EQUIPMENT is equipped with NON-LATCHED ALARM(S), the ALARM shall be SILENCED and RESET automatically (without any OPERATOR interaction) as soon as the monitored parameter(s) come(s) back within the adjusted limits, or if the abnormal PATIENT condition does not exist any longer.

*Compliance is checked by the following test:*

*A PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the simulator settings are changed to a value that does not exceed the ALARM limit. When the monitored parameter returns to a value, that does not exceed the ALARM limit, the auditory or the auditory and visual ALARM manifestations must cease without activating the function SILENCE/RESET.*

NOTE If EQUIPMENT guarantees minimum ALARM durations, the visual and auditory ALARM manifestations may continue until the minimum ALARM duration is reached.

#### **51.101.7 LATCHED ALARM(S)**

If EQUIPMENT is equipped with LATCHED ALARM(S), the ALARM manifestations shall not cease without activation of the function SILENCE/RESET.

*Compliance is checked by the following test:*

*A PHYSIOLOGICAL ALARM is simulated. After the visual and auditory ALARM devices indicate the ALARM, the simulator settings are changed to a value that no longer exceeds the ALARM limit. The auditory or the auditory and visual ALARM manifestations must not cease without activating the function SILENCE/RESET.*

#### **51.101.8 System ALARM delay time**

The ACCOMPANYING DOCUMENTS shall specify the delay time of making ALARM(S) available from the alarming EQUIPMENT to remote equipment at the SIGNAL OUTPUT PART.

*Compliance is checked by inspection.*

NOTE For guidance on this requirement, it is recommended that the delay time not exceed 0,5 s.



**\*51.101.9 Remote control of INHIBITION and SUSPENSION of ALARMS**

Means may be provided to suspend or inhibit ALARMS remotely. The selection (configuration) of remote SUSPENSION or INHIBITION shall be protected. The ACCOMPANYING DOCUMENTS shall describe the selection procedure.

**51.101.10 Remote control of SILENCE/RESET**

Means may be provided to SILENCE/RESET ALARMS remotely. The selection (configuration) of remote SILENCE/RESET shall be protected. The ACCOMPANYING DOCUMENTS shall describe the selection procedure.

**51.102 PHYSIOLOGICAL ALARMS****51.102.1 INHIBITION of individual PHYSIOLOGICAL ALARMS**

EQUIPMENT may be equipped with means to inhibit its individual PHYSIOLOGICAL ALARMS. The said means shall inhibit the auditory or the auditory and visual manifestations of individual PHYSIOLOGICAL ALARMS.

*Compliance is checked by the following test:*

*A PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the INHIBITION of the individual PHYSIOLOGICAL ALARM is activated. The function INHIBITION must disable immediately the auditory or the auditory and visual ALARM manifestations permanently, depending on the configuration.*

**\*51.102.2 SILENCE/RESET of PHYSIOLOGICAL ALARMS**

After SILENCE/RESET, the ALARM devices shall reset automatically to respond to a new ALARM when the monitored parameter returns to a value within the adjusted limits, or if the abnormal PATIENT condition does not exist any longer.

*Compliance is checked by testing according to 51.102.*

**51.102.3 PHYSIOLOGICAL ALARM selection, ALARM limit range, and delay time of PHYSIOLOGICAL ALARMS**

The delay time of PHYSIOLOGICAL ALARMS after the parameter value has exceeded an ALARM limit, may be adjustable.

NOTE The PHYSIOLOGICAL ALARM selection (e.g. systolic or diastolic pressure) and the ALARM limit range should be described in particular standards.

Adjustment ranges of PHYSIOLOGICAL ALARMS shall be specified in the ACCOMPANYING DOCUMENTS.

**51.102.4 Auditory manifestation of PHYSIOLOGICAL ALARMS**

The auditory manifestation shall be discontinuous.

*Compliance is checked by inspection.*

After SILENCE/RESET the auditory manifestation shall disappear.

SILENCE/RESET shall apply for the PHYSIOLOGICAL ALARM(S) that are being annunciated. New PHYSIOLOGICAL ALARM(S) that begin after the activation of SILENCE/RESET shall resume the auditory and visual ALARM manifestations.

*Compliance is checked by inspection.*

#### 51.102.5 Visual manifestation of PHYSIOLOGICAL ALARMS

The visual manifestation shall be continuous or discontinuous.

*Compliance is checked by inspection.*

In addition to the visual ALARM manifestation, each PHYSIOLOGICAL ALARM-generating parameter shall be continuously and legibly indicated.

NOTE: As guidance on this requirement, it is recommended that manufacturers consider continuously indicating each PHYSIOLOGICAL ALARM-generating parameter as well as the visual ALARM manifestation.

*Compliance is checked by inspection.*

If EQUIPMENT is provided with means to suspend the visual manifestation of PHYSIOLOGICAL ALARMS, the SUSPENSION time shall be the same as for the auditory ALARM manifestation.

*Compliance is checked by inspection.*

SILENCE/RESET shall not stop the visual ALARM manifestation as long as the parameter is not within the adjusted limits or if the abnormal PATIENT condition still exists.

If the EQUIPMENT provides means to inhibit or suspend visual PHYSIOLOGICAL ALARMS, the said means shall also inhibit or suspend the auditory PHYSIOLOGICAL ALARMS.

#### LATCHED ALARMS:

After SILENCE/RESET, the visual ALARM device shall reset automatically if the monitored parameter is within adjusted limits or if the abnormal PATIENT condition does not exist any longer.

#### NON-LATCHED ALARMS:

The visual ALARM device shall reset automatically (with or without SILENCE/RESET) when the monitored parameter returns to a value within the adjusted limits or if the abnormal PATIENT condition does not exist any longer.

#### *Compliance test of the function SILENCE/RESET with LATCHED ALARMS:*

*First, a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the function SILENCE/RESET is activated by the OPERATOR, which must disable the auditory ALARM manifestation immediately. Second, the simulator settings are changed to a value that does not exceed the alarm limit. The visual ALARM manifestations must cease without activating the function SILENCE/RESET again.*



*Compliance test of the function SILENCE/RESET with NON-LATCHED ALARMS:*

a) *SILENCE/RESET is activated by the OPERATOR before the ALARM condition ceases*

*First, a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the function SILENCE/RESET is activated by the OPERATOR, which must disable the auditory ALARM manifestation immediately. Second, the simulator settings are changed to a value that does not exceed the ALARM limit. The visual ALARM manifestations must cease without activating the function SILENCE/RESET.*

b) *SILENCE/RESET is not activated by the OPERATOR*

*First, a PHYSIOLOGICAL ALARM is simulated. As soon as the visual and auditory ALARM devices indicate the ALARM, the simulator settings are changed to a value that does not exceed the ALARM limit. The visual and auditory ALARM manifestations must cease without activating the function SILENCE/RESET.*

*The tests a) and b) have to be repeated with simulated TECHNICAL ALARMS.*

### **\*51.103 TECHNICAL ALARM**

TECHNICAL ALARMS should be NON-LATCHED ALARMS.

*Compliance is checked by inspection.*

In case of a TECHNICAL ALARM the measured value(s) of the concerned function(s) shall be displayed in such a way that the validity of the measured value(s) can be identified by the OPERATOR.

*Compliance is checked by inspection.*

NOTE: During a TECHNICAL ALARM the concerned physiological function(s) might not be capable of initiating PHYSIOLOGICAL ALARMS.

#### **51.103.1 Auditory manifestation of TECHNICAL ALARMS**

The auditory manifestation shall be discontinuous.

*Compliance is checked by inspection.*

The auditory manifestation of a TECHNICAL ALARM shall be indicated as soon as the EQUIPMENT detects the TECHNICAL ALARM condition.

*Compliance is checked by testing*

INHIBITION and SUSPENSION shall disable or SILENCE and disable the auditory manifestation of TECHNICAL ALARMS.

*Compliance is checked by testing.*

After SILENCE/RESET the auditory manifestation shall disappear.

SILENCE/RESET shall apply to all TECHNICAL ALARMS that are being annunciated. New TECHNICAL ALARMS that begin after the activation of SILENCE/RESET shall resume the auditory and visual ALARM manifestations.

*Compliance is checked by inspection.*

#### **\*51.103.2 Visual manifestation of TECHNICAL ALARMS**

The visual manifestation shall be continuous or discontinuous.

*Compliance is checked by inspection.*

- INHIBITION or SUSPENSION of ALARMS shall not disable or stop and disable the visual manifestation of TECHNICAL ALARMS.

*Compliance is checked by testing.*

In addition to the visual ALARM manifestation, the cause for each TECHNICAL ALARM shall be visually indicated.

*Compliance is checked by inspection.*

SILENCE/RESET shall not stop the visual ALARM manifestation.

*Compliance is checked by testing according to 51.102.5.*

SILENCE/RESET may disable the visual ALARM manifestation if sensors, probes, or modules are intentionally disconnected by the OPERATOR as specified by the manufacturer in subclause 6.8.2 aa).

#### **51.104 Remote equipment**

If EQUIPMENT is equipped with interfaces to remote equipment to duplicate ALARMS, the EQUIPMENT shall be so designed that a failure in the remote equipment or network will not affect the correct ALARM function of the ALARM-generating EQUIPMENT.

*Compliance is checked by testing.*

#### **51.105 Sound pressure level of the auditory ALARM manifestation**

The sound pressure level of auditory ALARM signals generated by the EQUIPMENT shall be in the range from 45 dB(A) to 85 dB(A) peak value at a distance of 1 m and may be adjustable.

*Compliance is checked by testing.*

### **SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS**

This section of the General Standard applies.

### **SECTION TEN – CONSTRUCTIONAL REQUIREMENTS**

This section of the General Standard applies except as follows:



## 56 Components and general assembly

### \*56.3

#### c) Addition:

- The air clearance between connector pins and a flat surface shall be at least 0,5 mm.

#### Addition:

aa) For APPLIED PARTS having multiple PATIENT CONNECTIONS any connector in a LEAD having a CONDUCTIVE CONNECTION TO EQUIPMENT shall comply with one of the following requirements:

- The air clearance between connector pins and a flat surface shall be at least 0,5 mm

*Compliance shall be checked by inspection.*

or

- EQUIPMENT shall pass the limits of the total PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION (see 19.3 ff) and KK.107) when measured between different SINGLE FUNCTIONS.

### 56.7

#### c) Battery state

#### Replacement:

- 1) The EQUIPMENT shall provide a TECHNICAL ALARM at least 5 minutes prior to the time that the EQUIPMENT can no longer function in accordance with the manufacturer's specification when powered from the INTERNAL ELECTRICAL POWER SOURCE.

*Compliance is checked by inspection and measurement.*

NOTE For testing, it is recommended to use a fully charged battery.

- 2) When the state of discharge of any INTERNAL ELECTRICAL POWER SOURCE is such that the EQUIPMENT can no longer function in accordance with the manufacturer's specification: the EQUIPMENT shall power down in a manner which causes no hazard to the PATIENT.

*Compliance is checked by operating the EQUIPMENT from the INTERNAL ELECTRICAL POWER SOURCE and by inspection and measurement.*

## **Appendix L** (normative)

### **References – Publications mentioned in this standard**

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*  
Amendment 1 (1991)  
Amendment 2 (1995)

IEC/TR3 60513:1994, *Fundamental aspects of safety standards for medical electrical equipment*

IEC 60529:1989, *Degree of protection provided by enclosures (IP code)*



## Annex AA (informative)

### Guidance and rationale

#### Rationale for particular clauses and subclauses

This annex provides a concise rationale for the important requirements of this Standard. It is intended for those who are familiar with the subject of the Standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the Standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any future revision of the Standard necessitated by these developments.

#### 1.1 Scope

The standard specifies safety requirements of MULTIFUNCTION PATIENT MONITORING EQUIPMENT as defined in 2.2.101. MEDICAL ELECTRICAL EQUIPMENT that does not comply with definition 2.2.101, such as catheter laboratory systems or stress test systems, is excluded from the scope of this standard because the requirements for those devices may be different.

#### 2.1.5

If, for example, the monitor can be placed on a trolley and therefore contact the PATIENT, with the retention of the 2<sup>nd</sup> dash the whole monitor will become an APPLIED PART and therefore has to fulfil all APPLIED PART requirements.

#### 2.5.102

The definition PART LEAKAGE CURRENT specifies a leakage current, which may flow in NORMAL USE between SINGLE FUNCTIONS on the same APPLIED PART. PART LEAKAGE CURRENTS do not provide any function to support the proper operation of an APPLIED PART such as bias current of an amplifier, or current used to sense an impedance. In contrast to the PATIENT AUXILIARY CURRENT, the PART LEAKAGE CURRENT is a parasitic LEAKAGE CURRENT that is caused by voltage differences between SINGLE FUNCTIONS and their CONDUCTIVE CONNECTION on the same APPLIED PART.

The measurement set-up and test limits are comparable to the measurement of a PATIENT AUXILIARY CURRENT (see also Annex KK, figures KK.105 and KK.106). PART LEAKAGE CURRENTS between SINGLE FUNCTIONS of different APPLIED PARTS may be neglected for the following reasons:

- different APPLIED PARTS are electrically isolated by BASIC INSULATION;
- the measurement of the PATIENT LEAKAGE CURRENT as outlined in 19.3 aa) and bb) includes the isolation barrier 'BASIC INSULATION' between APPLIED PARTS even under SINGLE FAULT CONDITION (MAINS VOLTAGE on the APPLIED PART).

#### 2.12.107

The combined term SILENCE/RESET was consciously used. The combined term SILENCE/RESET implies that two functions may be initiated by a single OPERATOR interaction which is the intent of the definition. Combining both functions may simplify the USER interface and improve the usability.



## 5.2

MULTIFUNCTION PATIENT MONITORING EQUIPMENT is frequently used in environments in which some or many other medical devices are connected to the same PATIENT. The reference to TYPE B APPLIED PARTS is therefore deleted, as it is important for the safety of the PATIENT that all such devices have F-TYPE APPLIED PARTS to avoid unwanted current paths to earth. The application of MULTIPARAMETER PATIENT MONITORING EQUIPMENT with an F-TYPE APPLIED PART presents no technical difficulties.

In addition, this standard was adapted to A.3.5 of IEC 60513:1994: 'For non-intracardiac applications, the significant difference between F-TYPE and B-TYPE APPLIED PARTS is that, if the PATIENT accidentally contacts mains voltage, an F-TYPE APPLIED PART restricts the current flowing through it to a reasonably safe level, while the current flowing in a TYPE B APPLIED PART may only be limited by the impedance of the PATIENT and may present a serious electrocution hazard.'

## 17 h)

1. EQUIPMENT should not inadvertently shunt defibrillation currents from the PATIENT. The result might be reduced efficiency of defibrillation, burning of the PATIENT at the ELECTRODE contact sites, and reduced likelihood that the ELECTRODE could continue sensing the ECG. These problems are minimized by allowing the device to absorb no more than 10 % of the energy intended for delivery to the PATIENT.

## 19.3 aa), bb)

The General Standard does not specify measurement methods for testing PATIENT LEAKAGE CURRENT of EQUIPMENT having more than one APPLIED PART. EQUIPMENT with multiple APPLIED PARTS introduces new isolation barriers between an APPLIED PART and the remaining APPLIED PARTS of which PATIENT CONNECTIONS may be grounded in NORMAL USE: hazards emerge with EQUIPMENT having multiple APPLIED PARTS. Therefore, this particular standard adopts the measurement methods for testing PATIENT LEAKAGE CURRENT of EQUIPMENT having more than one APPLIED PART.

## 19.3 cc)

The values of LEAKAGE CURRENT in the General Standard are for a single APPLIED PART. There is an increase in LEAKAGE CURRENT when multiple APPLIED PARTS are connected to the PATIENT. This total LEAKAGE CURRENT is the vector sum of the individual LEAKAGE CURRENTS. The LEAKAGE CURRENT safety considerations for existing EQUIPMENT that connect more than one APPLIED PART to the PATIENT and for MULTIFUNCTION PATIENT MONITORING EQUIPMENT are identical. Although this rationale applies to MULTIFUNCTION PATIENT MONITORING EQUIPMENT, it also covers safety considerations for existing EQUIPMENT that have more than one APPLIED PART connected to the PATIENT.

This standard does not fix the number of APPLIED PARTS connected to a single PATIENT. It has been estimated that the number of APPLIED PARTS connected to a single patient ranges from one to five.

## PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS

For TYPE CF APPLIED PARTS the PATIENT LEAKAGE CURRENT for the NORMAL CONDITION is 0,05 mA. The rationale in the General Standard for clause 19 (Figure A.1) gives a 0,01 probability for ventricular fibrillation for 0,05 mA directly entering the heart. The following must be considered for MULTIFUNCTION PATIENT MONITORING EQUIPMENT:

- a) The current entering the heart is distributed over all of the APPLIED PARTS and is not applied to the same small sensitive area of the cardiac tissue.



- b) The number of APPLIED PARTS connected directly to cardiac tissue is not likely to exceed three. Accordingly, the LEAKAGE CURRENT entering a single small area of the heart is less than 0,05 mA and is in the vicinity of 0,015 to 0,02 mA for an algebraic summation of the currents. The current would be less for a vector summation. The probability of ventricular fibrillation, according to the General Standard, is in the range of 0,003. This is not much different from the probability of 0,002 that is accepted for a single APPLIED PART connected directly to the heart.
- c) The LEAKAGE CURRENT from APPLIED PARTS on the surface of the body flows in a distributed manner through the body. According to the General Standard, 5 mA entering the chest produces a current density at the heart of 0,00025 mA/mm<sup>2</sup>. There is little concern with LEAKAGE CURRENT from APPLIED PARTS on the surface of the body.

50 µA for normal condition for TYPE CF MULTIFUNCTION PATIENT MONITORING EQUIPMENT is considered acceptable.

For SINGLE FAULT CONDITION the LEAKAGE CURRENT for TYPE CF EQUIPMENT has been increased to 0,1 mA. Figure A.1 in the General Standard gives a probability of 0,07 of ventricular fibrillation for current directly entering the heart. The probability of a SINGLE FAULT CONDITION was given as 0,1. This was over a decade ago. Because of improvements in design, more reliable components, better materials, and the use of hazard analysis according to IEC 60601-1-4, the probability of a SINGLE FAULT CONDITION should be much less. It is now felt to be in the vicinity of at least 0,02. The probability of ventricular fibrillation is  $0,07 \times 0,02$ , or 0,0014, close to that accepted for a single TYPE CF APPLIED PART.

#### PATIENT LEAKAGE CURRENT for TYPE BF APPLIED PARTS

The total PATIENT LEAKAGE CURRENT has been increased to 0,5 mA for NORMAL CONDITION and to 1 mA for SINGLE FAULT CONDITION. As explained in c) above, the current density at the heart for current of 5 mA is quite small. There should be no concern for either the NORMAL CONDITION or the SINGLE FAULT CONDITION.

#### PATIENT LEAKAGE CURRENT with MAINS VOLTAGE on the APPLIED PART

For TYPE CF APPLIED PARTS NORMAL CONDITION, the limit has been increased to 0,1 mA. The General Standard states that the probability of failure of PROTECTIVE EARTHING of CLASS I EQUIPMENT is 0,1 and that the probability of a fault in BASIC INSULATION is less than 0,1. This was a decade ago. As explained earlier, these probabilities should be much lower today and are considered to be no worse than 0,02. The probability of MAINS VOLTAGE appearing on the PATIENT is  $0,02 \times 0,02$ , or 0,0004. This is below the probability of 0,001 accepted in the General Standard.

There has been no change in the value of the current for TYPE BF APPLIED PARTS SINGLE FAULT CONDITION.

Figure KK.103 illustrates the compliance test for EQUIPMENT having only one type of APPLIED PARTS (TYPE BF or TYPE CF). Figure KK.104 shows EQUIPMENT that consists of TYPE BF and TYPE CF APPLIED PARTS.

#### 19.3 dd), ee)

The PART LEAKAGE CURRENT is a current that may flow between SINGLE FUNCTIONS of the same APPLIED PART through the PATIENT in NORMAL USE. In contrast to the PATIENT AUXILIARY CURRENT the PART LEAKAGE CURRENT is an unwanted current that is not needed for a measurement function. The PART LEAKAGE CURRENT is caused by voltage differences that may exist between SINGLE FUNCTIONS. The effects of the PART LEAKAGE CURRENT on the PATIENT are the same as those of the PATIENT AUXILIARY CURRENT. Therefore, the PART LEAKAGE CURRENT has to be limited to values that are outlined in subclauses k) and l).



Figures KK.105 and KK.106 illustrate the measurement of PART LEAKAGE CURRENTS; the measurement set-up is comparable to the measurement of the PATIENT AUXILIARY CURRENT.

## 20.2 Requirements for EQUIPMENT with an APPLIED PART

Insulation of the insulation paths B-b and B-d can be based on insulation incorporated in ACCESSORIES (e.g. TRANSDUCERS or PATIENT CABLES)

## 36 Electromagnetic compatibility

Individual and preconfigured PATIENT monitors ('EQUIPMENT') that are used today in intensive care units or operating theatres allow many different combinations of PHYSIOLOGICAL MONITORING UNITS. The requirement of clause 36 is based on the assumption that EQUIPMENT configured with all specified PHYSIOLOGICAL MONITORING UNITS represents the worst case configuration for EMC testing. Testing of all possible combinations of PHYSIOLOGICAL MONITORING UNITS with all specified accessories is economically not feasible.

### 51.101.3 SUSPENSION or INHIBITION of all PHYSIOLOGICAL ALARMS and TECHNICAL ALARMS

Unless otherwise noted, the function INHIBITION is a global function and disables all ALARMS of an EQUIPMENT.

The function SUSPENSION is a global function and disables all ALARMS of an EQUIPMENT temporarily. The function SUSPENSION cannot be applied for individual PHYSIOLOGICAL ALARMS.

INHIBITION or SUSPENSION of ALARMS disables the auditory or the auditory and visual ALARM indications of all PHYSIOLOGICAL ALARMS and the auditory indications of all TECHNICAL ALARMS. The activation of INHIBITION or SUSPENSION allows the OPERATOR to prevent false ALARMS. Clinical conditions in which INHIBITION or SUSPENSION may be used are, for instance, setting up the EQUIPMENT, treatment of the PATIENT, suctioning, washing etc. The reason that only one of the functions INHIBITION and SUSPENSION has to be provided to the OPERATOR in NORMAL USE is the following: the selection (configuration) of only one choice (either INHIBITION or SUSPENSION) prevents the OPERATOR from misusing two similar functions with different consequences as far as the PATIENT safety is concerned.

The configuration of the functions INHIBITION or SUSPENSION has to be protected. Protected means that the OPERATOR of the device must not have access to the selection of INHIBITION or SUSPENSION during NORMAL USE. Adequate protection mechanisms may be device internal switches or password protection to prevent entering a configuration mode.

### 51.101.9 Remote control of INHIBITION and SUSPENSION of ALARMS

The configuration that enables the function remote INHIBITION or remote SUSPENSION has to be protected. Protected means that the OPERATOR of the device must not have access to the selection of remote INHIBITION or remote SUSPENSION during NORMAL USE. Adequate protection mechanisms may be device internal switches or password protection to prevent entering a configuration mode.

### 51.102.2 SILENCE/RESET of PHYSIOLOGICAL ALARMS

Abnormal PATIENT condition means ALARMS that may occur but are not related to an exceeded ALARM limit. For instance, a ventricular fibrillation or a low flat pressure line are PHYSIOLOGICAL ALARMS but are not related to an exceeded ALARM limit.



### 51.102.5 Visual manifestation of PHYSIOLOGICAL ALARMS

SUSPENSION or INHIBITION of visual PHYSIOLOGICAL ALARMS only would not allow the OPERATOR to identify the source of the ALARM. INHIBITION or SUSPENSION of PHYSIOLOGICAL ALARMS may be applied for auditory PHYSIOLOGICAL ALARMS only. In this case, the auditory ALARMS are disabled but the visual ALARMS are indicated. INHIBITION or SUSPENSION of auditory PHYSIOLOGICAL ALARMS but not the visual PHYSIOLOGICAL ALARMS is commonly used for attended monitoring.

### 51.103 TECHNICAL ALARM

A TECHNICAL ALARM may influence the validity of the measured value. For instance, the TECHNICAL ALARM 'ECG leads-off' prevents that a heart rate is calculated and displayed. Continuing to display the previously calculated heart rate may lead to misinterpretations by the OPERATOR because this value is invalid during the TECHNICAL ALARM. Appropriate means to display the invalidity of the heart rate might be a blank heart rate field or a symbol that replaces the heart rate and indicates that a valid heart rate is not available. In other cases, the measurement tolerance might be influenced or the measurement might be unreliable. In those cases, the OPERATOR should be informed that the currently displayed value might be questionable. The displayed value should be marked accordingly.

### 51.103.2 Visual manifestation of TECHNICAL ALARMS

Last paragraph: TECHNICAL ALARMS are also indicated when sensors, probes, or modules are intentionally disconnected by the OPERATOR because the EQUIPMENT may not differ between intentional and unintentional disconnection. In cases where a sensor, a probe, or a module is intentionally disconnected by the OPERATOR, a means is required that allows to disable the visual manifestation of those TECHNICAL ALARMS. Possible situations are, for instance, that a non-invasive blood pressure measurement is intentionally discontinued because a non-invasive pressure measurement is adequate and associated with a lower risk.

### 56.3

There are two sets of circumstances to guard against.

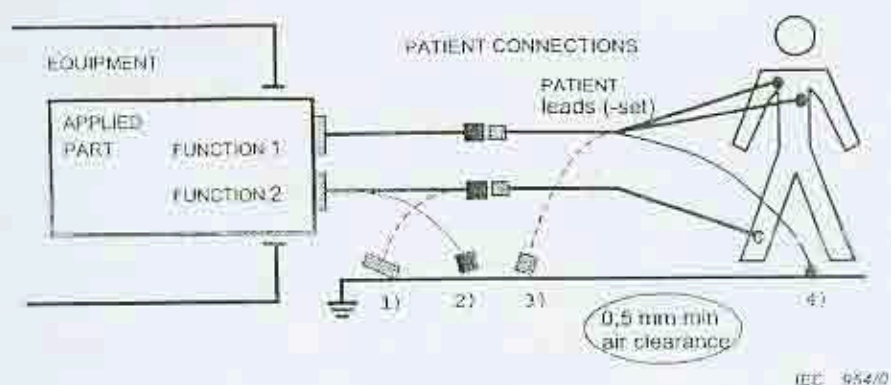
- Firstly, for TYPE BF and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any LEAD which may become detached from the EQUIPMENT or the PATIENT; however, this standard does not specify any protection within a function. The requirements for each function are specified in their particular standard.
- Secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to any LIVE parts or hazardous voltages via any LEAD that may become detached from the PATIENT or EQUIPMENT.

These requirements prevent, for instance, the use of exposed metal connectors such as banana plugs, clips etc. on ECG lead cables.

As indicated in Annex A of the General Standard, such an incident is rendered safe by the requirement for the PATIENT connector (all connectors of a PATIENT CONNECTION) to be protected by insulation having a CREEPAGE DISTANCE of at least 1.0 mm and a dielectric strength of at least 1 500 V.

Figure AA.101 illustrates the requirements and rationale of 56.3 c).

Figure AA.102 illustrates multiple SINGLE FUNCTIONS on the same APPLIED PART and SINGLE FUNCTIONS on multiple APPLIED PARTS.



#### Legend

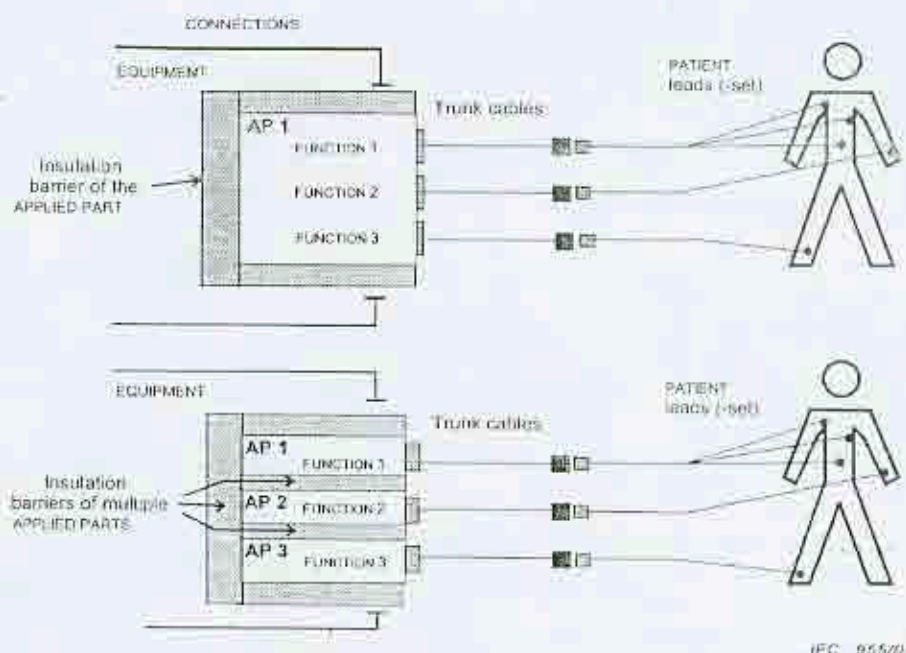
- CONDUCTIVE CONNECTION to the PATIENT illustrating 56.3 c); connectors remote to the PATIENT
- CONDUCTIVE CONNECTION to the PATIENT illustrating 56.3 aa); connectors remote to the EQUIPMENT

Items 1 to 4 illustrate CONDUCTIVE CONNECTIONS to and from the PATIENT. Without protective means, disconnected CONDUCTIVE CONNECTIONS may earth the PATIENT.

- 1), 3) CONDUCTIVE CONNECTION to a PATIENT (56.3 c) of the General Standard)  
– 1 mm/1 500 V if the connector is able to be plugged into a mains socket;
- 2), 4) PATIENT-to-earth connection via the APPLIED PART (additions 19.3 g) and 56.3 c) of this Particular Standard)  
– 0,5 mm air clearance

Figure AA.101 – Single APPLIED PART with multiple SINGLE FUNCTIONS and PATIENT CONNECTIONS





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**Legend:**

- ☐ CONDUCTIVE CONNECTION to the PATIENT illustrating 56.3 c) connectors remote to the PATIENT
- ☒ CONDUCTIVE CONNECTION to the PATIENT illustrating 56.3 aa) connectors remote to the EQUIPMENT

**Figure AA.102 – Single APPLIED PART (AP1) with multiple SINGLE FUNCTIONS and PATIENT CONNECTIONS and MULTIPLE APPLIED PARTS (AP1-3) with SINGLE FUNCTIONS and PATIENT CONNECTIONS**

## Annex BB (informative)

### Alarm diagrams of clause 51

The following ALARM status diagrams illustrate the auditory and visual ALARM indications for LATCHED and NON-LATCHED ALARMS as defined in clause 51.

#### NON-LATCHING ALARM w/o SILENCE/RESET

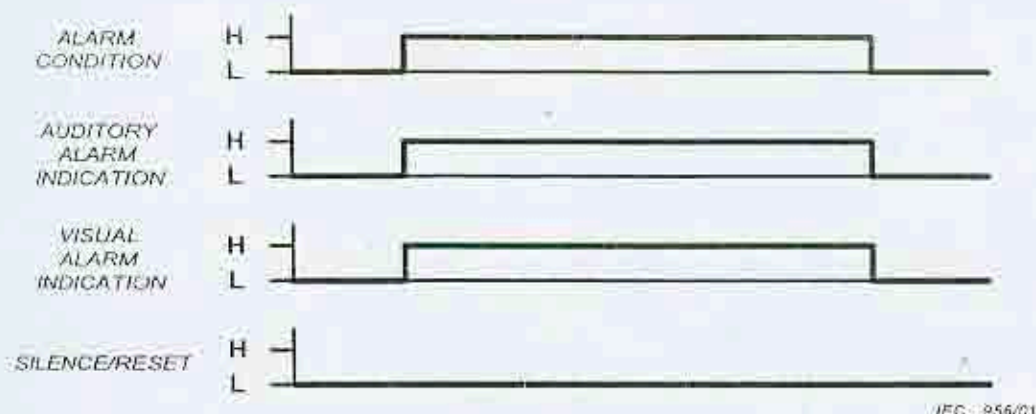
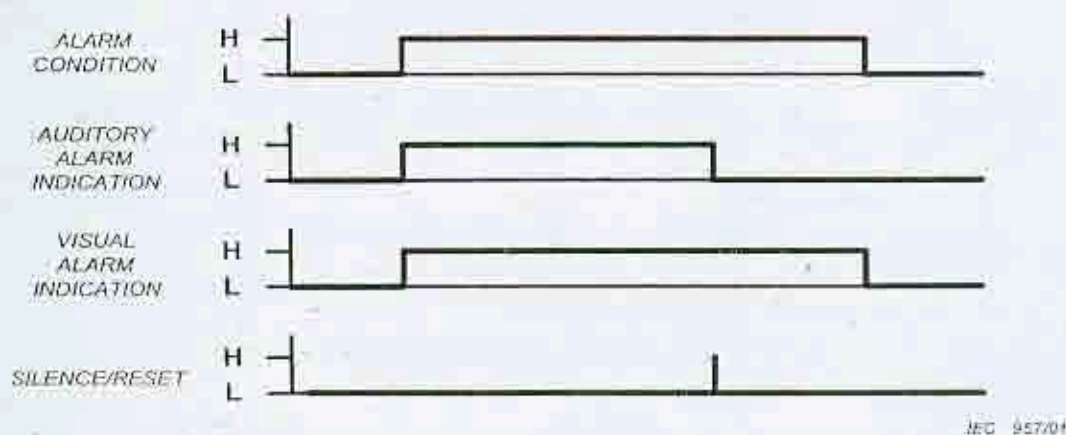


Figure BB.101 – Non-LATCHING ALARMS w/o SILENCE/RESET

Illustration of 51.101.6 (figure BB.101): Without OPERATOR interaction, the auditory and visual ALARM indications are given as long as the ALARM condition exists. As soon as the ALARM condition ceases, the auditory and visual ALARM indications are removed automatically.

#### NON-LATCHING ALARM with SILENCE/RESET



#### Legend:

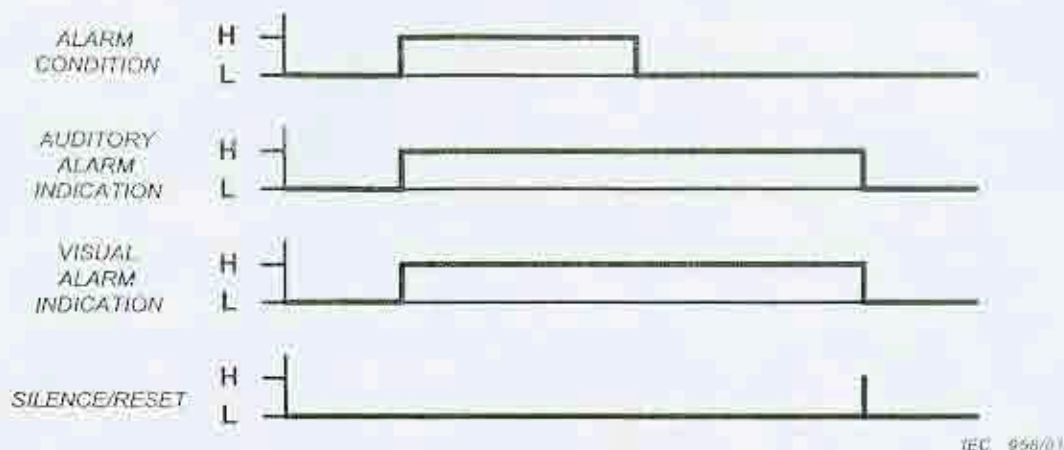
H ACTIVATED STATE  
L DEACTIVATED STATE

Figure BB.102 – Non-LATCHING ALARMS with SILENCE/RESET

Illustration of 51.101.6, 51.102.4 and 51.102.5: SILENCE/RESET stops the auditory ALARM indication (figure BB.102). As soon as the ALARM condition ceases the visual ALARM indication is removed.



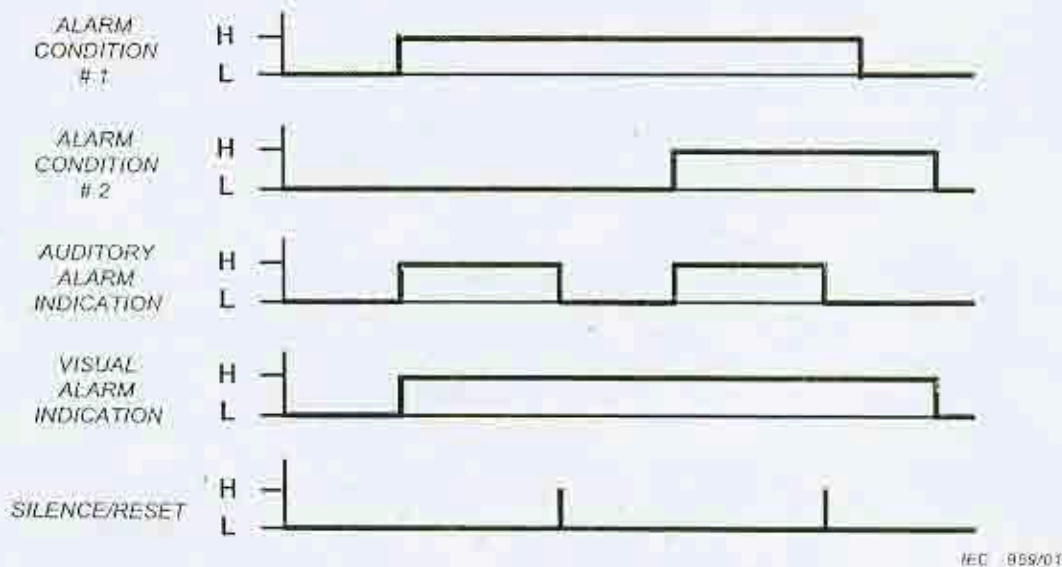
**LATCHING ALARM with SILENCE/RESET**



**Figure BB.103 – Latched alarms with silence/reset**

Illustration of subclauses 51.101.7, 51.102.4, and 51.102.5 (figure BB.103): Without OPERATOR interaction, the auditory and visual ALARM indications are given for an unlimited time. The OPERATOR is forced to SILENCE/RESET a PHYSIOLOGICAL ALARM. After SILENCE/RESET the ALARM behavior compares to NON-LATCHED ALARMS.

**Two ALARMS with SILENCE/RESET**



**Legend:**

H ACTIVATED STATE  
L DEACTIVATED STATE

**Figure BB.104 – Two ALARMS with SILENCE/RESET**

Illustration of 51.102.4 and 51.102.5 (figure BB.104): a new ALARM condition of another physiological parameter reactivates the auditory ALARM indication.

## INHIBITION of ALARMS

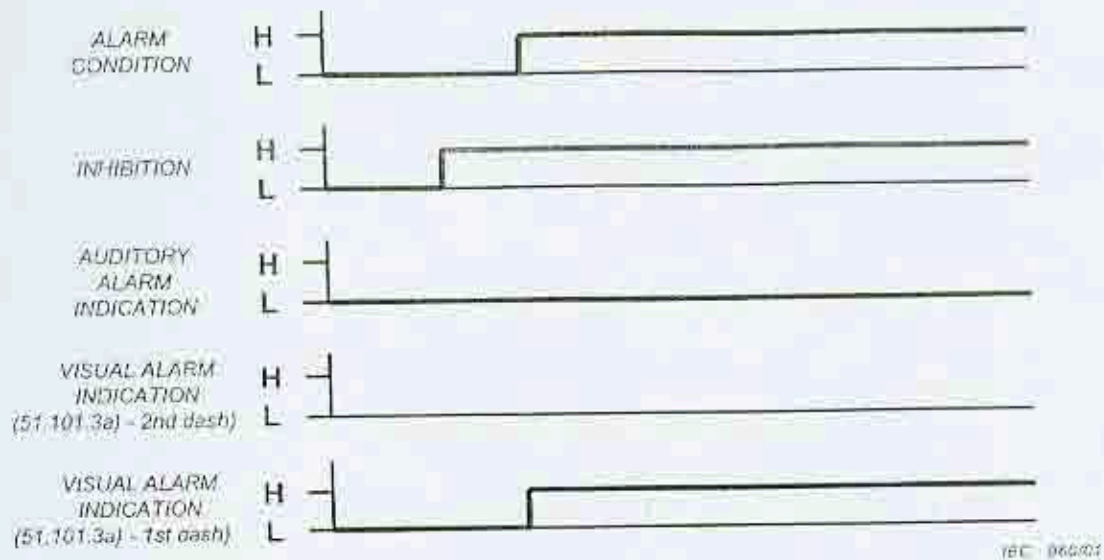
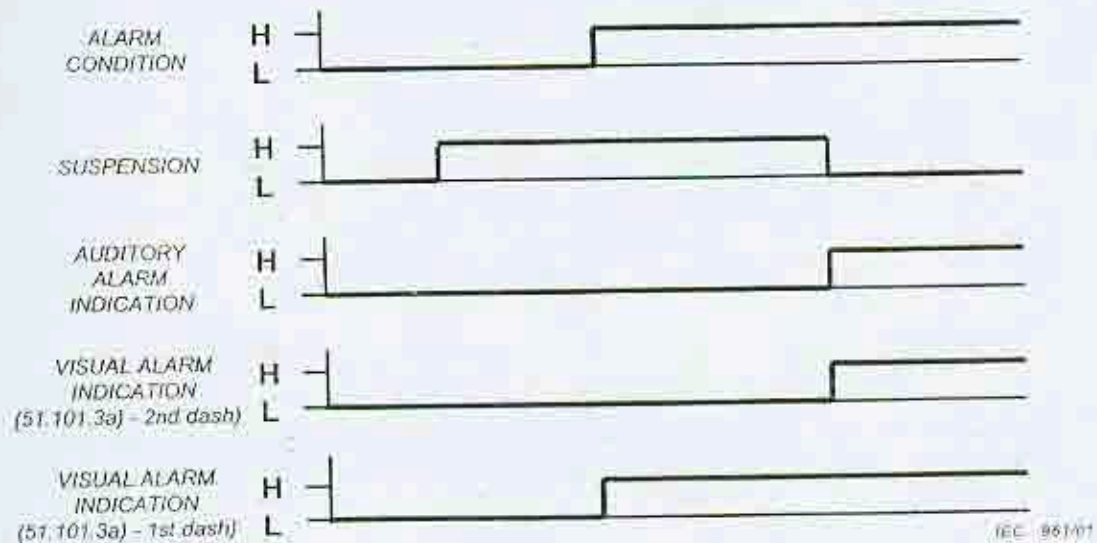


Figure BB.105 – INHIBITION of ALARMS

Illustration of 51.101.3, 51.102.4, and 51.102.5: INHIBITION of ALARMS disables the auditory ALARM indication and may disable the visual ALARM indication (figure BB.105).

## SUSPENSION of ALARMS



## Legend:

H ACTIVATED STATE  
L DEACTIVATED STATE

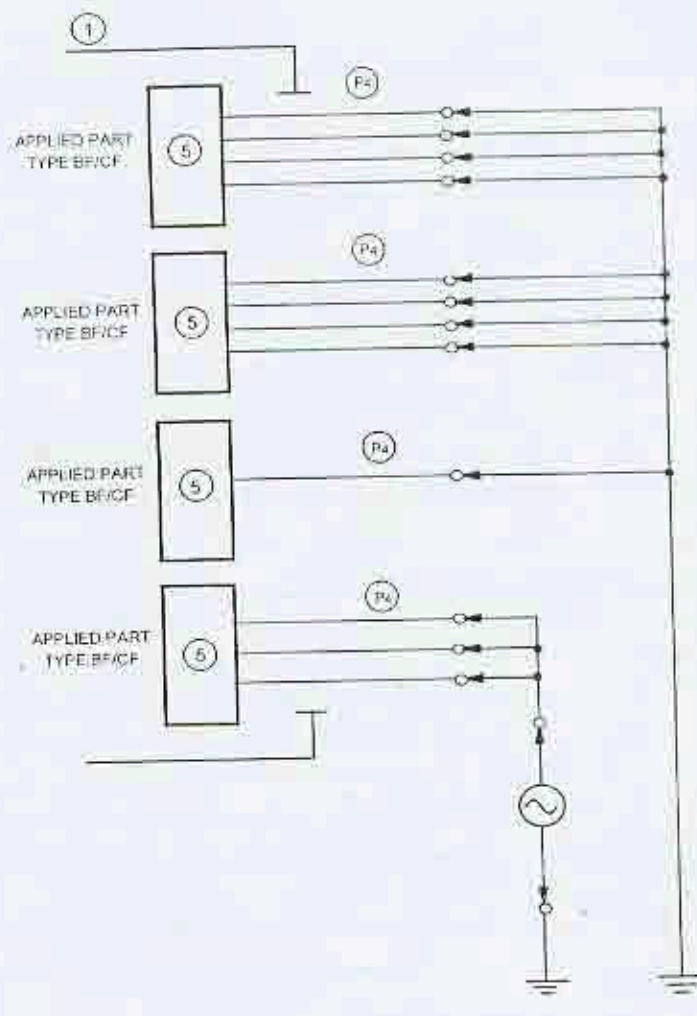
Figure BB.106 – SUSPENSION of ALARMS

Illustration of 51.101.3, 51.102.4, and 51.102.5: SUSPENSION of ALARMS disables the auditory ALARM indication and may disable the visual ALARM indication temporarily (figure BB.106).



# Annex EE (informative)

## Survey of insulation paths and test circuit (See 20.4)



MEC 962/01

TYPE BF/CF MULTIPARAMETER PATIENT MONITORING EQUIPMENT: between input terminals of one APPLIED PART and all remaining APPLIED PARTS whose input terminals are connected together.

### Legend

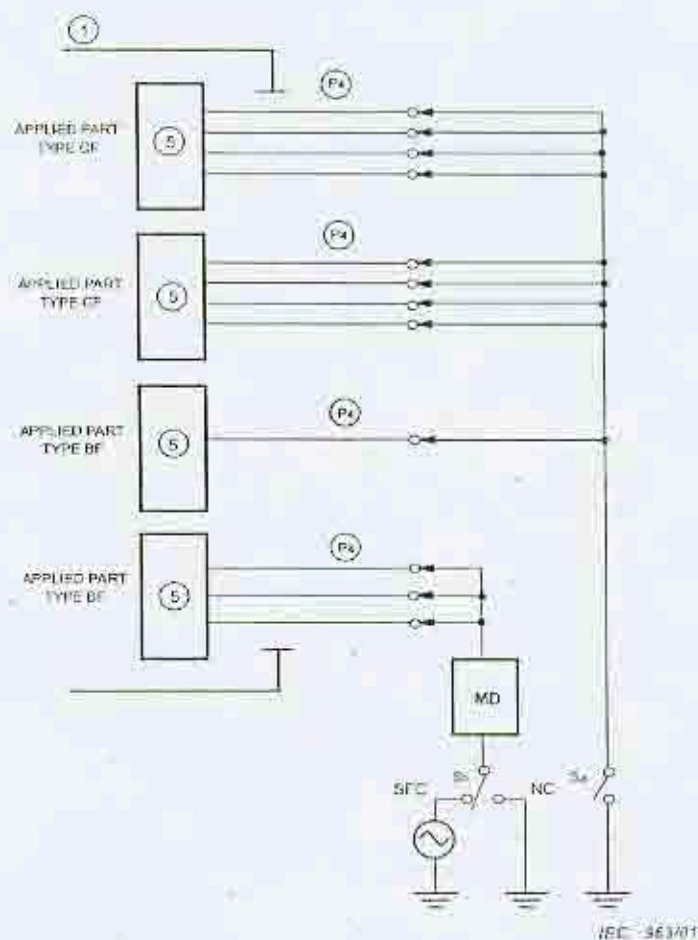
- 1 EQUIPMENT ENCLOSURE
- 5 APPLIED PART
- P4 PATIENT CONNECTIONS

Figure EE.101 – Dielectric strength measurement of EQUIPMENT having more than one APPLIED PART.

## Annex KK (informative)

### Examples of PATIENT LEAKAGE CURRENT measurements

The following figures provide examples of the connection of APPLIED PARTS for measurement of PATIENT LEAKAGE CURRENTS and PART LEAKAGE CURRENTS as discussed in clause 19.



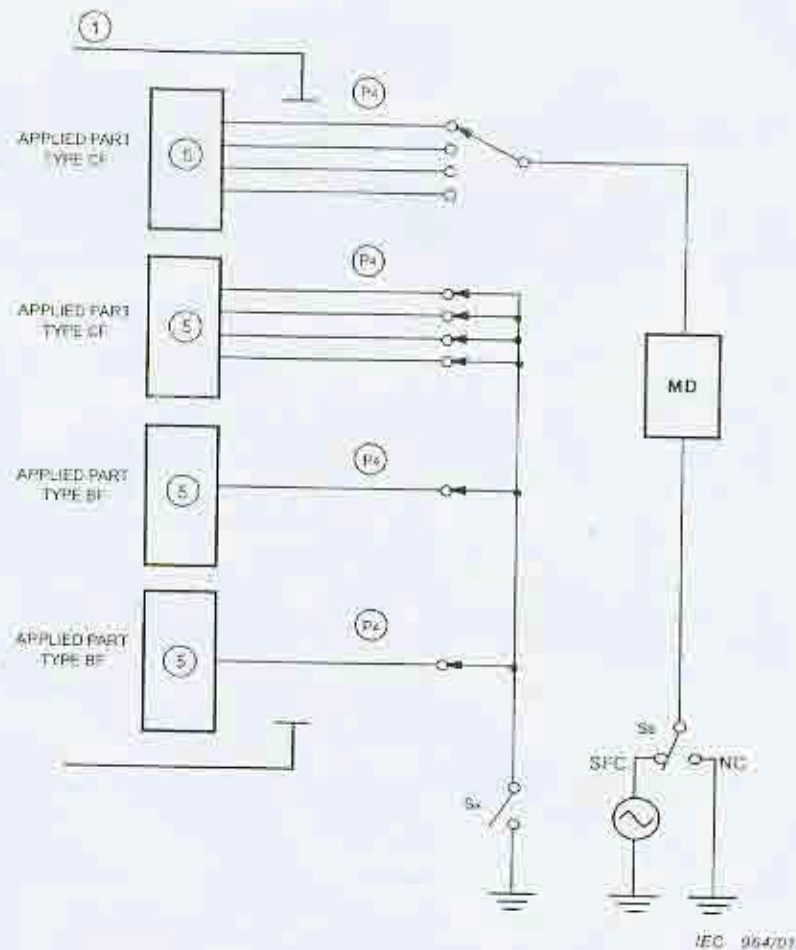
TYPE BF APPLIED PARTS OF MULTIPARAMETER PATIENT MONITORING EQUIPMENT: from and to all PATIENT CONNECTIONS of an APPLIED PART connected together.

#### Legend

1	EQUIPMENT ENCLOSURE
5	APPLIED PART
P4	PATIENT CONNECTIONS
Sa	Switch a; connects/disconnects APPLIED PARTS to/from earth
Sb	Switch b; switches between N.C. and S.F.C.
N.C.	NORMAL CONDITION
S.F.C.	SINGLE FAULT CONDITION

Figure KK.101 – PATIENT LEAKAGE CURRENT measurement of TYPE BF APPLIED PARTS  
(see 19.3 aa) 2))



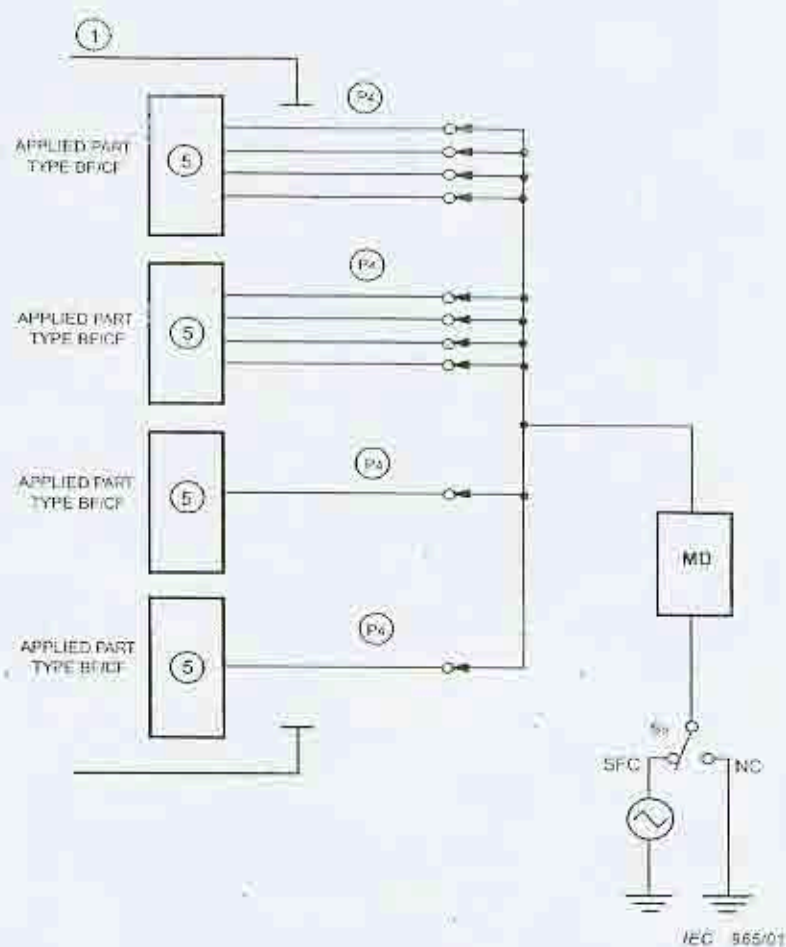


TYPE CF MULTIPARAMETER PATIENT MONITORING EQUIPMENT from and to every PATIENT CONNECTION of the APPLIED PART

Legend

- 1 EQUIPMENT ENCLOSURE
- 5 APPLIED PART
- P4 PATIENT CONNECTIONS
- Sa Switch a; connects/disconnects APPLIED PARTS to/from earth
- Sb Switch b; switches between N.C. and S.F.C.
- N.C. NORMAL CONDITION
- S.F.C. SINGLE FAULT CONDITION

Figure KK.102 – PATIENT LEAKAGE CURRENT measurement of TYPE CF APPLIED PARTS (see 19.3 bb))



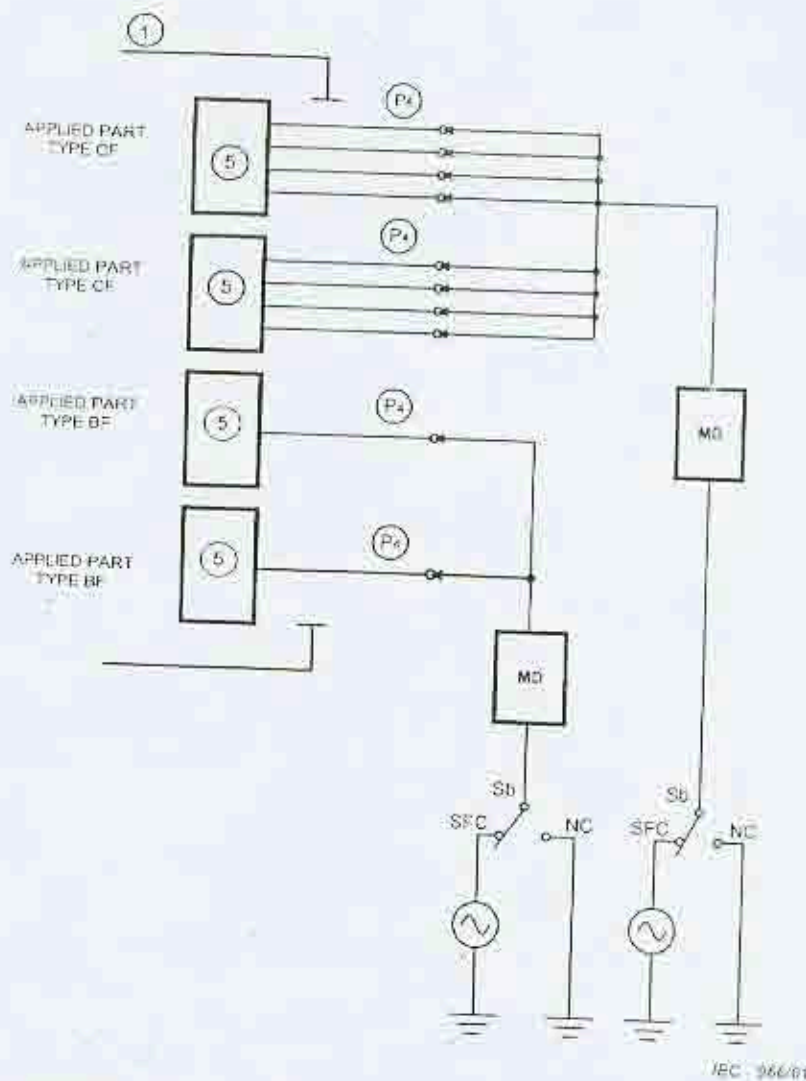
MULTIPARAMETER PATIENT MONITORING EQUIPMENT consisting of TYPE BF or TYPE CF APPLIED PARTS: all PATIENT CONNECTIONS of only TYPE BF or only TYPE CF APPLIED PARTS connected together

#### Legend

1	EQUIPMENT ENCLOSURE
5	APPLIED PART
P4	PATIENT CONNECTIONS
S <sub>b</sub>	Switch b; switches between N.C. and S.F.C.
N.C.	NORMAL CONDITION
S.F.C.	SINGLE FAULT CONDITION

Figure KK.103 – TOTAL PATIENT LEAKAGE CURRENT of only TYPE BF or only CF APPLIED PARTS under NORMAL CONDITION and SINGLE FAULT CONDITION (see 19.3 cc))



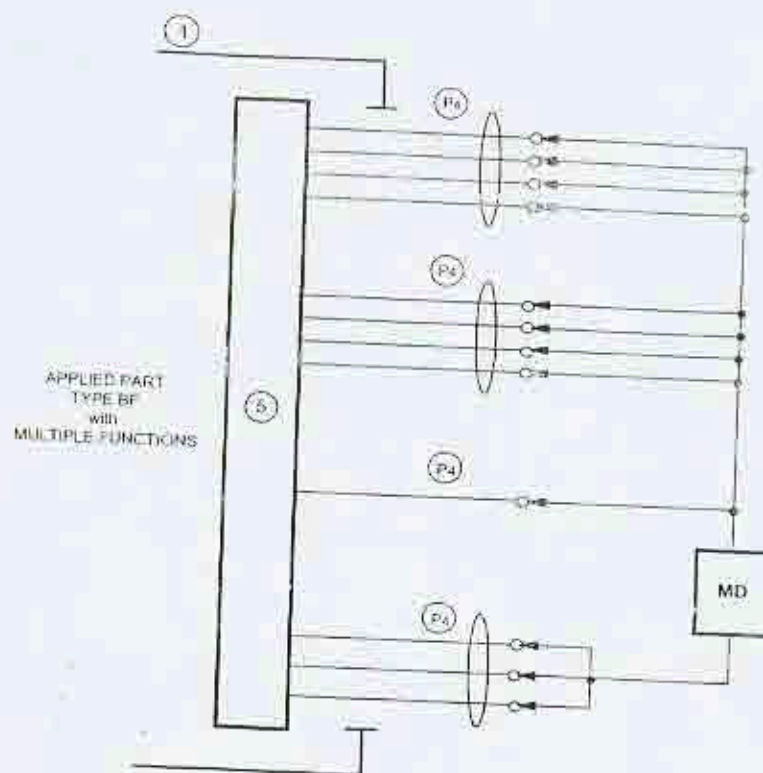


MULTIPARAMETER PATIENT MONITORING EQUIPMENT consisting of TYPE BF and TYPE CF APPLIED PARTS: all PATIENT CONNECTIONS of the same type of APPLIED PARTS connected together.

**Legend**

- 1 EQUIPMENT ENCLOSURE
- 5 APPLIED PART
- P4 PATIENT CONNECTIONS
- Sb Switches; switches between N.C. and S.F.C.
- N.C. NORMAL CONDITION
- S.F.C. SINGLE FAULT CONDITION

**Figure KK.104 – TOTAL PATIENT LEAKAGE CURRENT of EQUIPMENT having TYPE BF and TYPE CF APPLIED PARTS under NORMAL CONDITION and SINGLE FAULT CONDITION (see 19.3 cc))**



IEC 957/01

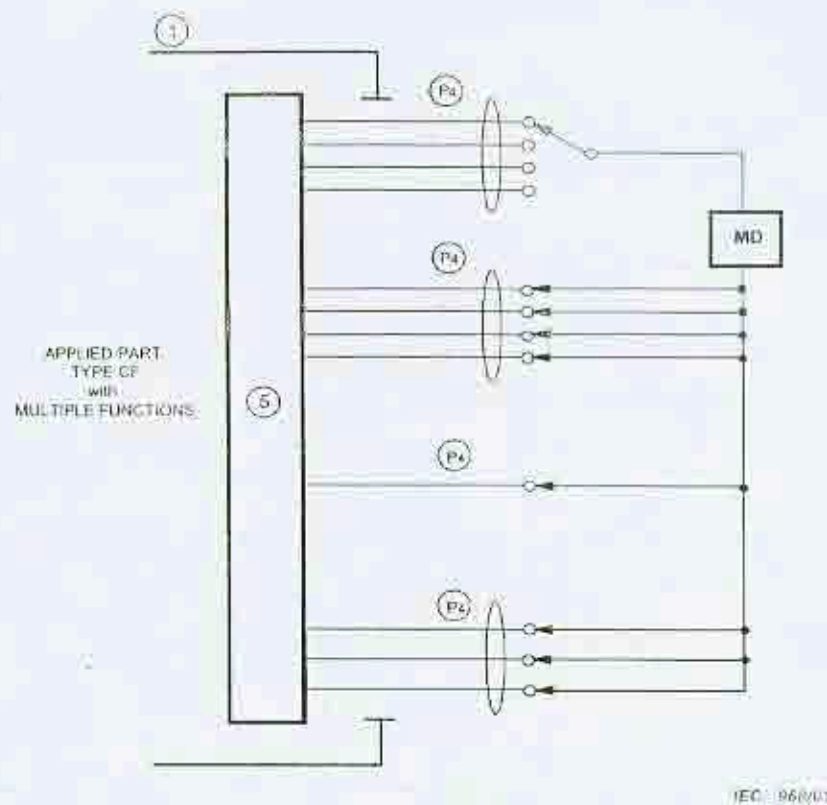
TYPE BF MULTIPARAMETER PATIENT MONITORING EQUIPMENT: between any SINGLE FUNCTION and the remaining SINGLE FUNCTIONS of the same APPLIED PART in turn.

#### Legend

- 1 EQUIPMENT ENCLOSURE
- 5 APPLIED PART
- P4 PATIENT CONNECTIONS of a SINGLE FUNCTION

Figure KK.105 – PART LEAKAGE CURRENT measurement  
of TYPE BF APPLIED PARTS with MULTIPLE FUNCTIONS  
(see 19.3 dd))



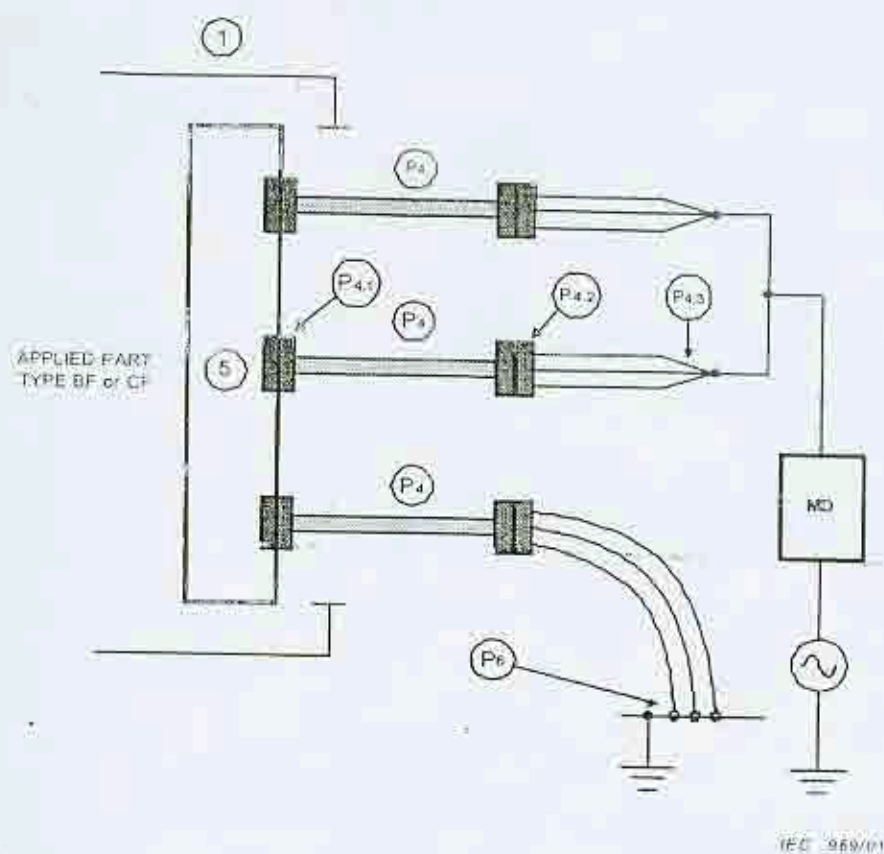


TYPE CF MULTIPARAMETER PATIENT MONITORING EQUIPMENT: between any single PATIENT CONNECTION of a SINGLE FUNCTION and all other PATIENT CONNECTIONS of the same APPLIED PART connected together.

#### Legend

- 1 EQUIPMENT ENCLOSURE
- 5 APPLIED PART
- P4 PATIENT CONNECTIONS of a SINGLE FUNCTION

Figure KK.106 – PART LEAKAGE CURRENT measurement  
of TYPE CF APPLIED PARTS with MULTIPLE FUNCTIONS  
(see 19.3 ee))



#### Legend

- 1 EQUIPMENT ENCLOSURE
- 5 APPLIED PART WITH MULTIPLE FUNCTIONS
- P4 PATIENT CONNECTION may consist of a PATIENT CABLE and lead cable
  - P4.1 connectors APPLIED PART to PATIENT CONNECTION
  - P4.2 connectors PATIENT CABLE to lead cable
  - P4.3 lead cable
- P6 conductive part (for example lead connectors) having earth connection

**Figure KK.107 – Total PATIENT LEAKAGE CURRENT of TYPE BF and CF APPLIED PARTS with MULTIPLE FUNCTIONS under SINGLE FAULT CONDITION (see 19.3 ff)**



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