INTERNATIONAL STANDARD

IEC 60601-2-16

Second edition
1998-02

Medical electrical equipment –

Part 2-16:
Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

Appareils électromédicaux –

Partie 2-16:
Règles particulières de sécurité pour les appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration

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The attention of readers is drawn to the end pages of this publication which list the IEC publications issued by the technical committee which has prepared the present publication.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration 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.
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3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
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International Standard IEC 60601-2-16 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/254/FDIS	62D/271/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.

Annex AA is for information only.

In this standard, the following print types are used:

– requirements, compliance with which can be tested and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller type;
– *test specifications: italic type*;
– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 60601-1: SMALL CAPITALS.

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

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

This particular standard does not take into consideration the specific safety aspects of systems using regeneration of DIALYSING FLUID.

This particular standard amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a 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.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This particular standard specifies the minimum safety requirements for single PATIENT HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT (as defined in 2.101). These devices are intended for use either by medical staff or under the supervision of medical expertise, including HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT operated by the PATIENT. These particular requirements do not apply to

– EXTRACORPOREAL CIRCUITS,
– DIALYSERS,
– DIALYSING FLUID CONCENTRATES,
– water purification EQUIPMENT,
– EQUIPMENT used to perform peritoneal dialysis (see IEC 60601-2-39).

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 IEC 60601-1 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. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this particular standard.

"Addition" means that the clause or subclause 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.

1.5 Collateral standards

IEC 60601-1-2 applies (see clause 36).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The EXTRACORPOREAL CIRCUIT and the DIALYSING FLUID circuit and/or all parts permanently and conductively connected to it.

2.2.15 MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT)

Addition:

Under the scope of this particular standard EQUIPMENT means HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT.

Additional definitions:

2.101 HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT

A system or combination of units used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION (also refer to 2.2.15).

2.102 HAEMODIALYSIS (HD)

Process whereby solute imbalances in a PATIENT's blood are corrected mainly by diffusion across a semi-permeable membrane.

NOTE – This process normally includes fluid removal.

2.103 HAEMOFILTRATION (HF)

A process whereby solute imbalances of a PATIENT's blood are corrected mainly by filtration across a semi-permeable membrane.

NOTE – This process includes fluid exchange and normally fluid removal.

2.104 HAEMODIAFILTRATION (HDF)

A process whereby solute imbalances in a PATIENT's blood are corrected by means of simultaneous filtration and diffusion across a semi-permeable membrane.

NOTE – This process includes fluid exchange and normally fluid removal.

2.105 BUFFER-FREE HAEMODIAFILTRATION

A specific form of HDF where the buffer is not given to the PATIENT with the DIALYSING FLUID, but with the SUBSTITUTION FLUID.

2.106 DIALYSER

For the purpose of this particular standard, the term DIALYSER is used to describe any device containing a semi-permeable membrane that is used to perform HD/HDF/HF.

2.107 DIALYSING FLUID

A solution which is intended to exchange solutes and/or water with blood during HD/HDF.

NOTE – The words "dialysate" and "dialysis fluid" are commonly used as synonyms of DIALYSING FLUID.

2.108 DIALYSING FLUID CONCENTRATE

A solution of chemicals which, when appropriately diluted, produces the DIALYSING FLUID.

2.109 SUBSTITUTION FLUID

A fluid which during HF or HDF is administered to the PATIENT via the EXTRACORPOREAL CIRCUIT.

2.110 ULTRAFILTRATION

The process of fluid removal from the PATIENT's blood across the DIALYSER.

2.111 EXTRACORPOREAL CIRCUIT

Blood lines and any integral ACCESSORY thereof.

2.112 TRANSMEMBRANE PRESSURE (TMP)

Hydrostatic PRESSURE exerted across a semi-permeable membrane.

NOTE – For practical reasons the mean TMP is generally expressed as either

a) the difference between the arithmetic mean of inlet and outlet PRESSURES of the blood and DIALYSING FLUID compartments of a DIALYSER, or

b) the difference between the arithmetic mean of the inlet and outlet PRESSURES of the blood compartment, and the filtrate PRESSURE of a haemofilter or a haemoconcentrator.

2.113 BLOOD LEAK

A leakage of blood from the blood compartment to the DIALYSING FLUID compartment of the DIALYSER due to a rupture of the semi-permeable membrane.

2.114 ARTERIAL PRESSURE

The PRESSURE measured in the EXTRACORPOREAL CIRCUIT between the PATIENT and the arterial blood pump.

2.115 VENOUS PRESSURE

The PRESSURE measured in the EXTRACORPOREAL CIRCUIT between the outlet from the DIALYSER and the return to the PATIENT.

2.116 VENOUS PART

Part of the EXTRACORPOREAL CIRCUIT between the outlet of the DIALYSER and the PATIENT.

2.117 PROTECTIVE SYSTEM

An automatic system which senses a specified parameter (or parameters), or a constructional feature, specifically designed to protect the PATIENT against SAFETY HAZARDS which may arise.

3 General requirements

This clause of the General Standard applies except as follows:

3.6

Addition:

j) Failure of a PROTECTIVE SYSTEM (see 51.101);

k) The following is not regarded as a SINGLE FAULT CONDITION:

Air in the EXTRACORPOREAL CIRCUIT.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall additionally include:

– a statement pointing out the importance of compliance with any local regulation in respect of separation of devices in the water supply, back syphonage and the air clearance between the EQUIPMENT waste connector and the drain.

6.8.2 Instructions for use

Addition:

aa) The instructions for use shall additionally include the following:

1) a statement that it is essential for the EQUIPMENT to be installed and used in compliance with appropriate regulations/recommendations on quality of water and other relevant fluids;

2) a statement of the importance of the quality of the protective earth in the installation when CLASS I EQUIPMENT is used;

3) a statement of the applications in which a POTENTIAL EQUALIZATION CONDUCTOR should be used;

4) a description of the method(s) by which disinfection or sterilization is achieved;

5) a statement that the test procedure by which the effectiveness of disinfection or sterilization has been verified is available on request;

6) a description of the range of inlet water PRESSURES, DIALYSING FLUID CONCENTRATE supply PRESSURES, temperatures and flows necessary for operation of the EQUIPMENT;

7) a definition of TRANSMEMBRANE PRESSURE if the manufacturer makes use of one different from that stated in 2.112;

*8) a statement which draws the OPERATOR's attention to the precautions necessary to prevent cross-infection between PATIENTS;

9) a statement which draws the OPERATOR's attention to the SAFETY HAZARDS associated with connection and disconnection of the PATIENT;

10) a statement which draws the OPERATOR's attention to the potential SAFETY HAZARDS arising from improper connections of the EXTRACORPOREAL CIRCUIT;

11) information on possible deviations from the intended ULTRAFILTRATION rate because of single needle specific parameters as e.g. phase sensitive PRESSURE variations;

12) information on the delivered blood volume per time unit related to the pre-setting of the EQUIPMENT for single needle treatments;

13) a statement that comments are available on request, concerning the expected recirculation of the blood flow in the EXTRACORPOREAL CIRCUIT in single needle treatments, if the recommended administration sets, DIALYSERS, fistula needles and catheters are used;

14) information on DIALYSING FLUID CONCENTRATES intended to be used together with the EQUIPMENT;

15) a statement on the SAFETY HAZARDS related to incorrect choice of DIALYSING FLUID CONCENTRATE(S);

16) an explanation of the coloured markings on the concentrate connectors;

17) statements on the potential SAFETY HAZARDS related to reverse ULTRAFILTRATION;

18) a statement about the limited sensitivity of a PROTECTIVE SYSTEM employed according to 51.104;

19) an explanation of the adequate OPERATOR action upon an alarm from any PROTECTIVE SYSTEM;

20) a statement pointing out that, in override mode, the OPERATOR is responsible for monitoring those parameters of any PROTECTIVE SYSTEM which are being overriden;

21) a statement on the possible SAFETY HAZARDS associated with external radio or electromagnetic disturbance which may affect the safe operation of the EQUIPMENT.

6.8.3 Technical description

Addition:

aa) The technical description shall, additionally include the following:

1) the particular measures or conditions to be observed when installing the EQUIPMENT or bringing it into use. These shall include guidance on the type and number of tests to be carried out;

2) for EQUIPMENT that includes integral anti-coagulant pump(s): the type of the pump(s), the range and the accuracy of the flow for such pump(s) and the PRESSURES against which this accuracy is maintained;

3) for EQUIPMENT that includes integral blood pump(s): the range and accuracy of the flows for such pump(s) and the inlet and outlet PRESSURE range over which this accuracy is maintained;

*4) the type, accuracy and limitations of the PROTECTIVE SYSTEM(S) required by 51.101;

5) the type and accuracy of the PROTECTIVE SYSTEM required by 51.102;

6) the method employed, range, accuracy and limitations for the PROTECTIVE SYSTEM required by 51.103;

7) the type and accuracy of the PROTECTIVE SYSTEM required by 51.104.1;

8) the method for the PROTECTIVE SYSTEM required by 51.104.2 and the sensitivity of the PROTECTIVE SYSTEM at the minimum and maximum specified DIALYSING FLUID flow;

9) the type of the PROTECTIVE SYSTEM required by 51.104.3;

10) the type and the accuracy of the PROTECTIVE SYSTEM required by 51.105;

11) the method employed and the sensitivity under test conditions specified by the manufacturer for the PROTECTIVE SYSTEM required by 51.106;

12) the type of the PROTECTIVE SYSTEM required by 51.111;

13) the override time(s) for any PROTECTIVE SYSTEM;

14) the audible alarm silence period;

15) the range of sound PRESSURE levels of any adjustable audible alarm source;

*16) a disclosure of all materials intended to come into contact with the water, DIALYSING FLUID and DIALYSING FLUID CONCENTRATE.

Compliance is checked by inspection.

SECTION 2: ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

19 Continuous LEAKAGE CURRENT and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

19.4 Tests

h) Measurement of the PATIENT LEAKAGE CURRENT

Addition:

12) The point of measurement shall be where both DIALYSING FLUID lines are connected or where both extracorporeal blood lines are connected, whichever is worse. For the duration of the test, a test solution with a conductivity of (14 ± 1) mS/cm, referenced to a temperature of 25 °C, shall be flowing in the DIALYSING FLUID circuit and in the EXTRACORPOREAL CIRCUIT. The EQUIPMENT shall be fully equipped for the intended use as specified by the manufacturer.

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply except as follows:

36 Electromagnetic compatibility

Collateral standard IEC 60601-1-2 applies.

SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

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

This clause 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 (causing accidental wetting) no SAFETY HAZARD shall result.

Compliance is checked by the following test.

The EQUIPMENT is placed in the position of NORMAL USE and subjected for 30 s 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. The test is carried out using tap water. An interrupting device may be used to determine the duration of the test. Immediately after the 30 s exposure, visible moisture on the BODY OF THE EQUIPMENT shall be removed.

Immediately after the above test, inspection shall show that the tap water which may have entered the EQUIPMENT does not wet parts which may cause a SAFETY HAZARD. In case of doubt, the EQUIPMENT shall be subjected to the dielectric strength test specified in clause 20 of the General Standard and it shall function normally.

*44.4 Leakage

Replacement:

The liquid-carrying parts of the EQUIPMENT shall be so shielded against the electrical parts that liquid which may leak under normal working PRESSURE does not lead to the PATIENT being exposed to SAFETY HAZARDS, for example due to short-circuiting of CREEPAGE DISTANCES.

Compliance is checked by the following test.

By means of a pipette, drops of tap water are applied to couplings, to seals and to hoses which might rupture, moving parts being in operation or at rest, whichever is the less favourable.

After these procedures, the EQUIPMENT shall show no signs of wetting of uninsulated LIVE parts or of electrical insulation which is liable to be adversely affected by tap water. In case of doubt, the EQUIPMENT shall be subjected to the dielectric strength test as specified in clause 20 of the General Standard.

The likelihood of other SAFETY HAZARDS is checked by inspection.

In case of doubt when using the above compliance test, the following test may be used.

The test is carried out using the liquid appropriate to that part of the EQUIPMENT. By means of a syringe, a jet of the liquid is directed from couplings, from seals and from hoses that might rupture, moving parts being in operation or at rest, whichever is the less favourable. After these procedures the EQUIPMENT shall show no signs of wetting of uninsulated LIVE parts or of electrical insulation which is liable to be adversely affected by the liquid. In case of doubt, the EQUIPMENT shall be subjected to the dielectric strength test specified in clause 20 of the General Standard.

44.7 Cleaning, sterilization and disinfection

Addition:

For EQUIPMENT employing non-disposable DIALYSING FLUID pathways, means shall be provided for disinfection and/or sterilization to be carried out.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and of the EQUIPMENT.

49 Interruption of the power supply

This clause of the General Standard applies except as follows:

Addition:

49.5 In the event of an interruption of the power supply to the EQUIPMENT, the following safe conditions shall be achieved:

– activation of an audible alarm, lasting for at least 1 min (see 51.107);
– stopping of the DIALYSING FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION to its minimum value.

Compliance is checked by inspection and by functional tests.

SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply except as follows:

51 Protection against hazardous output

This clause of the General Standard applies except as follows:

51.2 Indication of parameters relevant to safety

Addition:

If the EQUIPMENT can be used for different operation modes, the selected operation mode shall be obvious to the OPERATOR.

Compliance is checked by inspection.

*51.101 DIALYSING FLUID composition

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any fluid preparation control system, which prevents the DIALYSING FLUID from reaching the DIALYSER, which, due to its composition, may cause a SAFETY HAZARD.

NOTE – An acceptable method of complying with this requirement is for example a PROTECTIVE SYSTEM utilizing measurement of conductivity by a temperature compensated (25 °C) method.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

- activation of an audible and visual alarm (see 51.107);
- stopping of the DIALYSING FLUID flow to the DIALYSER.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

*51.102 DIALYSING FLUID and SUBSTITUTION FLUID temperature

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any temperature control system, which prevents the DIALYSING FLUID from reaching the DIALYSER and the SUBSTITUTION FLUID from reaching the blood at a temperature higher than 41 °C, measured at the EQUIPMENT DIALYSING FLUID and/or SUBSTITUTION FLUID outlet.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

- activation of an audible and visual alarm (see 51.107);
- stopping of the DIALYSING FLUID flow to the DIALYSER and/or SUBSTITUTION FLUID flow to the blood.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

*51.103 ULTRAFILTRATION

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any ULTRAFILTRATION control system, which prevents a variation in the output of the EQUIPMENT from the set value of the controlling parameter that can cause a SAFETY HAZARD.

In case of HDF and HF there shall be a PROTECTIVE SYSTEM, independent of any SUBSTITUTION FLUID control system, which prevents an incorrect administration of the SUBSTITUTION FLUID that can cause a SAFETY HAZARD.

NOTE – Acceptable methods of complying with this requirement are for example a PROTECTIVE SYSTEM utilizing measurement of TRANSMEMBRANE PRESSURE, DIALYSING FLUID PRESSURE, ULTRAFILTRATION/SUBSTITUTION FLUID volume or rate.

b) Operation of the PROTECTIVE SYSTEM shall activate an audible and visual alarm (see 51.107).

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

51.104 Extracorporeal blood loss

51.104.1 Extracorporeal blood loss to the environment

*a) The EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment that can cause a SAFETY HAZARD.

NOTE – An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing measurement of the VENOUS PRESSURE and of the PRESSURES of the other parts of the EXTRACORPOREAL CIRCUIT which are separated from the VENOUS PART by occluding parts (blood pumps, clamps etc.).

*b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

- activation of an audible and visual alarm (see 51.107);
- stopping of the blood pump(s);
- interruption of any SUBSTITUTION FLUID flow;
- clamping of the venous return line;
- reduction of ULTRAFILTRATION to its minimum value.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

51.104.2 BLOOD LEAK

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from a BLOOD LEAK that can cause a SAFETY HAZARD (see 51.108).

NOTE – An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing a photometric blood detector.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

- activation of an audible and visual alarm (see 51.107);
- stopping of the blood pump(s);
- interruption of any SUBSTITUTION FLUID flow;
- reduction of ULTRAFILTRATION to its minimum value.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by a functional test using fresh whole human or bovine blood adjusted to a haematocrit of 0,32 ± 0,02. The test shall be performed with the DIALYSING FLUID in the DIALYSING FLUID flow path and under the worst condition of the specified DIALYSING FLUID flow.

51.104.3 Extracorporeal blood loss due to coagulation

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from blood loss due to coagulation as a consequence of the interruption of the blood flow that can cause a SAFETY HAZARD.

NOTE – An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM operating if the blood pump(s) stops inadvertently.

b) Operation of the PROTECTIVE SYSTEM shall activate an audible and visual alarm (see 51.107).

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

*51.105 ARTERIAL PRESSURE

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from SAFETY HAZARDS caused by an excessive ARTERIAL PRESSURE.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

- activation of an audible and visual alarm (see 51.107);
- stopping of the blood pump(s);

– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION to its minimum value.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

*51.106 Air infusion

a) The EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from air infusion which may cause a SAFETY HAZARD.

NOTE – An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing photometric or ultrasonic air detectors.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:
– activation of an audible and visual alarm (see 51.107);
– stopping of the blood pump(s);
– interruption of any SUBSTITUTION FLUID flow;
– clamping of the venous return line;
– reduction of ULTRAFILTRATION to its minimum value.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

51.107 Alarm conditions and override modes

a) All PROTECTIVE SYSTEMS shall be operational throughout treatment.

NOTE 1 – For exceptions, see item e) below

NOTE 2 – Within the meaning of this subclause treatment is considered to have started when the PATIENT's blood is returned to the PATIENT, treatment is considered to be finished when the arterial needle is disconnected.

*b) Unless otherwise specified by this particular standard, alarms shall be both audible and visual. The visual alarm shall continue to operate throughout the alarm condition, whereas the audible alarm may be silenceable.

c) Audible alarms shall comply with the following:
– produce a sound pressure level of at least 65 dB(A) at 1 m unless adjustable by a special means, for example a TOOL;
– if capable of being silenced, have a silence period not exceeding 2 min.

Compliance is checked by measuring the A-weighted sound PRESSURE level, with an instrumentation complying with the requirements for a type 1 instrument laid down in IEC 60651 or IEC 60804 and free-field conditions according to ISO 3744.

d) Alarms from
– PRESSURE monitoring (see 51.104.1),
– BLOOD LEAK monitoring (see 51.104.2),
– ARTERIAL PRESSURE monitoring (see 51.105),
– air infusion detection (see 51.106),

which occur during an alarm silence period shall cause this silence period to be interrupted and shall achieve the safe conditions specified in 51.104.1, 51.104.2, 51.105 and 51.106.

e) During an alarm condition, temporary override modes (maximum 2 min) may apply individually to PROTECTIVE SYSTEMS utilizing the following measurements:
– PRESSURE (see 51.104.1);
– BLOOD LEAK (see 51.104.2);
– ARTERIAL PRESSURE monitoring (see 51.105);
– air infusion detection (see 51.106).

If over-riding the protective system required by 51.106 allows blood to be pumped to the patient while the air detector is deactivated, the risk of air infusion shall be minimized.

NOTE – An acceptable method of complying with this requirement is to restrict the speed of the blood pump so that air is prevented from reaching the patient during the override period and the OPERATOR is able to inspect the venous return line.

f) Operation of the override mode shall activate a visual indication.

g) Overriding a particular PROTECTIVE SYSTEM (specified in 51.107*)* shall have no effect on any other subsequent alarm conditions. Subsequent alarm conditions shall achieve the safe conditions specified. A remaining alarm condition shall, after the elapsed silence period, re-achieve the safe condition specified.

NOTE – Within the meaning of this subclause, override is the facility to allow the EQUIPMENT to function under alarm conditions by the OPERATOR consciously selecting to temporarily disable the PROTECTIVE SYSTEM.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

51.108 PROTECTIVE SYSTEMS

a) Failure of those PROTECTIVE SYSTEMS listed in table 1 shall become obvious to the OPERATOR within the limits specified.

NOTE – Three acceptable methods of complying with this requirement are for example:

– periodic functional check of all PROTECTIVE SYSTEMS initiated and controlled by the OPERATOR;

– periodic functional check of all PROTECTIVE SYSTEMS initiated by the OPERATOR and controlled by the EQUIPMENT;

– redundancy of PROTECTIVE SYSTEMS with self-checking by the EQUIPMENT.

*b) Stopping the blood pump and clamping the venous return line shall be designed as a redundant function to achieve the safe condition specified in 51.106 b).

Table 1 – PROTECTIVE SYSTEM inspection times

Potential SAFETY HAZARD arising from:	**Example of a PROTECTIVE SYSTEM**	**PROTECTIVE SYSTEM inspection**	**Resulting SAFETY HAZARD due to failure of the PROTECTIVE SYSTEM**
DIALYSING FLUID composition (51.101)	Conductivity measurement	A	High or low DIALYSING FLUID concentration
DIALYSING FLUID temperature (51.102)	Temperature measurement	A	High DIALYSING FLUID temperature
ULTRAFILTRATION (51.103)	TRANSMEMBRANE PRESSURE measurement, DIALYSING FLUID pressure measurement, ULTRAFILTRATE volume measurement	A	Incorrect ULTRAFILTRATION
Extracorporeal blood loss to the environment (51.104.1)	VENOUS PRESSURE measurement	A	Blood loss
ARTERIAL PRESSURE (51.105)	ARTERIAL PRESSURE measurement	A	Damage to the vascular access
BLOOD LEAK (51.104.2)	Photometric blood detection	A	Blood loss
Extracorporeal blood loss due to coagulation (51.104.3)	Detection of blood pump(s) rotation	A	Blood coagulation in the EXTRACORPOREAL CIRCUIT
Air infusion (51.106)	Ultrasonic or photometric air detection	a) output activating the blood pump(s) and venous line clamp: time < B b) blood pump and venous line clamp: A	Air embolism
BUFFER-FREE HDF (51.111)	Measurement of DIALYSING FLUID and SUBSTITUTION FLUID flows	A	Incorrect acid-base balance

A = At least at the beginning of each treatment.

$$B = \frac{\text{volume of the EXTRACORPOREAL CIRCUIT between the air detection sensor and the venous cannula}}{\text{maximum blood flow *}}$$

* (maximum set rate of the blood pump)

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by functional tests.

51.109 Prevention of treatment during cleaning, sterilization and/or disinfection

It shall not be possible to treat the PATIENT while the EQUIPMENT is in the cleaning, sterilization or disinfection mode. Subclauses 3.6 and 49.2 of the General Standard apply.

Compliance is checked by functional tests.

51.110 Blood pump(s) and/or SUBSTITUTION FLUID pump(s) reversal

A method shall be included to prevent inadvertent reversal of the blood and/or SUBSTITUTION FLUID pump(s) during the treatment.

NOTE – One method of complying with this requirement is, for example, to use a unidirectional pump.

Compliance is checked by inspection and by functional tests.

51.111 BUFFER-FREE HDF

a) EQUIPMENT intended to perform BUFFER-FREE HDF shall include a PROTECTIVE SYSTEM, independent of any fluid distribution control system, to protect the patient from SAFETY HAZARDS caused by an incorrect acid-base balance.

NOTE – An acceptable method of complying with this requirement is, for example a PROTECTIVE SYSTEM utilizing measurement of DIALYSING FLUID and SUBSTITUTION FLUID flows.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe conditions:

- activation of an audible and visual alarm (see 51.107);
- interruption of DIALYSING FLUID and SUBSTITUTION FLUID flow.

Compliance is checked by inspection and by functional tests.

51.112 Selection and change of operation modes

Inadvertent selection and change of operation modes shall be prevented.

Compliance is checked by inspection and by functional tests.

SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION 10: CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply except as follows:

Addition :

54 General

This clause of the General Standard applies except as follows:

54.101 The concentrate connector(s) of the EQUIPMENT shall be permanently colour marked to prevent a mixing of the various DIALYSING FLUID CONCENTRATES.

The colour marking shall be affixed in such a way that the OPERATOR can easily match the connector(s) to any coloured marked DIALYSING FLUID CONCENTRATE containers. The following colours shall be used:

- connector for acetate concentrate: white
- connector for acidic concentrate: red
- connector for bicarbonate concentrate: blue
- connector for BUFFER-FREE HDF concentrate: green
- for common usage of one connector for different concentrates, the respective coloured markings shall be affixed on each connector. For example, a common connector for acetate and acidic concentrate shall be marked white/red.

NOTE – An ISO standard* stipulating requirements for the colour coding of DIALYSING FLUID CONCENTRATE containers is currently under consideration.

Compliance is checked by inspection.

* At present ISO/CD 13958.

54.102 Connectors for blood pressure transducers

The external connections to the blood PRESSURE transducers system shall comply with the functional safety aspects of ISO 594-2.

Compliance is checked by inspection and by functional tests.

56 Components and general assembly

This clause of the General Standard applies except as follows:

56.6 Temperature and overload control devices

Addition:

aa) a non-SELF RESETTING THERMAL CUT-OUT is not required for the PROTECTIVE SYSTEM of the DIALYSING FLUID temperature.

Compliance is checked by inspection.

57 MAINS PARTS, components and layout

This clause of the General Standard applies except as follows:

Addition:

57.2 MAINS CONNECTORS, APPLIANCE INLETS and the like

ee) If an AUXILIARY MAINS SOCKET OUTLET is provided for controlled operation of a blood pump and/or a SUBSTITUTION FLUID pump, it shall be of a type not interchangeable mutually or with other AUXILIARY MAINS SOCKET OUTLETS on the EQUIPMENT.

The annexes of the General Standard apply except as follows:

Annex L

References – Publications mentioned in this standard

This annex of the General Standard applies except as follows:

IEC Standards

Addition:

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

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

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

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

IEC 60651:1979, *Sound level meters*
Amendment 1 (1993)

IEC 60801-3:1984, *Electromagnetic compatibility for industrial-process measurement and control equipment – Part 3: Radiated electromagnetic field requirements*

IEC 60804:1985, *Integrating-averaging sound level meters*
Amendment 1 (1989)
Amendment 2 (1993)

ISO publications

Addition:

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

ISO 3744:1994, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Engineering method in an essentially free field over a reflecting plane*