IEC 60601-2-16

Edition 3.0 2008-04

INTERNATIONAL STANDARD

Medical electrical equipment –
Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment



IEC 60601-2-16:2008(E)

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland
Email: inmail@iec.ch
Web: www.iec.ch

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

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ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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International standard IEC 60601-2-16 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition of IEC 60601-2-16, published in 1998. This edition constitutes a technical revision. Changes since the previous edition include, among others, a summary of additional essential performance requirements, revision of terms and definitions, classification of applied parts and limits as numbers for protection against hazardous outputs, in the annex.

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

FDIS	Report on voting
62D/671/FDIS	62D/681/RVD

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

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

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

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

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

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

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

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

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

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

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

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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.

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MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005 applies, except as follows:

201.1.1 Scope

Addition:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT, hereafter referred to as HAEMODIALYSIS EQUIPMENT.

This International standard does not take into consideration the DIALYSING FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSING FLUID and CENTRAL DELIVERY SYSTEMS. It does however take into consideration the specific safety requirements of such HAEMODIALYSIS EQUIPMENT concerning electrical safety and PATIENT safety.

This International standard specifies the minimum safety requirements for HAEMODIALYSIS EQUIPMENT. These devices are intended for use either by medical staff or for use by the PATIENT or other trained personnel under the supervision of medical expertise.

This International standard includes all ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT suffering from kidney failure.

The particular requirements in this International standard do not apply to:

– EXTRACORPOREAL CIRCUITS;
– DIALYSERS;
– DIALYSING FLUID CONCENTRATES;
– water treatment equipment;
– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39).

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

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-1.

NOTE See also 4.2 of IEC 60601-1:2005.

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1*,* and Clause 201.2 of this International Standard. (See also Clauses 202, 203, 206, 208, 209 and 210)

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,* as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1.

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

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

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

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

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

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

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

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

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 52.

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

Addition:

IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

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

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

ISO 8638, *Cardiovascular implants and artificial organs – Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, and IEC 60601-1-10:2007 apply, except as follows:

NOTE An index of defined terms is found beginning on page 53.

201.3.8
***APPLIED PART**

Replacement:

EXTRACORPOREAL CIRCUIT and all parts permanently and conductively connected to it (e.g. DIALYSING FLUID circuit)

NOTE See Figure AA.1 in Annex AA.

201.3.78

PATIENT CONNECTION

Addition:

NOTE The PATIENT blood lines connectors are the individual points on the APPLIED PART through which current can flow between the PATIENT and the HAEMODIALYSIS EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

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Additions:

201.3.201
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

NOTE When the term ME EQUIPMENT is used in headings it is equivalent to HAEMODIALYSIS EQUIPMENT. When the term ME EQUIPMENT is used in the text it is referring to a general ME EQUIPMENT.

201.3.202
HAEMODIALYSIS
HD
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT with renal insufficiency are corrected by bidirectional diffusive transport and ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSING FLUID

NOTE This process normally includes fluid removal by filtration. This process is usually also accompanied by diffusion of substances from the DIALYSING FLUID into the blood.

201.3.203
HAEMOFILTRATION
HF
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT with renal insufficiency are corrected by unidirectional convective transport via ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSING FLUID. Ultrafiltrate is simultaneously replaced by an approximately isoosmolar SUBSTITUTION FLUID at a rate such that the difference between the ULTRAFILTRATION rate and the rate of SUBSTITUTION FLUID addition will lead to removal of the excess fluid over the course of the treatment

201.3.204
HAEMODIAFILTRATION
HDF
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT with renal insufficiency are corrected by a simultaneous combination of HD and HF

201.3.205
DIALYSER
a device containing a semi-permeable membrane that is used to perform HD, HDF or HF

201.3.206
DIALYSING FLUID
solution intended to exchange solutes and/or water with blood during HD or HDF

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

201.3.207
DIALYSING FLUID CONCENTRATE
substances which, when appropriately diluted or dissolved with purified water, produce the DIALYSING FLUID

201.3.208
SUBSTITUTION FLUID
a fluid administered to the PATIENT via the EXTRACORPOREAL CIRCUIT during HF or HDF

201.3.209
***ULTRAFILTRATION**
process of fluid removal from the PATIENT'S blood across the DIALYSER

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201.3.210
EXTRACORPOREAL CIRCUIT
blood lines and any integral ACCESSORY thereof

201.3.211
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across a semi-permeable membrane

NOTE Generally the mean TMP is used. In practice, the displayed TRANSMEMBRANE PRESSURE is usually estimated from the measured EXTRACORPOREAL CIRCUIT pressure and the measured DIALYSING FLUID pressure, each obtained at a single point.

201.3.212
***BLOOD LEAK**
leakage of blood from the blood compartment to the DIALYSING FLUID compartment of the DIALYSER

NOTE When performing an HF process, this involves the filtration fluid section.

201.3.213
ARTERIAL PRESSURE
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT

NOTE 1 A difference can be made between the pre-pump pressure, which is upstream of the blood pump, and post pump pressure, which is downstream of the blood pump .

201.3.214
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT

201.3.215
***PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDS which can arise

201.3.216
***ONLINE HDF**
HAEMODIAFILTRATION procedure where the HAEMODIALYSIS EQUIPMENT, based on the DIALYSING FLUID, produces the SUBSTITUTION FLUID for the HDF treatment, suitable for injection

201.3.217
***ONLINE HF**
HAEMOFILTRATION procedure where the HAEMODIALYSIS EQUIPMENT, based on the DIALYSING FLUID, produces the SUBSTITUTION FLUID for the HF treatment, suitable for injection

201.3.218
CENTRAL DELIVERY SYSTEM

Part of a ME SYSTEM which proportions DIALYSING FLUID CONCENTRATE and water for distribution as DIALYSING FLUID to the HAEMODIALYSIS EQUIPMENT or distributes DIALYSING FLUID CONCENTRATE

201.3.219
NET FLUID REMOVAL
fluid loss from the PATIENT

NOTE Historically this term was “weight loss”.

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201.4 General requirements

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

201.4.3 * ESSENTIAL PERFORMANCE

Additional subclauses:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

ESSENTIAL PERFORMANCE of HAEMODIALYSIS EQUIPMENT includes, but is not limited to the functions found in the subclauses listed in Table 201.101, which must be met within the tolerances specified by the MANUFACTURER, if applicable:

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Blood flow	201.4.3.102
DIALYSING FLUID flow	201.4.3.103
NET FLUID REMOVAL	201.4.3.104
SUBSTITUTION FLUID flow	201.4.3.105
Dialysis time	201.4.3.106
DIALYSING FLUID composition	201.4.3.107
DIALYSING FLUID temperature	201.4.3.108
SUBSTITUTION FLUID temperature	201.4.3.109

NOTE Some ESSENTIAL PERFORMANCES listed in Table 201.101 are dependent on the characteristics of the disposable used (e.g. blood flow is dependent upon the pump segment inner diameter in rotary peristaltic pumps).

201.4.3.102 Blood flow

The blood flow for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

NOTE 1 Only a blood flow lower than the set value is considered as negative for the treatment. Therefore the goal of testing is to find the highest negative blood flow error.

Compliance is checked under the following test conditions for typical peristaltic pumps.

– *Apply a pump segment to the HAEMODIALYSIS EQUIPMENT and let it run for at least 30 min.*
– *Apply a fluid (e.g. water) with a temperature of 37 °C in the EXTRACORPOREAL CIRCUIT.*
– *Set the blood flow of the HAEMODIALYSIS EQUIPMENT to 400 ml/min or – if not possible - to the highest possible blood flow.*
– *Set the ARTERIAL PRESSURE to -200 mmHg.*
– *Measure the blood flow.*

The values of the measured blood flow shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

NOTE 2 Pump segment fatigue can reduce the blood flow rate.

NOTE 3 The blood flow rate in peristaltic pumps can be affected by negative input pressures

201.4.3.103 DIALYSING FLUID flow

The DIALYSING FLUID flow for the DIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

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NOTE Only a DIALYSING FLUID flow lower than the set value is considered as negative for the treatment.

Compliance is checked under the following test conditions.:

– *Set the HAEMODIALYSIS EQUIPMENT to the HAEMODIALYSIS mode as specified by the MANUFACTURER.*
– *Set the HAEMODIALYSIS EQUIPMENT to maximum DIALYSING FLUID flow.*

  Measure the DIALYSING FLUID flow during 30 min.
– *Set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSING FLUID flow.*
– *Measure the DIALYSING FLUID flow during 30 min.*

The values of the DIALYSING FLUID flow shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.104 NET FLUID REMOVAL

The NET FLUID REMOVAL for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

Compliance is checked under the following test conditions.

Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT only:

– *Set the HAEMODIALYSIS EQUIPMENT in the HAEMODIALYSIS mode, if applicable, with a DIALYSER according to the MANUFACTURER's recommendation.*
– *Apply fluid (e.g. water) in THE EXTRACORPOREAL CIRCUIT.*
– *Set the highest DIALYSING FLUID flow, if applicable.*
– *Set the DIALYSING FLUID temperature to 37 °C, if applicable.*
– *Set the NET FLUID REMOVAL rate to 0 ml/h or the lowest adjustable value.*
– *Create a blood outlet pressure of 50 mmHg below the highest specified pressure.*
– *Measure the NET FLUID REMOVAL during an appropriate time interval.*

Continue with test 2:

– *Set the NET FLUID REMOVAL rate to the maximum value.*
– *Measure the net fluid removal during an appropriate time interval.*

Continue with test 3:

– *Create a blood outlet pressure 20 mmHg above the lowest specified pressure.*
– *Measure the NET FLUID REMOVAL during an appropriate time interval.*

The values of the NET FLUID REMOVAL shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.105 SUBSTITUTION FLUID flow

For HAEMOFILTRATION and HAEMODIAFILTRATION equipment only:

The SUBSTITUTION FLUID flow for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

NOTE Only a SUBSTITUTION FLUID flow lower than the set value is considered as negative for the treatment.

Compliance is checked under the following test conditions:

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Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT and of the therapeutic relevant SUBSTITUTION FLUID flow:

– *Set the HAEMODIALYSIS EQUIPMENT to the HDF or HF mode with a DIALYSER according to the MANUFACTURER's recommendation.*
– *Apply fluid (e.g. water) in the EXTRAXCORPOREAL CIRCUIT.*
– *Set the NET FLUID REMOVAL flow to 0 ml/h, or – if not possible – to the minimum.*
– *Set the maximum SUBSTITUTION FLUID flow.*
– *Set the temperature of the SUBSTITUTION FLUID to 37 °C, if applicable.*
– *Measure the SUBSTITUTION FLUID flow and the NET FLUID REMOVAL.*

Continue with test 2:

– *Set the minimum SUBSTITUTION FLUID flow.*
– *Measure the SUBSTITUTION FLUID flow and the NET FLUID REMOVAL.*

The values of SUBSTITUTION FLUID flow and NET FLUID REMOVAL shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.106 Dialysis time

The accuracy of the Dialysis Time for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

Compliance is checked by functional measurements relevant for the definition of Dialysis Time specified by the MANUFACTURER.

201.4.3.107 * DIALYSING FLUID composition

Test method specified by the MANUFACTURER.

201.4.3.108 DIALYSING FLUID temperature

The DIALYSING FLUID temperature for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the DIALYSING FLUID.

Compliance is checked under the following test conditions:

– *Let the HAEMODIALYSIS EQUIPMENT run until it is in a thermally stable condition.*
– *The environmental temperature shall be within 20 °C to 25 °C.*
– *Set the DIALYSING FLUID temperature to 37 °C, if applicable.*
– *Set the highest DIALYSING FLUID flow.*
– *Measure the temperature at the DIALYSER inlet.*
– *Record the temperature during a period of 30 min.*
– *Set the lowest DIALYSING FLUID flow.*
– *Measure the temperature at the DIALYSER inlet.*
– *Record the temperature during a period of 30 min.*

The values of the DIALYSING FLUID temperature shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

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201.4.3.109 SUBSTITUTION FLUID temperature

The tolerances of the SUBSTITUTION FLUID temperature for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the SUBSTITUTION FLUID.

Compliance is checked under the following test conditions.

– *Let the HAEMODIALYSIS EQUIPMENT run until it is in a thermally stable condition.*
– *The environmental temperature is within 20-25 °C.*
– *Set the SUBSTITUTION FLUID temperature to 37 °C, if applicable.*
– *Set the highest SUBSTITUTION FLUID flow.*
– *Measure the temperature of the SUBSTITUTION FLUID at the connection point of the SUBSTITUTION FLUID line to the blood line.*
– *Record the temperature over a period of 30 min.*
– *Set the lowest SUBSTITUTION FLUID flow.*
– *Measure the temperature of the SUBSTITUTION FLUID at the connection point of the SUBSTITUTION FLUID line to the blood line.*
– *Record the temperature over a period of 30 min.*

The values of the SUBSTITUTION FLUID temperature shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

An example of SINGLE FAULT CONDITION is a failure of a PROTECTIVE SYSTEM (see 201.12.4.4.101, 201.12.4.4.102, 201.12.4.4.103, 201.12.4.4.104, 201.12.4.4.105);

NOTE If air is permanently present in the EXTRACORPOREAL CIRCUIT when the HAEMODIALYSIS EQUIPMENT is used as intended by the MANUFACTURER, the air is not regarded as a SINGLE FAULT CONDITION, but as NORMAL CONDITION.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.4.3 Units of measure

Addition:

mmHg may be used for measurement of pressures in any part of the HAEMODIALYSIS EQUIPMENT.

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201.7.8.1 *Colours of indicator lights

Addition:

NOTE A red ALARM SIGNAL activated in case of extracorporeal blood loss to the environment (see 201.12.4.4.104.1) is one example of an alarm that requires immediate response by the OPERATOR. If the blood flow is stopped for an extended period of time (201.12.4.4.104.3), this is another example for a red ALARM SIGNAL. In most other ALARM CONDITIONS the PROTECTIVE SYSTEM puts the HAEMODIALYSIS EQUIPMENT in a state, which is safe for the PATIENT, at least temporarily, and therefore such ALARM SIGNAL is indicated by a yellow ALARM SIGNAL. Other ALARM SIGNALS shall be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

It is acceptable to implement other colour coding schemes in addition to 7.8.1 and 7.8.2 of the general standard.

If additional colour coding schemes are implemented,

a) for all alarms needing immediate response by the OPERATOR a red alarm signal shall be activated;

b) the scheme defined by this clause of the general standard shall be the factory default;

c) only the RESPONSIBLE ORGANIZATION shall be able to change the colour coding scheme.

Compliance is checked by functional tests

201.7.9.2 Instructions for use

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally include the following, if applicable:

– a statement which draws the OPERATOR's attention to the precautions necessary to prevent any cross-infection between PATIENTS;

– a statement which draws the OPERATOR's attention to the HAZARDs associated with connection and disconnection of the PATIENT;

– a statement which draws the OPERATOR's attention to the potential HAZARDs including any HAZARDOUS SITUATIONs arising from improper connections of the EXTRACORPOREAL CIRCUIT;

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

– a quantitative description of the possible deviation of each component of the DIALYSING FLUID in SINGLE FAULT CONDITION depending on the alarm limits of the PROTECTIVE SYSTEM;

– * a statement on the potential HAZARDS related to a possible transport of undesired substances from the DIALYSING FLUID compartment to the blood compartment of the DIALYSER;

– for the PROTECTIVE SYSTEM employed according to 201.12.4.4.104 1a) Note 2:

  - a warning stating that this PROTECTIVE SYSTEM reduces the HAZARD in part only and an explanation of the remaining HAZARDs;
  - a description of further measures to reduce the RISK;

– an explanation of the adequate OPERATOR action upon an alarm and potential HAZARDs, if the alarm is repeatedly cleared without solving the underlying problem.;

– * a warning specifying that any narrow passages in the EXTRACORPOREAL CIRCUIT (such as kinks in the blood line or cannula that are too thin) may cause haemolysis and that this HAZARDOUS SITUATION may not be detected by the PROTECTIVE SYSTEMS;

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– if a PROTECTIVE SYSTEM, according to 201.12.4.4.105 a) Note 1, is applied: a warning stating that improper functioning of an ultrasonic air detector may be caused by a coagulum or the application of ultrasound gel;
– a warning stating that air may enter into the EXTRACORPOREAL CIRCUIT at connection points downstream of the air detector, if pressures are negative; this can occur in cases such as single needle applications or central venous catheter applications;
– for ONLINE HDF and ONLINE HF:
  - a warning stating that only the disinfection procedures defined and validated by the MANUFACTURER may be used for ONLINE HDF and ONLINE HF;
  - information on the required quality of the incoming water and of the DIALYSING FLUID CONCENTRATES used;
  - intervals at which wearing parts (e.g. filter) should be exchanged;
– a warning that the blood flow and thus the treatment efficacy may be reduced when the pre-pump ARTERIAL PRESSURE is extremely negative; and the range and accuracy of the flow of such pump(s) and the inlet and outlet pressure range over which this accuracy is maintained.

201.7.9.2.5 ME EQUIPMENT description

Addition:

The instructions for use shall additionally include the following, if applicable:

– a definition of TRANSMEMBRANE PRESSURE if the MANUFACTURER makes use of one different from that stated in 201.3.211;
– an explanation of the coloured markings on the DIALYSING FLUID CONCENTRATE connectors;
– information on the effective delivered blood flow in single-needle treatments;
– information on the recirculation of blood in the EXTRACORPOREAL CIRCUIT in single-needle treatments;
– the delay time after which an audible alarm is activated after interruption of the power supply
– for PHYSIOLOGICAL CLOSED LOOP CONTROLLER functions:
  a) the technical working principle;
  b) the PATIENT parameters which are measured and the physiological parameters which are controlled;
  c) the methods by which these feedback control modes have been evaluated including beneficial and adverse effects recorded during clinical testing;

  see also the collateral standard IEC 60601-1-10.
– * for any data that is displayed or indicated by the HAEMODIALYSIS EQUIPMENT and that may be used for adjusting the treatment or measuring or confirming the treatment efficacy:
  a) a description of the technical working principle;
  b) if the measurement is indirect: a statement to the accuracy and possible influencing factors;
  c) the method by which the technical working principle has been evaluated relative to standard medical care
– for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS a statement if this HAEMODIALYSIS EQUIPMENT can be used together with central venous catheters. If the HAEMODIALYSIS EQUIPMENT is not suitable for central venous catheters possible HAZARDs shall be listed.

201.7.9.2.6 Installation

Addition:

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The instructions for use shall additionally include the following, if applicable:

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

– for CLASS I HAEMODIALYSIS EQUIPMENT, a statement of the importance of the quality of the protective earth in the electrical installation;

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

– the acceptable range of temperature, flow and pressure for inlet water and any CENTRAL DELIVERY SYSTEM;

– a note emphasizing the importance of compliance with all local regulations regarding the separation of the HAEMODIALYSIS EQUIPMENT from the water supply, the prevention of back flow to the potable water source, and prevention of contamination via the drain connection of the HAEMODIALYSIS EQUIPMENT from any sewer connection;

– if different schemes for colour coding of visual alarms can be configured, a statement that the RESPONSIBLE ORGANIZATION should select the colour coding scheme which minimizes the RISK of confusion in their environment;

– if settings of operating parameters or PROTECTIVE SYSTEMs can be configured, a statement that the RESPONSIBLE ORGANIZATION should select the configuration(s) or explicitly confirm the default configuration.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

The instructions for use shall additionally include the following, if applicable:

– a description of the method(s) by which sanitization or disinfection is achieved;

– * a statement that the test procedure by which the effectiveness of sanitization or disinfection has been verified is available on request;

– a warning stating to follow the MANUFACTURER'S instructions to disinfect the HAEMODIALYSIS EQUIPMENT. If other procedures are used it is the responsibility of the RESPONSIBLE ORGANIZATION to validate the disinfection procedure for efficacy and safety. This warning shall specifically list HAZARDs including the failure mode that may result from other procedures;

– a warning that the RESPONSIBLE ORGANIZATION is responsible for the hygienic quality of any delivery system(s), e.g. central water supply system, CENTRAL DELIVERY SYSTEMS, HAEMODIALYSIS EQUIPMENT connecting devices, including the fluid lines from connection points to the HAEMODIALYSIS EQUIPMENT.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall additionally include the following, if applicable:

– information on DIALYSING FLUID CONCENTRATES, DIALYSERS and blood lines intended to be used together with the HAEMODIALYSIS EQUIPMENT.

Compliance is checked by inspection of the instructions for use.

201.7.9.3 Technical description

201.7.9.3.1 General

Addition:

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The technical description shall additionally include the following, if applicable:

- *Installation:*

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

– the maximum temperature which can occur at the drain of the HAEMODIALYSIS EQUIPMENT:

– * information about energy consumption, energy delivery to the environment and energy delivery to the drain under typical operating conditions and as a function of inlet water temperature;

– * information about consumption of water and DIALYSING FLUID CONCENTRATE(S) under typical operating conditions;

- *Device specification:*

– * for HAEMODIALYSIS EQUIPMENT that includes integral anticoagulant 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;

– any additional measures foreseen by the MANUFACTURER in case of the interruption of the power supply;

– the type, the measurement accuracy and the value(s) or range(s) of the alarm limit(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.101 (DIALYSING FLUID composition);

– the type, the measurement accuracy and the value(s) or range of the alarm limit(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.102 (DIALYSING FLUID and SUBSTITUTION FLUID temperature);

– the type, the measurement accuracy and the value(s) or range(s) of the alarm limit(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.103 (NET FLUID REMOVAL);

– the type, the measurement accuracy and the value(s) or range(s) of the alarm limit(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.1 (extracorporeal blood loss to the environment);

– * the type and the measurement accuracy of the PROTECTIVE SYSTEM required by 201.12.4.4.104.2 (BLOOD LEAK to the DIALYSING FLUID) and the alarm limit of the PROTECTIVE SYSTEM at the minimum and maximum flow through the BLOOD LEAK detector;

– the type and the alarm limit(s) of the PROTECTIVE SYSTEM required by 201.12.4.4.104.3 (extracorporeal blood loss due to coagulation);

– the method employed and the sensitivity under test conditions specified by the MANUFACTURER for the PROTECTIVE SYSTEM required by 201.12.4.4.105 (air infusion);

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

– the audible alarm silence period;

– the range of sound pressure levels of any adjustable audible alarm source;

– a disclosure of all materials intended to come into contact with the water, DIALYSING FLUID and DIALYSING FLUID CONCENTRATE;

– for ONLINE HDF and ONLINE HF: the method of preparation of the SUBSTITUTION FLUID, the method of the automatic integrity test of the SUBSTITUTION FLUID filters (if applicable) and the accuracy of these tests.

Compliance is checked by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

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201.8.3 * Classification of APPLIED PARTS

Addition:

HAEMODIALYSIS EQUIPMENT with LEAKAGE CURRENTS complying with TYPE CF APPLIED PARTS requirements are considered to be suitable for being used with central venous catheters.

If HAEMODIALYSIS EQUIPMENT having an APPLIED PART other than a TYPE CF APPLIED PART is intended to be used for treatment of PATIENTS with central venous catheter(s), the following shall apply:

1) under NORMAL CONDITION, the PATIENT LEAKAGE CURRENTS and the TOUCH CURRENTS must be within the limits for TYPE CF APPLIED PARTS.

If ME-EQUIPMENT complies with these special leakage current limits in NORMAL CONDITION, but does not comply in SINGLE FAULT CONDITION (i.e. with the PROTECTIVE EARTH CONDUCTOR interrupted), an external potential equalization cable may be used for reducing the LEAKAGE CURRENTS to the necessary lower levels. The external potential equalization cable has to be protected against unintentional disconnection (unintentional disconnection of the plug). Intentional disconnection of the plug without use of TOOLS may be possible.

2) under SINGLE FAULT CONDITION, the PATIENT LEAKAGE CURRENTS, TOUCH CURRENTS and EARTH LEAKAGE CURRENTS must be within the limits for TYPE CF APPLIED PARTS.

If the HAEMODIALYSIS EQUIPMENT does not comply with point 2, external means have to be provided justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS to keep the PATIENT LEAKAGE CURRENT within the limits for TYPE CF APPLIED PARTS under SINGLE FAULT CONDITION.

NOTE For HAEMODIALYSIS EQUIPMENT tested according to the second edition of the general standard, the ENCLOSURE LEAKAGE CURRENTS are used instead of the TOUCH CURRENTS.

Compliance is checked by inspection

201.8.7.4.7 * Measurement of the PATIENT LEAKAGE CURRENT

Addition:

** aa) The measuring device shall be connected where both extracorporeal blood lines are connected to the PATIENT. For the duration of the test, a test solution with the highest selectable conductivity, referenced to a temperature of 25 °C, and to the highest selectable DIALYSING FLUID temperature in the application, shall be flowing in the DIALYSING FLUID circuit and in the EXTRACORPOREAL CIRCUIT. The HAEMODIALYSIS EQUIPMENT shall be operated in typical treatment mode with highest possible blood flow and no alarms activated.*

NOTE 101 For practical reasons the measuring device can be connected to the dialysing fluid connectors.

NOTE 102 The measurement of PATIENT LEAKAGE CURRENTS described above does not include the measurement according to 8.7.4.7b) (voltage applied to the APPLIED PART) of the general standard for HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS.

NOTE 3 The highest possible blood flow leads to the lowest resistance of the air gap in the venous drip chamber

201.8.11.2 * MULTIPLE SOCKET-OUTLETS

Addition:

If a MULTIPLE SOCKET-OUTLET is provided and a mutual interchange or interchange with other MULTIPLE SOCKET-OUTLETS of the HAEMODIALYSIS EQUIPMENT could create a HAZARDOUS SITUATION, the MULTIPLE SOCKET-OUTLET shall be of a type, which prevents such an interchange.

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Compliance is checked by inspection and functional test

201.9 Protection against mechanical hazards of me equipment and me systems

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.6.3 Spillage on ME EQUIPMENT and ME SYSTEMS

Addition:

Compliance is checked by test according to code IPX1 of IEC 60529.

201.11.6.6 *Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

Addition:

For HAEMODIALYSIS EQUIPMENT employing non-disposable fluid lines, means shall be provided for disinfection of such fluid lines.

The disinfection procedures shall not deteriorate internal components or external accessories (e.g. DIALYSING FLUID filters) that could become a HAZARD.

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

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

Addition:

a) HAEMODIALYSIS EQUIPMENT without INTERNAL ELECTRICAL POWER SOURCE:

In the event of an interruption of the power supply / SUPPLY MAINS to the HAEMODIALYSIS EQUIPMENT, the following safe conditions shall be achieved:

- activation of an audible alarm, lasting for at least 1 min;
- additional measures may be needed as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;
- the HAEMODIALYSIS EQUIPMENT may restart automatically on restoration of the power supply, only if this does not cause any HAZARD to the PATIENT as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

b) HAEMODIALYSIS EQUIPMENT with INTERNAL ELECTRICAL POWER SOURCE:

In the event of an interruption of the power supply / SUPPLY MAINS to the HAEMODIALYSIS EQUIPMENT, the following safe conditions shall be achieved:

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– activation of a visual alarm signal;

– activation of an audible alarm signal after a time interval specified by the MANUFACTURER;

– additional measures may be needed as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

– if functions of the HAEMODIALYSIS EQUIPMENT were stopped in the event of an interruption of the power supply they may restart automatically on restoration of the power supply only if this does not cause any HAZARD to the PATIENT as determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS;

– if the INTERNAL ELECTRICAL POWER SOURCE is interrupted or discharged, the HAEMODIALYSIS EQUIPMENT must meet the requirements described in 201.11.8 a).

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by functional tests.

201.12 * Accuracy of controls and instruments and protection against hazardous outputs

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

Additional subclause:

201.12.101 General

The test procedures in the following subclauses give an overview of the minimum requirements for the validation of a HAEMODIALYSIS EQUIPMENT. All details are not included for each test procedure and it is incumbent upon the test laboratory to address these details based on the specific HAEMODIALYSIS EQUIPMENT and the MANUFACTURER'S RISK MANAGEMENT PROCESS.

201.12.3 Alarm systems

Additional subclauses:

201.12.3.101 *Visual and audible alarm signals

Unless otherwise specified by this particular standard, ALARM SIGNALS must be activated both visually and audibly. The visual alarm must remain activated for the entire duration of the ALARM CONDITION, whereas it is allowed to silence the audible alarm for the amount of time specified in 201.12.3.102.c).

201.12.3.102 *Audible alarm signals

Audible alarm signals must meet the following requirements:

a) In the initial setting by the MANUFACTURER the HAEMODIALYSIS EQUIPMENT must generate a sound pressure level of at least 65 dB(A) at a distance of 1 m.

Compliance is checked by measuring the A-rated sound pressure level with instruments meeting the requirements for measuring instruments of Class 1 according to IEC 61672-1 and free field conditions as specified in ISO 3744.

b) If the HAEMODIALYSIS EQUIPMENT enables the OPERATOR to set the audible alarm volume to lower values, a minimum value must be defined. This minimum value may only be changed by the RESPONSIBLE ORGANIZATION. If the RESPONSIBLE ORGANIZATION can reduce the audible alarm volume to zero, there shall be an alternative means to notify the OPERATOR under SINGLE FAULT CONDITION.

c) If it is possible to silence the audible alarm signal, the alarm silence period may not exceed 3 min.

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Exception: for alarm signals as described in 201.12.4.4.101 (DIALYSING FLUID composition) the alarm silence period may not exceed 10 min.

d) If during an alarm silence period another alarm occurs requiring the immediate response by the OPERATOR to prevent any HAZARD, then the silence period shall be interrupted.

Compliance is checked by functional tests.

201.12.4.4 Incorrect output

Additional subclauses:

201.12.4.4.101 *DIALYSING FLUID composition

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

The design of the protective system to prevent a hazardous composition of the dialysing fluid must consider a potential failure in any phase of preparation of the dialysing fluid.

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

– activation of an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102). The audible alarm may be delayed as specified in 201.12.3.102.c.;

– stopping of the DIALYSING FLUID flow to the DIALYSER;

– in ONLINE HDF or ONLINE HF mode; stopping of the SUBSTITUTION FLUID flow to the EXTRACORPOREAL CIRCUIT.

b) Conductivity profiles and PHYSIOLOGIC CLOSED LOOP CONTROLLERS:

In case of pre-programmed time-dependent variation of the DIALYSING FLUID composition or in case of feedback control of the DIALYSING FLUID composition by measuring a physiologic relevant parameter of the PATIENT, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the CONTROL SYSTEM, which prevents any unintentional changes in the control system that could cause a HAZARD.

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

– activation of an audible and visual alarm signal (see 201.12.3.101 and 201.12.3.102);

– other measures, if defined by MANUFACTURER'S RISK MANAGEMENT PROCESS.

c) If the HAEMODIALYSIS EQUIPMENT is equipped with a concentration bolus administration feature, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents the concentration bolus administration function to cause a HAZARD to the PATIENT.

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

– activation of an audible and visual alarm signal (see 201.12.3.101 and 201.12.3.102);

– interruption of the concentration bolus administration.

Compliance is checked by functional tests and by the following tests.

- *Test 1 for determining the alarm limits*
  - *Set the unit under test to the lowest and the highest alarm signal free compositions of the DIALYSING FLUID respectively.*
  - *Slowly change the DIALYSING FLUID composition until the PROTECTIVE SYSTEM activates an alarm signal.*
  - *Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the alarm.*
  - *Determine the difference of the DIALYSING FLUID composition of the samples taken in NORMAL CONDITION and after alarm (e.g. by flame photometry).*
- *Test 2 for in-time alarm reaction*

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– *Set the unit under test to the highest possible DIALYSING FLUID flow*

– *Simulate complete interruption of each DIALYSING FLUID CONCENTRATE supply, one at a time.*

– *Take samples at the DIALYSER inlet under NORMAL CONDITION and immediately after the alarm.*

– *Determine the difference of the DIALYSING FLUID composition of the samples taken under NORMAL CONDITION and after alarm (e.g. by flame photometry).*

- *Test 3 for foreseeable misuse*

  – *Exchange DIALYSING FLUID CONCENTRATES, if possible.*

  – *Determine the alarm activation.*

201.12.4.4.102 *DIALYSING FLUID and SUBSTITUTION FLUID temperature

a) The range for setting the temperature of the DIALYSING FLUID and SUBSTITUTION FLUIDS shall not be outside the range of 33ºC to 42ºC unless justified by the MANUFACTURER'S RISK MANAGEMENT PROCESS.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any temperature control system, which prevents DIALYSING FLUID reaching the DIALYSER and SUBSTITUTION FLUID reaching the EXTRACORPOREAL CIRCUIT at a temperature below 33 °C or above 42 °C, measured at the HAEMODIALYSIS EQUIPMENT DIALYSING FLUID outlet and/or at the SUBSTITUTION FLUID outlet.

c) For a short time temperatures up to 46 °C and below 33 °C are acceptable, but time and value have to be justified in the MANUFACTURER's RISK MANAGEMENT PROCESS.

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

– activation of an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102);

– stopping of the DIALYSING FLUID flow to the DIALYSER and/or SUBSTITUTION FLUID flow to the EXTRACORPOREAL CIRCUIT.

Compliance is checked by functional tests and by the following tests.

- *Test 1 for DIALYSING FLUID*

  – *Set the unit under test to the highest DIALYSING FLUID flow, if this setting is possible.*

  – *Set the highest DIALYSING FLUID temperature.*

  – *Wait for stable temperatures at the DIALYSER inlet.*

  – *Slowly increase the temperature of DIALYSING FLUID until the PROTECTIVE SYSTEM activates an alarm signal.*

  – *Measure the temperature continuously at the DIALYSER inlet and determine the maximum value.*

- *Test 2 for SUBSTITUTION FLUID*

  – *Set the unit under test to the highest SUBSTITUTION FLUID flow, if this setting is possible.*

  – *Set the highest DIALYSING FLUID temperature.*

  – *Wait for stable temperatures at the inlet to the EXTRACORPOREAL CIRCUIT.*

  – *Slowly increase the temperature of the SUBSTITUTION FLUID until the PROTECTIVE SYSTEM activates an alarm signal.*

  – *Measure the temperature of the SUBSTITUTION FLUID at the inlet to the EXTRACORPOREAL CIRCUIT and determine the maximum value.*

201.12.4.4.103 *NET FLUID REMOVAL

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of any ULTRAFILTRATION control system, which prevents a variation in the NET FLUID REMOVAL of the HAEMODIALYSIS EQUIPMENT from the set value of the controlling parameter that may cause a HAZARD.

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

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

– activation of an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102);

– prevention of the continuation of the fluid balancing error.

b) ULTRAFILTRATION profiles and physiological closed loop controllers:

In case of pre-programmed time dependent variation of ULTRAFILTRATION or in case of feedback control of ULTRAFILTRATION by a monitor measuring a physiologic relevant parameter of the PATIENT, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents any unintentional changes in the control system that could cause a HAZARD.

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

– activation of an audible and visual alarm signal (see 201.12.3.101 and 201.12.3.102);

– other measures, if defined by MANUFACTURER'S RISK MANAGEMENT PROCESS.

c) If the HAEMODIALYSIS EQUIPMENT is equipped with a fluid bolus administration feature, the HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM, independent of the control system, which prevents the fluid bolus administration function to cause a HAZARD to the PATIENT.

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

– activation of an audible and visual alarm signal (see 201.12.3.101 and 201.12.3.102);

– interruption of the fluid bolus administration.

Compliance is checked by functional tests and failure simulations, including the following tests.

- *Test for deviations of the NET FLUID REMOVAL rate*
  - *Set the unit under test to the highest DIALYSING FLUID flow.*
  - *Set the highest SUBSTITUTION FLUID flow, if this is adjustable.*
  - *Set the DIALYSING FLUID temperature to 37°C, if applicable.*
  - *Set the highest and the lowest ULTRAFILTRATION flow rates (one at a time).*
  - *Simulate a low and a high failure in each of the pump control systems (one at a time) which influence the NET FLUID REMOVAL rate until the PROTECTIVE SYSTEM activates an alarm signal.*
  - *Determine the volume difference in relation to the theoretical volume.*

201.12.4.4.104 Extracorporeal blood loss

201.12.4.4.104.1 * Extracorporeal blood loss to the environment

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

NOTE 1 Today no system has been developed that can totally be relied upon to detect blood loss to the environment. The recommendation in Note 2 is the best known system to detect blood loss to the environment.

NOTE 2 If a PROTECTIVE SYSTEM is utilizing measurement of the VENOUS PRESSURE, the user should have at least the possibility to adjust the lower alarm limit manually as closely as possible to the current measurement value. The single needle treatment mode needs additional measures.

b) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from extracorporeal blood loss to the environment caused by a rupture or separation in the EXTRACORPOREAL CIRCUIT due to excessive pressure, unless this is prevented by inherent safe design.

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NOTE 3 This is not related to separation of the PATIENT CONNECTION or access needle but related to the potential pressure that can be generated by the pump which could cause tubing rupture or joint separation in the EXTRACORPOREAL CIRCUIT.

*c) Operation of the PROTECTIVE SYSTEM shall achieve the following safe condition:

– activation of an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102);

– stoppage of the blood flow to the environment caused by the HAEMODIALYSIS EQUIPMENT, even under SINGLE FAULT CONDITION.

– In the case of HAEMOFILTRATION or HAEMODIAFILTRATION, stoppage of the SUBSTITUTION FLUID flow.

Compliance is checked by functional tests and by the following test:

- *Test for PROTECTIVE SYSTEMS utilizing the VENOUS PRESSURE measurement*
  - *Set the unit under test to the medium blood flow.*
  - *Adjust the VENOUS PRESSURE to a medium value.*
  - *Lower the VENOUS PRESSURE until an alarm signal is activated.*
  - *Determine the difference between the alarm point and the reference value.*

201.12.4.4.104.2 *BLOOD LEAK to the DIALYSING FLUID

a) The HAEMODIALYSIS EQUIPMENT shall include a PROTECTIVE SYSTEM to protect the PATIENT from a BLOOD LEAK that may cause a HAZARD.

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

– activation of an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102);

– prevention of further blood loss to the DIALYSING FLUID.

Compliance is checked by functional tests and by the following test.

- *Test for determining the alarm limits:*
  - *Create maximum flow through the BLOOD LEAK detector (highest DIALYSING FLUID flow, highest ULTRAFILTRATION flow, if relevant also highest SUBSTITUTION FLUID flow).*
  - *Add bovine blood (Hct 32%) to the DIALYSING FLUID so that the flow through the BLOOD LEAK detector represents the BLOOD LEAK alarm limit as specified by the MANUFACTURER.*

201.12.4.4.104.3 * Extracorporeal blood loss due to coagulation

a) The HAEMODIALYSIS 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 may cause a HAZARD.

NOTE An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM operating if the blood pump(s) advertently or inadvertently stop(s) for a longer period of time.

b) Operation of the PROTECTIVE SYSTEM shall activate an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102).

c) Other effects which may result in a blood loss due to coagulation, e.g. stopping or missing start of any anticoagulation pump, or excessive substitution flow in case of HDF with post-dilution, shall be addressed in the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Compliance is checked by functional tests and failure simulation

201.12.4.4.105 * Air infusion

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

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NOTE 1 An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing an air detector (e. g. ultrasonic) capable of detecting non-dissolved air.

b) Operation of the PROTECTIVE SYSTEM shall achieve the following safe condition:
   – activation of an audible and visual alarm signal (see 201.12.3.101, 201.12.3.102);
   – prevention of further air infusion via the arterial and venous bloodlines, even under SINGLE FAULT CONDITION.

NOTE 2 The prevention of further air infusion can typically be accomplished by stopping the blood pump and clamping the venous bloodline.

Compliance is checked by functional tests and by the following tests.

NOTE 3 As a matter of principle, there are two methods for monitoring air infusion:

a) at an air trap (e.g. at the venous drip chamber) where buoyancy forces act on the air bubbles so that bubbles are prevented from exiting the air trap with a correctly set level; the air bubble monitoring method used here is the method of monitoring the level;

b) directly at the bloodline (air bubbles are delivered in the fluid stream), where the air volume can be determined by means of the flow velocity.

There are two different test procedures independent of the above air monitoring methods.

- *Continuous air infusion:*

– *Set up the HAEMODIALYSIS EQUIPMENT with a standard capillary DIALYSER with a surface area between 1 and 1,5 m^2, the recommended EXTRACORPOREAL CIRCUIT and 16 g cannulas.*

– *Clamp or close the DIALYSING FLUID lines after priming.*

NOTE This is a worst case condition. If degassed dialysate is running, gas will be removed by the DIALYSER.

– *Operate the EXTRACORPOREAL CIRCUIT with heparinized blood with hct between 0,25 and 0,35 (human blood, bovine blood, pig's blood) or an appropriate test fluid.*

NOTE 4 An appropriate test fluid has a viscosity of 3,5 mPa·s at 37°C and contains a surfactant causing spallation of gas bubbles.

– *Position a storage container for the test fluid at a level of 100 cm (± 20 cm).*

– *Position a collection container for the test fluid at a level of 100 cm (± 20 cm) or recirculate the fluid into the storage container.*

– *Position at least one vertically positioned test tube with diameter of around 8 mm and a length of around 2,0 m in line with a second tube with smaller diameter directly at the venous patient connector in the venous path between the PATIENT connector and collection container (see as an example the set-up in Figure 201.101)*

– *Insert a 22 g cannula into the arterial blood tubing in the section of negative pressures close to the connection to the arterial (blood withdrawal) cannula and connect it to a pump capable of controlling air injection under negative pressure condition.*

NOTE 5 A possible method is the use of a small reversible peristaltic pump. This pump is initially primed with test fluid by operating it in reverse mode to avoid uncontrolled injection of air when the blood pump is started. A check valve between needle and pump is recommended.

– *Adjust the blood pump speed such that the pre-pump negative pressure is between −200 mmHg and 250 mmHg.*

– *Inject air at slowly increasing rates specified by the MANUFACTURER until the air detector alarms.*

NOTE 6 The rational of this test is based on the assumption that, with the DIALYSING FLUID line closed, air can not escape from the EXTRACORPOREAL CIRCUIT and will eventually be pumped to the fluid collection vessel at the same rate as pumped in.

– *Clamp the test tube at both ends immediately after the air detector alarm.*

– *Measure after 15 min the air volume building at the top of the small diameter test tube.*

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– *Calculate the air flow rate by blood flow speed, test tube volume and measured air volume.*

- *If the heamodialysis equipment allows the dialyser to be operated with blood flowing upwards through the dialyser and, alternatively with blood flowing downwards through the dialyser, separate tests shall be done with both flow directions.*
- *If risk analysis reveals pathways for injecting air post blood pump (e.g., by a level adjust pump) the test must be repeated by pumping air at the specified rate into the EXTRACORPOREAL CIRCUIT at this point.*

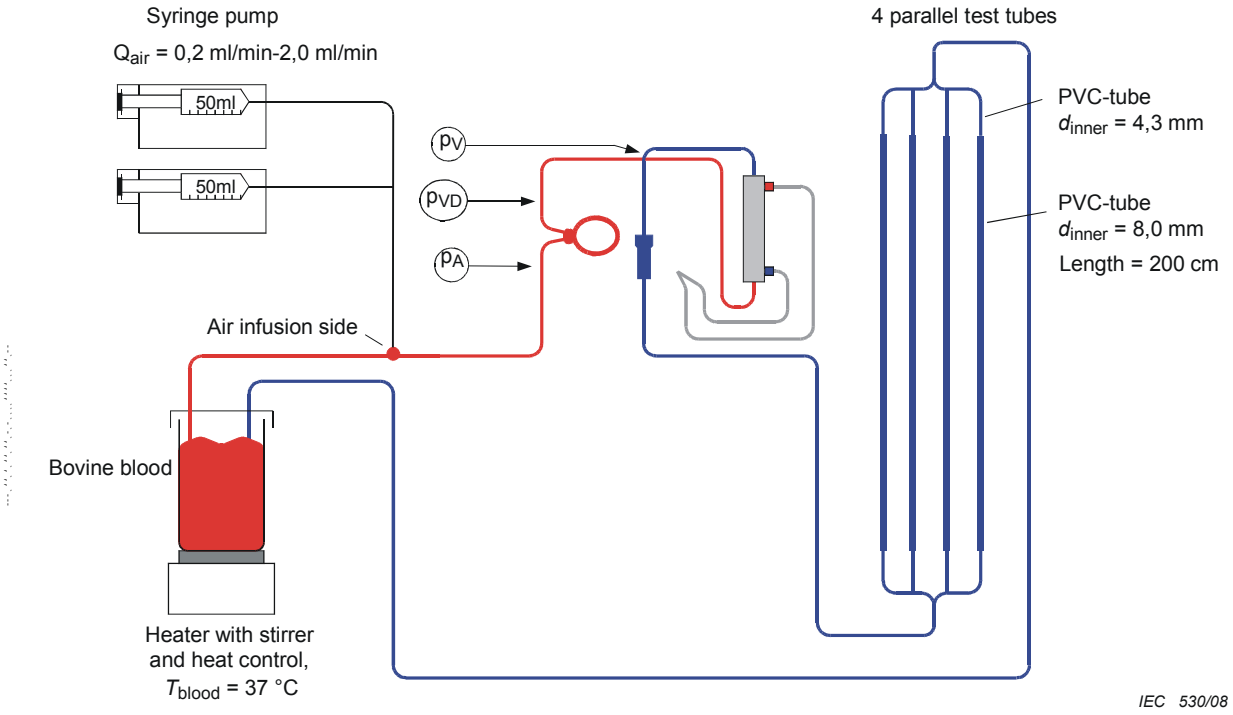

Figure 201.101 – Continuous air infusion test set-up

- *Bolus air infusion:*

– *Set up the HAEMODIALYSIS EQUIPMENT with a DIALYSER with a standard capillary DIALYSER with a surface area between 1 m^2 and 1,5 m^2, the recommended EXTRACORPOREAL CIRCUIT and 16 g cannulas.*

– *Clamp or close the DIALYSING FLUID lines after priming.*

NOTE 7 This is a worst case condition. If degassed dialysate is running, gas will be removed by the DIALYSER.

– *Operate the EXTRACORPOREAL CIRCUIT with heparinized blood with hct between 0,25 and 0,35 (human blood, bovine blood, pig's blood) or an appropriate test fluid.*

NOTE 8 An appropriate test fluid has a viscosity of 3,5 mPa·s at 37°C and contains a surfactant causing spallation of gas bubbles.

– *Position a storage container for the test fluid at a level of 100 cm (± 20 cm).*

– *Position a collection container for the test fluid at a level of 100 cm (± 20 cm) or recirculate the fluid into the storage container*

– *Position a graduated measuring cylinder or the same test tubes as in the previous test case such that any air that may be pumped through the return (venous) cannula is collected.*

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– *Insert a T-piece with luer-connectors between the blood tubing and the arterial (blood withdrawal) cannula.*

– *Connect a 5 cm long piece of tubing with a luer connector to the T.*

– *Prime the EXTRACORPOREAL CIRCUIT and said piece of tubing. Clamp the piece of tubing.*

– *Adjust the blood pump speed such that the pre-pump negative pressure is between 0 mmHg and –250 mmHg and no pressure alarm arises with the opening of the clamp.*

– *Open the clamp at the piece of tubing and wait until the air detector activates an alarm signal.*

– *Check the amount of air collected in the graduated measuring cylinder or in the test tube. The amount must be less than the specified bolus limit.*

- *If the HAEMODIALYSIS EQUIPMENT allows the DIALYSER to be operated with blood flowing upwards through the DIALYSER and, alternatively with blood flowing downwards thorough the DIALYSER, separate tests shall be done with both flow directions.*
- *If RISK ANALYSIS reveals pathways for injecting air post blood pump (e.g., by a level adjust pump) the test must be repeated by pumping air at the maximum rate into the EXTRACORPOREAL CIRCUIT at this point.*

*** 201.12.4.4.106 Alarm override modes**

a) All PROTECTIVE SYSTEMS shall be operational throughout treatment.

NOTE 1 For exceptions, see item b) 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 through the EXTRACORPOREAL CIRCUIT, treatment is considered to be finished when the venous needle is disconnected.

b) The PROTECTIVE SYSTEMS for DIALYSING FLUID composition and temperature shall be operational before the first contact of DIALYSING FLUID with blood in the DIALYSER.

c) During an alarm condition, temporary override modes may apply individually to the PROTECTIVE SYSTEMS utilizing BLOOD LEAK monitoring (see 201.12.4.4.104.2).

d) The override time shall not exceed 3 min, but under certain clinical conditions it may be necessary to deactivate the BLOOD LEAK detector completely or partially for unlimited time.

e) Operation of the override mode shall maintain a visual indication that the PROTECTIVE SYSTEM is being overridden.

f) Overriding a particular PROTECTIVE SYSTEM (see item b*)* shall have no effect on any other subsequent alarm conditions. Subsequent alarm conditions shall achieve the safe condition specified. A remaining alarm condition shall, after the elapsed override period, re-achieve the safe condition specified.

NOTE 3 Within the meaning of this subclause, override is the facility to allow the HAEMODIALYSIS EQUIPMENT to function under alarm conditions if the OPERATOR consciously selects to temporarily disable the PROTECTIVE SYSTEM. A delayed start is not regarded as an override of the HAEMODIALYSIS EQUIPMENT if it does not cause a HAZARD.

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

201.12.4.4.107 PROTECTIVE SYSTEMS

A failure of the PROTECTIVE SYSTEMS required by 201.12.4.4 shall become obvious to the OPERATOR within the following limits:

a) for all PROTECTIVE SYSTEMS except 201.12.4.4.105 (air infusion):

– at least once per day or, if this is not possible, as determined by the MANUFACTURER'S RISK MANAGEMENT process;

NOTE Acceptable methods of complying with this requirement are for example:

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

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- periodic functional check of the PROTECTIVE SYSTEMS initiated by the OPERATOR and controlled by the HAEMODIALYSIS EQUIPMENT;
- redundancy of the PROTECTIVE SYSTEMS with self-checking by the HAEMODIALYSIS EQUIPMENT;
- periodic functional check of the PROTECTIVE SYSTEMS initiated by the HAEMODIALYSIS EQUIPMENT and controlled by the HAEMODIALYSIS EQUIPMENT. The control function of the PROTECTIVE SYSTEM must be designed such that it cannot fail simultaneously with the PROTECTIVE SYSTEM by a single failure.

b) for the PROTECTIVE SYSTEM required by 12.4.4.105 (air infusion):

– if an amount of air can be infused to the PATIENT which may cause a HAZARD as a result of a first fault of the air detector, the maximum detection time for this fault is calculated as the fault tolerance time:

- the volume of the extracorporeal circuit between the air detector and the venous cannula, divided by the highest blood flow;

– in all other cases a) applies.

Compliance is checked by functional tests and failure simulations.

201.12.4.4.108 Prevention of contamination by chemicals

a) It shall not be possible to treat the PATIENT while the HAEMODIALYSIS EQUIPMENT is in the cleaning, sterilization or disinfection mode. Subclauses 4.7 and 11.8 of the general standard apply.

b) Chemicals (e.g. water, DIALYSING FLUID, disinfectant or DIALYSING FLUID CONCENTRATE) must not flow from the HAEMODIALYSIS EQUIPMENT to any supply line, even under SINGLE FAULT CONDITION.

Compliance is checked by functional tests and failure simulations.

201.12.4.4.109 *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 that may cause a HAZARD.

The applicable HAZARDS (e.g. air infusion via the arterial bloodline) have to be determined by the MANUFACTURER'S RISK MANAGEMENT PROCESS. Human errors have to be taken into account as well as technical failures.

Compliance is checked by inspection and by functional tests.

201.12.4.4.110 Selection and change of operation modes

Inadvertent selection and change of operation modes shall be prevented. Human errors have to be taken into account as well as technical failures.

Compliance is checked by inspection and by functional tests.

201.12.4.4.111 ONLINE HDF and ONLINE HF

If the HAEMODIALYSIS EQUIPMENT is intended for ONLINE HAEMOFILTRATION (ONLINE HF) or ONLINE HAEMODIAFILTRATION (ONLINE HDF), the MANUFACTURER shall ensure that the HAEMODIALYSIS EQUIPMENT shall be capable of producing SUBSTITUTION FLUID that complies with the requirements (e.g. microbiological) for a solution intended for large-volume intravenous applications when the MANUFACTURER'S instructions are followed. This requirement shall also be complied with under SINGLE FAULT CONDITION.

Compliance is checked by inspection and by functional tests.

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201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies, except as follows:

201.13.2.6 * Leakage of liquid

Addition:

The liquid-carrying parts of the HAEMODIALYSIS 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 HAZARDS, for example due to short-circuiting of CREEPAGE DISTANCES.

Compliance is checked by the following test:

a) by means of a pipette, drops of potable water are applied to couplings, to seals and to tubings which might rupture, moving parts being in operation or at rest, whichever is least favourable;

and in case of doubt in test a):

b) by means of a syringe, a jet of an appropriate liquid for the part of the HAEMODIALYSIS EQUIPMENT is directed from couplings, from seals and from tubings which might rupture, moving parts being in operation or at rest, whichever is the least favourable.

After these procedures, the HAEMODIALYSIS EQUIPMENT shall show no signs of wetting of uninsulated electrical parts or of electrical insulation which is liable to be adversely affected by potable water or the selected liquid. In case of doubt, the HAEMODIALYSIS EQUIPMENT shall be subjected to the dielectric strength test specified in 8.8 of the general standard.

The determination of other HAZARDS is checked by inspection of the HAEMODIALYSIS EQUIPMENT.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies, except as follows:

201.14.13 *Connection of PEMS by NETWORK/DATA COUPLING to other equipment

Addition:

Data transfer between NETWORK/DATA COUPLING and HAEMODIALYSIS EQUIPMENT must not cause a HAZARD to the PATIENT under SINGLE FAULT CONDITION.

201.15 Construction of ME EQUIPMENT

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

201.15.4.1 Construction of connectors

Addition:

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201.15.4.1.101 * DIALYSING FLUID CONCENTRATE connectors

NOTE 1 The various DIALYSING FLUID CONCENTRATE supply containers and cleaning solutions should be differentiated by mechanical connections to the DIALYSING FLUID CONCENTRATE connectors of the HAEMODIALYSIS EQUIPMENT or be permanently colour marked. (See ISO 13958)

The HAEMODIALYSIS EQUIPMENT shall additionally prevent a mixing of the various DIALYSING FLUID CONCENTRATES and cleaning solutions which may cause a HAZARD for the PATIENT, by mechanical differentiation of the connectors or by colour coding of the connectors.

NOTE 2 The use of various DIALYSING FLUID CONCENTRATES presents a problem in that connection of the wrong DIALYSING FLUID CONCENTRATE may cause a HAZARD to the PATIENT. The design of connectors and colour coding were recognized as methods to minimize this RISK. There is always the possibility that the OPERATOR will cause a HAZARD by not following the MANUFACTURER's instructions for use. The MANUFACTURER should make every effort to minimize the possible mix-up in the connection of DIALYSING FLUID CONCENTRATES.

The following colours shall be used for DIALYSING FLUID CONCENTRATE connectors:

– connector for acetate shall be white;
– connector for acidic component in bicarbonate dialysis shall be red;
– connector for bicarbonate component in bicarbonate dialysis shall be blue;
– for common usage of one connector for different DIALYSING FLUID CONCENTRATES, on the HAEMODIALYSIS EQUIPMENT the respective coloured markings shall be affixed on that connector. For example, a common connector for acetate and acidic DIALYSING FLUID CONCENTRATE shall be marked white/red.

Compliance is checked by inspection.

NOTE 3 ISO 13958 gives requirements for the colour coding of DIALYSING FLUID CONCENTRATE containers.

201.15.4.1.102 *Connectors for blood pressure transducers

The connection between blood lines and blood pressure transducers shall have an equivalent safety according to ISO 594-2, as stipulated by ISO 8638.

Any potential HAZARDS to the PATIENT, such as air infusion, cross contamination and blood loss, must be taken into account in the MANUFACTURER'S RISK MANAGEMENT process.

Compliance is checked by functional tests and inspection of the RISK MANAGEMENT FILE.

201.16 * ME SYSTEMS

NOTE ME SYSTEMS have not yet been examined comprehensively with regard to the whole field of dialysis in this particular standard. Application of RISK MANAGEMENT with consideration of ME SYSTEMS is therefore also recommended for MANUFACTURERS of HAEMODIALYSIS EQUIPMENT, since definite identification of a particular MANUFACTURER of the complete ME SYSTEM is often not possible in a dialysis clinic. (See IEC 60601-1, Annex A, Clause A.4, Subclauses 4.2 and 16.1)

Clause 16 of the general standard applies, except as follows:

201.16.2 ACCOMPANYING DOCUMENTS of an ME SYSTEM

d) advice to the RESPONSIBLE ORGANIZATION

Addition:

– a listing of RISKs and measures in case of a connection of HAEMODIALYSIS EQUIPMENT to CENTRAL DELIVERY SYSTEMS or other fluid-carrying central systems (increased LEAKAGE CURRENTS).

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

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201.16.6.3 PATIENT LEAKAGE CURRENT

Addition:

NOTE A possible method for reducing PATIENT LEAKAGE CURRENTS is the utilization of conductive rings in central water supply systems, or all connection points of the dialysis unit should have the same potential and should be PROTECTIVELY EARTHED (see ISO 11197).

201.16.9.1 * Connection terminals and connectors

Addition:

– The connectors on the CENTRAL DELIVERY SYSTEM shall be permanently colour marked. See 201.15.4.1.101.
– The colour markings must be affixed such that the OPERATOR can easily assign the DIALYSING FLUID CONCENTRATE to the appropriately colour-marked DIALYSING FLUID CONCENTRATE container or the CENTRAL DELIVERY SYSTEM (see 201.15.4.1.101).

Compliance is checked by inspection and testing.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.3.18
LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM

Addition:

NOTE A HAEMODIALYSIS EQUIPMENT is not considered to be a LIFE-SUPPORTING EQUIPMENT or SYSTEM as defined in 3.18 of IEC 60601-1-2:2007, since a premature termination of the dialysis treatment is not likely to lead to serious injury or death of a PATIENT

203 General requirements for radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008 does not apply.

206 Usability

IEC 60601-1-6:2006 applies.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows:

208.5.2.1 Instructions for use

Addition:

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NOTE 101 In the listing and description of every possible ALARM CONDITION only these conditions need to be written with a remaining HAZARD beside the safe state of the HAEMODIALYSIS EQUIPMENT.

208.6.3.2.2 Characteristics of visual ALARM SIGNALS

For additional colour coding schemes described in 201.7.8.1, Table 2 is not applicable.

208.6.3.3.1 Characteristics of auditory ALARM SIGNALS

For additional colour coding schemes described in 201.7.8.1, Tables 3 and 4 are not applicable.

NOTE 101 The use of additional colour coding schemes described in 201.7.8.1 means an implementation of a second different set of ALARM SIGNALS in the HAEMODIALYSIS EQUIPMENT.

208.6.3.3.2 Volume of auditory ALARM SIGNALS and INFORMATIONS SIGNALS

For additional colour coding schemes described in 201.7.8.1 this subclause is not applicable.

209 Requirements for the reduction of environmental impacts

IEC 60601-1-9:2007 applies.

210 Process requirements for the development of physiologic closed-loop controllers

IEC 60601-1-10:2007 applies except as follows:

Annex A – General guidance and rationale

A.2 Rationale for particular clauses and subclauses

Definition 210.3.20 PHYSIOLOGIC CLOSED-LOOP CONTROLLERS

Addition:

Physiological parameters are, for example, blood temperature, blood pressure, pulse and haematocrit. The controller in the control circuit compares the physiological parameter with a reference value and, using the resulting difference, varies a control signal that takes effect on the variable quantities, such as ULTRAFILTRATION flow, conductivity and temperature.

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Annexes

The annexes of the general standard apply, except as follows:

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of the general standard does not apply.

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Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

Clause A.1 of the general standard applies.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this particular standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.3.8 APPLIED PART

The PATIENT is in direct contact with the HAEMODIALYSIS EQUIPMENT and the ME SYSTEM via fluids. It is also important to consider the parts of the ME SYSTEM or non-ME SYSTEM coming into direct or indirect contact with the PATIENT via the OPERATOR, in order to determine the PATIENT LEAKAGE CURRENTS.

Subclause 201.3.201 HAEMODIALYSIS EQUIPMENT

The type of HD, HDF and HF equipment can be classified as HAEMODIALYSIS EQUIPMENT with or without preparation of DIALYSING FLUID. HAEMODIALYSIS EQUIPMENT with preparation of DIALYSING FLUID usually requires a water treatment system (RO system) and may also be connected to a CENTRAL DELIVERY SYSTEM.

The HDF HAEMODIALYSIS EQUIPMENT can also be used for performing the HD or HF treatment procedures. The treatment procedure is then defined by the accessories and the setting parameters.

Subclause 201.3.209 ULTRAFILTRATION

In HF or HDF treatment, ULTRAFILTRATION must not be confused with the reduction in the PATIENT's weight (NET FLUID REMOVAL), because in this procedure, the volume equivalent to the SUBSTITUTION FLUID flow also flows across the DIALYSER membrane.

ULTRAFILTRATION rate = NET FLUID REMOVAL rate + SUBSTITUTION FLOW rate.

Subclause 201.3.212 BLOOD LEAK

Blood appears in the DIALYSING FLUID compartment only if there is a pressure gradient from the blood compartment to the DIALYSING FLUID compartment and a rupture in the semi-permeable membrane in the DIALYSER.

A BLOOD LEAK can also be accompanied by back-contamination caused by backfiltration.

The BLOOD LEAK detector detects a rupture of the semi-permeable membrane only if the blood volume entering the DIALYSING FLUID exceeds the detection value of the BLOOD LEAK detector.

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Subclause 201.3.215 PROTECTIVE SYSTEM

See Polaschegg HD, Levin N. Hemodialysis machines and monitors. Winchester J, Koch R, Lindsay R, Ronco C, Horl W, editors. Replacement of Renal Function by Dialysis, 5th Edition. Kluwer Academic Publishers,2004:323 – 447 (page 342). The authors point out that HAEMODIALYSIS EQUIPMENT comprises redundancy or PROTECTIVE SYSTEMS in addition to control systems. A HAZARD to the PATIENT is only possible if the control system and the PROTECTIVE SYSTEM both fail. The likelihood for failure for any of these systems is less than 10^{-4}/ treatment resulting in a combined likelihood of less than 10^{-8} per treatment (4 h – 6 h). This observation was made by the first author in the mid-1980s based on quality feedback data from ~ 3 000 HAEMODIALYSIS EQUIPMENTS and is corroborated by the low number of serious accidents caused by HAEMODIALYSIS EQUIPMENT malfunction in the US where accident reports are published by the FDA.

Subclause 201.3.216 and 201.3.217 ONLINE HDF and ONLINE HF

According to the state of art, the SUBSTITUTION FLUID is produced from the DIALYSING FLUID produced by the HAEMODIALYSIS EQUIPMENT. The process comprises microbiological filtering and delivery into the EXTRACORPOREAL CIRCUIT.

Subclause 201.4.3 ESSENTIAL PERFORMANCE

The following general philosophy for the definition of test procedures was applied.

When defining the test procedures, it was the opinion of the committee that a safety standard for HAEMODIALYSIS EQUIPMENT should not duplicate what is common knowledge in test laboratories, for example:

– selection of a suitable method of measurement (e.g. flow measurement by flow meter or by volume and time);
– the use of instruments with sufficient accuracy;
– the use of calibrated instruments.

Therefore the test procedures contain only the basic information needed for testing HAEMODIALYSIS EQUIPMENT.

Subclause 201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

The ESSENTIAL PERFORMANCE for HAEMODIALYSIS EQUIPMENT was determined with the following aspects taken into account: on one hand, all parameters required for the therapeutic effectiveness of the procedure should be included; on the other hand, definition of more parameters than necessary should be avoided, because the ESSENTIAL PERFORMANCE must be complied with even under the irradiation conditions of the EMC immunity test. The observation and documentation of a great number of ESSENTIAL PERFORMANCE features would cause impractically high time and cost expenditures during the EMC test. The list of ESSENTIAL PERFORMANCE features defined here is a compromise between these two contrary aspects. (See IEC 60601-1-2.)

Since a standard cannot describe all possible special procedures modifying or expanding the classical dialysis procedure, this clause involves merely a standard HAEMODIALYSIS EQUIPMENT. If special procedures require further parameters for therapeutic effectiveness or if parameters that are defined as ESSENTIAL PERFORMANCE in this standard are not required, the list of ESSENTIAL PERFORMANCE features should be adjusted to the HAEMODIALYSIS EQUIPMENT concerned by the MANUFACTURER. The MANUFACTURER should list ESSENTIAL PERFORMANCES and appropriate rationales.

Comment to Note: If peristaltic pumps are used, the blood flow may considerably decrease in case of high negative pressures on the suction side.

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Subclause 201.4.3.107 DIALYSING FLUID composition

Due to the complexity of determining the DIALYSING FLUID composition, a simple solution practical for all kind of HAEMODIALYSIS EQUIPMENT was not found to date. Ideas for determining the DIALYSING FLUID composition are:

- measurement by ion sensitive electrodes. However, the standard laboratory methods used for blood analysis are not accurate enough for measurement of absolute values in DIALYSING FLUID;
- measurement of the dilution by adding a dye to the DIALYSING FLUID CONCENTRATE. The adsorption is measured before and after mixing;
- theoretical calculation of conductivity, based on the known composition of the DIALYSING FLUID CONCENTRATE. Create a systematic matrix of settings, e.g.:
  - highest sodium with lowest bicarbonate;
  - lowest sodium with highest bicarbonate;
  - highest sodium with highest bicarbonate;
  - lowest sodium with lowest bicarbonate;
- compare measured and theoretical values or the relative differences or ratios between the elements of the matrix;
- measurement of conductivity and pH in order to separate the sodium from the bicarbonate.

Subclause 201.7.8.1 Colours of indicator lights

It was recognized that there are two different fields of application for HAEMODIALYSIS EQUIPMENT.

a) In environments where HAEMODIALYSIS EQUIPMENT present only one of many alarm sources, such as intensive care units, there is a need for a harmonized colour coding scheme which lets the OPERATOR compare the urgency of alarms generated by different kinds of ME EQUIPMENT. Such a harmonized colour coding scheme is defined by 7.8.1 of the general standard. Therefore the committee decided that all HAEMODIALYSIS EQUIPMENT shall by default comply with this clause.

b) In most dialysis units HAEMODIALYSIS EQUIPMENT are the only ME EQUIPMENT initiating alarms. For that reason, colour coding of alarms harmonized with other kinds of ME EQUIPMENT is less important. In addition, many dialysis units will have a mixture of old and new HAEMODIALYSIS EQUIPMENT for several years of transition. If the new harmonized colour coding scheme were mandatory for all HAEMODIALYSIS EQUIPMENT, such units would have old and new HAEMODIALYSIS EQUIPMENT indicating the same alarm by different colours. This could be a source of misunderstanding and could create HAZARDOUS SITUATIONS.

To serve both fields of application in the best possible way, the committee considered it acceptable if the colour coding scheme can be configured by the RESPONSIBLE ORGANIZATION so to comply either with 7.8.1 of the general standard or with existing ME EQUIPMENT.

This particular standard does not mandatorily require for HAEMODIALYSIS EQUIPMENT with a screen that the visual alarm must be indicated by an indicator light that is independent of the screen, since there may be applications where it is appropriate if the alarm is indicated on the screen. In large-size dialysis units, however, it is probably more appropriate to provide an indicator light that can be seen from a far distance and is installed at an up-raised position, so that the HAEMODIALYSIS EQUIPMENT activating the alarm signal can be readily located.

Subclause 201.7.9.2.2 Warnings and safety notices (6th dash)

Because of counter current flow in the dialyser, backfiltration of DIALYSING FLUID takes place in at least one part of the DIALYSER even in low flux DIALYSERs (ULTRAFILTRATION coefficient < 10

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ml/(h*mmHg)). If high-flux DIALYSERs are used, backfiltration cannot be avoided even by high ULTRAFILTRATION rates acceptable for fluid removal from the PATIENT.

The effect of backfiltration through an intact DIALYSER membrane is limited to the increased backtransport of larger molecules from the DIALYSING FLUID to the blood. DIALYSING FLUID does not contain such substances intentionally. In case of bacterial contamination the DIALYSING FLUID contains endotoxins and other bacterial cell debris. Intact endotoxin molecules are too large to pass through the membrane but they split into smaller components. The molecular weight of Lipid A, the active component causing pyrogenic reactions has a molecular weight of ~ 2 000 mass units and will readily diffuse even through low flux membranes. Other molecules causing adverse cell reactions in blood have even lower molecular weight.

Backfiltration only contributes less than 50 % to backtransport even for high-flux membranes under unfavourable conditions. Considering that bacterial and endotoxin contamination is scaled by orders of magnitudes, a factor of 2 is not relevant. „Avoiding“ backfiltration by increasing TMP or ULTRAFILTRATION cannot be regarded as a sufficient measure to prevent backtransport. It is therefore necessary to avoid contamination of DIALYSING FLUID by bacteria by appropriate means.

The effect of backfiltration through structural leaks in the DIALYSER is usually limited to the amount not detected by the BLOOD LEAK detector. Because of the pulsating flow produced by a peristaltic blood pump, back and forward ULTRAFILTRATION will alternate in the DIALYSER. During the backfiltration phase, bacteria may enter into the blood stream undetected. Assuming that the back flow is 1 ml/min (three times larger than the typical sensitivity of a BLOOD LEAK detector) the hypothetical contamination of blood is 100 CFU/min – 200 CFU/min, if water for dialysis or DIALYSING FLUID is according to EuPharm or AAMI guidelines respectively. It is extremely unlikely that a small leak below the detection limit of the BLOOD LEAK detector persists in a DIALYSER. Usually small leaks close by clotting within a few minutes.

Subclause 201.7.9.2.2 Warnings and safety notices (9th dash)

Haemolysis may be caused by excessive shear which is the result of high blood flow through a narrow passage, especially when flow becomes turbulent. Static pressure (–600 mmHg to +1000 mmHg) does not cause haemolysis. Elevated pressures measured in the EXTRACORPOREAL CIRCUIT indicate increased flow resistance which may cause subclinical haemolysis. Acute haemolysis has been reported to be caused by obstructions in the blood tubing system downstream of the blood pump but upstream of the pressure monitor. Such obstructions are not detected by the VENOUS PRESSURE monitor. For a review of accident reports see:

POLASCHEGG, HD, LEVIN, N. Hemodialysis machines and monitors. Winchester, J., Koch, R., Lindsay, R., Ronco, C., Horl, W., editors. *Replacement of Renal Function by Dialysis*, 5th Edition. Kluwer Academic Publishers, 2004:323 – 447 (pp 328-332)

Subclause 201.7.9.2.5 ME EQUIPMENT description (7th dash, item c))

For Kt/V, applicable standards are e.g. K/DOQI guidelines and the European Best Practise Guidelines for Haemodialysis

Subclause 201.7.9.2.12 Cleaning, disinfection and sterilization (2nd dash)

This description of the test procedure should at least include:

– the recommended type of disinfectant;
– the required concentration of disinfectant in the container;
– the resulting concentration of disinfectant in the HAEMODIALYSIS EQUIPMENT;

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– the required minimum time of the disinfection phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT);
– the required minimum rinse phase (if not automatically set by the HAEMODIALYSIS EQUIPMENT).

Subclause 201.7.9.3.1 General (3rd and 4th dashes)

Proposal for typical operating conditions of chronic HD treatments with HAEMODIALYSIS EQUIPMENT to compare different features:

– dialysing time: 4 h plus preparation time and post treatment operation;
– DIALYSING FLUID flow: 500 ml/min;
– blood flow: 300 ml/min;
– ULTRAFILTRATION flow: 0,5 l/h;
– DIALYSING FLUID temperature: 37 °C;
– chemical and/or heat disinfection according to the MANUFACTURER'S specification.

Subclause 201.7.9.3.1 General (5th dash)

Where systems with anticoagulant solution-delivering equipment are concerned, it should be considered that the following HAZARDS may occur if a system / PROTECTIVE SYSTEM fails:

– fluid flow from the EXTRACORPOREAL CIRCUIT via the arterial PATIENT CONNECTION with the blood delivery equipment not running;
– HAZARD caused by improperly dosing the anticoagulant solution;
– air infusion via the arterial PATIENT CONNECTION, because the anticoagulant pump doses upstream of the blood pump (wrong delivery rate or delivery while the blood pump is not running).

Subclause 201.7.9.3.1 General (11th dash)

The flow through the BLOOD LEAK detector depends on the treatment type. In HD and ONLINE HDF it is the DIALYSING FLUID flow plus the ULTRAFILTRATION flow. In "sequential" therapy it is the ULTRAFILTRATION flow. In HF it is the filtrate flow plus the ULTRAFILTRATION flow.

Subclause 201.8.3 Classification of APPLIED PARTS

Compliance with TYPE CF APPLIED PART requirements for HAEMODIALYSIS EQUIPMENT that are provided with a permanent water connection and/or connection to CENTRAL DELIVERY SYSTEM, can be achieved with high technical expenditures only. For that reason, an exception rule has been established for the use of HAEMODIALYSIS EQUIPMENT with TYPE B APPLIED PARTS on PATIENTS with central venous catheter.

The goal of the exception rule is to protect the PATIENT under NORMAL CONDITION and under SINGLE FAULT CONDITION from LEAKAGE CURRENTs with the same effectiveness as HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PART. Two sources of LEAKAGE CURRENTs have to be distinguished;

1) LEAKAGE CURRENTS originating from the HAEMODIALYSIS EQUIPMENT.

   These LEAKAGE CURRENTS could flow through the central venous catheter via the heart of the PATIENT to the grounded PATIENT bed. Under NORMAL CONDITION these LEAKAGE CURRENTS flows to earth via the PROTECTIVE EARTH CONDUCTOR of the HAEMODIALYSIS EQUIPMENT. Under SINGLE FAULT CONDITION (PROTECTIVE EARTH CONDUCTOR of the HAEMODIALYSIS EQUIPMENT is broken) the LEAKAGE CURRENTS needs to be minimized by other means.

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If ME-EQUIPMENT complies with these special leakage current limits in NORMAL CONDITION, but does not comply in SINGLE FAULT CONDITION (i.e. with the PROTECTIVE EARTH CONDUCTOR interrupted), an external potential equalization cable may be used for reducing the LEAKAGE CURRENTS to the necessary lower levels.

The external potential equalization cable has to be protected against unintentional disconnection (unintentional disconnection of the plug). Intentional disconnection of the plug without use of TOOLS may be possible.

2) LEAKAGE CURRENTs originating from other electrical equipment and ME EQUIPMENT set up in the PATIENT ENVIRONMENT.

These LEAKAGE CURRENTS could flow through the body of the PATIENT via the heart and the central venous catheter to the earth via the HAEMODIALYSIS EQUIPMENT. Under NORMAL CONDITION these LEAKAGE CURRENTS flows to earth via the PROTECTIVE EARTH CONDUCTOR of the external equipment.

Under SINGLE FAULT CONDITION (PROTECTIVE EARTH CONDUCTOR of the external equipment is broken) and if the HAEMODIALYSIS EQUIPMENT has a TYPE CF APPLIED PART, the isolation barrier between the APPLIED PART and the rest of the HAEMODIALYSIS EQUIPMENT would prevent these LEAKAGE CURRENTS from reaching the PATIENT.

If the HAEMODIALYSIS EQUIPMENT has a TYPE B APPLIED PART, these LEAKAGE CURRENTS need to be minimized by other means.

Since measures that have to be applied to non-HAEMODIALYSIS EQUIPMENT are not subject to this particular standard, the normative requirement of this particular standard is the only information found in the ACCOMPANYING DOCUMENTS for the OPERATOR (201.7.9.2.5 8th dash) and for the RESPONSIBLE ORGANIZATION (201.7.9.2.6 3rd dash).

Subclause 201.8.7.4.7 aa) Measurement of the PATIENT LEAKAGE CURRENT

"Typical treatment mode with no alarms activated" means e.g. that a heater is on during measurement. If valves can block the current path between the heater and the PATIENT, these valves should be in open condition.

Subclause 201.8.11.2 Multiple socket-outlets

An example is a socket for an external heater which is switched off by the HAEMODIALYSIS EQUIPMENT in case of a temperature ALARM CONDITION.

Subclause 201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

The surface of the HAEMODIALYSIS EQUIPMENT should be designed in such a way that there are no gaps and corners at the surface, where microorganisms may remain after surface disinfection.

The following is an example how disinfection efficiency and disinfectant residuals can be tested.

a) Testing of disinfection efficiency

1) Chemical disinfection

The disinfection efficiency test consists of the following steps:

(1) It has to be shown that in the disinfection phase the fluid in the HAEMODIALYSIS EQUIPMENT really reaches the intended concentration of disinfectant. The goal of this test is to verify the correct function of the hydraulic components and of the software in the disinfection process. The test is done by taking a sample of fluid from the HAEMODIALYSIS EQUIPMENT at different locations of the DIALYSING FLUID circuit and measuring the disinfectant concentration of these samples.

(2) It has to be shown that the contact time of the disinfectant in the HAEMODIALYSIS EQUIPMENT is as intended. Using coloured test liquid instead of disinfectant, it is

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checked by visual inspection in each section of the fluid path that the contact time is as expected.

(3) It has to be shown that all internal tubing is included in the disinfection process. This is done by performing a normal disinfection, but sucking a coloured test liquid instead of real disinfectant. Then it is checked by visual inspection that in the disinfection phase all parts of the fluid system are filled with coloured liquid. No tubes or containers should be only partly filled, or filled with a liquid that is considerably lighter in colour. Such test liquids are e.g. "Methylene blue" or "Fluorescein".

An alternative method is measuring the conductivity of a conductive fluid.

(4) It has to be shown by a “quantitative suspension test” that in the worst case condition that is acceptable according to the OPERATOR's manual (lowest concentration, shortest time), the disinfectant concentration and disinfection time deactivate the microorganisms to the necessary degrees. This test includes several types of microorganisms.

The following set of microorganisms is considered to cover the typical chemical disinfection methods in HAEMODIALYSIS EQUIPMENT. For validation of a specific chemical disinfection method the relevant subset (at least 4) is chosen:

– pseudomonas aeroginosa;
– staphylococcus aureus;
– bacillus subtilis spores;
– candida albicans;
– aspergillus niger;
– enterococcus hirae.

ATCC strains are recommended.

This step 4 can be done in one of three ways:

a) A disinfection is performed on the HAEMODIALYSIS EQUIPMENT, inserting a known number of microorganisms per ml of fluid, and it is checked that the number of microorganisms is reduced to the necessary degree. The necessary degree is determined by relevant standards, e.g. 10^5 for the bacteria (EN 1040) and 10^4 for the yeast (EN 1275). The test can be done either with each type of microorganism separately or with a mixture of some microorganism types. The relevant subset of microorganisms indicated above is used (at least 4).

b) A laboratory test (in test tubes) is performed, including all of the above types of microorganisms, and using the same conditions (disinfectant concentration, temperature and time) as in the HAEMODIALYSIS EQUIPMENT.

c) By literature, e.g. the validation data of the disinfectant.

2) Heat disinfection

The MANUFACTURER identifies which of the relevant microorganisms is the most heat resistive.

The following highly heat-resistive microorganism can be used: bacillus subtilis spores.

This identified type is added to the pool of at least 4 of the microorganisms indicated above and a heat disinfection is performed in the HAEMODIALYSIS EQUIPMENT.

It has to be shown that in the heat disinfection phase the fluid in the HAEMODIALYSIS EQUIPMENT really reaches the intended temperature for the necessary time. The goal of this test is to verify the correct function of the involved components and of the software in the disinfection process. The test is done by measuring the temperature in the HAEMODIALYSIS EQUIPMENT at different locations of the DIALYSING FLUID circuit over the time.

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3) Combination of chemical and heat disinfection

The temperature and the concentration distribution within the HAEMODIALYSIS EQUIPMENT are verified over the time of the disinfection procedure.

b) Testing of disinfectant residuals

It has to be shown that the rinsing process after disinfection reduces the disinfectant concentration to an acceptable level. As a standard the “Lethal dose” [LD <50] should be used as the reference limit. The test is done in the following way:

A normal disinfection and rinse are performed, but a coloured test liquid (e.g. Methylene blue or Fluorescein) is sucked instead of disinfectant. Then it is checked that in the rinse phase all parts of the fluid system are filled with coloured liquid. No tubes or containers should be only partly filled, or filled with a liquid that is considerably lighter in colour.

After rinsing, no parts of the fluid system should show traces of the coloured liquid. The remaining concentration of the coloured liquid can be measured photometrically.

Using a colour test liquid results in higher sensitivity of the measurement than using real disinfectant but does not cover the effect of diffusion of disinfectant into plastic.

An alternative method is conductivity measurement as follows: Increase the conductivity level within the fluid and take samples from the most critical parts of the HAEMODIALYSIS EQUIPMENT for analysis.

Subclause 201.11.8 Interruption of the power supply / SUPPLY MAINS to HAEMODIALYSIS EQUIPMENT

The following items are examples for additional measures which may be necessary;

– stopping of the DIALYSING FLUID flow to the DIALYSER;
– interruption of any SUBSTITUTION FLUID flow;
– reduction of ULTRAFILTRATION to its minimum value;
– clamping of the venous blood line.

Clause 12 Accuracy of controls and instruments and protection against hazardous outputs

The preceding second edition of this particular standard (IEC 60601-2-16:1998) usually did not specify any definite values for the necessary alarm limits of the PROTECTIVE SYSTEMS. It was up to the MANUFACTURER to define the deviation from the value that presented a HAZARD which had to be detected by the PROTECTIVE SYSTEM and justified in the MANUFACTURER’S RISK MANAGEMENT PROCESS.

The objective of the present third edition of this particular standard was to reach an agreement between the MANUFACTURERS and other interested organizations as to that part of the RISK MANAGEMENT PROCESS that is applicable to all systems and to describe the result in the present standard. It was intended to avoid any unnecessary redundant work on the part of the MANUFACTURER and to facilitate a uniform evaluation by the testing agencies.

When preparing this particular standard, the committee took a "typical" dialysis HAEMODIALYSIS EQUIPMENT for the treatment of acute or chronic renal failures as a basis. If the properties of a HAEMODIALYSIS EQUIPMENT deviates from the “typical” values, the MANUFACTURER can and must define and justify the alarm limits in the MANUFACTURER’S RISK MANAGEMENT PROCESS.

Subclause 201.12.3.101 Visual and audible alarm signals

If the OPERATOR is allowed to configure the contents of the screen, the MANUFACTURER must use constructive measures (and not notes in the instructions for use) to ensure that the alarms are indicated under any and all circumstances.

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Subclause 201.12.3.102 Audible alarm signals

It is intended to prevent the OPERATOR from misusing the volume adjustment function for silencing alarms, since such a silencing could not be terminated automatically. The RESPONSIBLE ORGANIZATION, however, should have the possibility of adjusting the alarm volume to a reasonable value depending on the sound level on site.

There are alarms which do not present any HAZARD if they are silenced for more than 3 min, but where elimination of the cause of the alarm often takes more than 3 min, e.g. in case of a conductivity alarm caused by an empty DIALYSING FLUID CONCENTRATE container. In this case, the PATIENT's state will not aggravate during the alarm silence period and the activated bypass mode.

Subclause 201.12.4.4.101 Composition of the DIALYSING FLUID

The requirement for a PROTECTIVE SYSTEM is also applicable to human errors (e.g. mistaking of DIALYSING FLUID CONCENTRATES) and also refers to Clause 15 (Construction of ME EQUIPMENT) and Clause 16 (ME SYSTEMS).

In acetate treatment it is considered to be appropriate if the PROTECTIVE SYSTEM is designed such that it prevents a deviation beyond the following limits:

– conductivity of final DIALYSING FLUID 12 mS/cm – 16 mS/cm
– sodium in DIALYSING FLUID ±5 % from set point

Additionally in bicarbonate treatment:

– bicarbonate in DIALYSING FLUID ±25 % from set point

If other components can be added individually, additionally:

– other electrolytes in DIALYSING FLUID ±20 % from set point

Where HAEMODIAFILTRATION without buffer (special form of HDF where the buffer is given to the PATIENT not as part of the DIALYSING FLUID but as part of the SUBSTITUTION FLUID) and other special procedures are concerned, the technical safety requirements must be defined in the scope of the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Subclause 201.12.4.4.102 DIALYSING FLUID and SUBSTITUTION FLUID temperature

Long-term application of DIALYSING FLUID temperatures above body temperature will result in a positive thermal energy balance for the PATIENT, which is associated with physiological reactions. Increased body temperature leads to increased perfusion of the skin and in consequence frequently to clinically relevant blood pressure drop. Temperatures above 46 °C cause haemolysis.

Decrease of body temperature results in discomfort and trembling. The tolerance limits of the body are some tenths of a °C.

Increasing the temperature above 42 °C for a short time is permitted to enable e.g. the measurement of recirculation by temperature measurement. A short-term increase is uncritical because it doesn't lead to perturbation of the energy balance of the body.

Blood damage (thermal haemolysis) occurs when blood is heated to more than 46 °C for prolonged time. Blood temperatures up to 46 °C in the EXTRACORPOREAL CIRCUIT have been used for hyperthermia treatment. Low temperatures have no adverse effect on blood. Historically blood has been dialysed at 5 °C.

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The DIALYSER is a very efficient heat exchanger and any temperature gradient will change the thermal energy balance of the PATIENT. A prolonged positive thermal energy balance is known to cause hypotension while a prolonged large negative balance will be uncomfortable for the PATIENT and cause shivering.

To avoid high positive energy balances that may cause hypotension, the maximum DIALYSING FLUID temperature is limited to 42 °C or less.

No adverse effects besides PATIENT discomfort are known for low DIALYSING FLUID temperatures. Ventricular fibrillation has been reported after cooling of the heart to less than 33 °C by rapid infusion of large amounts (>5 l) of cold (4 °C) blood. In HAEMODIALYSIS cooling to 33 °C would take > 15 min even assuming high blood flow, low DIALYSING FLUID temperature (10°C) and low body weight (50 kg).

Subclause 201.12.4.4.103 NET FLUID REMOVAL

The direction of a fluid balancing error is an essential factor: insufficient removal is un-hazardous in case of chronic dialysis, if it is detected and corrected before the PATIENT is discharged. Excessive removal is hazardous. Hyperhydration (fluid supplied) can be hazardous and depends on the initial situation.

Monitoring of the following limits by the PROTECTIVE SYSTEM is usually considered to be appropriate for 4 hours of dialysis:

1) the NET FLUID REMOVAL is within ±0,1 l/h of the set point, and
2) the target NET FLUID REMOVAL is to be kept within ±400 ml at any time during the treatment.

Safe limits for an acceptable NET FLUID REMOVAL error cannot be derived from physiological data, however, the medical industry has many years of experience with fluid balancing systems. The limits given in 201.12.4.4.103 are derived from this experience.

TMP monitoring is not considered to be an adequate protection against fluid balancing errors in the case of high-flux DIALYSERS. (However, TMP monitoring can improve the safety and performance in a different way, e.g. with regard to the detection of a secondary membrane, interdialytic hyperuraemia, undetected membrane rupture, "rescuing" the DIALYSER if heparinisation is inadequate.)

Possible sources of fluid balancing errors which should be covered by a PROTECTIVE SYSTEM are, for example: leaks at connectors (including SUBSTITUTION FLUID), errors in the balancing system (e.g. flow meter, balancing chamber).

Subclause 201.12.4.4.104.1 a) Extracorporeal blood loss to the environment

Monitoring of the VENOUS PRESSURE is not always suitable for detecting a blood loss in time, in case the venous puncture cannula slips out. The VENOUS PRESSURE is determined mainly by the hydraulic resistance of the venous puncture cannula, particularly with today's usual high blood flow rates of up to 500 ml/min. A VENOUS PRESSURE alarm system is, hence, not able to always detect whether or not the puncture cannula slips out.

If dialysis is performed in the single-needle mode with only one blood pump ("single-needle single pump", "SN click-clack"), the VENOUS PRESSURE measurement is an integral part of the control system. An error in this control system (e.g. pressure sensor stuck to low value) might lead to the upper changeover point of the VENOUS PRESSURE never being reached. As a result, the pressure becomes too high, the tubing system may burst, and the PATIENT may loose a great amount of blood. This may require a PROTECTIVE SYSTEM which is independent of the control system, e.g. monitoring of the phase duration by an independent microprocessor.

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Inherent safe design is e.g. a pump rotor that is spring-mounted so smoothly that bursting of the tubing is not possible. However, in this case the HAZARD of haemolysis may exist.

Other measures for prevention of overpressure are holders for the EXTRACORPOREAL CIRCUIT lines and the DIALYSER which make kinking sufficiently unlikely.

Blood loss to the environment caused by disconnections or faults in the EXTRACORPOREAL CIRCUIT can not be prevented by any PROTECTIVE SYSTEM. The PROTECTIVE SYSTEM should be designed so that blood loss is detected and major blood loss is prevented. Most reported cases of fatal blood loss are caused by blood access cannulas slipping from the fistula or graft. This cannot be prevented by the HAEMODIALYSIS EQUIPMENT. Traditionally, VENOUS PRESSURE monitors have been used for protection of blood loss to the environment. These sensors detect a drop of the pressure in the return bloodline. In case of a bloodline rupture or disconnection of the bloodline from the blood access device (cannula or central venous catheter) the pressure will drop considerably because of the high flow resistance in the blood access device. When the venous cannula slips from a fistula the pressure change is usually too low to be detected by the VENOUS PRESSURE monitor. The pressure drops only by the amount of the fistula pressure which is typically 5 mmHg – 20 mmHg. To avoid frequent nuisance alarms caused by PATIENT movement the difference between the actual VENOUS PRESSURE and the lower pressure alarm limit is usually adjusted to 10 mmHg – 20 mmHg.

Monitors employing pressure pulses or other parameters may offer greater sensitivity but may also require up to a minute to detect the fault condition and switch off the blood pump. With high blood flow this may cause blood losses of 500 ml, which are usually not fatal for adults.

The effects of haemorrhage are described by:

GUYTON AC. Circulatory Shock and Physiology of Its Treatment. Guyton AC, editor, *Textbook of Medical Physiology*, Eight Edition. W.B. Saunders Company,1991:263-71

Subclause 201.12.4.4.104.1 c) Extracorporeal blood loss to the environment

As alarm reaction, the stopping of an occluding blood pump is considered as sufficient. The additional closing of the safety clamp adds only little value because a rupture will occur most likely at the point of highest pressure, which normally is between blood pump and DIALYSER. In this case “retrograde” blood loss via the venous bloodline is negligible in respect to the direct blood loss through the arterial bloodline.

If staff is not present (e.g. home patient) or delayed for a long period in the case of venous puncture cannula slippage, the blood loss from the venous access (backwards) may become hazardous to the patient.

Subclause 201.12.4.4.104.2 BLOOD LEAK to the DIALYSING FLUID

An acceptable method of complying with this requirement is, for example, a PROTECTIVE SYSTEM utilizing a BLOOD LEAK detector.

BLOOD LEAKS of less than 0,35 ml/min blood (with an Hct of 32 %) are not considered to present a HAZARD.

Historically, BLOOD LEAK sensitivity has been specified in milligrams of haemoglobin per liter (mgHb/l) of DIALYSING FLUID, probably because of the established spectrophotometric tests for determination of haemoglobin. Specification in mgHb, however, requires calculation to determine the quantity of blood lost, which is the parameter of interest to the practitioner. The threshold limits of 55 mg Hb/l were translated to 0,35 ml/min of blood, respectively. Calculations were based on the assumption of 14 grams Hb/100 ml blood in normal subjects, a haematocrit of 46 % (0,46) in normal subjects, a haematocrit possibly as low as 25 % (0,25) in typical HAEMODIALYSIS PATIENTS, and a DIALYSING FLUID flow rate of 500 ml/min.

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Subclause 201.12.4.4.104.3 Extracorporeal blood loss due to coagulation

In this case, an independent PROTECTIVE SYSTEM is not required because the degree of harm is limited to the blood loss in the EXTRACORPOREAL CIRCUIT.

At the time of writing of this standard there are no scientific publications available about coagulation of blood as a function of the stopping time of the extracorporeal blood flow. A maximum alarm delay time of three minutes has been proven by experience to be appropriate.

Subclause 201.12.4.4.105 Air infusion

At the time of writing of this standard there was not enough scientific literature to define a safe alarm limit in this particular standard. In *Replacement of renal function by dialysis*, 5th ed., chapter 14, Polaschegg and Levin consider the continuous infusion of air of less than 0,03 ml/(kg*min) and infusion of a bolus of 0,1 ml/kg not to be a HAZARD.

If there is no air in the tubing system with the HAEMODIALYSIS EQUIPMENT being used as intended, the presence of air presents already a first fault, and it may be improbable that an independent second fault (e.g. failure of the air detector) occurs during the same treatment. In this case, the air detector would not need to be failsafe. This has to be determined by RISK MANAGEMENT.

If air is permanently present in the tubing system with the HAEMODIALYSIS EQUIPMENT being used as intended, e.g. if a partially filled drip chamber is used, air in the system is the NORMAL CONDITION (not a first fault). If a normal operating mode (not a technical failure) can lead to infuse this air to the PATIENT, the air detector has to be failsafe.

An air detector is failsafe, if, for example:

a) it is designed with two channels and each channel is tested prior to each treatment; or

b) it is designed with one channel and is tested periodically during the treatment, with the test interval having to be shorter than the fault tolerance time. The fault tolerance time is the shortest time required by an air bubble to move from the air detector to the PATIENT CONNECTION.

A failsafe method to stop the blood flow to the PATIENT is for example as follows:

a) it is completely designed with two channels (e.g. stopping of the pumps and closing of the clamps) and both channels are tested; or

b) the blood pump(s) and all pumps delivering in the direction of the PATIENT are turned off via two channels and even a mechanical failure (e.g. breakage of a rotor spring) cannot cause a loss of occlusion.

If air, accumulated in the EXTRACORPOREAL CIRCUIT can reach the PATIENT by expansion even if the blood pump is stopped by an air detector alarm, an additional clamp must be provided to prevent air infusion into the PATIENT.

This is typically the case when the air detector is positioned downstream of the DIALYSER.

No additional clamp is typically required if the air detector is positioned downstream of the blood pump but upstream of the DIALYSER and, if a leak in the negative pressure section of the EXTRACORPOREAL CIRCUIT is the only pathway for ingress of air.

Where HAEMODIALYSIS EQUIPMENT are concerned which can raise or lower the level in the drip chamber by means of an electrically operated air pump, a malfunction of this air pump may cause air in the tubing system. If this air pump is able to build up a pressure that is higher than the occlusion pressure of the venous clamp, the venous clamp no longer presents a safe switch off path. In this case, the air pump must also be switched off in a failsafe manner. In

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addition, it must be noted that the air pump might be able to press air into the PATIENT via the arterial bloodline when the blood flow is stopped (e.g. because of an alarm) and that this air would not be detected by the air detector.

In case of single-needle procedures, it must be noted that, owing to the compressed air present in the system, the actual blood flow may be temporarily higher than the set blood flow. This must be taken into consideration when the scanning interval of the air detector and the fault tolerance time are determined.

In case of a failure of the power supply, air in the EXTRACORPOREAL CIRCUIT under pressure may also generate flows in direction of the venous and/or arterial PATIENT CONNECTION. In this case, air must be prevented from reaching the PATIENT.

At least the following potential sources of air must be considered in the RISK ANALYSIS:

– air in the drip chamber;
– residual air in the bloodline;
– residual air in the DIALYSER;
– air in the monitor lines leading to the pressure transducers;
– air entering the system in the recirculation path of a single needle treatment;
– air entering the EXTRACORPOREAL CIRCUIT.

Non-dissolved air can appear in bulk and in the form of bubbles of different sizes.

The physical principle used for any air detector and electronic delay or dead times must be taken into account in the RISK ANALYSIS. Today ultrasonic air detectors are used almost exclusively for the detection of air in the EXTRACORPOREAL CIRCUIT. Some of these air detectors are positioned on the partially air-filled venous drip chamber. They are usually designed as level detectors, which means that they will generate an alarm if the level decreases or if the drip chamber is filled with foam.

Other air detectors are positioned directly on the blood tubing and are usually capable of detecting single bubbles with volumes much lower than the volumes believed to cause a HAZARD. The important parameter of the air detector is the accumulated volume of these single bubbles. In order to avoid nuisance alarms the number of detected bubbles is integrated with a time function.

Subclause 201.12.4.4.106 Alarm override modes

It should not be possible to deactivate the BLOOD LEAK detector inadvertently. Possible solutions might, for example, be two independent actions on the OPERATOR's part and automatic restart on commencement of the next treatment. Deactivation of the BLOOD LEAK detector should not increase the RISK of blood loss to a higher degree than necessary. An acceptable method is to design the BLOOD LEAK detector such that it is not only possible to switch it off completely but also to reduce its sensitivity and that this reduction will be automatically cancelled again on commencement of the next treatment.

Subclause 201.12.4.4.109 Blood pump(s) and/or SUBSTITUTION FLUID pump(s) reversal

Example of a HAZARD caused by human error:

In case of mains power failure in a dialysis unit it is very likely that the staff is under high stress and therefore human error is relative likely. In this situation the HAZARD of air infusion via the arterial bloodline (if applicable) by wrong blood pump direction can be avoided e.g. by:

a) prevention of wrong hand cranking direction by

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- a unidirectional cranking mechanism or
- a clearly marked arrow on the pump(s); or

b) avoidance of hand cranking by continuation of the blood blow with battery power.

Example of a HAZARD caused by a technical fault:

A technical fault could cause the blood pump(s) and/or SUBSTITUTION FLUID pump(s) to rotate in the wrong direction. This can be avoided e.g. by:

a) wiring a DC motor with electromechanical commutation such that no random hardware failure can reverse the direction of the current; or

b) implementation of a PROTECTIVE SYSTEM independent of the motor control system, which stops the motor in case of wrong direction.

Subclause 201.13.2.6 Leakage of liquid

The test considers that fluid may flow out under pressure. Although its performance and reproduction is difficult, the test specified in this particular standard is considered to be suitable for this type of equipment.

Subclause 201.14.13 Connection of PEMS by NETWORK/DATA COUPLING to other equipment

A method proven to reduce RISK for the transfer of HAEMODIALYSIS EQUIPMENT settings via a network is the explicit test of the data transferred, performed by the OPERATOR and confirmation by the OPERATOR before these settings become effective in the HAEMODIALYSIS EQUIPMENT.

Subclause 201.15.4.1.101 DIALYSING FLUID CONCENTRATE connectors

DIALYSING FLUID CONCENTRATEs may be used in the form of powder or fluid. For DIALYSING FLUID CONCENTRATEs in the form of powder and "DIALYSING FLUID ions for sodium chloride (powdered)", constructional features preventing their misuse are usually provided in the HAEMODIALYSIS EQUIPMENT designs. Liquid DIALYSING FLUID CONCENTRATEs are taken either from containers or from CENTRAL DELIVERY SYSTEMS, which are not prevented from being misused by constructional features.

At least the following DIALYSING FLUID CONCENTRATE types should be taken into consideration in the RISK MANAGEMENT PROCESS:

- acetate DIALYSING FLUID CONCENTRATE;
- acid DIALYSING FLUID CONCENTRATE for use with bicarbonate DIALYSING FLUID CONCENTRATE without sodium chloride;

  NOTE 1 With 35X, 36.83X, 45X dilution.

- acid DIALYSING FLUID CONCENTRATE for use with bicarbonate DIALYSING FLUID CONCENTRATE with sodium chloride;

  NOTE 2 With 35X, 36.83X, 45X dilution.

- bicarbonate DIALYSING FLUID CONCENTRATE without sodium chloride;

  NOTE 3 Can be supplied as liquid or powder.

- bicarbonate DIALYSING FLUID CONCENTRATE with sodium chloride;
- sodium chloride;

  NOTE 4 Can be supplied as liquid or powder.

- concentrates complementary to sodium and bicarbonate;

  NOTE 5 Used for mixing systems with separate sodium and bicarbonate concentrate supplies.

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NOTE 6 Can be supplied as liquid or powder.

Subclause 201.15.4.1.102 Connectors for blood pressure transducers

An internal transducer protector placed between the internal pressure transducer and the connection to the external transducer protector is one method of preventing HAEMODIALYSIS EQUIPMENT contamination.

Subclause 201.16 ME SYSTEMS

A ME SYSTEM for dialysis can be comprised of one ore more HAEMODIALYSIS EQUIPMENT and one or more of the following:

– water treatment system;
– discharge (drain);
– data transfer;
– CENTRAL DELIVERY SYSTEM;
– staff call system.

NOTE Since TOUCH CURRENTS of other equipment exist in the PATIENT ENVIRONMENT (e.g. dialysis chairs), a POTENTIAL EQUALIZATION CONDUCTOR could be necessary for such equipment.

The water treatment systems and the CENTRAL DELIVERY SYSTEMs are usually set up at a location that is remote from the HAEMODIALYSIS EQUIPMENT and cannot be connected via a MULTIPLE SOCKET-OUTLET. HAZARDS must be minimized via the installation, by applying the supply lines, for example, to the same potential as the HAEMODIALYSIS EQUIPMENT.

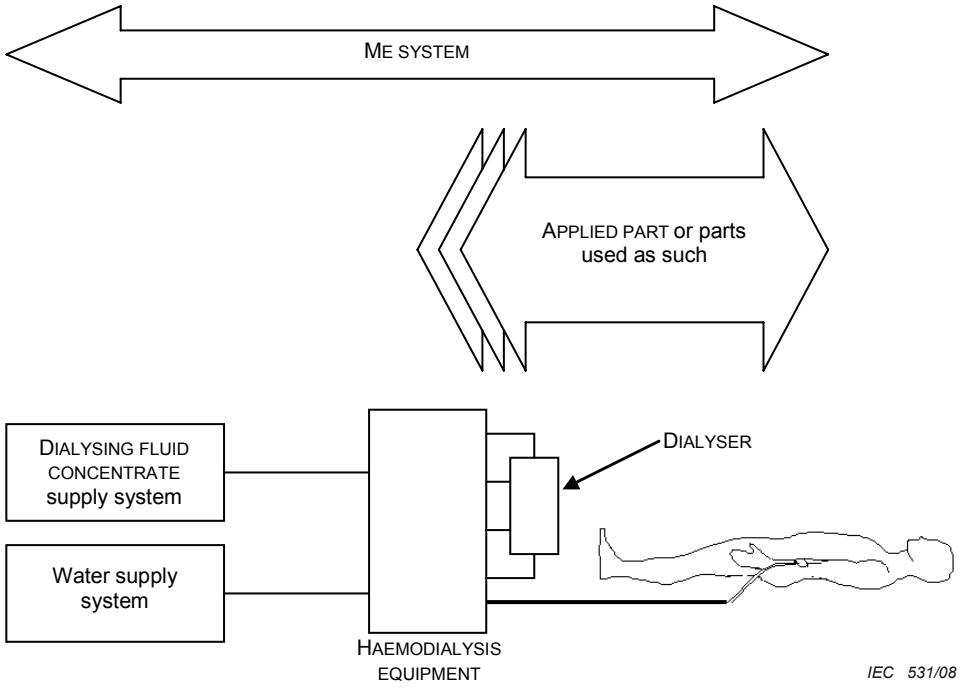

Figure AA.1 – Example of the HAEMODIALYSIS ME SYSTEM

For HAEMODIALYSIS EQUIPMENT with TYPE CF APPLIED PARTS the following item should be considered:

The bloodlines of the EXTRACORPOREAL CIRCUIT are not considered to be insulating. It must be assumed that conducting solutions in and around the tubing establish an electrical contact to the PATIENT.

An EXTRACORPOREAL CIRCUIT or DIALYSING FLUID circuit is considered isolating if:

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a) the material is electrically isolating, and

b) the circuit is built such that a rupture is sufficiently unlikely.

Point a) is tested by applying 1 500 V AC to the relevant segments of the circuit, filled with 0,9% NaCl. A conductive foil is wrapped over the tube over a length of 10 cm. No breakthrough between foil and fluid should occur over 1 min.

Point b) is demonstrated by the MANUFACTURER of the circuit by RISK MANAGEMENT which includes the interface between HAEMODIALYSIS EQUIPMENT and circuit and the manufacturing process.

Subclause 201.16.9.1 Connection terminals and connectors

According to the state of technology, the PROTECTIVE SYSTEM for "composition of the DIALYSING FLUID" is based on the measurement of the conductivity or the volumetric admixture. Depending on the operating mode (acetate, bicarbonate), an incorrect DIALYSING FLUID CONCENTRATE is frequently detected via the conductivity or the volumetric admixture.

Additional measures besides colour coding of the CENTRAL DELIVERY SYSTEM may be required by RISK MANAGEMENT in case of DIALYSING FLUID CONCENTRATES which, although they deliver a conductivity within the expected range, are hazardous for the treatment type concerned in their composition (e.g. acid DIALYSING FLUID CONCENTRATE 45X ratio for acetate dialysis).

In such cases, the RESPONSIBLE ORGANIZATION should initiate the appropriate measures which are equivalent to colour coding with the pertinent operating mode, such as disabling the operating mode of acetate dialysis or mechanically coding the HAEMODIALYSIS EQUIPMENT and the DIALYSING FLUID CONCENTRATE container.

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1) Second edition, withdrawn and replaced by IEC 60601-1:2005.

2) Second edition, withdrawn and replaced by IEC 60601-2-16:2008 (this publication).

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

3, rue de Varembé
P.O. Box 131
CH-1211 Geneva 20
Switzerland

Tel: + 41 22 919 02 11
Fax: + 41 22 919 03 00
info@iec.ch
www.iec.ch

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