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AS/NZS IEC 60601.2.16:2015

Australian/New Zealand Standard™

# Medical electrical equipment

# Part 2.16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 20 August 2015 and on behalf of the Council of Standards New Zealand on 21 August 2015.
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The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
Medical Technology Association of Australia
Ministry of Business, Innovation and Employment, New Zealand
New Zealand Institute of Healthcare Engineering
Testing Interests, Australia
Therapeutic Goods Administration
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# Medical electrical equipment

# Part 2.16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

Originated in Australia as AS 3207—1981.
Previous and first New Zealand edition AS/NZS 3200.2.16:1999.
Jointly revised and redesignated as AS/NZS IEC 60601.2.16:2015.

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# PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee, HE-003 Medical Electrical Equipment, to supersede AS/NZS 3200.2.16:1999, *Medical electrical equipment,* Part 2.16: *Particular requirements for safety—Haemodialysis, haemodiafiltration and haemofiltration equipment.*

The objective of this Standard is to establish basic safety and essential performance requirements for haemodialysis, haemodiafiltration and haemofiltration equipment. It does not take into consideration the dialysis fluid control system of haemodialysis equipment using regeneration of dialysis 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.

The particular requirements of this Standard make reference to IEC 60601-1, which has been adopted as AS/NZS IEC 60601, *Medical electrical equipment*, Part 1: *General requirements for basic safety and essential performance*. Reference to the general requirements is essential for the application of this Standard.

This Standard is identical with, and has been reproduced from IEC 60601-2-16, Ed.4.0 (2012), *Medical electrical equipment*, Part 2-16: *Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand standard’.

(b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

| *Reference to International Standards* | | *Australian/New Zealand Standards* | |
|---|---|---|---|
| ISO | | AS | |
| 594 | Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment | 1600 | Medical equipment—Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment |
| 594-2 | Part 2: Lock fittings | 1600.2 | Part 2: Lock fittings |

Only normative references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

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# IEC FOREWORD

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 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 A.

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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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AUSTRALIAN/NEW ZEALAND STANDARD

# Medical electrical equipment

## Part 2.16:
## Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

### 201.1 Scope, object and related standards

Clause 1 of the general standard[1] 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 DIALYSIS FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS 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;
– DIALYSIS 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.

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

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### 201.1.2 Object

*Replacement:*

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.

IEC 60601-1-2, IEC 60601-1-8, IEC 60601-1-10 and IEC 60601-11 apply as modified in Clauses 202, 208, 210 and 211 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published..

### 201.1.4 Particular standards

*Replacement:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT 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 IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 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, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, 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.

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

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 63.

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

*Amendment:*

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

*Addition:*

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 60601-1-11:2010, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

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*

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## 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 64.

**201.3.8**
***APPLIED PART**

*Replacement:*

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

Note 1 to entry: See Figure AA.1 in Annex AA.

**201.3.78**
**PATIENT CONNECTION**

*Addition:*

Note 1 to entry: 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.

*Additions:*

**201.3.201**
**ARTERIAL PRESSURE**
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT

Note 1 to entry: 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 .

**201.3.202**
***BLOOD LEAK**
leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: When performing an HF process, this involves the filtration fluid section.

**201.3.203**
**CENTRAL DELIVERY SYSTEM**

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

**201.3.204**
**DIALYSER**
a device containing a semi-permeable membrane that is used to perform HD, HDF or HF

**201.3.205**
**DIALYSIS FLUID**
solution intended to exchange solutes and/or water with blood during HD or HDF

Note 1 to entry: The words "dialysate", “dialysis solution” and "dialysing fluid" are commonly used as synonyms of DIALYSIS FLUID.

**201.3.206**
**DIALYSIS FLUID CONCENTRATE**
substances which, when appropriately diluted or dissolved with purified water, produce the DIALYSIS FLUID

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**201.3.207**
**EXTRACORPOREAL CIRCUIT**
blood lines and any integral ACCESSORY thereof

**201.3.208**
**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

**201.3.209**
**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 DIALYSIS FLUID

Note 1 to entry: This process normally includes fluid removal by filtration. This process is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

**201.3.210**
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

Note 1 to entry: 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.

**201.3.211**
**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 DIALYSIS FLUID AND 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

**201.3.212**
**NET FLUID REMOVAL**
fluid loss from the PATIENT

Note 1 to entry: Historically this term was “weight loss”.

**201.3.213**
***ONLINE HDF**
HAEMODIAFILTRATION procedure where the HAEMODIALYSIS EQUIPMENT, based on the DIALYSIS FLUID, produces the SUBSTITUTION FLUID for the HDF treatment, suitable for injection

**201.3.214**
***ONLINE HF**
HAEMOFILTRATION procedure where the HAEMODIALYSIS EQUIPMENT, based on the DIALYSIS FLUID, produces the SUBSTITUTION FLUID for the HF treatment, suitable for injection

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

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**201.3.216**
**SUBSTITUTION FLUID**
a fluid administered to the PATIENT via the EXTRACORPOREAL CIRCUIT during HF or HDF

**201.3.217**
**TRANSMEMBRANE PRESSURE**
**TMP**
fluid pressure difference exerted across a semi-permeable membrane

Note 1 to entry: Generally the mean TMP is used. In practice, the displayed TRANSMEMBRANE PRESSURE is usually estimated from the measured EXTRACORPOREAL CIRCUIT pressure and the measured DIALYSIS FLUID pressure, each obtained at a single point.

**201.3.218**
***ULTRAFILTRATION**
process of fluid removal from the PATIENT'S blood across the DIALYSER

**201.3.219**
**VENOUS PRESSURE**
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT

## 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 shall be met within the tolerances specified by the MANUFACTURER under NORMAL CONDITION, if applicable:

**Table 201.101 – ESSENTIAL PERFORMANCE requirements**

| Requirement | Subclause |
|---|---|
| Blood flow | 201.4.3.102 |
| DIALYSIS 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 |
| DIALYSIS FLUID composition | 201.4.3.107 |
| DIALYSIS 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.

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*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 DIALYSIS FLUID flow**

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

NOTE Only a DIALYSIS 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 DIALYSIS FLUID flow.*
  *Measure the DIALYSIS FLUID flow during 30 min.*
– *Set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSIS FLUID flow.*
– *Measure the DIALYSIS FLUID flow during 30 min.*

*The values of the DIALYSIS 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 DIALYSIS FLUID flow, if applicable.*
– *Set the DIALYSIS 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 pressure specified by the MANUFACTURER.*
– *Measure the NET FLUID REMOVAL during an appropriate time interval.*

*Continue with test 2:*

– *Set the NET FLUID REMOVAL rate to the maximum value.*

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– *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:*

*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 * DIALYSIS FLUID composition

*Test method specified by the MANUFACTURER.*

#### 201.4.3.108 DIALYSIS FLUID temperature

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

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NOTE This test applies only to HAEMODIALYSIS EQUIPMENT having a heater for the DIALYSIS 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 °C to 25 °C.*
– *Set the DIALYSIS FLUID temperature to 37 °C, if applicable.*
– *Set the highest DIALYSIS FLUID flow.*
– *Measure the temperature at the DIALYSER inlet.*
– *Record the temperature during a period of 30 min.*
– *Set the lowest DIALYSIS FLUID flow.*
– *Measure the temperature at the DIALYSER inlet.*
– *Record the temperature during a period of 30 min.*

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

#### 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 °C to 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.

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## 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.

### 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 DIALYSIS FLUID CONCENTRATE(S);

– a quantitative description of the possible deviation of each component of the DIALYSIS 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 DIALYSIS 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;

– 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;

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- information on the required quality of the incoming water and of the DIALYSIS 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.

– for HAEMODIALYSIS EQUIPMENT with APPLIED PARTS other than TYPE CF APPLIED PARTS a warning, addressed to both the OPERATOR and the RESPONSIBLE ORGANIZATION, to ensure that no electrical equipment (non-ME EQUIPMENT and ME EQUIPMENT) with TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS above the respective limits for type CF APPLIED PARTS is used in the PATIENT ENVIRONMENT in combination with central venous catheters with atrial location.

NOTE For information see subclause 201.8.3 in Annex AA

#### 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 201.3.217;

– an explanation of the coloured markings on the DIALYSIS 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 PHYSIOLOGIC 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 with atrial location. If the HAEMODIALYSIS EQUIPMENT is not suitable for central venous catheters with atrial location possible HAZARDs shall be listed.

#### 201.7.9.2.6 Installation

*Addition:*

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

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– 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 DIALYSIS 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 DIALYSIS 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 (DIALYSIS 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 (DIALYSIS 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 DIALYSIS 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 AUDIO PAUSED 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, DIALYSIS FLUID and DIALYSIS 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 with atrial location.

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) with atrial location, the following shall apply:

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

bb) under SINGLE FAULT CONDITION, the PATIENT LEAKAGE CURRENTS, TOUCH CURRENTS and EARTH LEAKAGE CURRENTS shall 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.

*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 DIALYSIS FLUID temperature in the application, shall be flowing in the DIALYSIS 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. For practical reasons the measuring device may be connected to the DIALYSIS FLUID connectors.*

NOTE 101 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 102 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.

*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.

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