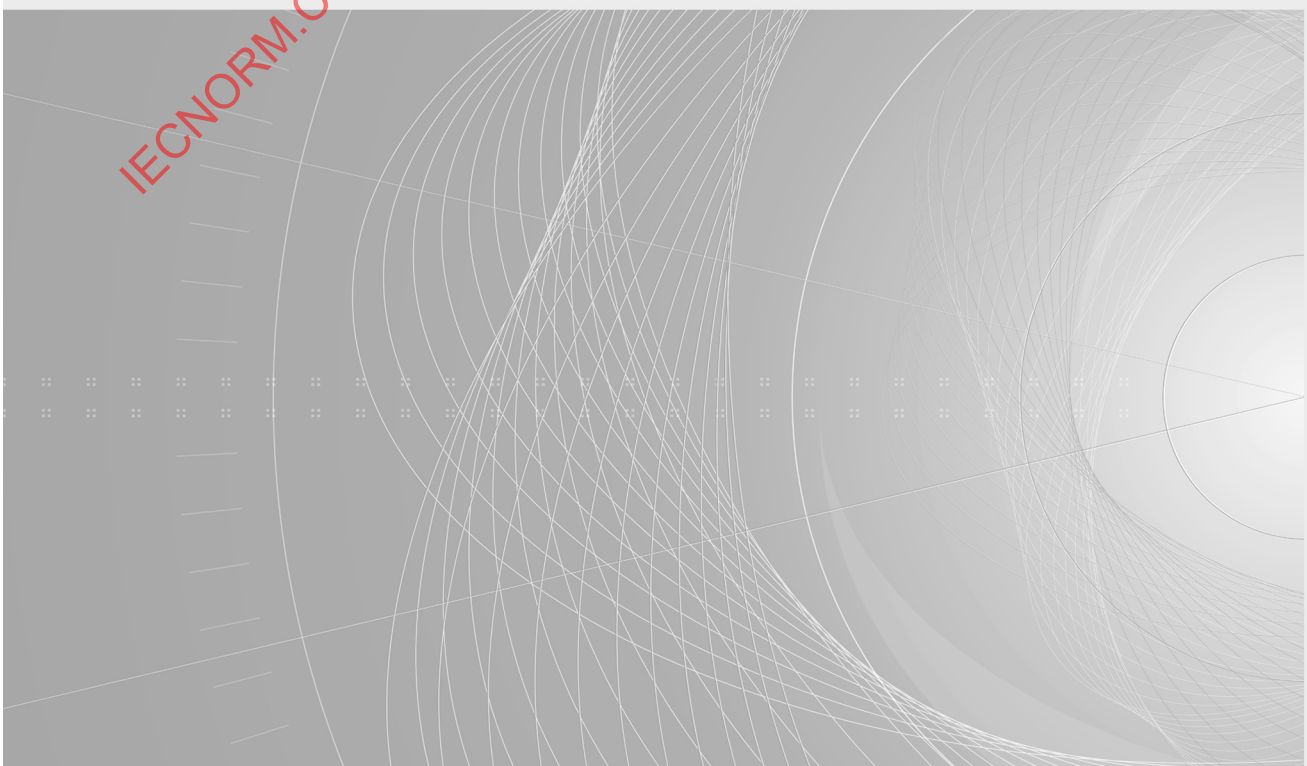
IEC TR 62653

Edition 2.0 2020-04
REDLINE VERSION

TECHNICAL REPORT

colour inside

Guideline for safe operation of medical equipment used for haemodialysis treatments



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC TR 62653, which is a technical report, has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) update the relevant references to the new numbering scheme of the ISO 23500 family;
b) alignment with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 62353:2014 and 60601-2-16:2018;
c) technical additions in several sections.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62D/1698/DTR	62D/1744/RVDTR

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

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

The verbal forms used in this document are conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2, 2018.

For the purpose of this document, the auxiliary verb “should” means that this statement of the document is recommended for safe operation. This term is not to be interpreted as indicating requirements.

In this document the following print types are used:

– requirements and definitions: roman type;
– informative material, such as notes, examples and references: smaller type;
– TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

HAEMODIALYSIS is a therapeutic method for treating ~~terminal~~ renal insufficiency, in addition to peritoneal dialysis and renal transplantation. HAEMODIALYSIS is often used as a general term for related extracorporeal methods of renal replacement therapy. At present, HAEMODIALYSIS is a standard procedure in renal replacement therapy, which, when applied properly, yields high-quality results. The treatment is a complex procedure which is under the influence of medical-biological, physical-chemical and technical processes.

Numerous guidelines, agreements, codes, decrees and laws have been established with regard to HAEMODIALYSIS. They contain detailed regulations about the quality of structures, processes and results, laid down by the legislative body, executive bodies of self-government, and funding agencies.

Since the safety of PATIENT treatment and the legal provisions are highly important, it is reasonable to introduce a quality management system. This document may be an integral part of a quality management system of the ORGANIZATION. The ORGANIZATION should ~~identify~~ be aware of the residual risks and identify appropriate measures, for example based on these guidelines. The ORGANIZATION should minimise such risks by the use of appropriate standard operating procedures. This document is intended to support the clinical management responsible for the quality management of HAEMODIALYSIS therapies.

GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

1 Scope

This document describes the technical ~~requirements~~ recommendations for use of medical equipment in chronic HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles ~~should~~ are important to be complied with to ensure safe, permissible and ~~proper~~ appropriate application.

The term HAEMODIALYSIS is used in this document as synonym for all therapy modalities.

The scope can be applicable to the use of the medical equipment in home, acute and pediatrics environment. The scope may also be applicable to SORBENT DIALYSIS SYSTEMS.

The physician is responsible for the ~~HAEMODIALYSIS~~ treatment prescription. However, the ORGANIZATION administering the treatment is responsible for all resources, structures and processes used in connection with the treatment. These responsibilities will not be described here.

~~If applicable, the scope may be applicable to the use of the equipment in paediatrics, home HAEMODIALYSIS, acute and SORBENT DIALYSIS SYSTEMS.~~

The requirements of IEC 60601-2-16 ensure that medical electrical equipment used for extracorporeal renal replacement therapy operates with a high level of safety. Despite that high level of safety, however, some residual risk remains, related to medical-biological, physical-chemical and technical HAZARDS. The ORGANIZATION administering the treatment is responsible for managing the residual risk.

This document is not intended to be used as the basis of regulatory inspection or certification assessment activities.

2 Normative references

~~None.~~

There are no normative references in this document.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography starting on page 30.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 34.

3.1
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

Note 1 to entry: Accessories can be objects, substances, preparations of substances and software which do not constitute any medical ~~devices~~ equipment themselves.

[SOURCE: IEC 60601-1:2005, 3.3, modified – A note to entry has been added.]

3.2
ARTERIAL PRESSURE
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT between the PATIENT connection and DIALYSER connection

Note 1 to entry: A difference can be made between the pre-pump pressure, which is upstream of the blood pump (typically negative), and post-pump pressure (typical positive), which is downstream of the blood pump.

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.201, modified – Direction of pressure added.]

3.3
BLOOD LEAK
leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: Not to be mistaken for blood loss to the environment.

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.202, modified – The original note to entry has been replaced.]

3.4
CENTRAL CONCENTRATE SYSTEM
system that prepares and/or stores concentrate at a central point for subsequent distribution to its points of use

3.5
CENTRAL DIALYSIS FLUID DELIVERY SYSTEM
system that produces DIALYSIS FLUID from DIALYSIS WATER and concentrate or powder at a central point and distributes the DIALYSIS FLUID from the central point to individual dialysis consoles

3.6
DIALYSER
device containing a semi-permeable membrane that is used to perform HAEMODIALYSIS, HAEMODIAFILTRATION or HAEMOFILTRATION

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.204]

*** 3.7**
DIALYSIS FLUID
aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS and HEMODIAFILTRATION

Note 1 to entry: The term "DIALYSIS FLUID" is used throughout this document to mean the fluid made from DIALYSIS WATER and concentrates that is delivered to the DIALYSER by the DIALYSIS FLUID delivery system. Such phrases as "dialysate" or "dialysis solution" ~~or "dialysing fluid" may be~~ are used in place of DIALYSIS FLUID in some countries; however, that usage is discouraged to avoid confusion.

Note 2 to entry: ISO 23500-5 defines three levels of DIALYSIS FLUID: standard DIALYSIS FLUID, ultrapure DIALYSIS FLUID, and online-prepared substitution fluid used for HAEMODIAFILTRATION.

Note 3 to entry: The DIALYSIS FLUID entering the DIALYSER is referred to as "fresh DIALYSIS FLUID", while the fluid leaving the DIALYSER is referred to as "spent DIALYSIS FLUID".

Note 4 to entry: DIALYSIS FLUID does not include prepackaged parenteral fluids used in some renal replacement therapies, such as HAEMODIAFILTRATION and HAEMOFILTRATION.

[SOURCE: ~~ISO 11663:2009, 3.7~~ ISO 23500-1:2019, 3.15, modified – The terms "dialysate" and "dialysis solution" were deleted.]

*** 3.8**
DIALYSIS MACHINE
HAEMODIALYSIS MACHINE
HAEMODIAFILTRATION MACHINE
HAEMOFILTRATION MACHINE
~~system or combination of units~~ medical electrical equipment used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

Note 1 to entry: The DIALYSIS MACHINE can be a batch DIALYSIS MACHINE filled with the entire DIALYSIS FLUID prior to treatment (see A.6).

Note 2 to entry: The DIALYSIS MACHINE can be supplied with DIALYSIS FLUID from a CENTRAL DIALYSIS FLUID DELIVERY SYSTEM and synonymously named individual dialysis console in this context (see A.7).

3.9
DIALYSIS WATER
water that has been treated to meet the requirements of ~~ISO 13959~~ ISO 23500-3 and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of concentrates and preparation of substitution fluid for online convective therapies

[SOURCE: ~~ISO 13959:2009, 2.5~~ ISO 23500-1:2019, 3.17]

3.10
ENCLOSURE
exterior surface of electrical equipment or parts thereof

Note 1 to entry: Including all touchable parts, such as rotary knobs, handles, and the like.

[SOURCE: IEC 60601-1:2005, 3.26, modified – The original note to entry has been replaced.]

*** 3.11**
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY ~~thereof~~

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.207, modified – Deletion of Note to entry.]

3.12
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

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.208]

3.13
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: ~~Usually, this process includes bidirectional filtration, with fluid removal normally being predominant.~~ This process typically includes fluid removal by filtration. This process is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.209~~, modified – the original note to entry has been replaced~~]

3.14
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 ultrafiltrate and ultrafiltrate is simultaneously replaced by an approximately iso-osmolar 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~~
process whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by convective transport via ultrafiltration and partial replacement by a substitution fluid resulting in the required net fluid removal

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.211~~, modified – an error has been corrected~~]

3.15
HAZARD
potential source of harm

[SOURCE: ISO 14971:~~2007, 2.3~~ 2019, 3.4]

3.16
HAZARDOUS SITUATION
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.40]

3.17
INCIDENT
malfunction, failure or MODIFICATION of the features or the performance, or an inadequate or incorrect labeling or instructions for use of a medical ~~device~~ equipment, which directly or indirectly resulted in, could have resulted in or might result in the death or a severe deterioration of the state of health of a PATIENT, an OPERATOR or another person

3.18
INTENDED USE
INTENDED PURPOSE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: ISO 14971:~~2007, 2.5~~ 2019, 3.6, modified – Deletion of the Note.]

3.19
MAINTENANCE
combination of all technical and administrative means, including supervising ones, to keep ~~or restore a unit in working condition~~ medical electrical equipment or a medical electrical system in a normal working condition or restored to normal working condition

~~Note 1 to entry: Unit can be a device or a system.~~

[SOURCE: IEC 62353:~~2007~~2014, ~~3.19, modified – a note to entry has been added~~ 3.21]

3.20
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging or labelling of medical ~~electrical~~ equipment, assembling a medical ~~electrical~~ system, or adapting medical ~~electrical~~ equipment or a medical ~~electrical~~ system, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: In the context of this document the term medical equipment is used as umbrella term for medical electrical equipment and non-active medical devices.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.55, modified – The original notes to entry have been deleted.]

3.21
MODIFICATION
changing constructional or functional features of medical ~~electrical~~ equipment or a medical ~~electrical~~ system in a way not described in its instruction for use or other accompanying documents ~~(instructions for use)~~

[SOURCE: IEC 62353:~~2007~~2014, ~~3.23~~ 3.25, modified – A note to entry has been deleted and a reference to instructions for use has been added.]

3.22
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73, modified – The original note to entry has been deleted ~~because not relevant in the context of the present document~~.]

3.23
ORGANIZATION
entity of the persons and/or institutions responsible for the ~~use~~ application and MAINTENANCE of systems for extracorporeal renal replacement therapy

EXAMPLES ~~Doctor's office~~ Medical doctors, dialysis centers and dialysis clinics and their responsible parties.

3.24
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A PATIENT can be an OPERATOR.

Note 2 to entry: For the purpose of this document PATIENT is a human being

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.76, modified – Addition of a new Note 2 to entry.]

3.25
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the medical electrical equipment or medical electrical system or between a PATIENT and other persons touching parts of the medical electrical equipment or medical electrical system

Note 1 to entry: Volume here means room area.

Note 2 to entry: An example of PATIENT ENVIRONMENT is shown in Figure 1.

Dimensions in metres

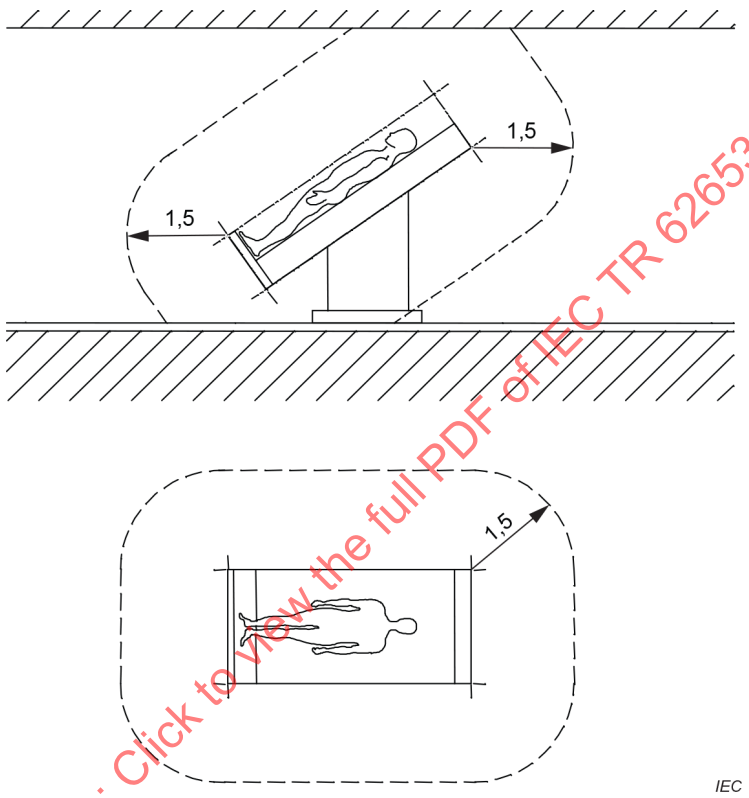

Figure 1 – Example PATIENT ENVIRONMENT

[SOURCE: IEC 60601-1:2005, 3.79, modified – Two notes to entry have been added, including a figure illustrating the term.]

*** 3.26**
PATIENT LEAKAGE CURRENT
current coming from a medical electric ~~device~~ equipment and flowing through the PATIENT to the ground

Note 1 to entry: The source of such a current may, for example, be a defective electric heater of the DIALYSIS MACHINE. The current may be transmitted through the conducting DIALYSIS FLUID and to the PATIENT.

~~[SOURCE: IEC 60601-1:2005, 3.80, modified – definition simplified and a note to entry has been added.]~~

3.27
POTENTIAL EQUALIZATION CONDUCTOR
conductor other than a protective earth conductor or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

[SOURCE: IEC 60601-1:2005, 3.86, modified – Note deleted.]

3.28
PROTECTIVE SYSTEM
automatic system, or a constructional feature, specifically designed to protect the PATIENT against ~~HAZARDS which can arise~~ HAZARDOUS SITUATIONS

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.215]

3.29
REPAIR
means for ~~reconstitution of a defined~~ restoring to a safe, functional, normal condition

[SOURCE: IEC 62353:~~2007~~2014, ~~3.35~~ 3.39]

3.30
SERVICING
combination of all means for maintaining the medical electrical equipment or medical electrical system within requirements of the MANUFACTURER

[SOURCE: IEC 62353:2014, ~~3.37~~ 3.41]

3.31
SORBENT DIALYSIS SYSTEM
method of dialysis where DIALYSIS FLUID is generated from potable water and spent DIALYSIS FLUID is regenerated into fresh DIALYSIS FLUID by recirculation through a sorbent cartridge which removes uremic toxins from the DIALYSIS FLUID while replenishing other beneficial chemicals

*** 3.32**
TOUCH CURRENT
current not necessary for ~~proper~~ appropriate functioning, coming from the ENCLOSURE or parts thereof (except PATIENT connectors), which the OPERATOR or PATIENT may touch while using the medical electrical equipment as intended and flowing to the ground or another part of the ENCLOSURE after having passed through an external connection (except the protective earth conductor)

3.33
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across the semi-permeable membrane of the DIALYSER

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 minus the measured DIALYSIS FLUID pressure, each obtained at a single point.

[SOURCE: IEC 60601-2-16:2018, 201.3.217]

3.34
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT connection (typically positive)

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.219, modified – Direction of pressure added]

4 ~~Requirements~~ Recommendations

4.1 Personnel, qualification

OPERATORS should be qualified and have received the appropriate training for the activities assigned to them, including the operation of ~~all~~ the medical electrical equipment, medical devices, ACCESSORIES and associated disposables and supplies.

If treatment is undertaken at home, the PATIENT and/or the person taking care of the PATIENT should also be appropriately trained not only in the operation of the medical ~~device~~ electrical equipment, medical devices, but also in the procedures that should be followed in the event of an INCIDENT arising from the use of the medical equipment.

4.2 Training

OPERATORS/PATIENTS should be trained for the activity assigned to them:

a) The ORGANIZATION should only assign persons who have been trained in the INTENDED USE of the ~~devices~~ medical electrical equipment, medical devices or systems that they will operate (see 7.3). Particular attention should be paid to the OPERATOR´s responsibility in following the instructions for use, the warnings and precautions outlined by the MANUFACTURERS, because these instructions are crucial to avoid remaining / residual risks not technically mitigated by the medical equipment themselves.

b) The training should be based on the valid instructions for use and include any unit protocols, actions or interventions needed in case of alarms, cautions, or medical equipment failure. The instructions for use should be available at any time.

c) Only ORGANIZATIONS that have received training from the MANUFACTURERS of the medical electrical equipment or system can develop a training program to train additional personnel within that ORGANIZATION to operate the ~~devices~~ medical electrical equipment or system.

d) The ORGANIZATION should develop training material that ensures a comprehensive, structured training program to include 1) training outline, 2) goals and objectives, 3) maximum number of trainees, 4) duration of training program for the staff of the ORGANIZATION.

e) The training program for PATIENTS should include but not be limited to: techniques associated with the specific modality, modality prescription, ~~effective~~ administration of medications~~, how to detect, report, and manage dialysis complications~~ and procedures for the detection, reporting and management of both medical and non-medical complications arising from the treatment.

f) If MODIFICATIONS by the MANUFACTURER ~~become~~ are necessary, the MANUFACTURER ~~decides to what extent an additional training guided by the MANUFACTURER is necessary~~ should provide written documentation regarding the MODIFICATIONS undertaken. If necessary, the MANUFACTURER should also provide appropriate additional training.

g) The completion of any training program should be documented by the ORGANIZATION.

h) The medical electrical equipment, medical devices or systems should be operated in accordance to the MANUFACTURER'S instructions and based on the knowledge and skills required for the particular medical treatment.

These application principles and/or any brief operating instructions do not replace the detailed instructions for use or a qualified training in the handling of the medical equipment or systems.

4.3 Infrastructure

4.3.1 General

Safe performance of an extracorporeal renal replacement therapy requires that all components of the system work ~~harmoniously~~ as intended; the systems should be used in the

appropriate rooms and drugs (e.g. pre-manufactured fluid bags) and medical ~~devices~~ equipment should be used within specified tolerances. DIALYSIS MACHINES are provided with PROTECTIVE SYSTEMS (e.g. for monitoring the conductivity, the temperature of the DIALYSIS FLUID and the VENOUS PRESSURE as well as for detecting BLOOD LEAKS and air in the EXTRACORPOREAL CIRCUIT). Such PROTECTIVE SYSTEMS may be subject to damage and should, therefore, be checked for ~~proper~~ appropriate functioning at regular intervals according to the MANUFACTURER'S instructions. Failure to complete ~~the automated~~ checks ~~prior~~ according to ~~commencement of the dialysis procedure~~ the MANUFACTURER'S instructions places the PATIENT at risk, and technical advice prior to the commencement of the treatment should be sought.

4.3.2 Infrastructure ~~requirements~~ recommendations

4.3.2.1 Technical ~~requirements~~ recommendations in rooms

Rooms, except rooms in the home healthcare environment, which are intended for employment of HAEMODIALYSIS systems according to IEC 60601-1 are medically used rooms of Group 1 as defined in IEC 60364-7-710.

The electric connection of a DIALYSIS MACHINE of class I should be established by a socket outlet with tested grounding by protective earth and a plug which cannot be mistaken for other socket outlets.

~~Possible examples are: socket outlets and plugs according to IEC 60309-2, colour code identification of the power socket dedicated to the machine. Power cord and plugs should be according to MANUFACTURER´s instructions.~~

Use of adaptors or extension cords, not approved by the MANUFACTURER of the medical electrical equipment, with grounded machines could lead to electrical safety HAZARDS. ~~Each~~ The treatment location should be provided with an additional potential equalization connector tested according to IEC 60364-7-710, (see 710.413.1.6, additional potential equalization, of IEC 60364-7-710:2002). If central venous catheters ~~with atrial location~~ whose tip is in the right atrium are used for the vascular access, special measures might be necessary for complying with electrical safety requirements [13], [14], [15], [16].[1] The MANUFACTURER´S instructions should be followed.

Possible examples are: socket outlets and plugs according to IEC 60309-2, colour code identification of the power socket dedicated to the machine. Power cord and plugs should be according to MANUFACTURER´s instructions.

If an emergency occurs during the dialysis treatment, it should be possible to alert the person taking care of the PATIENTS and or emergency medical services.

In order to prevent the DIALYSIS MACHINE from being contaminated with viruses, bacteria, endotoxins and fungi by retroactive effect from the drain, the ~~device~~ medical electrical equipment MANUFACTURER'S instructions in the instructions for use should be followed for installation of the drain tube.

In addition, it is recommended that drains intended to discharge the spent DIALYSIS FLUID be provided with a stench trap.

Handling of waste liquids to the drain should comply with the local regulations.

If conditions are unfavorable, e.g. in case of backflow, the DIALYSIS MACHINE might become contaminated. To prevent this, the minimum distance of the drain opening from the level of the sewage water should not be less than 2 cm or according to the MANUFACTURER'S specification or according to local regulations.

[1] Numbers in square brackets refer to the Bibliography.

4.3.2.2 Water treatment and distribution

ISO 23500-2 should be taken as reference.

4.3.2.3 Concentrate supply

ISO 23500-4 should be taken as reference.

4.3.2.4 Responsibilities for on-site preparation of fluids

ISO 23500-1 should be taken as reference.

4.3.2.5 Infection control

Each ORGANIZATION should have in place an infection control ~~plan~~ policy for the protection of PATIENTS and personnel ~~against infections~~ [1], [2]. This policy should be dated, with its review date clearly indicated.

The infection control ~~plan~~ policy should include specifications of how to manage both sterile supplies and ~~aseptic~~ handling techniques.

The infection control policy should include specifications for prevention and control of blood borne virus infection in PATIENTS and staff. If treatment is performed away from the normal treatment location (hospital/home) the measures needed to protect PATIENTS, support workers, and others from the risk of blood-borne virus infections should be outlined.

Correct handling techniques typically include:

- hand hygiene,
- use of gloves and other protective equipment,
- use of face masks,
- technique for preparation of supplies to be used during the treatment,
- use of materials within use-by dates,
- technique for access preparation and access care,
- technique for blood and fluid connections,
- waste disposal,
- used disinfection methods.

In addition, the infection control ~~plan~~ policy should describe~~s~~ the management of cleaning and disinfecting equipment and environmental services according to MANUFACTURER's instructions and country specific regulations.

When the fluid pathways of DIALYSIS MACHINES are disinfected, the MANUFACTURER's instructions should be followed.

The infection control ~~plan~~ policy should include the disinfectant to be used for surface disinfections, the required concentration and the minimum exposure time required by the disinfecting agent in terms of bactericidal efficacy and inactivation of bloodborne viruses such as HBV, HCV and HIV. Since surface disinfectants may damage the materials of the device, MANUFACTURER'S recommendations should be taken into account.

If the infection status of PATIENTS is unknown with regard to blood-borne virus infections, the appropriate measures should be taken to exclude any contamination of other PATIENTS. Special measures are required for PATIENTS with virus infection transferred by blood according to country regulations [2], [3], [4].

Measures for the return of DIALYSIS MACHINES used on PATIENTS with blood-borne virus infections to a non-infectious area are, for example, described in "Guideline for Applied Hygiene in Dialysis ~~Units"~~ – In German" [1] or local Infection Control Policies.

4.3.2.6 Other prerequisites

~~The equipment combinations covered by the INTENDED USE of the system are defined by the MANUFACTURERS in their instructions for use and are applicable.~~

To assure compatibility of medical equipment and ACCESSORIES comprising the system, the INTENDED USES and compatibilities of the medical equipment found in the instructions for use should be taken into account.

4.3.2.7 Home HAEMODIALYSIS ~~requirements~~ recommendations

If the ~~HAEMODIALYSIS equipment~~ DIALYSIS MACHINE and associated water treatment equipment are used in the PATIENT'S home, the requirements specified by the MANUFACTURER should be followed. To comply with local requirements, it may additionally be necessary for the installation to be examined by an approved expert to ensure that the quality of the alterations meets the requirements specified by the MANUFACTURER of the DIALYSIS MACHINE and by the MANUFACTURER of the water treatment and/or DIALYSIS FLUID preparation equipment.

It is recommended that home HAEMODIALYSIS PATIENTS have a communication ~~device~~ equipment to permit contact with the supervising ORGANIZATION in the event of a medical emergency and a backup communication ~~device~~ equipment in case of malfunction of the first communication ~~device~~ equipment.

It is recommended that the room used for HAEMODIALYSIS contains emergency lighting equipment such a flashlight or torch to provide illumination in the event of a power failure.

The PATIENT or carer should also be appropriately trained as to what procedures to follow in the event of a mains power failure.

It is recommended that initial and periodic assessment of the home environment be performed to ensure that it meets the necessary technical and operational requirements; physical space, plumbing requirements, water requirements, electrical requirements, storage and waste management, and documentation.

NOTE The considerations in Annex F of ISO 23500-1:2019 and in IEC 60601-1-11 ~~should also~~ are important to be taken into account.

4.3.2.8 Information technology (IT) management

There is widespread utilization of IT technology in hospitals or provided by third parties, and in many dialysis units the ~~HAEMODIALYSIS~~ DIALYSIS MACHINES can also be linked to such infrastructures, whilst for home HAEMODIALYSIS PATIENTS there may be a linkage to remote monitoring infrastructures that may be operated by third parties rather than the hospital. The use of IT infrastructures poses two issues: safety of the PATIENT, and data protection.

It is recommended for the ORGANIZATION to follow the standards below in dealing with above issues:

- IEC 80001 (all parts), *Application of risk management for IT-networks incorporating medical devices*;
- ISO/IEC 27001, *Information technology – Security techniques – Information security management systems – Requirements*;
- ISO/IEC TS 27008, *Information technology – Security techniques – Guidelines for the assessment of information security controls.*

IT risk management should be established from the beginning and subject to continuous review. Technical and organizational security measures [23] cannot be treated casually in either a hospital or an office setting; there need to be defined objectives, safeguards and responsibilities as well as defined policies well-known to all staff members. IT security should be checked regularly, including existing work routines to ensure that they are suitable and efficient.

5 Treatment

5.1 General

The HAEMODIALYSIS treatment should be carried out by qualified OPERATORS under the physician's responsibility. The physician determines the prescription of the HAEMODIALYSIS treatment, e.g. dialysis time, treatment frequency, DIALYSER, composition of the DIALYSIS FLUID, blood flow, DIALYSIS FLUID temperature, anticoagulation if needed, and ultrafiltration rate or ultrafiltration volume. The OPERATOR should only use information on DIALYSIS MACHINE displays for its INTENDED USE. The OPERATOR should use information provided by the DIALYSIS MACHINE only in the way described as INTENDED USE by the MANUFACTURER.

5.2 Preparation

5.2.1 DIALYSIS MACHINE

Before the dialysis treatment the DIALYSIS MACHINE should be checked for correct connections (e.g. power supply, POTENTIAL EQUALIZATION CONDUCTOR, water, concentrate or DIALYSIS FLUID supply as well as fluid drain).

If local check lists exist, they should be followed.

The DIALYSIS MACHINE should be disinfected according to the MANUFACTURER´s instructions and checked for residual disinfectant if necessary. In the case of a malfunction of the disinfection program or if the OPERATOR is in doubt whether disinfection was completed properly, the procedure should be repeated, or the DIALYSIS MACHINE should be disabled until checked by a technician.

NOTE 1 In case of prolonged downtimes, an additional disinfection cycle ~~should~~ can be ~~performed~~ necessary (see instructions for use of the DIALYSIS MACHINE).

NOTE 2 Be aware that non-operational periods with closed clamps ~~might~~ can damage the lines and impair function.

The DIALYSIS MACHINE should be subjected to a functional/safety check according to the MANUFACTURER's instructions.

The DIALYSIS MACHINE should be set up in accordance with the PATIENT's treatment plan. The allocation of the PATIENT to the DIALYSIS MACHINE should be documented.

5.2.2 * DIALYSIS FLUID preparation by DIALYSIS MACHINE

The concentrates used and the DIALYSIS MACHINE or multiple-PATIENT DIALYSIS FLUID supply equipment (MDSE, see A.7) settings for the composition of the DIALYSIS FLUID should be documented and verified for correspondence with the medical prescription.

Electrolyte concentrate additives, if used, should be added and mixed according to the additive MANUFACTURER´s instructions. The mixture should be labeled with the name of the additive, date, dose and signature. Before the mixture is used, the labeling of the mixed concentrate should be checked to ensure correct composition.

NOTE 1 The conductivity measurement of the DIALYSIS MACHINES does not detect any concentration of physiologically low electrolyte concentrations (e.g. K, Ca, Mg), which poses a RISK to the PATIENT.

In order to prevent RISKs, such as using ~~wrong concentrates, contamination or different~~ contaminated, degraded fluids or concentrates with incorrect chemical composition:

- canisters, bags or cartridges that have already been opened should be used up either according to the medical device's MANUFACTURER'S instructions or to the ORGANIZATION's standard operating procedures. ~~Residual concentrates in canisters, bags or cartridges should not be mixed.~~
- residual concentrates in canisters, bags or cartridges should not be mixed.
- used fluids should be visually checked for particulate matter, if possible.
- bagged dialysate or replacement fluid should not be overheated or frozen.
- chlorine and/or chloramines in the DIALYSIS WATER should be checked, if applicable.

NOTE 2 Preventive methods to avoid biological contaminants in central storage tanks and delivery pipes are regular disinfection procedures.

5.2.3 * EXTRACORPOREAL CIRCUIT

The following steps should be taken according to the instructions for use of the EXTRACORPOREAL CIRCUIT:

– check the disposable (packaging) for damage and valid sterility expiration date;
– check for use of correct EXTRACORPOREAL CIRCUIT and for its correct insertion;
– check for use of correct anticoagulation syringe type and size, if applicable;
– prime and remove air from the EXTRACORPOREAL CIRCUIT;
– attach, prime and use the medical devices and ACCESSORIES required for the treatment;
– check all ~~connectors~~ connections, caps and lines for tightness, absence of leaks, kinking and air entrapment.

5.2.4 DIALYSIS FLUID compartment

The following steps should be taken according to the instruction for use of the DIALYSER:

– connect the DIALYSIS FLUID tubes and check for leakage and flow direction;
– ~~rinse~~ prime and ~~deaerate~~ remove air from the DIALYSER ~~completely~~.

NOTE A procedure deviating from the above description ~~may~~ can be applicable to batch or disposable single use DIALYSIS FLUID path DIALYSIS MACHINES.

5.2.5 PATIENT

5.2.5.1 Setting treatment data

The treatment parameters should be verified for compliance with the medical prescription.

5.2.5.2 Entering individual PATIENT'S treatment parameters

As applicable the PATIENT treatment parameters should be entered on the DIALYSIS MACHINE and verified for correct input.

The following settings are common for dialysis treatment:

– treatment time;
– ultrafiltration volume / ultrafiltration flow rate, taking into account correction for additional food, drinks, infusions, saline boluses and rinseback volume;
– concentrate selection and electrolyte settings to determine DIALYSIS FLUID composition;
– DIALYSIS FLUID temperature;
– DIALYSIS FLUID flow rate and volume, if applicable;

– dosage and infusion flow rate of anticoagulants, ~~as appropriate~~ if applicable;

– substitution volume / substitute flow rate, ~~as appropriate~~ if applicable.

If ultrafiltration profiles are used, it should be noted that the maximum ultrafiltration rate which is tolerable and permitted for the PATIENT might be exceeded.

If conductivity/electrolyte-sodium profiles and “parameter-controlled automatic feedback loop” procedures are used, it should be noted that the electrolyte balance and the acid-base balance might be affected.

If parameter-controlled automatic feedback loops are used (e.g. ultrafiltration rate controlled by haematocrit), the corresponding limits as specified by the ~~MANUFACTURER~~ instruction for use or other accompanying documents should be set instead of the controlled parameters (electrolyte concentration, temperature) taking into account the intake of food and drinks as well as residual urine production during the dialysis treatment.

NOTE 1 Other PATIENT-related parameters ~~may~~ can be applicable to batch DIALYSIS MACHINES.

NOTE 2 Ultrafiltration here means amount of fluid removed to reach the prescribed dry weight of the PATIENT.

5.3 Treatment

5.3.1 Preparing the vascular access

The access to the PATIENT’s vascular system should be prepared according to requirements defined by the ORGANIZATION.

After completing puncture, the needles and ancillary devices for vascular access leak detection, if applicable, should be fixed securely to prevent dislodgement.

If central venous catheters are used, cracks and damage may be caused by application of inappropriate disinfectants or mechanical impacts, resulting in blood loss or infusion of air. The catheter should be visually checked for integrity prior to each use [20].

The OPERATOR should only cover the puncture sites during the treatment with sterile dressings, gauze or see through covering [6]. If covered by dressings or sheets, their size should allow detection of even small blood losses. To allow detection of blood loss, the PATIENT should be advised not to cover the puncture sites with a blanket. Additional medical electrical equipment can help to detect blood losses automatically.

NOTE The VENOUS PRESSURE monitor may not reliably detect leaks, blood tubing separation from the blood access device, or needle dislodgement. Failure to detect a problem is more likely when blood pump speeds are set above 450 ml/min or when a catheter is used at lower blood flow rates (100 ml/min to 200 ml/min). Little or no pressure change may occur depending on the circumstances. It is unlikely but possible for a leak to occur, the blood tubing to separate, or access needle to dislodge without a VENOUS PRESSURE alarm. For that reason, the PATIENT’s safety is only ensured by careful monitoring by the OPERATOR [17], [18], [19].

~~For that reason, the PATIENT’s safety is only ensured by careful monitoring by the OPERATOR [14, 15, 16]. The OPERATOR should only cover the puncture sites during the treatment with sterile dressings or gauze [4]. If covered by dressings or sheets their size should allow detection of even small blood losses. To allow detection of blood loss, the PATIENT should be advised not to cover the puncture sites with a blanket. Additional devices can help to detect blood losses automatically.~~

~~If central venous catheters are used, cracks and damage may be caused by application of inappropriate disinfectants or mechanical impacts, resulting in blood loss or infusion of air. The catheter should be visually checked for integrity prior to each use [17].~~

5.3.2 * Connection to the EXTRACORPOREAL CIRCUIT

It should be checked, that the DIALYSIS MACHINE is ready for PATIENT connection.

When the PATIENT is connected to the EXTRACORPOREAL CIRCUIT:

– Connection sites should be tight, secure and the lines torsion stress relieved. The connection of the EXTRACORPOREAL CIRCUIT to the appropriate needle or catheter port should be checked (e.g. arterial line to arterial needle etc.).

– Before the blood pump is turned on, the appropriate tube clamps of the EXTRACORPOREAL CIRCUIT and, if applicable, the HDF system's tube clamps and ports should be opened.

– The initial blood flow should not be too high (usually 100 ml/min to 200 ml/min).

– Air embolism and blood loss should be prevented by direct observation with special considerations for catheters [10], [11].

NOTE If the VENOUS PRESSURE is negative and there are leaks/disconnections while the access clamp is open, air ~~may~~ can be sucked in downstream of the air monitoring unit; such air will not be detected and will be directly infused into the PATIENT.

5.3.3 Initiation of treatment

To start the treatment, the ~~MANUFACTURER's~~ instruction for use or other accompanying documents of the DIALYSIS MACHINE should be followed. The following steps should be carried out:

a) Start the treatment and observe the ARTERIAL PRESSURE and the VENOUS PRESSURE, then increase to prescribed blood flow rate. Check for any unusual noise emitted by the blood pump.

   Such noise may indicate

   – mechanical damage of the pump;

   – use of an inappropriate EXTRACORPOREAL CIRCUIT;

   – stenoses, kinks and clamped lines in the EXTRACORPOREAL CIRCUIT;

   – improperly installed EXTRACORPOREAL CIRCUIT.

b) Check puncture sites, for example to detect any formation of haematoma or vascular collapse.

c) Check the EXTRACORPOREAL CIRCUIT for kinks and ~~proper~~ appropriate attachment to the DIALYSIS MACHINE.

   Ensure that kinks cannot develop even after the lines have been heated up to blood temperature. If the PATIENT's bed or the DIALYSIS MACHINE is moved or displaced while the treatment is in progress, the EXTRACORPOREAL CIRCUIT should be checked again.

d) Set the alarm limits for the VENOUS PRESSURE and check the VENOUS PRESSURE. In the positive pressure range, the lower alarm limit for VENOUS PRESSURE monitoring should be set as closely to the current value as possible ~~(e.g. 20 mm Hg)~~. If alarm limits are set automatically, check this setting and, if necessary, readjust manually.

   NOTE 1 The pressure alarm at the lower VENOUS PRESSURE limit is intended as a protection against blood loss to the environment. Pressure monitoring will not reliably detect blood loss due to leaks and separations in the venous return or dislocation of the venous access device. During dialysis, one of the most frequent complications resulting in death is caused by dislocation of the venous cannulae (slipping out of the blood vessel). Such a dislocation is not reliably detected by the PROTECTIVE SYSTEMS of the DIALYSIS MACHINES and ~~might~~ can result in a life-threatening blood loss to the environment [17], [18], [19]. Another complication that can result in serious injury or death is a leak, through separation of the venous access device (central venous catheter) from the venous bloodline [20].

e) If applicable, set the alarm limits for the ARTERIAL PRESSURE.

f) Verify that there are no fluid leaks.

g) Complete any documentation in accordance with the ORGANIZATION's requirements.

NOTE 2 Batch DIALYSIS MACHINEs and CENTRAL DIALYSIS FLUID DELIVERY SYSTEMS ~~may require~~ often need the setting and monitoring of other parameters.

5.3.4 Checks to be repeated during the treatment

~~Carry out~~ The following checks should be performed regularly during treatment:

a) Check the EXTRACORPOREAL CIRCUIT including puncture sites for security:

Do not cover connections in the EXTRACORPOREAL CIRCUIT. Check all connections between blood tubing and catheter or cannulas for security and for leaks frequently and whenever an alarm occurs.

NOTE 1 During single-needle dialysis, blood flow occurs in phases. During the arterial phase, if there is a leak in the EXTRACORPOREAL CIRCUIT downstream of the venous clamp, e.g. at the Y-piece, air ~~may~~ can be sucked into the EXTRACORPOREAL CIRCUIT. This air will then be transported to the PATIENT during the venous phase.

b) Check for kinked EXTRACORPOREAL CIRCUIT, BLOOD LEAKS and for leaks of the DIALYSIS FLUID and substitution circuit. The EXTRACORPOREAL CIRCUIT should be checked again if the position of the PATIENT'S bed or the DIALYSIS MACHINE is adjusted during the treatment.

c) Check for correct clamping of not used administration lines.

d) If displayed, check the TRANSMEMBRANE PRESSURE, ARTERIAL PRESSURE and VENOUS PRESSURE values for deviations.

e) Check for wetted transducer protectors, if applicable. If wetted, proceed as described in 5.3.8.

f) Verify that the ultrafiltration rate, ultrafiltration volume and substitution rate (for HF and HDF), the blood flow and the DIALYSIS FLUID flow comply with the values prescribed.

g) If applicable, check the blood levels in the chambers for the appropriate height.

h) Check for formation of blood clots.

NOTE 2 If the DIALYSIS MACHINE uses air detection at the venous chamber, blood clots in the chamber ~~might~~ can affect the PROTECTIVE SYSTEM.

i) If applicable, check the anticoagulant infusion rate(s), volume(s) and/or corresponding lab values, e.g. Ca plasma values in Citrate/Calcium anticoagulation.

j) If applicable, check for defective filters or moisture in the hydrophobic filters in pressure relief lines.

k) Check the PATIENT-related parameters at regular intervals as specified in the prescription.

l) Prepare the documentation according to the ORGANIZATION'S internal specifications.

m) Document any repeated alarm situations and irregularities.

NOTE 3 Repeated override of alarms ~~may~~ can result in a HAZARD to the PATIENT because each alarm has been triggered by a deviation from a set value. In some cases (e.g. net fluid removal) these deviations ~~may~~ can accumulate.

If any abnormalities are detected during the checks, clarify the causes and initiate the appropriate ~~remedying~~ alleviating measures ~~if the safety or efficiency of the treatment is impaired~~. In the case of technical failures, proceed according to ~~the MANUFACTURER's instructions in~~ the instruction for use or other accompanying documents. If a failure or malfunction causes blood to enter inside the DIALYSIS MACHINE, do not use the DIALYSIS MACHINE on any other PATIENT without having taken the appropriate REPAIR measures and decontamination procedures [5].

NOTE 4 Batch DIALYSIS MACHINEs and CENTRAL DIALYSIS FLUID DELIVERY SYSTEMS ~~may require~~ often imply the monitoring of other parameters.

5.3.5 * HAZARDS during the treatment

OPERATORS of ~~HAEMODIALYSIS~~ DIALYSIS MACHINEs should not rely on ~~medical~~ the technical safety ~~standards~~ of the DIALYSIS MACHINEs alone, when performing a treatment. Assessment of HAZARDS requires fundamental knowledge of how to use the system [7], [8], [9].

Some examples of HAZARDOUS SITUATIONS include:

– incorrect alarm handling, e.g. failure to check PATIENT access on VENOUS PRESSURE alarm and incorrect air alarm handling;

- ingress of foreign particles, pathogens, their constituents or metabolic products into the blood pathway (e.g. by ~~improper~~ incorrect rinsing or disinfection);
- acute or chronic toxicity (e.g. caused by residual disinfectant in the EXTRACORPOREAL CIRCUIT, migration of plasticisers);
- incorrect handling of disinfectant containers, e.g. mixing;
- blood loss (e.g. caused by disconnection in the EXTRACORPOREAL CIRCUIT including the vascular access, bleedings, coagulation in the EXTRACORPOREAL CIRCUIT, puncturing problems, incorrect use of needleless injection ports or wrong positioning of puncture cannula);
- ~~improper~~ incorrect fluid balance (e.g. weighing, input or calculation errors);
- incompatibility reactions caused by materials used or caused by substances adhering thereto;
- improper use of cleaning agents or disinfectants;
- improper use or composition of the DIALYSIS FLUID;
- deficit between the dialysis parameters prescribed and what is actually delivered (e.g. by an insufficiency of the vascular access);
- haemolysis (e.g. caused by wrong setup or kinking of the EXTRACORPOREAL CIRCUIT);
- air embolism (e.g. caused by defects or improper use of central venous catheters, defects of access ports by improper handling);
- electrical HAZARDS (e.g. caused by defective power ~~lines~~ cords or lack of a POTENTIAL EQUALIZATION CONDUCTOR);
- chemical contaminants in DIALYSIS WATER;
- microbiological contamination of DIALYSIS WATER;
- ~~accidental bolus~~ incorrect administration of drugs if the DIALYSIS MACHINE is used together with infusion pumps through a single PATIENT access:
  - infusion rate higher than intended due to negative pressures in the bloodline exceeding the specification of the infusion pump;
  - infusion rate lower than intended or alarm of the infusion pump due to positive pressures in the bloodline exceeding the specification of the infusion pump;
  - bolus infusion due to stopped blood pump and ongoing delivery of the infusion pump;
  - air infusion via the arterial PATIENT bloodline from remaining air in the infusion pump due to stopped blood pump and bypassing the venous air separation chamber and air detector.
  - External infusion or syringe pumps used with the DIALYSIS MACHINE for infusion into the EXTRACORPOREAL CIRCUIT should be validated by the MANUFACTURER for use with the system.

Pumps for anticoagulants are not designed according to the safety requirements for infusion pumps. For that reason, they should not be used for application of other drugs.

5.3.6 Deviations from the prescribed treatment parameters ~~prescribed or treatment interruption~~

~~Any deviations from the treatment parameters prescribed require the attending physician's authorization. This measure should be documented according to the ORGANIZATION's internal policies.~~

~~Treatment interruptions may become necessary for medical reasons or they may be caused by technical malfunctions and defects (e.g. failure of the vascular access, examinations, coagulation in the EXTRACORPOREAL CIRCUIT, failure of the water supply, power failure, defective DIALYSIS MACHINE). Any interruption of the treatment is accompanied by risks for the PATIENT .Should the extracorporeal blood flow be interrupted for a prolonged time period, the~~

~~blood should be returned. In such a case, the ORGANIZATION's internal policies should be followed.~~

Deviations from the prescribed treatment parameters may occur. They may be a consequence of medical reasons or they may be caused by technical malfunctions and defects (e.g. failure of the vascular access, examinations, coagulation in the EXTRACORPOREAL CIRCUIT, failure of the water supply, power failure, defective DIALYSIS MACHINE).

The procedures to be followed in such an event, should be in accordance with the ORGANIZATION'S operational policy. Additionally, notification and authorization by the physician responsible for the care of the PATIENT may also be required to minimize any risk to the PATIENT.

Should the extracorporeal blood flow be interrupted for a prolonged time period, a risk of clotting exists. To minimize any risk to the PATIENT, the ORGANIZATION'S operational policy should be followed e.g. returning the blood.

5.3.7 Terminating the DIALYSIS treatment

Termination of treatment should be ~~accomplished~~ in accordance with ~~the instructions provided by the MANUFACTURER~~ the instruction for use or other accompanying documents of the DIALYSIS MACHINE and in accordance with locally used clinical protocols or operating practices. Blood should not be returned to the PATIENT by opening the arterial side of the EXTRACORPOREAL CIRCUIT to the atmosphere and running the blood pump to return blood to the PATIENT, because the risk of air infusion or remaining blood in the venous blood line is very high.

If drugs are administered through the EXTRACORPOREAL CIRCUIT at the end of the treatment, ensure there is no loss of the substance in the EXTRACORPOREAL CIRCUIT.

5.3.8 * After completion of the dialysis treatment

The system and environmental surfaces should be cleaned and disinfected in accordance with the MANUFACTURER's instructions and ORGANIZATION policies. The MANUFACTURER´s instructions should be followed in order not to damage the DIALYSIS MACHINE and/or harm the PATIENT. ~~The following steps are common for many DIALYSIS MACHINES:~~

If applicable:

– If during treatment blood or fluid is detected, that has passed the pressure transducer protector and entered into the DIALYSIS MACHINE, ~~take~~ the DIALYSIS MACHINE should be taken out of use until it has been REPAIRED, cleaned, disinfected and released by the authorized Technical Service [5].
– The surface of the treatment system should be cleaned and disinfected. The hydraulics pathway should be cleaned and/or disinfected and decalcified in accordance with the MANUFACTURER's instructions.

NOTE 1 Disinfection of DIALYSIS MACHINE is a procedure which can be ~~made by use of~~ performed using heat and/or chemicals. ~~The MANUFACTURER´s instructions should be followed in order not to damage the equipment and/or harm the PATIENT.~~

NOTE 2 Guidance on disinfection and testing is referenced in ISO 23500-1 and in MANUFACTURER'S instructions. Key parameters to be considered are choice of chemicals, chemical concentration, length of exposure, temperature and frequency.

6 Notification of INCIDENTS

INCIDENTS and near misses should be recorded and notified in accordance with local and regulatory requirements. ~~The form required for the notification of INCIDENTS should be accessible to the ORGANIZATION.~~

7 Handling medical electrical equipment and medical devices

7.1 Technical service, SERVICING and checks of medical electrical equipment and ~~plants~~ infrastructure

The good working order of medical electrical equipment and ~~plants~~ infrastructure should be ensured by MAINTENANCE work according to the MANUFACTURER's instructions (e.g. technical safety and measurement checks, MAINTENANCE and REPAIR). The good working order is achieved by complying with test schedules. Failures of medical electrical equipment or ~~plants~~ infrastructure should be identified and documented. The authorized Technical Service should be notified.

Medical electrical equipment which is not subjected to the necessary technical safety check within the time limit specified in the instructions for use should not be used for treatment of PATIENTS.

NOTE This also applies to any medical electrical equipment connected thereto, e.g. reverse osmosis systems and CENTRAL CONCENTRATE SYSTEMS or CENTRAL DIALYSIS FLUID ~~central~~ DELIVERY SYSTEMS.

Medical electrical equipment failing to function ~~properly~~ correctly should be marked accordingly, withdrawn from use and not ~~be~~ used until ~~REPAIR following~~ it has been REPAIRED in accordance with the MANUFACTURER's instructions.

Any MODIFICATIONS to the system, including water treatment, should be documented and coordinated with the MANUFACTURER. In respect of the MODIFICATION of the water treatment ~~plant~~ equipment, the ISO 23500-1 and ISO 23500-2 should be taken as reference.

7.2 * Medical electrical equipment safety and ~~device~~ medical electrical equipment combinations

The MANUFACTURER's instructions with regard to the PATIENT'S protection against electric shock should be taken into account.

Any contact with live defective power cords should be prevented. Power cords should be inspected at specified intervals according to the MANUFACTURER's instructions. If an insulation layer is damaged, the associated medical electrical equipment should be secured, taken out of routine use and REPAIRED.

Medical electrical equipment with damaged ENCLOSURE should be checked, and if necessary REPAIRED, in order to prevent unacceptable TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS. For the same reason, any spilled fluids should be removed from the medical electrical equipment immediately.

To avoid unacceptably high TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS when several medical ~~devices~~ electrical equipments are used in combination, the requirements according to IEC 60601-1 should be complied with, e.g. by using a POTENTIAL EQUALIZATION CONDUCTOR.

If it is intended to use the DIALYSIS MACHINE in combination with a central venous catheter with ~~atrial location~~ tip in the right atrium, the MANUFACTURER's instructions should be followed in order to prevent unacceptable high TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS [13], [14], [15], [16].

Mains-operated, non-medical electrical equipment (e.g. heating pads, computer, etc.) may cause ~~HAZARDS~~ harm to the PATIENT, especially for PATIENTS with central venous catheters with ~~atrial location,~~ tip in the right atrium as the insulation requirements for such non-medical electrical equipment are lower. The use of direct mains operation of non-medical electrical equipment should be restricted in the PATIENT ENVIRONMENT for PATIENTS with central venous catheters with ~~atrial location~~ tip in the right atrium while the treatment is in progress.

The proper functioning of medical electrical equipment might be impaired by electromagnetic fields. Wireless communication ~~devices~~ equipment may only be used if they do not affect ~~proper~~ the functioning of the machines. The MANUFACTURER's instructions should be observed.

7.3 Non-INTENDED USE

The ORGANIZATION should ensure the ~~INTENDED~~ use of the medical ~~devices~~ equipment according to the INTENDED USE and instructions for use by taking the appropriate training measures.

If the ORGANIZATION and/or the OPERATOR, consciously or unconsciously, uses medical equipment, disposables or systems as stand-alone units or together with medical equipment, disposables or systems that are not approved by one of the MANUFACTURERS, then this is considered to be non-INTENDED USE. In such cases, the ORGANIZATION and/or OPERATOR bears the responsibility for safe use of the medical equipment.

If an ORGANIZATION makes any MODIFICATIONS to the DIALYSIS MACHINES, medical equipment, systems or procedures without having the MANUFACTURER'S approval, the ORGANIZATION bears the responsibility for the ~~modified product~~ MODIFICATION. This applies to the use of ~~device~~ medical equipment combinations which the MANUFACTURER has not included in the INTENDED USE of the system. This also applies to ~~device~~ medical equipment combinations (e.g. separate ~~devices~~ medical electrical equipment for the operation of the EXTRACORPOREAL CIRCUIT and ~~DIALYZER set~~ the DIALYSIS FLUID delivery or separate infusion ~~devices~~ equipment connected to the EXTRACORPOREAL CIRCUIT) for which the MANUFACTURER has not provided information ~~if~~, that the compatibility has been tested according to the applicable safety standards. The ORGANIZATION bears the responsibility for complying with the INTENDED USE and/or the instructions for use when using and preparing disposables for the system.

NOTE Non-INTENDED USE is synonymous with off label use.

Annex A
(informative)

Explanatory technical remarks

A.1 Overview

The dialysis technology used today is intended to protect the PATIENT from operational risks related to dialysis treatment, such as extracorporeal blood loss, infusion of air, etc. That is why the DIALYSIS MACHINE and other medical devices used for treatment should comply with the state of the art as defined in other standards which are cited herein. Any user of DIALYSIS MACHINES and systems should be aware of the fact that it is not possible to exclude all potential HAZARDS which might arise to the PATIENT during dialysis by technical means alone, not even if all of the MANUFACTURER'S ~~regulations, such as~~ instructions in the instructions for use ~~and SERVICING instructions~~ or other accompanying documents, are complied with [7], [8], [9]. For example, the technical systems of DIALYSIS MACHINES do not provide reliable means to detect small leaks in the EXTRACORPOREAL CIRCUIT, or improper or wrongly applied prescriptions. These treatment-related risks may result in serious accidents in dialysis therapy. Such accidents cannot be detected or mitigated by the technical systems of the DIALYSIS MACHINES. The ORGANIZATION should be aware of the residual risks and identify ~~these risks~~ appropriate measures, for example based on these guidelines. The ORGANIZATION should minimize such risks by the use of appropriate standard operating procedures.

Home HAEMODIALYSIS is growing rapidly in popularity due to newer technologies and therapies. Although home HAEMODIALYSIS is fundamentally safe and effective and generally similar to in-center HAEMODIALYSIS, it is ~~a newer~~ an area of dialysis with new technologies and OPERATORS may benefit of guidance and recommendations to ensure best practices. Therefore we have included home HAEMODIALYSIS within these regulations.

A.2 DIALYSIS FLUID

DIALYSIS FLUID with incorrect electrolyte (particularly potassium) content or containing residual disinfectant, other toxic substances or with heavy bacterial contamination will not be detected either by the water treatment equipment, DIALYSIS WATER distribution system, CENTRAL CONCENTRATE SYSTEM or CENTRAL DIALYSIS FLUID ~~supply systems~~ DELIVERY SYSTEM nor by the DIALYSIS MACHINE, because there are no appropriate PROTECTIVE SYSTEMS. The commonly used conductivity measurement unit is not always able to detect ~~a wrong~~ an incorrect composition of the DIALYSIS FLUID, especially for minor ions (e.g calcium, potassium, magnesium). ~~For some PATIENTS, however, potassium-free DIALYSIS FLUID may be used which, for other PATIENTS, might have most serious consequences. Use of zero potassium DIALYSIS FLUID is discouraged due to most serious risks. Bacterial contaminations cannot be automatically detected in the fluid pathway. For these reasons, the ORGANIZATION and/or OPERATOR should take the appropriate measures to exclude risks arising from such HAZARDS.~~

The potassium concentration in the DIALYSIS FLUID is important. For some PATIENTS potassium-free DIALYSIS FLUID may be prescribed, which might have most serious consequences for other PATIENTS. Appropriate measures should be in place to ensure that under such circumstances, only the PATIENT for which the DIALYSIS FLUID is prescribed uses such DIALYSIS FLUID.

Bacterial and/or other chemical contaminations cannot be automatically detected in the fluid pathway. For these reasons, the ORGANIZATION and/or OPERATOR should take the appropriate measures to exclude risks arising from such HAZARDS.

The following ~~requirements~~ recommendations should be met in particular:

– procedures and responsibilities should be defined for emergency operation and/or disinfection of water treatment and distribution as well as CENTRAL CONCENTRATE SYSTEMS

or CENTRAL DIALYSIS FLUID DELIVERY SYSTEMS, ~~as appropriate~~ if applicable, and such a state should be clearly identified (see 4.3.2.2 and 4.3.2.3);

– DIALYSIS WATER quality should be monitored for chemical and microbiological contamination and operational data should be documented and evaluated (see ~~4.3.2.2~~ 4.3.2.4);

– composition of DIALYSIS FLUID and the DIALYSIS MACHINE being used should be documented (see 5.2.2);

– the DIALYSIS FLUID prescribed should be delivered to the intended PATIENT (see 5.2.2);

– when concentrates in e.g. containers or cartridges are ~~consumed~~ used, the MANUFACTURER's instructions ~~or~~, the ORGANIZATION's ~~standards~~ guidelines or the standard operation procedures should be strictly adhered to (see 5.2.1);

– when electrolyte additives, such as potassium or calcium, are added, the MANUFACTURER's instructions for use should be followed or a verified and validated mixing procedure should be established and maintained. The addition of the additives and resulting concentration should be labeled on the concentrate containers and documented. Verification testing of the resulting concentrate or the final composition of the DIALYSIS FLUID should be followed according the ORGANIZATIONS' policies. (see 5.2.2).

~~NOTE Particularly the last one of the above requirements, if unconsciously handled without care, has already resulted in severe and even fatal accidents.~~

A.3 Blood loss to the environment

One of the most frequent accidents during a dialysis treatment is an unnoticed blood loss to the environment [17], [18], [19], [20], caused by ~~minute leaks~~ seepage around the site of the vascular access, by a ~~slipped out~~ dislodged venous cannula or by small leaks / separations / disconnections in the venous line.

Today's DIALYSIS MACHINES are provided with a PROTECTIVE SYSTEM to detect such occurrences. This PROTECTIVE SYSTEM is usually based on the measurement of the VENOUS PRESSURE. Pressure limits that, when exceeded or fallen below, will initiate an alarm (which may also cause a stop of the blood pump) should be set around the measured pressure, either manually or automatically.

The measured VENOUS PRESSURE comprises a number of components. One of these components is the pressure in the PATIENT access at the tip of the venous cannula/catheter, i.e. inside the fistula, the plastic prosthesis or the central access. Other components are determined by the extracorporeal blood flow through any restrictions in the EXTRACORPOREAL CIRCUIT. These other components include the restrictions of the bloodline at the venous Luer connector and the lumen of the blood access device (needle or central venous catheter) through the narrow venous needle or through the long catheter leg, which may also be narrow. ~~This~~ The resulting pressure drop will also depend on the haematocrit. The VENOUS PRESSURE monitor may not adequately monitor the pressure in the venous return if the transducer protector is wetted or filled with blood or if there is severe clotting in the venous drip chamber.

Usually, a large-size leak, such as a disconnection of the EXTRACORPOREAL CIRCUIT from a small gauge needle, is reliably detected because the restriction caused by the narrow cannula is removed from the circuit. However, if a small-size leak occurs (e.g. a connector which fails to ~~be~~ remain tight), the drop in VENOUS PRESSURE may not be high enough to cause the PROTECTIVE SYSTEM to respond. If such a leak goes unnoticed for a prolonged time period, the total blood loss may reach critical values. To detect such conditions as early as possible, the lower alarm limit of the VENOUS PRESSURE monitor should~~, therefore,~~ be set as close to the current value as possible (see 5.3.3 d))~~, the venous Luer connection should be checked for integrity every time the care provider is at the bedside~~. The puncture sites and the EXTRACORPOREAL CIRCUIT should be checked ~~regularly~~ for leaks both at the beginning of and regularly during the dialysis treatment, (see 5.3.3 and 5.3.4).

If a venous cannula slips out, the backpressure provided by the access is removed from the circuit. The change in pressure may only be about 10 mmHg to 20 mmHg. The indicated VENOUS PRESSURE is then the result of only the blood flowing through the lumen of the cannula. Therefore, if a PROTECTIVE SYSTEM is based on VENOUS PRESSURE monitoring, it will, therefore, not respond reliably to dislodgement or disconnection of the venous blood access because the pressure in the circuit is too high to violate the lower VENOUS PRESSURE alarm limit. In this case, a high blood loss of, e.g., 300 ml/min, might occur. If it goes unnoticed, such a high blood loss may result in critical conditions within a short time. To prevent such cases, the cannulae should be securely fixed (see 5.3.1). The connectors should also be fixed securely and, in addition, stress-relieved (see 5.3.2). To ensure detection of such problems, the lower alarm limit for VENOUS PRESSURE monitoring should be set as closely to the current value as possible (5.3.3) and the puncture sites and connections to the venous blood access should always be visible during the entire treatment (see 5.3.1). This is the only way to ensure that the OPERATOR will detect such a problem visually because blood might ooze away unnoticed in an absorbing covering after the cannula has ~~slipped out~~ dislodged or the line separated.

Therefore other access monitoring devices for detecting blood loss should be considered to supplement the ORGANIZATION in monitoring PATIENT vascular access.

A.4 Air infusion

PROTECTIVE SYSTEMS prevent any active infusion of air [10], [11], [12] by the DIALYSIS MACHINE, provided the DIALYSIS MACHINE is operated according to the MANUFACTURER'S instructions and with approved ACCESSORIES. However, this high degree of protection from infusion of air should not obscure the fact that, downstream of the air detection system, air might still reach the PATIENT under certain circumstances.

Such circumstances may be caused by a central vascular access with catheter since, depending on the PATIENT's position; negative pressure may develop at the tip of the catheter while the PATIENT inhales. When the blood pump is not running, such a negative central VENOUS PRESSURE may suck in air which can be directly infused into the PATIENT.

Air can also be infused, if wrong disinfectants are used on the catheter; this may cause crack formation in the catheter and result in minor leaks. If there is a disconnection while the access clamp is open, considerable amounts of air may be introduced unnoticed, sometimes with fatal consequences.

Air may enter into the EXTRACORPOREAL CIRCUIT at connection points downstream of the air detector also in case of single needle applications due to negative pressure conditions created by the arterial cycle in the PATIENT return line.

That is why the central access should be observed and checked with particular care (see 5.3.1) and why its handling should be based on special measures (see 5.3.2). Central venous catheters should be clamped whenever they are disconnected from the venous bloodline.

A.5 Electrical safety

Usually, DIALYSIS MACHINES are mains-operated and electrical safety is important [13], [14], [15], [16]. For heating the DIALYSIS FLUID, a current is needed. The risk for electric shock to PATIENT and OPERATOR, caused by the TOUCH CURRENT, is a possibility. The risk can be prevented by appropriate insulation and further safety measures, e.g. grounding by the protective earth conductor in the power supply cord or by current circuit breakers (see 4.3.2.1).

If several ~~electrically operated~~ medical ~~devices~~ electrical equipment with different electric potentials are used, excessive TOUCH CURRENTS should be avoided by additionally connecting

such ~~devices~~ medical electrical equipment at the treatment location via the POTENTIAL EQUALIZATION CONDUCTOR and the potential equalization connector (see 4.3.1, 5.2.1 and 7.2).

Since the PATIENT is considered to be particularly at risk by close conducting contacts with the medical ~~device~~ electrical equipment (e.g. by the electrodes of an ECG monitoring equipment), the insulation requirements in the medical engineering field are usually set ten times as high as those for household appliances and ~~devices~~ equipment. That is why it should be ensured that the PATIENT cannot touch household appliances and ~~devices~~ equipment during his or her dialysis treatment. This includes electric cushions and electric blankets which are not approved for medical use as well as laptops and mobile phones connected directly to the mains power source. Operation of such appliances and ~~devices~~ equipment should, therefore, be protected in particular, e.g. by isolating transformers approved for medical use or by exclusive battery operation (see 7.2).

A special situation in dialysis arises by the fact that many ~~operating devices~~ components of a DIALYSIS MACHINE, such as sensors and heater, are in direct contact with the conducting DIALYSIS FLUID which is also in conducting contact with the PATIENT's blood through the pores of the membrane of the DIALYSER. Without taking other standards for medical ~~devices~~ equipment into account, it is clear that a DIALYSIS MACHINE should provide particularly high safety measures against an electric current coming from the external power supply system, which ~~is flowing~~ might flow through the DIALYSIS FLUID, the blood and the PATIENT and then be discharged to the ground. This current is called PATIENT LEAKAGE CURRENT and should not exceed a specific value. Usually, this flow of current will not happen as long as the DIALYSIS MACHINE is operated routinely according to the MANUFACTURER'S instructions.

If a central venous catheter with ~~atrial location~~ tip in the right atrium is used, the limits of the maximum PATIENT LEAKAGE CURRENT should be set lower. Such a central venous catheter with ~~atrial location~~ tip in the right atrium establishes a direct connection to the heart. This connection is electrically conducting as described above, and the response of the heart to external currents may be extremely sensitive. If such an application is intended, it is absolutely necessary that the instructions for use are consulted to find out the particular operating conditions for each ~~device~~ DIALYSIS MACHINE type. In cases of doubt, the MANUFACTURER should be consulted (see 7.2).

The situation may become critical if an additional condition (for which the MANUFACTURER cannot assume responsibility) negatively affecting the safety of the DIALYSIS MACHINE goes unnoticed. Such a condition may be a defective protective earth conductor in the power cord of the DIALYSIS MACHINE, or an external voltage that ~~is~~ can be introduced by the drain line or the CENTRAL CONCENTRATE SYSTEM or CENTRAL DIALYSIS FLUID DELIVERY SYSTEM. For that reason, the technical safety checks which should always be performed properly at the intervals prescribed should also cover any ~~devices~~ medical equipment and systems connected to the DIALYSIS MACHINE (see 7.1).

A.6 Proportioning type and batch DIALYSIS MACHINES

If the DIALYSIS MACHINE is of the proportioning type, the DIALYSIS FLUID is produced by mixing DIALYSIS WATER with DIALYSIS FLUID CONCENTRATE during treatment (online). Bicarbonate dialysis requires a second mixing SYSTEM for supplying bicarbonate concentrate. Immediately after having been produced, the ready-to-use DIALYSIS FLUID is monitored for the necessary composition and temperature. This is achieved by the appropriate measuring equipment.

When batch DIALYSIS MACHINEs are used, however, the DIALYSIS FLUID is produced completely before the actual dialysis treatment is started (offline). In this production process, a mixing system homogeneously mixes DIALYSIS WATER with all other necessary constituents of the DIALYSIS FLUID provided; this mixture is then stored for treatment in a storage container. In this case, it is not necessary to monitor the conductivity during the treatment; instead, this parameter should be checked in the DIALYSIS FLUID before the treatment is started according to the MANUFACTURER'S instructions using the appropriate measuring equipment. This difference in the production of DIALYSIS FLUID has far-reaching consequences, for example

relocation of numerous technical ~~devices~~ components, such as mixing systems, conductivity meter, degassing unit, etc., from the DIALYSIS MACHINE to central preparation systems, elimination of decentralized DIALYSIS WATER supply loops and waste water systems, and even elimination of alarm equipment, such as water alarms.

These differences require that different work processes be established.

A.7 CENTRAL DIALYSIS FLUID DELIVERY SYSTEM (CDDS)

~~There are several kinds of DIALYSIS FLUID delivery system; one of these is a 'single-PATIENT dialysis machine (SPDM)' and another is a 'central DIALYSIS FLUID delivery system (CDDS)'. In general SPDM enables to use different compositions of DIALYSIS FLUID for each PATIENT (so-called prescribed haemodialysis treatment). Most of the characteristics for CDDS in comparison with SPDM are:~~

- ~~less complex hydraulics and less maintenance for dialysis console;~~
- ~~simultaneous conductivity control of all consoles;~~
- ~~less storage space for containers of concentrates;~~
- ~~no composition adjustments of DIALYSIS FLUID for each dialysis console possible;~~
- ~~unsuitability in urgent dialysis treatment;~~
- ~~disinfection scheme totally different from SPDM in time and structure.~~

~~The outline of CDDS is shown in Figure A.1. DIALYSIS FLUID is prepared with acid concentrate, bicarbonate concentrate and product water in multiple-PATIENT DIALYSIS FLUID supply equipment (MDSE). MDSE supplies DIALYSIS FLUID to all dialysis consoles set at the bedside of each PATIENT. MDSE can be placed in another room separated from a dialysis room, consisting of water treatment devices and a DIALYSIS FLUID preparation device.~~

~~Concentrates are diluted with water, which is produced by water treatment system from tap water or well water. This system basically consists of pre-filter, softener, activated carbon filter, reverse osmosis equipment, tank with ultraviolet irradiator and ultrafilter.~~

~~In MDSE, bicarbonate DIALYSIS FLUID is prepared from acid concentrate, bicarbonate concentrate and water with a mixing ratio such as 1:1.26:32.74. The equipment usually consists of mixing part, integrated heater, and conductivity monitor. The number of dialysis consoles used with one MDSE ranges from 10 to 50.~~

~~All components used in DIALYSIS FLUID storage and delivery systems (including storage tanks, pumps, valves and piping) should be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the DIALYSIS FLUID to affect its purity, or with the germicides or germicidal procedure used to disinfect the system. The use of materials that are known to have toxicity in haemodialysis, such as copper, brass, zinc, galvanized material, lead and aluminium, is specifically prohibited.~~

There are a number of variants of DIALYSIS FLUID delivery systems in clinical use. Broadly they may be divided into systems that are intended for use by a single PATIENT, [single-PATIENT DIALYSIS MACHINE] and those which provide DIALYSIS FLUID for multiple PATIENTS [CENTRAL DIALYSIS FLUID DELIVERY SYSTEM (CDDS)] whereby the DIALYSIS FLUID is manufactured centrally and delivered to the PATIENT'S bedside.

A CDDS system consists of the water treatment equipment and multiple-PATIENT DIALYSIS FLUID supply equipment (MDSE), as well as individual dialysis consoles [IDC]. (Figure A.1)

Detailed descriptions of these approaches may be found in the literature [24], [25], [26], [27]

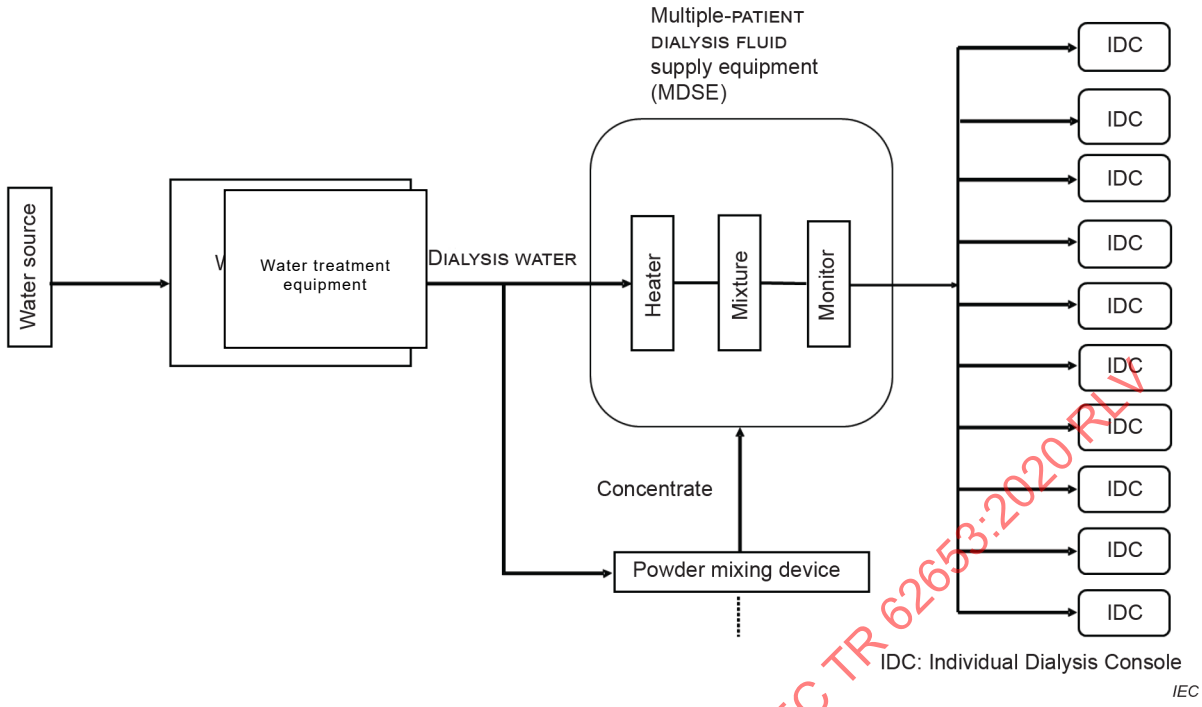

Figure A.1 – Typical CENTRAL DIALYSIS FLUID DELIVERY SYSTEM (CDDS)

A.8 Microbiological contamination of the DIALYSIS FLUID

~~Even~~ If a bacteria- and endotoxin retentive DIALYSIS FLUID filter is used, the DIALYSIS FLUID might be contaminated downstream of the filter due to ~~a possible technical failure~~ the use of inappropriate cleaning agents or insufficient disinfection regimes allowing bacterial growth over time.

If DIALYSIS FLUID endotoxin retentive filters are used, these shall be tested and routinely replaced in accordance with the MANUFACTURER'S instructions. More frequent replacements may be determined by the ORGANIZATION'S operations policy.

If a leak of the DIALYSIS FLUID filter or its connectors is detected and displayed by the DIALYSIS MACHINE before the treatment is started, proceed as described in the MANUFACTURER'S instructions.

~~In addition, the DIALYSIS FLUID filters of a DIALYSIS MACHINE should be maintained according to MANUFACTURER's instructions.~~

Special attention should be given to blood-contaminated dialyzer couplings in areas that are not involved into the hydraulic disinfection of the DIALYSIS MACHINE.

A.9 Bloodline INTENDED USE and potential risks

It is important to ensure that the bloodline is appropriately selected and installed on the DIALYSIS MACHINE to prevent serious adverse PATIENT events. Improperly fitting bloodlines can lead to kinking of the tubing and life-threatening haemolysis. The most susceptible region of the EXTRACORPOREAL CIRCUIT where mechanical blood damage may occur is between the roller blood pump and the DIALYSER [21], [22]. The most common type of occlusion, a tubing kink, is formed by excessive bending of the flexible blood tubing as it changes direction (e.g., at tubing support clips or the DIALYSER inlet), which causes a localized collapse of the tubing lumen. A tubing kink in the post-pump region can cause very high pressures, which forces blood through the narrow flow path, creating high velocity gradients and shear stresses that

damage the blood cells. In this manner, haemolysis can occur and go undetected until PATIENT symptoms appear.

The OPERATOR is responsible to ensure that labeling, INTENDED USE and specifications of bloodlines and DIALYSIS MACHINES are compatible. MANUFACTURERS of DIALYSIS MACHINES perform compatibility testing, including simulated use testing, to verify that the DIALYSIS MACHINES will work adequately with the recommended bloodlines and that the bloodlines fit correctly on the DIALYSIS MACHINES throughout the dialysis treatment. It is important to follow the MANUFACTURER'S instructions and to properly match DIALYSIS MACHINES and their bloodlines. This will ensure that the fit of the bloodlines onto the DIALYSIS MACHINE is appropriate, without extraneous lengths or overly taut segments of tubing that may kink during use. Similarly, the DIALYSIS MACHINES' labeling instructions should be strictly followed while installing the bloodlines, to ensure that all connections are made correctly and the tubing is routed in such a way that sudden bends are avoided, particularly at the tubing support clips and the DIALYSER inlet. Even with these precautions, the EXTRACORPOREAL CIRCUIT should be visually inspected throughout the treatment. The pressure alarm systems should be operated and monitored according to the MANUFACTURER'S instructions.

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2 This first edition cancels and replaces ISO 23500:2014.

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4 This first edition cancels and replaces ISO 13959:2014.

5 This first edition cancels and replaces ISO 13958:2014.

6 This first edition cancels and replaces ISO 11663:2014.

Index of defined terms used in this document

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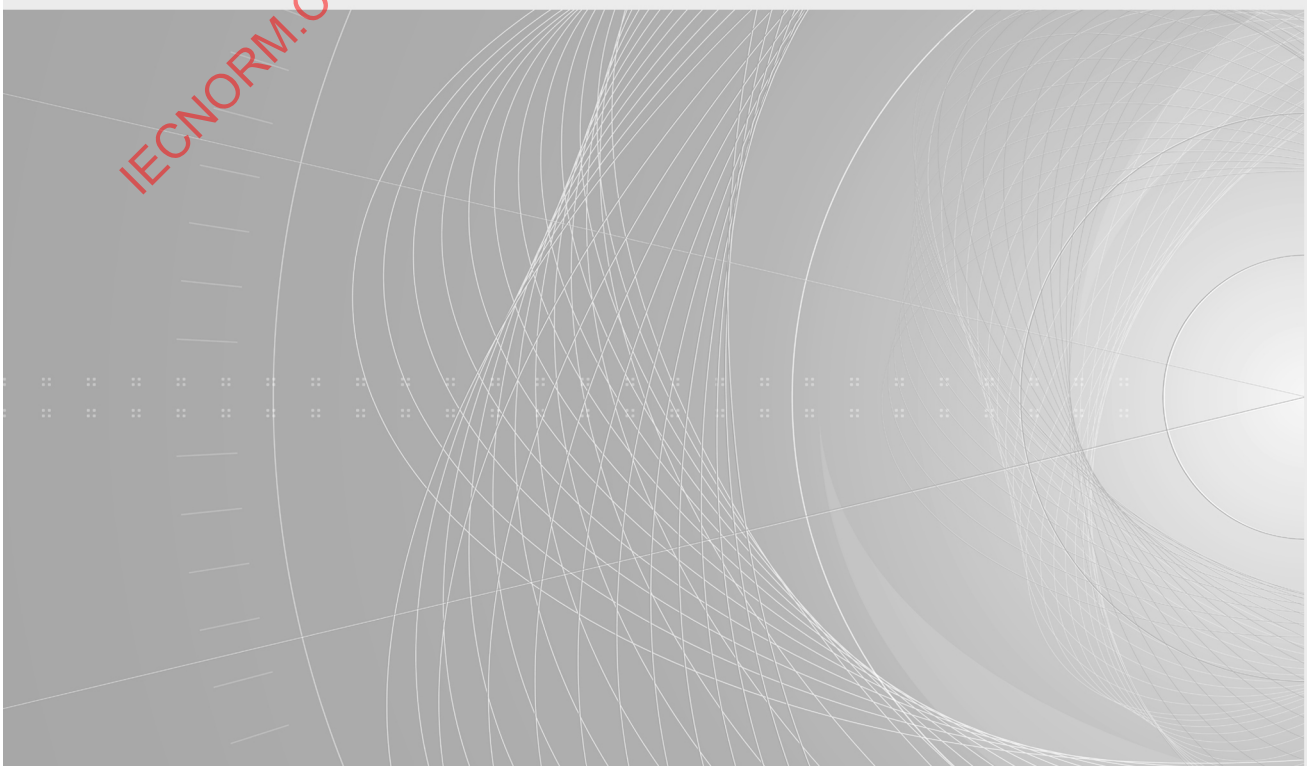
TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments



IEC TR 62653:2020-04 (en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

IEC TR 62653, which is a technical report, has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2012. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) update the relevant references to the new numbering scheme of the ISO 23500 family;
b) alignment with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 62353:2014 and 60601-2-16:2018;

c) technical additions in several sections.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62D/1698/DTR	62D/1744/RVDTR

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

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

The verbal forms used in this document are conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2, 2018.

For the purpose of this document, the auxiliary verb “should” means that this statement of the document is recommended for safe operation. This term is not to be interpreted as indicating requirements.

In this document the following print types are used:

– requirements and definitions: roman type;
– informative material, such as notes, examples and references: smaller type;
– TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

INTRODUCTION

HAEMODIALYSIS is a therapeutic method for treating renal insufficiency, in addition to peritoneal dialysis and renal transplantation. HAEMODIALYSIS is often used as a general term for related extracorporeal methods of renal replacement therapy. At present, HAEMODIALYSIS is a standard procedure in renal replacement therapy, which, when applied properly, yields high-quality results. The treatment is a complex procedure which is under the influence of medical-biological, physical-chemical and technical processes.

Numerous guidelines, agreements, codes, decrees and laws have been established with regard to HAEMODIALYSIS. They contain detailed regulations about the quality of structures, processes and results, laid down by the legislative body, executive bodies of self-government, and funding agencies.

Since the safety of PATIENT treatment and the legal provisions are highly important, it is reasonable to introduce a quality management system. This document may be an integral part of a quality management system of the ORGANIZATION. The ORGANIZATION should be aware of the residual risks and identify appropriate measures, for example based on these guidelines. The ORGANIZATION should minimise such risks by the use of appropriate standard operating procedures. This document is intended to support the clinical management responsible for the quality management of HAEMODIALYSIS therapies.

GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

1 Scope

This document describes the technical recommendations for use of medical equipment in chronic HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles are important to be complied with to ensure safe, permissible and appropriate application.

The term HAEMODIALYSIS is used in this document as synonym for all therapy modalities.

The scope can be applicable to the use of the medical equipment in home, acute and pediatrics environment. The scope may also be applicable to SORBENT DIALYSIS SYSTEMS.

The physician is responsible for the treatment prescription. However, the ORGANIZATION administering the treatment is responsible for all resources, structures and processes used in connection with the treatment. These responsibilities will not be described here.

The requirements of IEC 60601-2-16 ensure that medical electrical equipment used for extracorporeal renal replacement therapy operates with a high level of safety. Despite that high level of safety, however, some residual risk remains, related to medical-biological, physical-chemical and technical HAZARDS. The ORGANIZATION administering the treatment is responsible for managing the residual risk.

This document is not intended to be used as the basis of regulatory inspection or certification assessment activities.

2 Normative references

There are no normative references in this document.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography starting on page 32.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 36.

3.1
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,

– enhance its performance, or

– enable its functions to be integrated with those of other equipment

Note 1 to entry: Accessories can be objects, substances, preparations of substances and software which do not constitute any medical equipment themselves.

[SOURCE: IEC 60601-1:2005, 3.3, modified – A note to entry has been added.]

3.2
ARTERIAL PRESSURE
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT between the PATIENT connection and DIALYSER connection

Note 1 to entry: A difference can be made between the pre-pump pressure, which is upstream of the blood pump (typically negative), and post-pump pressure (typical positive), which is downstream of the blood pump.

[SOURCE: IEC 60601-2-16:2018, 201.3.201, modified – Direction of pressure added.]

3.3
BLOOD LEAK
leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: Not to be mistaken for blood loss to the environment.

[SOURCE: IEC 60601-2-16:2018, 201.3.202, modified – The original note to entry has been replaced.]

3.4
CENTRAL CONCENTRATE SYSTEM
system that prepares and/or stores concentrate at a central point for subsequent distribution to its points of use

3.5
CENTRAL DIALYSIS FLUID DELIVERY SYSTEM
system that produces DIALYSIS FLUID from DIALYSIS WATER and concentrate or powder at a central point and distributes the DIALYSIS FLUID from the central point to individual dialysis consoles

3.6
DIALYSER
device containing a semi-permeable membrane that is used to perform HAEMODIALYSIS, HAEMODIAFILTRATION or HAEMOFILTRATION

[SOURCE: IEC 60601-2-16:2018, 201.3.204]

3.7
DIALYSIS FLUID
aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS and HEMODIAFILTRATION

Note 1 to entry: The term "DIALYSIS FLUID" is used throughout this document to mean the fluid made from DIALYSIS WATER and concentrates that is delivered to the DIALYSER by the DIALYSIS FLUID delivery system. Such phrases as "dialysate" or "dialysis solution" are used in place of DIALYSIS FLUID in some countries; however, that usage is discouraged to avoid confusion.

Note 2 to entry: ISO 23500-5 defines three levels of DIALYSIS FLUID: standard DIALYSIS FLUID, ultrapure DIALYSIS FLUID, and online-prepared substitution fluid used for HAEMODIAFILTRATION.

Note 3 to entry: The DIALYSIS FLUID entering the DIALYSER is referred to as "fresh DIALYSIS FLUID", while the fluid leaving the DIALYSER is referred to as "spent DIALYSIS FLUID".

Note 4 to entry: DIALYSIS FLUID does not include prepackaged parenteral fluids used in some renal replacement therapies, such as HAEMODIAFILTRATION and HAEMOFILTRATION.

[SOURCE: ISO 23500-1:2019, 3.15, modified – The terms "dialysate" and "dialysis solution" were deleted.]

3.8
DIALYSIS MACHINE
HAEMODIALYSIS MACHINE
HAEMODIAFILTRATION MACHINE
HAEMOFILTRATION MACHINE
medical electrical equipment used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

Note 1 to entry: The DIALYSIS MACHINE can be a batch DIALYSIS MACHINE filled with the entire DIALYSIS FLUID prior to treatment (see A.6).

Note 2 to entry: The DIALYSIS MACHINE can be supplied with DIALYSIS FLUID from a CENTRAL DIALYSIS FLUID DELIVERY SYSTEM and synonymously named individual dialysis console in this context (see A.7).

3.9
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3 and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of concentrates and preparation of substitution fluid for online convective therapies

[SOURCE: ISO 23500-1:2019, 3.17]

3.10
ENCLOSURE
exterior surface of electrical equipment or parts thereof

Note 1 to entry: Including all touchable parts, such as rotary knobs, handles, and the like.

[SOURCE: IEC 60601-1:2005, 3.26, modified – The original note to entry has been replaced.]

3.11
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY

[SOURCE: IEC 60601-2-16:2018, 201.3.207, modified – Deletion of Note to entry.]

3.12
HAEMODIAFILTRATION
HDF
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT are corrected by a simultaneous combination of HD and HF

[SOURCE: IEC 60601-2-16:2018, 201.3.208]

3.13
HAEMODIALYSIS
HD
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT 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 typically includes fluid removal by filtration. This process is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

[SOURCE: IEC 60601-2-16:2018, 201.3.209]

3.14
HAEMOFILTRATION
HF
process whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by convective transport via ultrafiltration and partial replacement by a substitution fluid resulting in the required net fluid removal

[SOURCE: IEC 60601-2-16:2018, 201.3.211]

3.15
HAZARD
potential source of harm

[SOURCE: ISO 14971:2019, 3.4]

3.16
HAZARDOUS SITUATION
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.40]

3.17
INCIDENT
malfunction, failure or MODIFICATION of the features or the performance, or an inadequate or incorrect labeling or instructions for use of a medical equipment, which directly or indirectly resulted in, could have resulted in or might result in the death or a severe deterioration of the state of health of a PATIENT, an OPERATOR or another person

3.18
INTENDED USE
INTENDED PURPOSE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: ISO 14971:2019, 3.6, modified – Deletion of the Note.]

3.19
MAINTENANCE
combination of all technical and administrative means, including supervising ones, to keep medical electrical equipment or a medical electrical system in a normal working condition or restored to normal working condition

[SOURCE: IEC 62353:2014, 3.21]

3.20
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging or labelling of medical equipment, assembling a medical system, or adapting medical equipment or a medical system, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: In the context of this document the term medical equipment is used as umbrella term for medical electrical equipment and non-active medical devices.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.55, modified – The original notes to entry have been deleted.]

3.21
MODIFICATION
changing constructional or functional features of medical equipment or a medical system in a way not described in its instruction for use or other accompanying documents

[SOURCE: IEC 62353:2014, 3.25, modified – A note to entry has been deleted and a reference to instructions for use has been added.]

3.22
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73, modified – The original note to entry has been deleted]

3.23
ORGANIZATION
entity of the persons and/or institutions responsible for the application and MAINTENANCE of systems for extracorporeal renal replacement therapy

EXAMPLES Medical doctors, dialysis centers and dialysis clinics and their responsible parties.

3.24
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A PATIENT can be an OPERATOR.

Note 2 to entry: For the purpose of this document PATIENT is a human being

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.76, modified – Addition of a new Note 2 to entry.]

3.25
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the medical electrical equipment or medical electrical system or between a PATIENT and other persons touching parts of the medical electrical equipment or medical electrical system

Note 1 to entry: Volume here means room area.

Note 2 to entry: An example of PATIENT ENVIRONMENT is shown in Figure 1.

Dimensions in metres

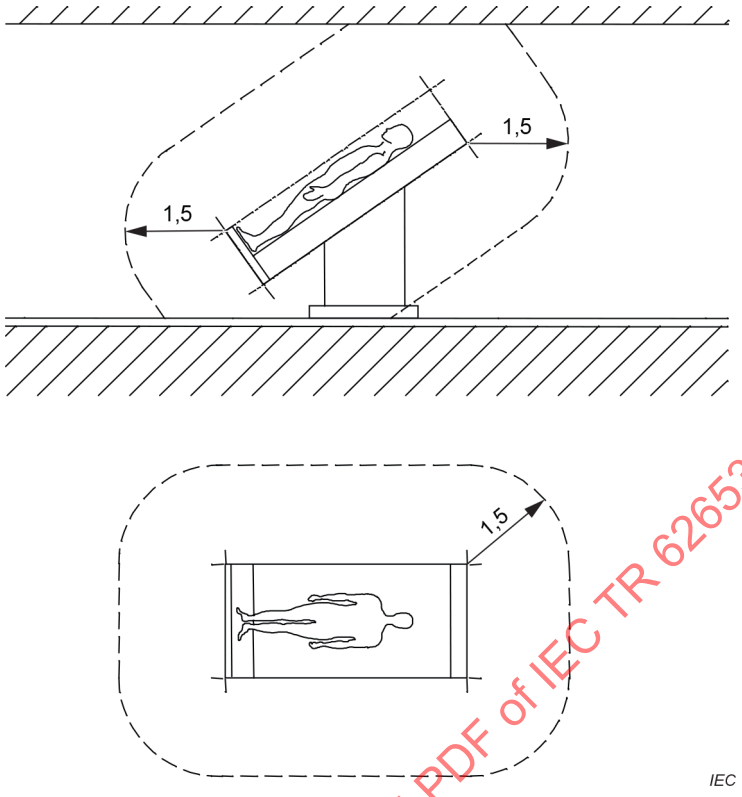

Figure 1 – Example PATIENT ENVIRONMENT

[SOURCE: IEC 60601-1:2005, 3.79, modified – Two notes to entry have been added, including a figure illustrating the term.]

3.26
PATIENT LEAKAGE CURRENT
current coming from a medical electric equipment and flowing through the PATIENT to the ground

Note 1 to entry: The source of such a current may, for example, be a defective electric heater of the DIALYSIS MACHINE. The current may be transmitted through the conducting DIALYSIS FLUID and to the PATIENT.

3.27
POTENTIAL EQUALIZATION CONDUCTOR
conductor other than a protective earth conductor or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

[SOURCE: IEC 60601-1:2005, 3.86, modified – Note deleted.]

3.28
PROTECTIVE SYSTEM
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

[SOURCE: IEC 60601-2-16:2018, 201.3.215]

3.29
REPAIR
means for restoring to a safe, functional, normal condition

[SOURCE: IEC 62353:2014, 3.39]

3.30
SERVICING
combination of all means for maintaining the medical electrical equipment or medical electrical system within requirements of the MANUFACTURER

[SOURCE: IEC 62353:2014, 3.41]

3.31
SORBENT DIALYSIS SYSTEM
method of dialysis where DIALYSIS FLUID is generated from potable water and spent DIALYSIS FLUID is regenerated into fresh DIALYSIS FLUID by recirculation through a sorbent cartridge which removes uremic toxins from the DIALYSIS FLUID while replenishing other beneficial chemicals

3.32
TOUCH CURRENT
current not necessary for appropriate functioning, coming from the ENCLOSURE or parts thereof (except PATIENT connectors), which the OPERATOR or PATIENT may touch while using the medical electrical equipment as intended and flowing to the ground or another part of the ENCLOSURE after having passed through an external connection (except the protective earth conductor)

3.33
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across the semi-permeable membrane of the DIALYSER

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 minus the measured DIALYSIS FLUID pressure, each obtained at a single point.

[SOURCE: IEC 60601-2-16:2018, 201.3.217]

3.34
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT connection (typically positive)

[SOURCE: IEC 60601-2-16:2018, 201.3.219, modified – Direction of pressure added]

4 Recommendations

4.1 Personnel, qualification

OPERATORS should be qualified and have received the appropriate training for the activities assigned to them, including the operation of the medical electrical equipment, medical devices, ACCESSORIES and associated disposables and supplies.

If treatment is undertaken at home, the PATIENT and/or the person taking care of the PATIENT should also be appropriately trained not only in the operation of the medical electrical equipment, medical devices, but also in the procedures that should be followed in the event of an INCIDENT arising from the use of the medical equipment.

4.2 Training

OPERATORS/PATIENTS should be trained for the activity assigned to them:

a) The ORGANIZATION should only assign persons who have been trained in the INTENDED USE of the medical electrical equipment, medical devices or systems that they will operate (see 7.3). Particular attention should be paid to the OPERATOR´s responsibility in following the instructions for use, the warnings and precautions outlined by the MANUFACTURERS, because these instructions are crucial to avoid remaining / residual risks not technically mitigated by the medical equipment themselves.

b) The training should be based on the valid instructions for use and include any unit protocols, actions or interventions needed in case of alarms, cautions, or medical equipment failure. The instructions for use should be available at any time.

c) Only ORGANIZATIONS that have received training from the MANUFACTURERS of the medical electrical equipment or system can develop a training program to train additional personnel within that ORGANIZATION to operate the medical electrical equipment or system.

d) The ORGANIZATION should develop training material that ensures a comprehensive, structured training program to include 1) training outline, 2) goals and objectives, 3) maximum number of trainees, 4) duration of training program for the staff of the ORGANIZATION.

e) The training program for PATIENTS should include but not be limited to: techniques associated with the specific modality, modality prescription, administration of medications and procedures for the detection, reporting and management of both medical and non-medical complications arising from the treatment.

f) If MODIFICATIONS by the MANUFACTURER are necessary, the MANUFACTURER should provide written documentation regarding the MODIFICATIONS undertaken. If necessary, the MANUFACTURER should also provide appropriate additional training.

g) The completion of any training program should be documented by the ORGANIZATION.

h) The medical electrical equipment, medical devices or systems should be operated in accordance to the MANUFACTURER'S instructions and based on the knowledge and skills required for the particular medical treatment.

These application principles and/or any brief operating instructions do not replace the detailed instructions for use or a qualified training in the handling of the medical equipment or systems.

4.3 Infrastructure

4.3.1 General

Safe performance of an extracorporeal renal replacement therapy requires that all components of the system work as intended; the systems should be used in the appropriate rooms and drugs (e.g. pre-manufactured fluid bags) and medical equipment should be used within specified tolerances. DIALYSIS MACHINES are provided with PROTECTIVE SYSTEMS (e.g. for monitoring the conductivity, the temperature of the DIALYSIS FLUID and the VENOUS PRESSURE as well as for detecting BLOOD LEAKS and air in the EXTRACORPOREAL CIRCUIT). Such PROTECTIVE SYSTEMS may be subject to damage and should, therefore, be checked for appropriate functioning at regular intervals according to the MANUFACTURER'S instructions. Failure to complete checks according to the MANUFACTURER'S instructions places the PATIENT at risk, and technical advice prior to the commencement of the treatment should be sought.

4.3.2 Infrastructure recommendations

4.3.2.1 Technical recommendations in rooms

Rooms, except rooms in the home healthcare environment, which are intended for employment of HAEMODIALYSIS systems according to IEC 60601-1 are medically used rooms of Group 1 as defined in IEC 60364-7-710.

The electric connection of a DIALYSIS MACHINE of class I should be established by a socket outlet with tested grounding by protective earth and a plug which cannot be mistaken for other socket outlets. Use of adaptors or extension cords, not approved by the MANUFACTURER of the

medical electrical equipment, with grounded machines could lead to electrical safety HAZARDS. The treatment location should be provided with an additional potential equalization connector tested according to IEC 60364-7-710, (see 710.413.1.6, additional potential equalization, of IEC 60364-7-710:2002). If central venous catheters whose tip is in the right atrium are used for the vascular access, special measures might be necessary for complying with electrical safety requirements [13], [14], [15], [16].[1] The MANUFACTURER´S instructions should be followed.

Possible examples are: socket outlets and plugs according to IEC 60309-2, colour code identification of the power socket dedicated to the machine. Power cord and plugs should be according to MANUFACTURER´s instructions.

If an emergency occurs during the dialysis treatment, it should be possible to alert the person taking care of the PATIENTS and or emergency medical services.

In order to prevent the DIALYSIS MACHINE from being contaminated with viruses, bacteria, endotoxins and fungi by retroactive effect from the drain, the medical electrical equipment MANUFACTURER'S instructions in the instructions for use should be followed for installation of the drain tube.

In addition, it is recommended that drains intended to discharge the spent DIALYSIS FLUID be provided with a stench trap.

Handling of waste liquids to the drain should comply with the local regulations.

If conditions are unfavorable, e.g. in case of backflow, the DIALYSIS MACHINE might become contaminated. To prevent this, the minimum distance of the drain opening from the level of the sewage water should not be less than 2 cm or according to the MANUFACTURER'S specification or according to local regulations.

4.3.2.2 Water treatment and distribution

ISO 23500-2 should be taken as reference.

4.3.2.3 Concentrate supply

ISO 23500-4 should be taken as reference.

4.3.2.4 Responsibilities for on-site preparation of fluids

ISO 23500-1 should be taken as reference.

4.3.2.5 Infection control

Each ORGANIZATION should have in place an infection control policy for the protection of PATIENTS and personnel [1], [2]. This policy should be dated, with its review date clearly indicated.

The infection control policy should include specifications of how to manage both sterile supplies and handling techniques.

The infection control policy should include specifications for prevention and control of blood borne virus infection in PATIENTS and staff. If treatment is performed away from the normal treatment location (hospital/home) the measures needed to protect PATIENTS, support workers, and others from the risk of blood-borne virus infections should be outlined.

[1] Numbers in square brackets refer to the Bibliography.

Correct handling techniques typically include:

- hand hygiene,
- use of gloves and other protective equipment,
- use of face masks,
- technique for preparation of supplies to be used during the treatment,
- use of materials within use-by dates,
- technique for access preparation and access care,
- technique for blood and fluid connections,
- waste disposal,
- used disinfection methods.

In addition, the infection control policy should describe the management of cleaning and disinfecting equipment and environmental services according to MANUFACTURER's instructions and country specific regulations.

When the fluid pathways of DIALYSIS MACHINES are disinfected, the MANUFACTURER's instructions should be followed.

The infection control policy should include the disinfectant to be used for surface disinfections, the required concentration and the minimum exposure time required by the disinfecting agent in terms of bactericidal efficacy and inactivation of bloodborne viruses such as HBV, HCV and HIV. Since surface disinfectants may damage the materials of the device, MANUFACTURER'S recommendations should be taken into account.

If the infection status of PATIENTS is unknown with regard to blood-borne virus infections, the appropriate measures should be taken to exclude any contamination of other PATIENTS. Special measures are required for PATIENTS with virus infection transferred by blood according to country regulations [2], [3], [4].

Measures for the return of DIALYSIS MACHINES used on PATIENTS with blood-borne virus infections to a non-infectious area are, for example, described in "Guideline for Applied Hygiene in Dialysis – In German" [1] or local Infection Control Policies.

4.3.2.6 Other prerequisites

To assure compatibility of medical equipment and ACCESSORIES comprising the system, the INTENDED USES and compatibilities of the medical equipment found in the instructions for use should be taken into account.

4.3.2.7 Home HAEMODIALYSIS recommendations

If the DIALYSIS MACHINE and associated water treatment equipment are used in the PATIENT'S home, the requirements specified by the MANUFACTURER should be followed. To comply with local requirements, it may additionally be necessary for the installation to be examined by an approved expert to ensure that the quality of the alterations meets the requirements specified by the MANUFACTURER of the DIALYSIS MACHINE and by the MANUFACTURER of the water treatment and/or DIALYSIS FLUID preparation equipment.

It is recommended that home HAEMODIALYSIS PATIENTS have a communication equipment to permit contact with the supervising ORGANIZATION in the event of a medical emergency and a backup communication equipment in case of malfunction of the first communication equipment.

It is recommended that the room used for HAEMODIALYSIS contains emergency lighting equipment such a flashlight or torch to provide illumination in the event of a power failure.

The PATIENT or carer should also be appropriately trained as to what procedures to follow in the event of a mains power failure.

It is recommended that initial and periodic assessment of the home environment be performed to ensure that it meets the necessary technical and operational requirements; physical space, plumbing requirements, water requirements, electrical requirements, storage and waste management, and documentation.

NOTE The considerations in Annex F of ISO 23500-1:2019 and in IEC 60601-1-11 are important to be taken into account.

4.3.2.8 Information technology (IT) management

There is widespread utilization of IT technology in hospitals or provided by third parties, and in many dialysis units the DIALYSIS MACHINES can also be linked to such infrastructures, whilst for home HAEMODIALYSIS PATIENTS there may be a linkage to remote monitoring infrastructures that may be operated by third parties rather than the hospital. The use of IT infrastructures poses two issues: safety of the PATIENT, and data protection.

It is recommended for the ORGANIZATION to follow the standards below in dealing with above issues:

- IEC 80001 (all parts), *Application of risk management for IT-networks incorporating medical devices*;
- ISO/IEC 27001, *Information technology – Security techniques – Information security management systems – Requirements*;
- ISO/IEC TS 27008, *Information technology – Security techniques – Guidelines for the assessment of information security controls*.

IT risk management should be established from the beginning and subject to continuous review. Technical and organizational security measures [23] cannot be treated casually in either a hospital or an office setting; there need to be defined objectives, safeguards and responsibilities as well as defined policies well-known to all staff members. IT security should be checked regularly, including existing work routines to ensure that they are suitable and efficient.

5 Treatment

5.1 General

The HAEMODIALYSIS treatment should be carried out by qualified OPERATORS under the physician's responsibility. The physician determines the prescription of the HAEMODIALYSIS treatment, e.g. dialysis time, treatment frequency, DIALYSER, composition of the DIALYSIS FLUID, blood flow, DIALYSIS FLUID temperature, anticoagulation if needed, and ultrafiltration rate or ultrafiltration volume. The OPERATOR should only use information on DIALYSIS MACHINE displays for its INTENDED USE. The OPERATOR should use information provided by the DIALYSIS MACHINE only in the way described as INTENDED USE by the MANUFACTURER.

5.2 Preparation

5.2.1 DIALYSIS MACHINE

Before the dialysis treatment the DIALYSIS MACHINE should be checked for correct connections (e.g. power supply, POTENTIAL EQUALIZATION CONDUCTOR, water, concentrate or DIALYSIS FLUID supply as well as fluid drain).

If local check lists exist, they should be followed.

The DIALYSIS MACHINE should be disinfected according to the MANUFACTURER´s instructions and checked for residual disinfectant if necessary. In the case of a malfunction of the disinfection program or if the OPERATOR is in doubt whether disinfection was completed properly, the procedure should be repeated, or the DIALYSIS MACHINE should be disabled until checked by a technician.

NOTE 1 In case of prolonged downtimes, an additional disinfection cycle can be necessary (see instructions for use of the DIALYSIS MACHINE).

NOTE 2 Be aware that non-operational periods with closed clamps can damage the lines and impair function.

The DIALYSIS MACHINE should be subjected to a functional/safety check according to the MANUFACTURER'S instructions.

The DIALYSIS MACHINE should be set up in accordance with the PATIENT's treatment plan. The allocation of the PATIENT to the DIALYSIS MACHINE should be documented.

5.2.2 DIALYSIS FLUID preparation by DIALYSIS MACHINE

The concentrates used and the DIALYSIS MACHINE or multiple-PATIENT DIALYSIS FLUID supply equipment (MDSE, see A.7) settings for the composition of the DIALYSIS FLUID should be documented and verified for correspondence with the medical prescription.

Electrolyte concentrate additives, if used, should be added and mixed according to the additive MANUFACTURER´s instructions. The mixture should be labeled with the name of the additive, date, dose and signature. Before the mixture is used, the labeling of the mixed concentrate should be checked to ensure correct composition.

NOTE 1 The conductivity measurement of the DIALYSIS MACHINES does not detect any concentration of physiologically low electrolyte concentrations (e.g. K, Ca, Mg), which poses a RISK to the PATIENT.

In order to prevent RISKs, such as using contaminated, degraded fluids or concentrates with incorrect chemical composition:

- canisters, bags or cartridges that have already been opened should be used up either according to the medical device's MANUFACTURER'S instructions or to the ORGANIZATION's standard operating procedures.
- residual concentrates in canisters, bags or cartridges should not be mixed.
- used fluids should be visually checked for particulate matter, if possible.
- bagged dialysate or replacement fluid should not be overheated or frozen.
- chlorine and/or chloramines in the DIALYSIS WATER should be checked, if applicable.

NOTE 2 Preventive methods to avoid biological contaminants in central storage tanks and delivery pipes are regular disinfection procedures.

5.2.3 EXTRACORPOREAL CIRCUIT

The following steps should be taken according to the instructions for use of the EXTRACORPOREAL CIRCUIT:

– check the disposable (packaging) for damage and valid sterility expiration date;
– check for use of correct EXTRACORPOREAL CIRCUIT and for its correct insertion;
– check for use of correct anticoagulation syringe type and size, if applicable;
– prime and remove air from the EXTRACORPOREAL CIRCUIT;
– attach, prime and use the medical devices and ACCESSORIES required for the treatment;
– check all connections, caps and lines for tightness, absence of leaks, kinking and air entrapment.

5.2.4 DIALYSIS FLUID compartment

The following steps should be taken according to the instruction for use of the DIALYSER:

– connect the DIALYSIS FLUID tubes and check for leakage and flow direction;
– prime and remove air from the DIALYSER.

NOTE A procedure deviating from the above description can be applicable to batch or disposable single use DIALYSIS FLUID path DIALYSIS MACHINES.

5.2.5 PATIENT

5.2.5.1 Setting treatment data

The treatment parameters should be verified for compliance with the medical prescription.

5.2.5.2 Entering individual PATIENT'S treatment parameters

As applicable the PATIENT treatment parameters should be entered on the DIALYSIS MACHINE and verified for correct input.

The following settings are common for dialysis treatment:

– treatment time;
– ultrafiltration volume / ultrafiltration flow rate, taking into account correction for additional food, drinks, infusions, saline boluses and rinseback volume;
– concentrate selection and electrolyte settings to determine DIALYSIS FLUID composition;
– DIALYSIS FLUID temperature;
– DIALYSIS FLUID flow rate and volume, if applicable;
– dosage and infusion flow rate of anticoagulants, if applicable;
– substitution volume / substitute flow rate, if applicable.

If ultrafiltration profiles are used, it should be noted that the maximum ultrafiltration rate which is tolerable and permitted for the PATIENT might be exceeded.

If conductivity/electrolyte-sodium profiles and "parameter-controlled automatic feedback loop" procedures are used, it should be noted that the electrolyte balance and the acid-base balance might be affected.

If parameter-controlled automatic feedback loops are used (e.g. ultrafiltration rate controlled by haematocrit), the corresponding limits as specified by the instruction for use or other accompanying documents should be set instead of the controlled parameters (electrolyte concentration, temperature) taking into account the intake of food and drinks as well as residual urine production during the dialysis treatment.

NOTE 1 Other PATIENT-related parameters can be applicable to batch DIALYSIS MACHINES.

NOTE 2 Ultrafiltration here means amount of fluid removed to reach the prescribed dry weight of the PATIENT.

5.3 Treatment

5.3.1 Preparing the vascular access

The access to the PATIENT's vascular system should be prepared according to requirements defined by the ORGANIZATION.

After completing puncture, the needles and ancillary devices for vascular access leak detection, if applicable, should be fixed securely to prevent dislodgement.

If central venous catheters are used, cracks and damage may be caused by application of inappropriate disinfectants or mechanical impacts, resulting in blood loss or infusion of air. The catheter should be visually checked for integrity prior to each use [20].

The OPERATOR should only cover the puncture sites during the treatment with sterile dressings, gauze or see through covering [6]. If covered by dressings or sheets, their size should allow detection of even small blood losses. To allow detection of blood loss, the PATIENT should be advised not to cover the puncture sites with a blanket. Additional medical electrical equipment can help to detect blood losses automatically.

NOTE The VENOUS PRESSURE monitor may not reliably detect leaks, blood tubing separation from the blood access device, or needle dislodgement. Failure to detect a problem is more likely when blood pump speeds are set above 450 ml/min or when a catheter is used at lower blood flow rates (100 ml/min to 200 ml/min). Little or no pressure change may occur depending on the circumstances. It is unlikely but possible for a leak to occur, the blood tubing to separate, or access needle to dislodge without a VENOUS PRESSURE alarm. For that reason, the PATIENT's safety is only ensured by careful monitoring by the OPERATOR [17], [18], [19].

5.3.2 Connection to the EXTRACORPOREAL CIRCUIT

It should be checked, that the DIALYSIS MACHINE is ready for PATIENT connection.

When the PATIENT is connected to the EXTRACORPOREAL CIRCUIT:

– Connection sites should be tight, secure and the lines torsion stress relieved. The connection of the EXTRACORPOREAL CIRCUIT to the appropriate needle or catheter port should be checked (e.g. arterial line to arterial needle etc.).
– Before the blood pump is turned on, the appropriate tube clamps of the EXTRACORPOREAL CIRCUIT and, if applicable, the HDF system's tube clamps and ports should be opened.
– The initial blood flow should not be too high (usually 100 ml/min to 200 ml/min).
– Air embolism and blood loss should be prevented by direct observation with special considerations for catheters [10], [11].

NOTE If the VENOUS PRESSURE is negative and there are leaks/disconnections while the access clamp is open, air can be sucked in downstream of the air monitoring unit; such air will not be detected and will be directly infused into the PATIENT.

5.3.3 Initiation of treatment

To start the treatment, the instruction for use or other accompanying documents of the DIALYSIS MACHINE should be followed. The following steps should be carried out:

a) Start the treatment and observe the ARTERIAL PRESSURE and the VENOUS PRESSURE, then increase to prescribed blood flow rate. Check for any unusual noise emitted by the blood pump.

   Such noise may indicate

   – mechanical damage of the pump;
   – use of an inappropriate EXTRACORPOREAL CIRCUIT;
   – stenoses, kinks and clamped lines in the EXTRACORPOREAL CIRCUIT;
   – improperly installed EXTRACORPOREAL CIRCUIT.

b) Check puncture sites, for example to detect any formation of haematoma or vascular collapse.

c) Check the EXTRACORPOREAL CIRCUIT for kinks and appropriate attachment to the DIALYSIS MACHINE.

   Ensure that kinks cannot develop even after the lines have been heated up to blood temperature. If the PATIENT's bed or the DIALYSIS MACHINE is moved or displaced while the treatment is in progress, the EXTRACORPOREAL CIRCUIT should be checked again.

d) Set the alarm limits for the VENOUS PRESSURE and check the VENOUS PRESSURE. In the positive pressure range, the lower alarm limit for VENOUS PRESSURE monitoring should be

set as closely to the current value as possible. If alarm limits are set automatically, check this setting and, if necessary, readjust manually.

NOTE 1 The pressure alarm at the lower VENOUS PRESSURE limit is intended as a protection against blood loss to the environment. Pressure monitoring will not reliably detect blood loss due to leaks and separations in the venous return or dislocation of the venous access device. During dialysis, one of the most frequent complications resulting in death is caused by dislocation of the venous cannulae (slipping out of the blood vessel). Such a dislocation is not reliably detected by the PROTECTIVE SYSTEMS of the DIALYSIS MACHINES and can result in a life-threatening blood loss to the environment [17], [18], [19]. Another complication that can result in serious injury or death is a leak, through separation of the venous access device (central venous catheter) from the venous bloodline [20].

e) If applicable, set the alarm limits for the ARTERIAL PRESSURE.

f) Verify that there are no fluid leaks.

g) Complete any documentation in accordance with the ORGANIZATION's requirements.

NOTE 2 Batch DIALYSIS MACHINES and CENTRAL DIALYSIS FLUID DELIVERY SYSTEMS often need the setting and monitoring of other parameters.

5.3.4 Checks to be repeated during the treatment

The following checks should be performed regularly during treatment:

a) Check the EXTRACORPOREAL CIRCUIT including puncture sites for security:

Do not cover connections in the EXTRACORPOREAL CIRCUIT. Check all connections between blood tubing and catheter or cannulas for security and for leaks frequently and whenever an alarm occurs.

NOTE 1 During single-needle dialysis, blood flow occurs in phases. During the arterial phase, if there is a leak in the EXTRACORPOREAL CIRCUIT downstream of the venous clamp, e.g. at the Y-piece, air can be sucked into the EXTRACORPOREAL CIRCUIT. This air will then be transported to the PATIENT during the venous phase.

b) Check for kinked EXTRACORPOREAL CIRCUIT, BLOOD LEAKS and for leaks of the DIALYSIS FLUID and substitution circuit. The EXTRACORPOREAL CIRCUIT should be checked again if the position of the PATIENT'S bed or the DIALYSIS MACHINE is adjusted during the treatment.

c) Check for correct clamping of not used administration lines.

d) If displayed, check the TRANSMEMBRANE PRESSURE, ARTERIAL PRESSURE and VENOUS PRESSURE values for deviations.

e) Check for wetted transducer protectors, if applicable. If wetted, proceed as described in 5.3.8.

f) Verify that the ultrafiltration rate, ultrafiltration volume and substitution rate (for HF and HDF), the blood flow and the DIALYSIS FLUID flow comply with the values prescribed.

g) If applicable, check the blood levels in the chambers for the appropriate height.

h) Check for formation of blood clots.

NOTE 2 If the DIALYSIS MACHINE uses air detection at the venous chamber, blood clots in the chamber can affect the PROTECTIVE SYSTEM.

i) If applicable, check the anticoagulant infusion rate(s), volume(s) and/or corresponding lab values, e.g. Ca plasma values in Citrate/Calcium anticoagulation.

j) If applicable, check for defective filters or moisture in the hydrophobic filters in pressure relief lines.

k) Check the PATIENT-related parameters at regular intervals as specified in the prescription.

l) Prepare the documentation according to the ORGANIZATION'S internal specifications.

m) Document any repeated alarm situations and irregularities.

NOTE 3 Repeated override of alarms can result in a HAZARD to the PATIENT because each alarm has been triggered by a deviation from a set value. In some cases (e.g. net fluid removal) these deviations can accumulate.

If any abnormalities are detected during the checks, clarify the causes and initiate the appropriate alleviating measures. In the case of technical failures, proceed according to the

instruction for use or other accompanying documents. If a failure or malfunction causes blood to enter inside the DIALYSIS MACHINE, do not use the DIALYSIS MACHINE on any other PATIENT without having taken the appropriate REPAIR measures and decontamination procedures [5].

NOTE 4 Batch DIALYSIS MACHINEs and CENTRAL DIALYSIS FLUID DELIVERY SYSTEMS often imply the monitoring of other parameters.

5.3.5 HAZARDS during the treatment

OPERATORS of DIALYSIS MACHINEs should not rely on the technical safety of the DIALYSIS MACHINEs alone, when performing a treatment. Assessment of HAZARDS requires fundamental knowledge of how to use the system [7], [8], [9].

Some examples of HAZARDOUS SITUATIONS include:

– incorrect alarm handling, e.g. failure to check PATIENT access on VENOUS PRESSURE alarm and incorrect air alarm handling;

– ingress of foreign particles, pathogens, their constituents or metabolic products into the blood pathway (e.g. by incorrect rinsing or disinfection);

– acute or chronic toxicity (e.g. caused by residual disinfectant in the EXTRACORPOREAL CIRCUIT, migration of plasticisers);

– incorrect handling of disinfectant containers, e.g. mixing;

– blood loss (e.g. caused by disconnection in the EXTRACORPOREAL CIRCUIT including the vascular access, bleedings, coagulation in the EXTRACORPOREAL CIRCUIT, puncturing problems, incorrect use of needleless injection ports or wrong positioning of puncture cannula);

– incorrect fluid balance (e.g. weighing, input or calculation errors);

– incompatibility reactions caused by materials used or caused by substances adhering thereto;

– improper use of cleaning agents or disinfectants;

– improper use or composition of the DIALYSIS FLUID;

– deficit between the dialysis parameters prescribed and what is actually delivered (e.g. by an insufficiency of the vascular access);

– haemolysis (e.g. caused by wrong setup or kinking of the EXTRACORPOREAL CIRCUIT);

– air embolism (e.g. caused by defects or improper use of central venous catheters, defects of access ports by improper handling);

– electrical HAZARDS (e.g. caused by defective power cords or lack of a POTENTIAL EQUALIZATION CONDUCTOR);

– chemical contaminants in DIALYSIS WATER;

– microbiological contamination of DIALYSIS WATER;

– incorrect administration of drugs if the DIALYSIS MACHINE is used together with infusion pumps through a single PATIENT access:

  - infusion rate higher than intended due to negative pressures in the bloodline exceeding the specification of the infusion pump;
  - infusion rate lower than intended or alarm of the infusion pump due to positive pressures in the bloodline exceeding the specification of the infusion pump;
  - bolus infusion due to stopped blood pump and ongoing delivery of the infusion pump;
  - air infusion via the arterial PATIENT bloodline from remaining air in the infusion pump due to stopped blood pump and bypassing the venous air separation chamber and air detector.
  - External infusion or syringe pumps used with the DIALYSIS MACHINE for infusion into the EXTRACORPOREAL CIRCUIT should be validated by the MANUFACTURER for use with the system.