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TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments

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Guideline for safe operation of medical equipment used for haemodialysis treatments

INTERNATIONAL
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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

FOREWORD

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

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

Enquiry draft	Report on voting
62D/976/DTR	62D/1006/RVC

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

The verbal forms used in this guideline are conform to usage described in Annex H of the ISO/IEC Directives, Part 2, 2011.

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

In this guideline the following print types are used:

– Requirements and definitions: roman type;
– Informative material, such as notes, examples and references: smaller type;
– TERMS DEFINED IN THIS GUIDELINE 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 publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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

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 technical report may be an integral part of a quality management system of the ORGANIZATION. The ORGANIZATION should identify the residual risks, 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 technical report describes the technical requirements for use of equipment in HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles should be complied with to ensure safe, permissible and proper application.

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

2 Normative references

None.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography on page 28.

3 Terms and definitions

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

NOTE An index of defined terms is found on page 30.

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 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

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

[SOURCE: IEC 60601-2-16:2012, 201.3.201]

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, 201.3.202, modified – the original note to entry has been replaced.]

3.4
DIALYSER
a device containing a semi-permeable membrane that is used to perform HAEMODIALYSIS, HAEMODIAFILTRATION or HAEMOFILTRATION

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

*** 3.5**
DIALYSIS FLUID
aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS

Note 1 to entry: The term "DIALYSIS FLUID" is used throughout this document to mean the fluid made from DIALYSIS WATER and concentrates which is delivered to the DIALYSER by the DIALYSIS FLUID delivery system. Such phrases as "dialysate", "dialysis solution" or "dialysing fluid" may be used in place of DIALYSIS FLUID.

Note 2 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 3 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]

*** 3.6**
DIALYSIS MACHINE
HAEMODIALYSIS MACHINE
HAEMODIAFILTRATION MACHINE
HAEMOFILTRATION MACHINE
system or combination of units 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 Clause A.6).

Note 2 to entry: The DIALYSIS MACHINE can be supplied with DIALYSIS FLUID from a central DIALYSIS FLUID delivery system (see Clause A.7).

3.7
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 13959 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]

3.8
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.]

*** 3.9**
EXTRACORPOREAL CIRCUIT
blood lines and any integral ACCESSORY thereof

[SOURCE: IEC 60601-2-16:2012, 201.3.207]

3.10
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, 201.3.208]

3.11
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.

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

3.12
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

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

3.13
HAZARD
potential source of harm

[SOURCE: ISO 14971:2007, 2.3]

3.14
HAZARDOUS SITUATION
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005, 3.40]

3.15
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, 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

3.16
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]

3.17
MAINTENANCE
combination of all technical and administrative means, including supervising ones, to keep or restore a unit in working condition

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

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

3.18
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

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

3.19
MODIFICATION
changing constructional or functional features of medical electrical equipment or a medical electrical system in a way not described in its accompanying documents (instructions for use)

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

3.20
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.]

3.21
ORGANIZATION
entity of the persons and/or institutions responsible for the use and MAINTENANCE of systems for extracorporeal renal replacement therapy

EXAMPLES Doctor's office, dialysis center and dialysis clinic.

3.22
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

[SOURCE: IEC 60601-1:2005, 3.76]

3.23
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.

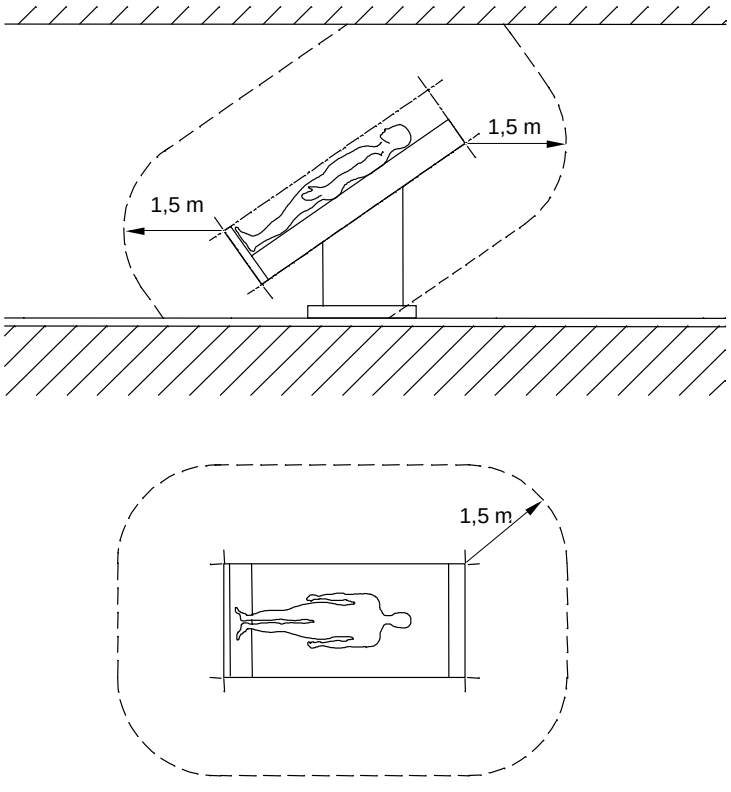

Figure 1 – Example PATIENT ENVIRONMENT

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

*** 3.24**
PATIENT LEAKAGE CURRENT
current coming from an electric device 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.]

3.25
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]

3.26
PROTECTIVE SYSTEM
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDS which can arise

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

3.27
REPAIR
means for reconstitution of a defined condition

[SOURCE: IEC 62353:2007, 3.35]

3.28
SERVICING
combination of all means for maintaining the medical electrical equipment or medical electrical system within requirements of the MANUFACTURER

[SOURCE: IEC 62353, 3.37]

3.29
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

*** 3.30**
TOUCH CURRENT
current not necessary for proper functioning, coming from the ENCLOSURE or parts thereof (except PATIENT connectors), which the OPERATOR or PATIENT may touch while using the 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)

3.31
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT

[SOURCE: IEC 60601-2-16:2012, 201.3.219]

4 Requirements

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 medical devices 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, but also in the procedures that should be followed in the event of an INCIDENT arising from the use of the 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 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 MANUFACTURER.

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

c) Only ORGANIZATIONS who have received training from the MANUFACTURER can develop a training program to train additional personnel within that ORGANIZATION to operate the devices.

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, prescription, effective administration of medications, how to detect, report, and manage dialysis complications both medical and non-medical.

f) If MODIFICATIONS by the MANUFACTURER become necessary, the MANUFACTURER decides to what extent an additional training guided by the MANUFACTURER is necessary.

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

The systems should be operated according 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 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 and medical devices should be 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 functioning at regular intervals according to the MANUFACTURER'S instructions. Failure to complete the automated checks prior to commencement of the dialysis procedure places the PATIENT at risk, and technical advice prior to the commencement of the treatment should be sought.

4.3.2 Infrastructure requirements

4.3.2.1 Technical requirements in rooms

Rooms 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.

Each 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 are used for the vascular access, special measures might be necessary for complying with electrical safety requirements [10, 11, 12, 13]. The MANUFACTURER´S instructions should be followed.

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

In order to prevent the DIALYSIS MACHINE from being contaminated with viruses, bacteria, endotoxins and fungi by retroactive effect from the drain, the device 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.

If conditions are unfavourable, 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.

4.3.2.2 Water treatment and distribution

ISO 23500 should be taken as reference.

4.3.2.3 Concentrate supply

ISO 23500 should be taken as reference.

4.3.2.4 Responsibilities for on-site preparation of fluids

ISO 23500 should be taken as reference.

4.3.2.5 Infection control

Each ORGANIZATION should have in place an infection control plan for the protection of PATIENTS and personnel against infections [1][1].

The infection control plan should include specification of how to manage both sterile supplies and aseptic techniques. In addition the infection control plan describes management of

1 Numbers in square brackets refer to the Bibliography.

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 should include the disinfectant to be used for surface disinfections, the required concentration and the minimum exposure time required by the disinfecting agent.

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].

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" [1].

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.

4.3.2.7 Home HAEMODIALYSIS requirements

If the HAEMODIALYSIS equipment 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 equipment.

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

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 and in IEC 60601-1-11 should also be taken into account.

4.3.2.8 Information technology (IT) management [20]

There is widespread utilization of IT technology in hospitals or provided by third parties, and in many dialysis units the HAEMODIALYSIS 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 series: *Application of risk management for IT-networks incorporating medical devices*;
- ISO/IEC 27001: *Information technology – Security techniques – Information security management systems – Requirements*.

IT risk management should be established from the beginning and subject to continuous review. Technical and organizational security measures 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. The OPERATOR should only use information on DIALYSIS MACHINE displays for its INTENDED USE.

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).

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 be performed (see instructions for use of the DIALYSIS MACHINE).

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

The DIALYSIS MACHINE should be subjected to a functional 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

The concentrates used and the DIALYSIS MACHINE 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 chemical composition, canisters, bags or cartridges that have already been opened should be used up either according to the MANUFACTURER'S instructions or to the ORGANIZATION's standard operating procedures. Residual concentrates in canisters, bags or cartridges should not be mixed.

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 instructions for use:

– check for use of correct EXTRACORPOREAL CIRCUIT and for its correct insertion;
– attach, prime and use the medical devices and ACCESSORIES required for the treatment;
– check all connectors 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 instruction for use:

– connect the DIALYSIS FLUID tubes and check for leakage and flow direction
– rinse and deaerate the DIALYSER completely;

NOTE A procedure deviating from the above description may be applicable to batch 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

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 rate;
– electrolyte settings;
– DIALYSIS FLUID temperature;
– DIALYSIS FLUID flow;
– dosage and infusion rate of anticoagulants, as appropriate;
– substitution volume / substitute rate, as appropriate.

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 should be set instead of the controlled parameters (electrolyte concentration, temperature).

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

NOTE 2 Ultrafiltration here means amount of fluid removed to reach the prescribed 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 should be fixed securely.

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 [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

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 blood flow should not be too high (usually 100 ml/min).
– Air embolism should be prevented by direct observation with special considerations for catheters [8, 9].

NOTE If the VENOUS PRESSURE is negative and there are leaks/disconnections while the access clamp is open, air may 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 instructions should be followed. The following steps should be carried out:

a) Start the treatment and observe the ARTERIAL and VENOUS PRESSURES, 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 and kinks 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 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 result in a life-threatening blood loss to the environment [14, 15, 16]. 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 [17].

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 setting and monitoring of other parameters.

5.3.4 Checks to be repeated during the treatment

Carry out the following checks:

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

d) 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.

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

f) 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 affect the PROTECTIVE SYSTEM.

g) If applicable, check the anticoagulant infusion rate.

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

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

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

k) Document any repeated alarm situations and irregularities.

NOTE 3 Repeated override of alarms may 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 accumulate.

If any abnormalities are detected during the checks, clarify the causes and initiate the appropriate remedying 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 instructions for use. 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 [3].

NOTE 5 Batch DIALYSIS MACHINES and central DIALYSIS FLUID delivery systems may require monitoring of other parameters.

5.3.5 * HAZARDS during the treatment

OPERATORS of HAEMODIALYSIS MACHINES should not rely on medical technical safety standards alone, when performing a treatment. Assessment of HAZARDS requires fundamental knowledge of how to use the system [5, 6, 7].

For example, common HAZARDOUS SITUATIONS include:

– ingress of foreign particles, pathogens, their constituents or metabolic products into the blood pathway (e.g. by improper rinsing or disinfection);
– acute or chronic toxicity (e.g. caused by residual disinfectant in the EXTRACORPOREAL CIRCUIT, migration of plasticisers);
– blood loss (e.g. caused by disconnection in the EXTRACORPOREAL CIRCUIT including the vascular access, bleedings, coagulation in the EXTRACORPOREAL CIRCUIT, puncturing problems, or wrong positioning of puncture cannulae);
– improper 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);
– electrical HAZARDS (e.g. caused by defective power lines or lack of a POTENTIAL EQUALIZATION CONDUCTOR);
– accidental bolus administration of drugs if the DIALYSIS MACHINE is used together with infusion pumps through a single PATIENT access.

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 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.

5.3.7 Terminating the DIALYSIS treatment

Termination of treatment should be accomplished in accordance with the instructions provided by the MANUFACTURER for the DIALYSIS MACHINE. 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.

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 following steps are common for many DIALYSIS MACHINES:

– If blood or fluid is detected that has passed the pressure transducer protector and entered into the DIALYSIS MACHINE, take the DIALYSIS MACHINE out of use until it has been cleaned, disinfected and released by the authorized Technical Service [3].
– 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 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 and in MANUFACTURER'S instructions. Key parameters to be considered are choice of chemicals, 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 devices

7.1 Technical service, SERVICING and checks of equipment and plants

The good working order of equipment and plants 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 equipment or plants should be identified and documented. The Technical Service should be notified.

Medical electrical equipment which is not subject 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 equipment connected thereto, e.g. reverse osmosis systems and concentrate or DIALYSIS FLUID central delivery systems.

Medical electrical equipment failing to function properly should be marked accordingly and not be used until REPAIR following 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, the ISO 23500 should be taken as reference.

7.2 * Equipment safety and device 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 equipment should be secured, taken out of routine use and REPAIRED.

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 equipment immediately.

To avoid unacceptably high TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS when several medical devices 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, the MANUFACTURER's instructions should be followed in order to prevent unacceptable high TOUCH CURRENTS and PATIENT LEAKAGE CURRENTS [10, 11, 12, 13].

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

Proper functioning of electric equipment might be impaired by electromagnetic fields. Wireless communication devices may only be used if they do not affect proper 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 according to the instructions for use by taking the appropriate training measures.

If the ORGANIZATION and/or the OPERATOR, consciously or unconsciously, uses equipment, disposables or systems as standalone units or together with 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 equipment.

If an ORGANIZATION makes any MODIFICATIONS to the machines, systems or procedures without having the MANUFACTURER'S approval, the ORGANIZATION bears the responsibility for the modified product. This applies to the use of device combinations which the MANUFACTURER has not included in the INTENDED USE of the system. This also applies to device combinations (e.g. separate devices for the operation of the EXTRACORPOREAL CIRCUIT and DIALYZER set delivery or separate infusion devices connected to the EXTRACORPOREAL CIRCUIT) for which the MANUFACTURER has not provided information if 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.

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 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 for use and SERVICING instructions, are complied with [5, 6, 7]. 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 identify these risks, 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 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 neither be detected by the water treatment, DIALYSIS WATER, concentrate or DIALYSIS FLUID supply systems 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 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 following requirements 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 concentrate or DIALYSIS FLUID delivery systems, as appropriate, and such a state should be clearly identified (see 4.3.2.2 and 4.3.2.3);

– DIALYSIS WATER quality should be monitored (see 4.3.2.2);

– 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, the MANUFACTURER's instructions or the ORGANIZATION's standards 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.

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 [14, 15, 16, 17]

One of the most frequent accidents during a dialysis treatment is an unnoticed blood loss to the environment, caused by minute leaks, by a slipped-out venous cannula or 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 which, 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. This includes 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 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 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 leak occurs (e.g. a connector which fails to be 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 and the EXTRACORPOREAL CIRCUIT should be checked regularly for leaks both at the beginning of and 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 VENOUS PRESSURE is a result of the blood flowing through the lumen of the cannula. 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, there might occur a high blood loss of, e.g., 300 ml/min. 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 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 [8, 9]

PROTECTIVE SYSTEMS prevent any active infusion of air 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. That is why the central access should be observed and checked with particular care (see 5.3.1) and why it's 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 [10, 11, 12, 13]

Usually, DIALYSIS MACHINES are mains-operated. 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 with different electric potentials are used, excessive TOUCH CURRENTS should be avoided by additionally connecting such devices 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 (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. That is why it should be ensured that the PATIENT cannot touch household appliances and devices 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 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 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 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 through the DIALYSIS FLUID, the blood and the PATIENT, and is then discharged to the ground. This current is called PATIENT LEAKAGE CURRENT and should not exceed a specific value. Usually, this 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 is used, the limits of the maximum PATIENT LEAKAGE CURRENT should be set lower. Such a central venous catheter with atrial location 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 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 which is introduced by the drain line or the central concentrate or 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 and systems connected to the DIALYSIS MACHINE (see 7.1).

A.6 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 as instructed by MANUFACTURER, using the appropriate measuring equipment.

This difference in the production of DIALYSIS FLUID has far-reaching consequences, for example relocation of numerous technical devices, 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.

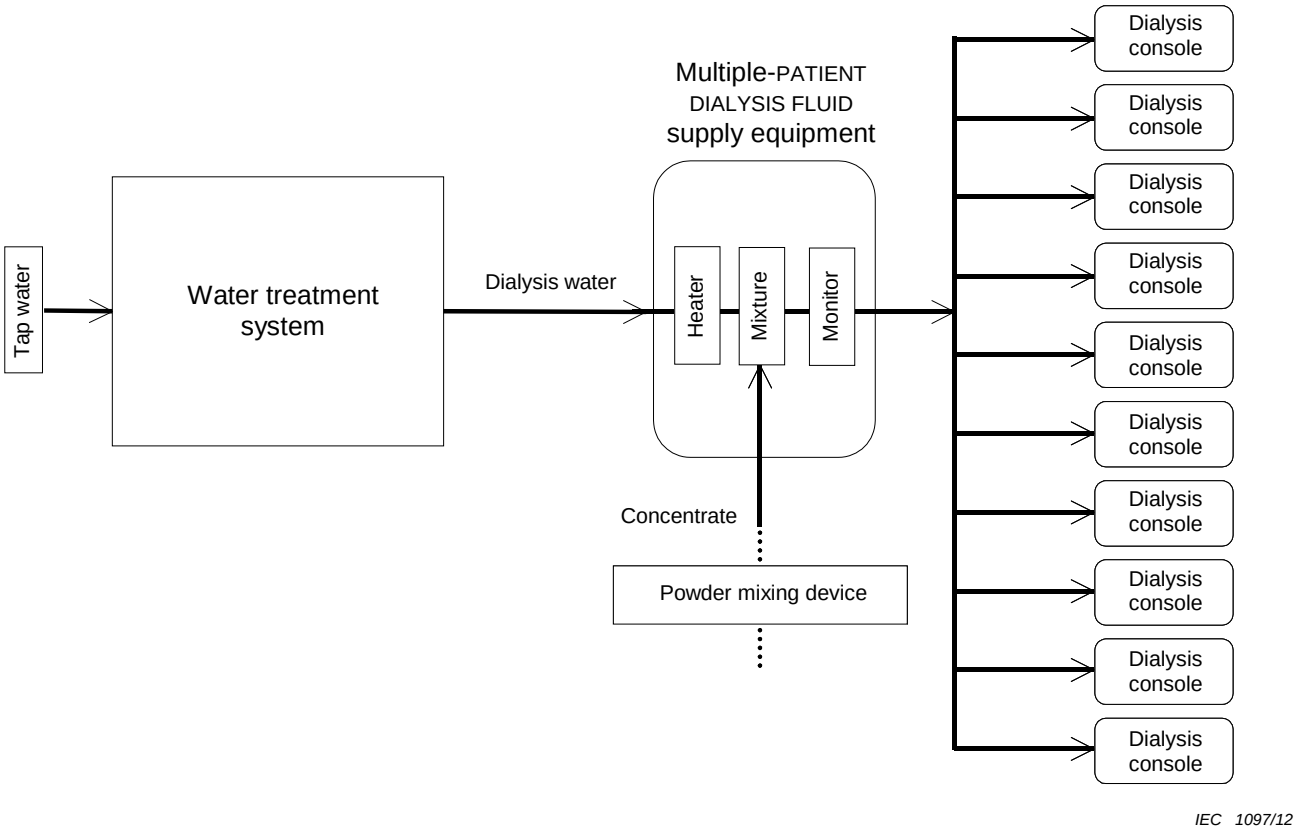

Figure A.1 – Typical central DIALYSIS FLUID delivery system, CDDS

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. 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.

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 [18, 19]. 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 force 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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Index of defined terms used in this guideline

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