



International
Standard

ISO 8637-2

Extracorporeal systems for blood purification —

Part 2:

Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Systèmes extracorporels pour la purification du sang —

Partie 2: Circuits sanguins extracorporels et liquidiens pour les hémodialyseurs, les hémodiafiltres, les hémo-filtres et les hémoconcentrateurs

**Second edition
2024-04**

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 8637-2:2018), which has been technically revised.

The main changes are:

- dimensional details of reference connectors for the testing of blood port connectors have been included together with an illustration of a conical gauge suitable to test the blood connector socket;
- blood and fluid circuits with haemodialysis equipment have been integrated throughout this document;
- the terms and definitions have been aligned with those used in other parts of the ISO 8637 series and IEC 60601-2-16;
- a risk-based approach to structural integrity testing has been introduced;
- haemocompatibility testing has been updated;
- the scope has been widened to include disposable fluid circuits.

A list of all the parts in the ISO 8637 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is concerned with the extracorporeal blood and fluid circuits manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters, haemofilters and haemodialysis equipment. The requirements specified in this document for the extracorporeal blood and fluid circuits will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This document therefore requires only that materials which have been tested and that the methods and results are made available upon request. There is no intention to specify, or to set limits on, the performance characteristics of the devices because such restrictions are unnecessary for the qualified user and would limit the alternatives available when choosing a device for a specific application. This document therefore requires only that materials have been tested and that the methods and results are made available upon request.

The dimensions of the connectors intended for connecting the extracorporeal blood and fluid circuits to a haemodialyser, haemodiafilter or haemofilter have been reviewed to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions selected are intended to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

This document reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use.

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Extracorporeal systems for blood purification —

Part 2:

Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

1 Scope

This document specifies requirements for disposable extracorporeal blood and fluid circuits and accessories used in combination with haemodialysis equipment intended for extracorporeal blood treatment therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration.

This document does not apply to:

- haemodialysers, haemodiafilters or haemofilters;
- plasmafilters;
- haemoperfusion devices;
- vascular access devices.

NOTE 1 Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1.

NOTE 2 Requirements for plasmafilters are specified in ISO 8637-3.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

IEC 60601-2-16:2018, *Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*

3 Terms and definitions

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

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

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

3.1

active medical device

medical device that relies on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of that energy or converting that energy

Note 1 to entry: Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.

3.2

non-active medical device

medical device without an integral power source

EXAMPLE A non-active medical device can be a disposable extracorporeal blood and *fluid circuits* (3.5).

3.3

haemodialysis system

extracorporeal blood and *fluid circuits* (3.5), in combination with its *haemodialysis equipment* (3.6), haemodialysers, haemodiafilters or haemofilters, and other additional accessory

Note 1 to entry: Haemodialysers, haemodiafilters or haemofilters are covered in ISO 8637-1.

3.4

extracorporeal blood circuit

disposable circuit with direct contact to blood or blood components, used to perform *haemodialysis* (3.8), haemodiafiltration and/or *haemofiltration* (3.9)

Note 1 to entry: The extracorporeal blood circuit can also contain accessory tubing for attaching the extracorporeal blood circuit to monitors forming part of the *haemodialysis system* (3.3).

Note 2 to entry: Extracorporeal blood circuits can also be used for other extracorporeal therapies such as plasmfiltration and plasma adsorption.

3.5

fluid circuit

disposable circuit with indirect or no contact to the blood or blood components, used to perform *haemodialysis* (3.8), haemodiafiltration and/or *haemofiltration* (3.9)

Note 1 to entry: Fluid circuits can also be used for other extracorporeal therapies such as plasmfiltration and plasma adsorption.

Note 2 to entry: System components regarding fluid circuit can include *dialysis fluid* (3.23), *dialysis water* (3.21) and concentrates and are covered by the ISO 23500 series.

Note 3 to entry: Dialysis water is defined as 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* (3.24) for online convective therapies (see ISO 23500-1:2019, 3.17).

3.6 haemodialysis equipment

active medical device (3.1) used to perform *haemodialysis* (3.8), haemodiafiltration and/or haemofiltration (3.9)

3.7 manufacturer

natural or legal person responsible for the design, manufacture, packaging or *labelling* (3.27) of the extracorporeal circuit or the *fluid circuit* (3.5), assembling an extracorporeal circuit or a fluid circuit, or adapting an extracorporeal circuit or a fluid circuit, 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 some jurisdictions, the responsible organization can be considered as a manufacturer when involved in the activities described.

3.8 haemodialysis

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* (3.23)

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]

3.9 haemofiltration

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* (3.24) resulting in the required *net fluid removal* (3.25)

Note 1 to entry: Convective transport is achieved by ultrafiltration across a high flux membrane. Fluid balance is maintained by the infusion of a replacement solution into the blood either before the haemofilter (pre-dilution haemofiltration) or after the haemofilter (post-dilution haemofiltration) or a combination of the two (mixed dilution haemofiltration).

Note 2 to entry: In haemofiltration, there is no *dialysis fluid* (3.23) stream.

[SOURCE: IEC 60601-2-16:2018, 201.3.211, modified — Notes 1 and 2 to entry have been added.]

3.10 haemodiafiltration

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 haemodialysis and haemofiltration

Note 1 to entry: Diffusive solute removal is achieved using a *dialysis fluid* (3.23) stream as in *haemodialysis* (3.8). Enhanced convective solute removal is achieved by adding ultrafiltration in excess of that needed to achieve the desired weight loss; fluid balance is maintained by the infusion of a replacement solution into the blood circuit either before (pre-dilution haemodiafiltration) or after (post-dilution haemodiafiltration) or a combination of the two (mixed dilution haemodiafiltration).

[SOURCE: IEC 60601-2-16:2018, 201.3.208], modified — Note 1 to entry has been added.]

3.11

basic safety

freedom from unacceptable risk caused directly by physical hazards when *haemodialysis system* (3.3) is used under normal condition and single fault condition

[SOURCE: IEC 60601-1:2020, 3.10]

3.12

protective measure

constructional feature, specifically designed to protect the patient or user against hazardous situations

3.13

essential performance

performance of a clinical function, other than that related to *basic safety* (3.11), where loss or degradation beyond the limits specified by the *manufacturer* (3.7) results in an unacceptable risk

Note 1 to entry: Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

[SOURCE: IEC 60601-1:2020, 3.27]

3.14

fluid pathway

internal surfaces of the *fluid circuit* (3.5)

3.15

blood pathway

internal surfaces of the blood circuit

3.16

arterial pressure

pressure measured in the blood withdrawal segment or line of the extracorporeal blood circuit between the patient connection and dialyzer connection

Note 1 to entry: The withdrawal segment of the extracorporeal circuit can be referred to as the arterial or blood access side.

Note 2 to entry: Pressure in the segment of the extracorporeal circuit taking the blood from the patient can be further differentiated as the pre-pump pressure, which relates to the extracorporeal circuit before the blood pump, and post-pump pressure, which relates to the segment of the extracorporeal blood circuit between the blood pump and the inlet to the dialyser.

3.17

venous pressure

pressure measured in the blood return segment or line of the extracorporeal blood circuit between the dialyzer connection and patient connection

Note 1 to entry: The return segment of the extracorporeal blood circuit between the dialyser connection and the patient connection can be referred to as the venous or blood return side.

3.18

pump system

portion of the *extracorporeal blood circuit* (3.4) and/or the *fluid circuit* (3.5) that is acted upon by the pumping mechanisms forming part of the *haemodialysis* (3.8) machine

3.19

air capture chamber

drip chamber

bubble trap

venous and arterial blood chamber

component intended to capture air, and which can also provide compliance to the blood circuit or allow pressure to be monitored

Note 1 to entry: Air capture chambers can be equipped with a filter that captures blood thrombi.

3.20

transducer protector

pressure-transmitting sterile barrier

component of the *extracorporeal blood circuit* (3.4) and/or the *fluid circuit* (3.5) that is intended to provide a sterile interconnection between the extracorporeal circuits and *haemodialysis equipment* (3.6) while allowing the pressure within the extracorporeal circuits to be measured by the haemodialysis equipment

3.21

dialysis water

water that has been treated to meet the requirements of ISO 23500-3 and which is suitable for use in *haemodialysis* (3.8) applications, including the preparation of *dialysis fluid* (3.23), reprocessing of dialyzers, preparation of concentrates and preparation of *substitution fluid* (3.24) for online convective therapies

Note 1 to entry: Ultrapure dialysis water is highly purified dialysis water ($<0,1$ CFU/ml and $< 0,03$ EU/ml) that is produced by some integrated validated systems, such as two stage RO systems with endotoxin filters. Other alternative design systems can also produce such water prior to mixing with concentrates to produce ultrapure dialysis fluid.

[SOURCE: ISO 23500-1:2019, 3.17, modified — Note 1 to entry has been deleted.]

3.22

dialysis fluid concentrate

mixture of chemicals and water or chemicals in a highly concentrated media which are mixed with *dialysis water* (3.21) to produce *dialysis fluid* (3.23)

Note 1 to entry: Chemicals can also be in the form of a dry powder.

3.23

dialysis fluid

dialysing fluid

DEPRECATED: dialysate

DEPRECATED: dialysis solution

aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during *haemodialysis* (3.8) or *haemodiafiltration* (3.10)

Note 1 to entry: The term “dialysis fluid” is used throughout this document to mean the fluid [made from *dialysis water* (3.21) and concentrates] which is delivered to the haemodialyser or haemodiafilter by a dialysis fluid delivery system.

Note 2 to entry: The dialysis fluid entering the haemodialyser or haemodiafilter is referred to as “fresh dialysis fluid”, while the fluid leaving the haemodialyser or haemodiafilter is referred to as “spent dialysis fluid”.

Note 3 to entry: Dialysis fluid does not include pre-packaged parenteral fluids used in some renal replacement therapies, such as haemodiafiltration and *haemofiltration* (3.9).

[SOURCE: ISO 23500-1:2019, 3.15, modified — Note 1 to entry has been shortened and Note 2 to entry has been deleted.]

3.24

substitution fluid

fluid used in haemofiltration and haemodiafiltration treatments which is directly infused into the extracorporeal circuit as a replacement for the fluid that is removed from the blood by filtration

[SOURCE: ISO 23500-1:2019, 3.40, modified — the words “patient's blood” and “ultrafiltration” have been respectively replaced by “extracorporeal circuit” and “filtration” in the definition, and Notes 1 and 2 to entry have been deleted.]

3.25

net fluid removal

DEPRECATED: weight loss

fluid loss from the patient

[SOURCE: IEC 60601-2-16:2018, 201.3.212]

3.26

blood leak

movement of blood from the blood compartment to the *dialysis fluid* (3.23) compartment of the dialyzer or movement from the blood compartment to the environment

[SOURCE: IEC 60601-2-16:2018, 201.3.202]

3.27

labelling

written, printed, graphic or electronic matter that is affixed to the extracorporeal blood and/or *fluid circuit* (3.5) packaging and container which is related to identification, technical description and use of the circuit but excluding shipping documents

3.28

rigid material

material with a modulus of elasticity either in flexure or in tension greater than 3 433 MPa e.g. metal, glass, some fibre-reinforced polymers and high-performance polymers

3.29

semi-rigid material

material with a modulus of elasticity either in flexure or in tension between 700 and 3 433 MPa e.g. thermoplastics

4 Requirements

4.1 General

[Clause 4](#) gives the requirements for an extracorporeal circuit.

4.2 Biological safety and haemocompatibility

Parts of the disposable circuit that are intended to come into direct or indirect contact with blood shall be evaluated for freedom from biological hazards in accordance with [5.2](#). Attention is drawn to the need to establish whether national standards governing toxicology and biocompatibility testing exist in the country in which the circuit is produced or to be marketed.

4.3 Sterility

The blood and fluid pathways of the circuit and the internal mating surfaces of all connectors in contact (directly or indirectly) with blood during use shall be sterile. Conformity shall be verified in accordance with [5.3](#). Elements of the blood and fluid circuits can have sections that are never in direct or indirect contact to the blood. Such elements do not require to be sterile.

4.4 Non-pyrogenicity

The blood and fluid pathways of the circuit and the internal mating surfaces of all connectors in contact with blood during use shall be non-pyrogenic. Conformity shall be verified in accordance with [5.4](#).

NOTE 1 Pyrogenicity in this context refers to endotoxin mediated pyrogenicity. Material mediated pyrogenicity is addressed under [4.2](#).

NOTE 2 Elements of the blood and fluid circuits can have sections that are never in direct or indirect contact to the blood. Such elements do not require to be non-pyrogenic.

4.5 Mechanical characteristics

4.5.1 Structural integrity

Structural integrity is the ability to withstand positive and negative pressures inside the device, to prevent blood or fluid loss to the outside, and to prevent air intake. Two approaches to define the ability to withstand positive and negative pressures may be used:

- the device shall be capable of withstanding a maximum positive pressure above atmospheric pressure and a maximum negative sub-atmospheric pressure that can occur at specific points of the device in the haemodialysis system in accordance with the outputs of the manufacturer's risk management process; or
- the device shall be capable of withstanding a positive pressure of 1,5 times the manufacturer's recommended maximum pressure above atmospheric pressure and a negative pressure not exceeding 66,7 kPa (500 mmHg) below atmospheric pressure; if the manufacturer does not derive the tested pressure values from the haemodialysis system with which the circuit is used, the recommended maximum pressure shall be stated for the user in the accompanying documentation.

Conformity shall be verified in accordance with [5.5.1](#).

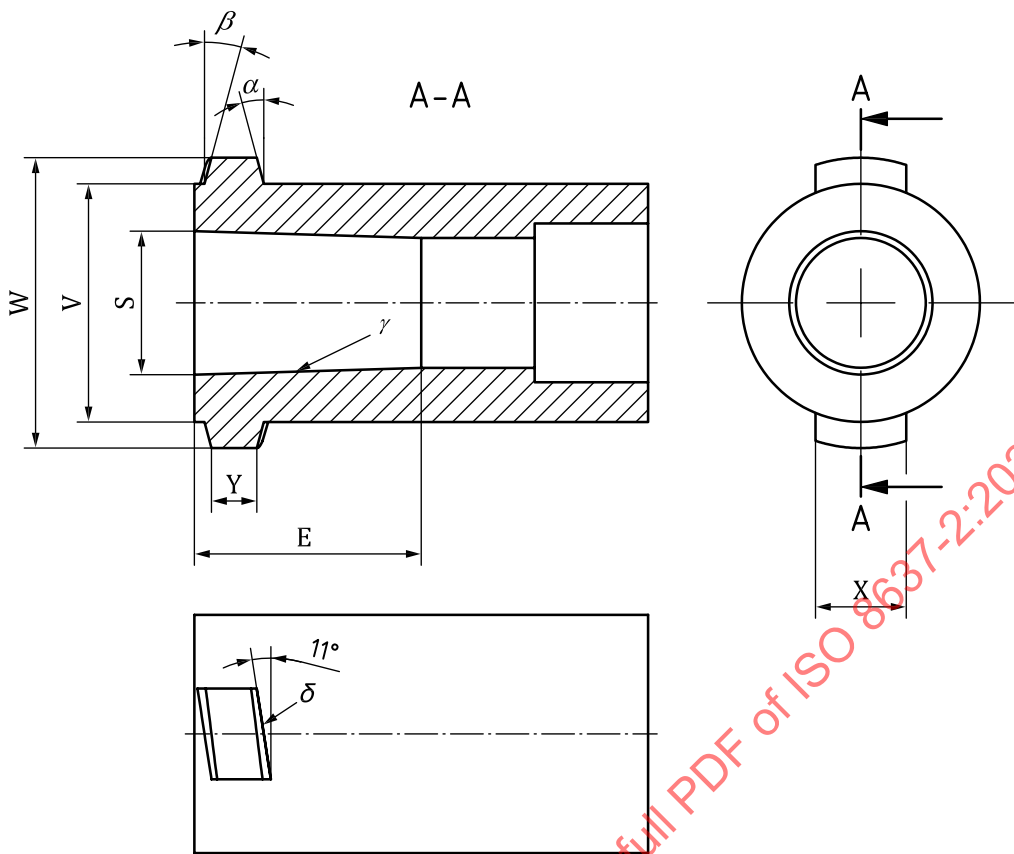
4.5.2 Connectors to haemodialyser, haemodiafilter or haemofilter

4.5.2.1 General

All connectors that connect haemodialysers, haemodiafilters haemofilters or haemoconcentrators shall provide a safe connection. To ensure a safe connection, leakage of air from the outside or loss of blood to the environment shall be avoided. The degree of acceptable leakage rate, minimum separation force, minimum separation torque and maximum connection torque at this position in the haemodialysis system shall be defined in accordance with the outputs of the manufacturer's risk management process. Boundary parameters used in tests such as torques, connection forces and disconnection forces, holding times, and ambient temperatures, shall be considered and defined as part of the manufacturer's assessment on the use of the product. The selected forces and torques used in tests shall be representative of the typical physical conditions of users. If necessary, occupational health and safety guidelines for maximum permissible torques and forces should be taken into account.

4.5.2.2 Dimensional requirements

Except where the haemodialysers, haemodiafilters haemofilters or haemoconcentrators and the extracorporeal blood circuit are designed as an integral system, the dimensions, and tolerances of the connectors to the haemodialysers, haemodiafilters or haemofilter shall conform to the dimensions and tolerances given in [Figure 1](#) and [Table 1](#). Conformity shall be verified in accordance with [5.5.2.2](#).



Key

α	angle of thread	S	cone diameter for socket
β	angle of thread	V	core diameter
γ	dimension taper rate	W	root diameter
δ	thread	X	thread length
E	length of tapered region	Y	thread width

Figure 1 — Main fitting dimensions of blood circuit connector to the blood compartment connector of haemodialysers, haemodiafilters haemofilters or haemoconcentrators

Table 1 — Blood circuit connector dimensions

	α °	β °	γ	δ^a mm	E mm	S^b mm	V^b mm	W mm	X mm	Y mm
Minimum	—	—	—	8,0	10 or more	6,33	—	12,60	—	1,90
Nominal	15	15	6:100			6,33	10,55 or less	12,80	4,00 or more	2,0
Maximum	—	—	—			6,405	—	12,80	—	2,10
Key α angle of thread β angle of thread γ dimension taper rate δ thread E length of tapered region S cone diameter for socket V core diameter W root diameter X thread length Y thread width ^a Double thread pitch. ^b Socket connectors manufactured from soft or semi-rigid materials are not required to fulfil dimensional requirements but are required to comply with functional requirements.										

4.5.2.3 Leakage by pressure decay

Connectors to the haemodialysers, haemodiafilters, haemofilters or haemoconcentrators made of soft or semi-rigid material, shall not exceed a defined leakage rate while being subjected to a defined pressure over a defined holding period using air as the medium. Conformity shall be verified in accordance with [5.5.2.3](#).

4.5.2.4 Sub-atmospheric pressure air leakage

Connectors to the haemodialysers, haemodiafilters, haemofilters or haemoconcentrators made of soft or semi-rigid material, shall be evaluated for sub-atmospheric pressure air leakage. Connectors to the haemodialysers, haemodiafilters, haemofilters or haemoconcentrators shall not leak by more than defined while being subjected to a defined sub-atmospheric pressure over a defined holding period. Conformity shall be verified in accordance with [5.5.2.4](#).

4.5.2.5 Stress cracking

Connectors to the haemodialysers, haemodiafilters, haemofilters or haemoconcentrators made of soft or semi-rigid material, shall be evaluated for stress cracking. Connectors to the haemodialysers, haemodiafilters or haemofilter shall meet the requirements of [4.5.2.2](#) after being subjected to stresses of ISO 80369-20:2015, Annex E. Conformity shall be verified in accordance with [5.5.2.5](#).

4.5.2.6 Resistance to separation from axial load

Connectors to the haemodialysers, haemodiafilters, haemofilters or haemoconcentrators made of soft or semi-rigid material, shall be evaluated for separation from axial load. Connectors to the haemodialysers, haemodiafilters, haemofilters or haemoconcentrators shall not separate from the reference connector over a defined holding period while being subjected to a defined axial disconnection force. Conformity shall be verified in accordance with [5.5.2.6](#).

4.5.2.7 Resistance to separation from unscrewing

Connectors to the haemodialysers, haemodiafilters or haemofilter made of soft or semi-rigid material, shall be evaluated for separation from unscrewing. Connectors to the haemodialysers, haemodiafilters or haemofilter shall not separate from the reference connector for a defined holding period while being subjected to a defined unscrewing torque. Conformity shall be verified in accordance with [5.5.2.7](#).

4.5.2.8 Resistance to overriding

Connectors to the haemodialysers, haemodiafilters haemofilters or haemoconcentrators made of soft or semi-rigid material, connectors shall be evaluated for resistance to overriding. Connectors to the haemodialysers, haemodiafilters or haemofilter shall not override the threads or lugs of the reference connector while being subjected to a defined torque over a defined holding period. Conformity shall be verified in accordance with [5.5.2.8](#).

4.5.3 Connectors to vascular access device

Except where the extracorporeal blood circuit and the vascular access device are an integral system, the dimensions of the connectors intended for connection to vascular access devices shall be a conical type 6 % (Luer) taper lock fitting and meet the performance requirements of ISO 80369-7. Connectors made of semi-rigid materials shall similarly meet the performance requirements of ISO 80369-7. Conformity shall be verified in accordance with [5.5.3](#).

4.5.4 Connectors to ancillary components

All parts of the extracorporeal blood circuit and fluid circuits intended for use with non-integral ancillary components, such as heparin lines, pressure-transducer lines, medication-administration lines and level-adjustment lines, shall terminate in fittings that meet the performance requirements of ISO 80369-7. Conformity shall be verified in accordance with [5.5.4](#).

4.5.5 Colour coding

The patient-connection end and connectors to haemodialysers, haemodiafilters haemofilters or haemoconcentrators of the arterial side shall be colour-coded red, those for the venous side shall be colour-coded blue. The colour coding shall be prominently displayed within 100 mm of the end of the tubing. Conformity with this requirement shall be verified in accordance with [5.5.5](#).

NOTE The arterial side is defined as the segment of the extracorporeal circuit taking the blood from the patient to the haemodialyser. The venous side is defined as the section of the haemodialysis circuit returning the blood to the patient.

Different colours shall be used to identify other parts of the system in accordance with to the outputs of the manufacturer's risk management process

4.5.6 Access ports**4.5.6.1 Needle access ports**

The access ports shall be designed so as to minimize the risk of the needle piercing the tube completely and causing injury to the user.

Needle access ports shall not leak when tested in accordance with [5.5.6.1](#).

4.5.6.2 Needleless access ports

Needleless access ports shall not leak when tested in accordance with [5.5.6.2](#).

4.5.7 Blood pathway volume

The range of the volume contained within the blood pathway volume of the extracorporeal blood circuits shall be specified by the manufacturer.

Conformity with this requirement shall be verified in accordance with [5.5.7](#).

NOTE The blood pathway volume together with the volume contained within the blood pathway of the device to which it is connected to is generally referred to as the circuit priming volume.

4.5.8 Air capture chamber fill level

The recommended fill level of the air capture chamber should be marked on the air capture chamber if that level is required for proper operation of the monitoring system.

Conformity with this requirement shall be verified in accordance with [5.5.8](#).

4.5.9 Transducer protectors

Extracorporeal blood and fluid circuits shall be supplied with integral or non-integral transducer protectors capable of preventing cross-contamination and enabling pressure monitoring, usually the arterial pressure and venous pressure. The transducer protector shall be capable of maintaining a secure and leak-free connection to the haemodialysis equipment via fittings that meet the performance requirements given in ISO 80369-7 when subjected to the operating pressure range as defined in [4.5.1](#). The haemodialysis equipment side of the transducer protector shall be transparent (clear) to allow for visual inspection of blood contamination during use. Conformity with this requirement shall be in accordance with [5.5.9](#).

4.6 Functional characteristics

4.6.1 General

Functional characteristics are haemodialysis system related properties that are typically a result of the combination of the non-active medical device referred to as the device and the active medical device, referred to as the haemodialysis equipment. Therefore, the compliance with the requirements is affected by the system behaviour and can only be determined in the combination of disposable and haemodialysis equipment. As a minimum requirement, all applicable basic safety and essential performance characteristic of the haemodialysis system shall be assessed.

There are two options to state conformance of functional characteristics, either may be used.

- Manufacturer of the disposable equipment confirms the requirements of haemodialysis equipment manufacturer and states conformity of the disposable equipment in the accompanying documentation.
- Manufacturer of the disposable equipment states own essential performance data in the accompanying documentation.

4.6.2 Blood pump system performance

The blood flow rate of the extracorporeal circuit in combination with a specified haemodialysis equipment shall be delivered as specified by the manufacturer.

The specification shall include the pump segment fatigue for the maximum specified usage life of the extracorporeal blood circuit.

Conformity with this requirement shall be verified in accordance with [5.6.2](#).

NOTE 1 A blood flow rate lower than the set value is considered detrimental for a typical treatment. Therefore, the goal of testing is to find the highest negative blood flow rate error.

NOTE 2 Due to the pump segment fatigue it can be reasonable to specify a delivered blood volume (blood flow rate integrated over the treatment time) instead of a blood flow rate.

4.6.3 Dialysis fluid pump performance

If the disposable circuit contains an element that is part of the dialysis fluid delivery, the dialysis fluid flow rate of the fluid circuit in combination with a specified haemodialysis equipment shall be delivered as specified by the manufacturer.

Conformity with this requirement shall be verified in accordance with [5.6.3](#).

NOTE A dialysis fluid flow rate lower than the set value is considered detrimental for a typical treatment.

4.6.4 Net fluid removal

If the extracorporeal circuit contains a fluid circuit that is used in the net fluid removal function of the haemodialysis equipment, the net fluid removal of the fluid circuit in combination with a specified haemodialysis equipment shall be achieved as specified by the manufacturer.

Compliance with this requirement shall be verified in accordance with [5.6.4](#).

4.6.5 Substitution fluid flow rate

If the extracorporeal circuit contains a fluid circuit that is used in the substitution fluid delivery, e.g. when performing haemofiltration or haemodiafiltration, the substitution fluid flow rate of the fluid circuit in combination with a specified haemodialysis equipment shall be specified by the manufacturer. Conformity with this requirement shall be verified in accordance with [5.6.5](#).

NOTE The essential performance requirements for substitution fluid rate are defined in IEC 60601-2-16:2018, 201.4.3.105.

4.6.6 Dialysis fluid composition

If the extracorporeal circuit contains a fluid circuit that is used in the preparation of dialysis fluid from dialysis water and dialysis fluid concentrate, the accuracy of the composition of the dialysis fluid shall be specified by the manufacturer and compliance checked accordingly.

Compliance with this requirement shall be verified in accordance with [5.6.6](#).

4.6.7 Dialysis fluid temperature

If the extracorporeal circuit contains a fluid circuit that is used in dialysis fluid temperature control (essential performance) or temperature monitoring (basic safety), the temperature of the dialysis fluid shall be achieved and monitored as specified by the manufacturer.

Compliance with this requirement shall be verified in accordance with [5.6.7](#).

4.6.8 Substitution fluid temperature

If the extracorporeal circuit contains a fluid circuit that is used in substitution fluid temperature control (essential performance) or temperature monitoring (basic safety), the substitution fluid temperature shall be achieved and monitored as specified by the manufacturer.

Compliance with this requirement shall be verified in accordance with [5.6.8](#).

4.6.9 Fluid path occlusion

The extracorporeal blood and fluid circuits shall be capable of being occlusively clamped by the control and safety line clamps of the haemodialysis equipment with which the extracorporeal and fluid circuits are intended to be used, as indicated in the labelling for the items.

Compliance with this requirement shall be verified in accordance with [5.6.9](#).

4.6.10 Prevention of air infusion

The extracorporeal blood circuit features a disposable element that links the extracorporeal circuit to the haemodialysis systems protective measures to prevent air infusion in accordance with the manufacturer's risk management process. Its functionality shall be as specified by the manufacturer. Compliance shall be verified in accordance with [5.6.10](#).

4.6.11 Pressure monitoring

The extracorporeal blood and fluid circuit features disposable elements that link to the haemodialysis systems protective measures for pressure monitoring and form part of the protective measures for pressure monitoring within the extracorporeal circuit in accordance with the manufacturer's risk management process.

The following characteristics are considered to be part of the haemodialysis system performance:

- accuracy of pressure measurement;
- range of measured pressure;
- response time to pressure change.

Compliance with this requirement shall be verified in accordance with [5.6.11](#).

4.6.12 Blood leak detection

If the disposable circuit contains a fluid circuit that is part of the blood leak detection system of the haemodialysis system, the blood leak detection functionality shall be achieved as specified by the manufacturer.

Compliance with this requirement shall be verified in accordance with [5.6.12](#).

4.7 Expiry date

The biological safety, sterility, performance data and mechanical integrity and functional characteristics of the device shall be proven after storage for a period corresponding to the expiry date. The expiry date can be established with accelerated stability studies or shall be confirmed with real time aging data.

Compliance shall be in accordance with [5.7](#).

5 Test methods

5.1 General

The performance characteristics specified in [Clause 4](#) shall be determined prior to marketing a new type of extracorporeal system and shall be re-evaluated after changes occur in the disposable circuit that can alter its performance.

For the tests, the disposable circuit and the haemodialysis equipment sample size shall be risk based and shall be capable of demonstrating statistical significance of the test results meeting the full range of specifications of the manufacturer.

Configuration of the disposable samples used for the test shall be representative of the final production configuration, including sterilization.

Measurements shall be made in vitro at therapy relevant temperature. When the relationship between variables is nonlinear, sufficient determinations shall be made to permit interpolation between the data points. The techniques of measurement given in this document are reference tests. Other test methods may be used, provided that they are validated and are of comparable precision and reproducibility.

The test systems shown do not indicate all the necessary details of practicable test apparatus. The design and construction of test systems shall also address the many factors contributing to measurement error, including, but not limited to:

- pressure measurement errors due to static head effects and dynamic pressure drops;
- parameter stabilization time;
- uncontrolled temperature variations at non-constant flow rates;
- pH;
- degradation of test substances due to heat, light and time;
- degassing of test fluids;
- trapped air; and
- system contamination by foreign material, algae and bacteria.

NOTE The commonly used therapy relevant temperature is $37\text{ °C} \pm 1\text{ °C}$. Testing at other temperatures is possible with risk management justification.

5.2 Biological safety and haemocompatibility

The biological safety of extracorporeal blood and fluid circuits that are intended to come into direct or indirect contact with the patient's blood shall be evaluated on samples of each new type of device prior to its marketing or after any change in the materials of construction of that type of device or after any change in the method of sterilization. Testing shall be carried out in accordance with ISO 10993-1 and the outputs of the manufacturers risk management process.

The interaction of the blood circuit with the haemodialysis equipment can have significant influence on the haemocompatibility, e.g. coagulation and complement activation. Therefore, in addition to the ISO 10993-1 selection process that focuses on the composition of the material, haemocompatibility of the device in regard to its interaction shall be verified in accordance with ISO 10993-4, using the applicable haemodialysis equipment. This applies to each new type of device prior to its marketing or after any change in the materials of construction, changes of design or after any change in the method of sterilization.

5.3 Sterility

Conformity with 4.3 shall be verified by inspection of the device records that show that the device has been exposed to a sterilization process that has been validated in accordance with ISO 11737-2.

5.4 Non-pyrogenicity

Conformity with 4.4 shall be verified in accordance with ISO 10993-11.

NOTE ISO 10993-11 does not specifically address requirements for endotoxin mediated pyrogenicity test methods but makes reference to ANSI/AAMI ST72^[18].

5.5 Mechanical characteristics

5.5.1 Structural integrity

5.5.1.1 Structural integrity under positive pressure

Conformity with 4.5.1 (positive pressure) shall be determined by either of the following tests.

- a) Fill the device with water. Cap all connections with applicable caps. Subject the device to either the maximum positive pressure that can occur at specific points of the device in the haemodialysis system

in accordance with the outputs of the manufacturers risk management process or a positive pressure of 1,5 times the manufacturer's recommended maximum pressure above atmospheric pressure. Maintain pressure for a minimum of 10 min and inspect for visible signs of leakage.

- b) Cap all ports with applicable caps. Submerge the device in water. Subject the lumen of the device to the maximum positive pressure that can occur in the haemodialysis system in normal operation and single fault condition in accordance with the outputs of the manufacturers risk management process. Maintain pressure for a minimum of 10 min and inspect the device for leakage of air bubbles.

If the intended use includes a supporting structure from the haemodialysis equipment, the device should be tested with the representative supporting structure.

Equivalent or superior tests may be used if available.

5.5.1.2 Structural integrity under negative pressure

Compliance with [4.5.1](#) (negative pressure) shall be determined by either of the following tests.

- a) Cap all ports with applicable caps. Submerge the device in water. Subject the device to the maximum negative pressure that can occur at specific points of the device in the haemodialysis system in accordance with the outputs of the manufacturers risk management process or at least 66,7 kPa (500 mmHg) below atmospheric pressure. Maintain pressure for a minimum of 10 min and inspect the device for visual signs of leakage into the device.
- b) Fill the device with water. Cap all ports with applicable caps. Subject the lumen of the device to the maximum negative pressure that can occur in the haemodialysis system or at least 66,7 kPa (500 mmHg) below atmospheric pressure. Maintain pressure for a minimum of 10 min and inspect the device for leakage of air bubbles into the device.

If the intended use includes a supporting structure from the haemodialysis equipment, the device shall be tested with the representative supporting structure.

Equivalent or superior tests may be used if available.

5.5.2 Connectors to haemodialyser, haemodiafilter or haemofilter

5.5.2.1 General

Connectors shall allow for secure connections.

Test and acceptance criteria shall be used as defined by the manufacturer's risk management process in accordance with [4.5.2.1](#). The methods to be used in respect of inspection and test conditions are specified in ISO 80369-20.

For the required tests a reference connector representing the relevant worst case dimensions of the corresponding conical blood compartment connector of the haemodialyser, haemodiafilter or haemofilter shall be used. The gauge described in [Figures 2 to 5](#) and in [Tables 2 to 4](#) is suitable for determining conformity to the specification for cone diameter, S , and dimensional taper rate, γ .

[Figure 2](#) and [Table 2](#) indicate the overlap of the cone and socket blood inlet and outlet connectors.

[Figure 3](#) and [Table 3](#) indicate the required dimensions and the tolerances of the gauge.

[Figure 4](#) illustrates a conical reference connector for measuring the connecting socket.

[Figure 5](#) illustrates a socket engaged with the gauge meeting the specifications for cone diameter and taper rate of [Table 1](#) whereby the tip of the cone is within the acceptance window 'a'.

Tests for resistance to separation from an axial load are defined in ISO 80369-20. Locking connections shall demonstrate compliance with [4.5.3](#) or by applying the appropriate test method. Non-locking connections shall not separate under an axial force of 23 N to 25 N.

Connectors made of soft materials can be tested according to the manufacturer's specified test method in place of the ISO 80369-20 test method.

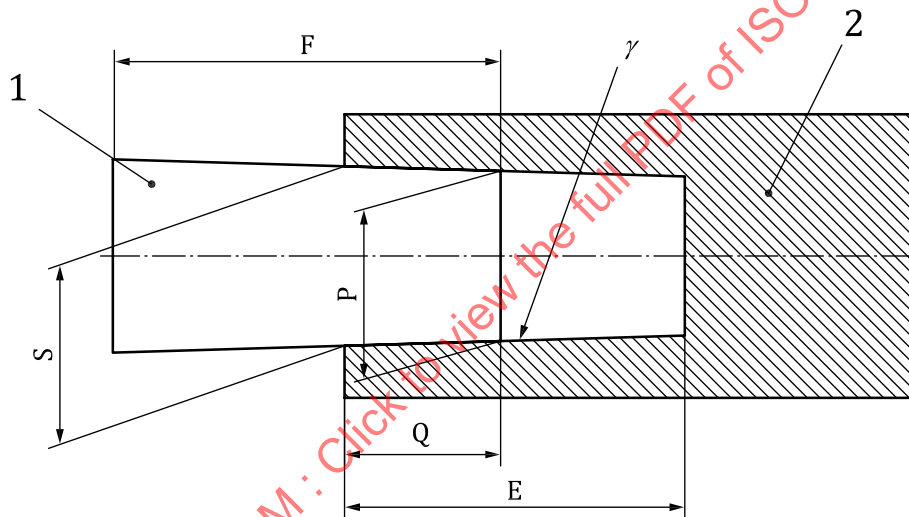
Dimensional conformance shall be determined using any one or combination of the following:

- digital contact measurement instruments,
- optical measurement,
- three-dimensional X-ray imaging,
- analogue gauges, or
- another validated method.

Dimensional assessment may involve destructive methods to gain access to features for measurement.

5.5.2.2 Dimensional requirements

Conformity to 4.5.2.2 shall be determined by inspection, using gauges as described in Figures 2 to 5 and Tables 2 to 5.



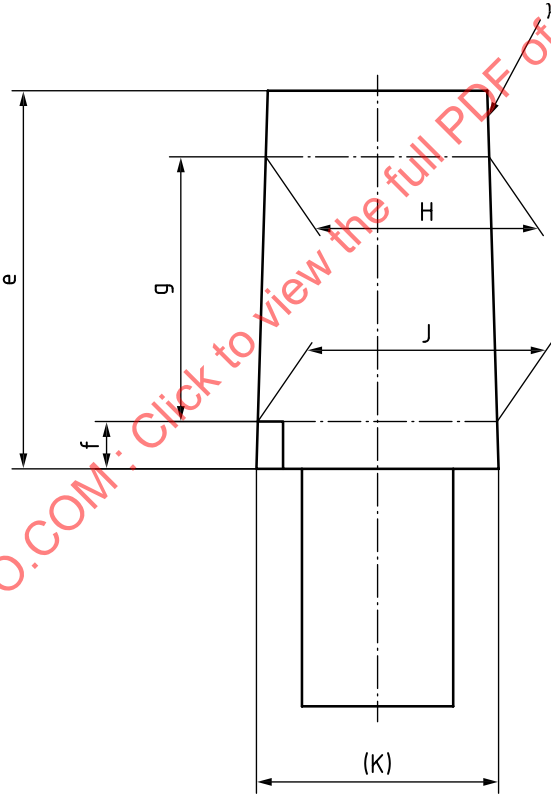
Key

1	outer cone	F	length of taper
2	inner cone	P	cone diameter
γ	dimension taper rate	Q	overlap
E	length of taper inner cone	S	socket diameter

Figure 2 — Illustration of the overlap of the cone connector with the blood inlet and outlet socket connectors

Table 2 — Cone connector dimensions

	<i>E</i> mm	<i>F</i> mm	<i>P</i> mm	<i>Q</i> ^a mm	<i>S</i> ^b mm	<i>γ</i>
Minimum	10 or more	9 or more	5,97	5,0 or more	6,33	6:100
Nominal			6,0	—	6,33	
Maximum			6,03	7,26 or less	6,405	
Key <i>E</i> length of taper inner cone <i>F</i> length of taper <i>P</i> cone diameter <i>Q</i> overlap <i>S</i> socket diameter <i>γ</i> dimension taper rate ^a Based on values for <i>P</i> . ^b Socket connectors manufactured from soft or semi-rigid materials are not required to fulfil dimensional requirements but are required to comply with functional requirements.						

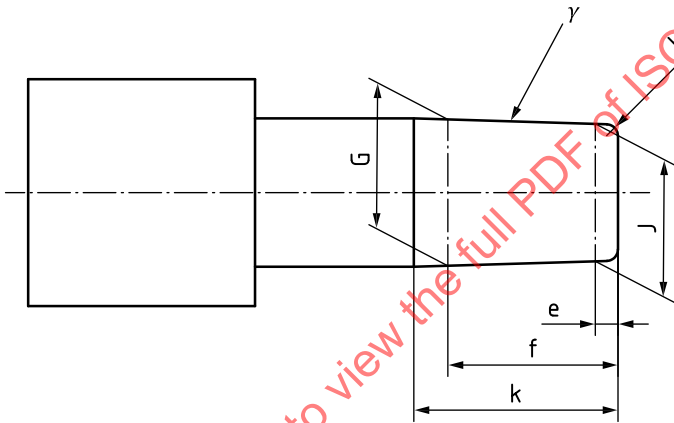


Key	
<i>e</i>	minimal length of gauge
<i>f</i>	testing dimension length range
<i>g</i>	reference dimension length
<i>H</i>	taper cone
<i>J</i>	taper cone
<i>K</i>	taper cone
γ	dimension taper rate

Figure 3 — Conical reference connector for testing the blood socket connector

Table 3 — Conical reference connector dimensions

	e mm	f mm	g mm	H mm	J mm	K mm	γ
Minimum	10	1,24	—	5,905	6,325	6,405	6:100
Nominal	—	1,25	7	5,910	6,330		
Maximum	—	1,25	—	5,910	6,330		
Key e minimal length of gauge f testing dimension length range g reference dimension length H taper cone J taper cone K taper cone γ dimension taper rate							

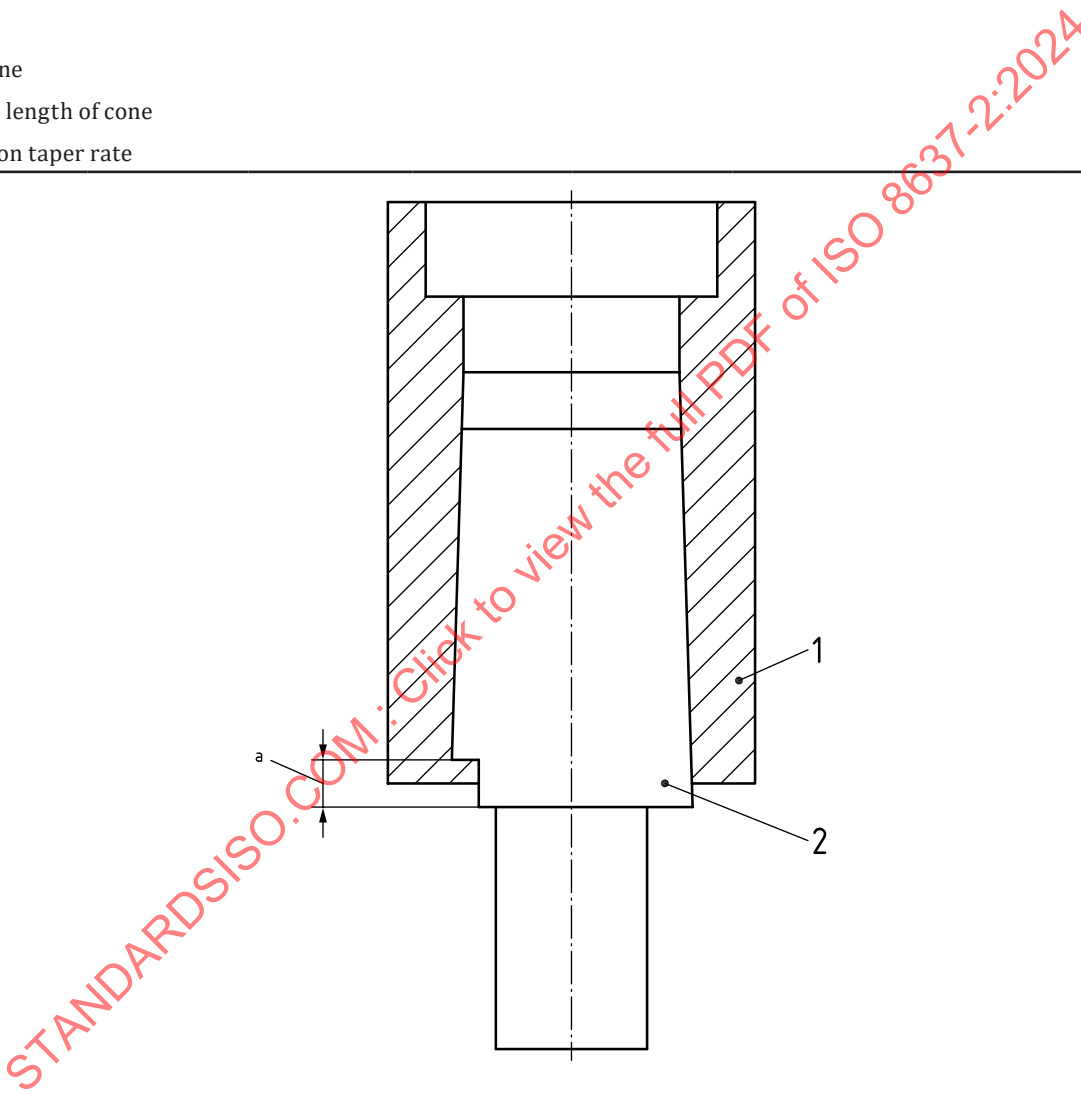


Key			
<i>e</i>	minimal length of gauge	<i>J</i>	taper cone
<i>f</i>	testing dimension length range	<i>k</i>	taper cone
<i>g</i>	reference dimension length	γ	dimension taper rate
<i>H</i>	taper cone		

Figure 4 — Cone reference connector for testing the blood socket connector

Table 4 — Cone reference connector dimensions

	e mm	f mm	G mm	H mm	J mm	k mm	γ
Minimum	—	—	6,444	—	6,054	9	6:100
Nominal	1	7	6,449	—	6,059	—	
Maximum	—	—	6,449	0,5	6,059	—	
Key e reference dimension length f reference dimension length G taper cone H radius J taper cone k minimal length of cone γ dimension taper rate							



- Key**
- 1 conical socket
 - 2 conical gauge
 - a Testing dimension range (see F of [Figure 2](#)).

Figure 5 — Illustration of the conical gauge for testing the blood socket connector

5.5.2.3 Leakage by pressure decay

Conformity shall be established by applying the tests of ISO 80369-20:2015, Annex B, using an appropriate reference connector.

5.5.2.4 Sub-atmospheric pressure air leakage

Conformity shall be established by applying the tests of ISO 80369-20:2015, Annex D, using an appropriate reference connector.

5.5.2.5 Stress cracking

Conformity shall be established by applying the tests of ISO 80369-20:2015, Annex E, using an appropriate reference connector.

5.5.2.6 Resistance to separation from axial load

Conformity shall be established by applying the tests of ISO 80369-20:2015, Annex F, using an appropriate reference connector.

5.5.2.7 Resistance to separation from unscrewing

Conformity shall be established by applying the tests of ISO 80369-20:2015, Annex G, using an appropriate reference connector.

5.5.2.8 Resistance to overriding

Conformity shall be established by applying the tests of ISO 80369-20:2015, Annex H, using an appropriate reference connector.

5.5.3 Connectors to vascular access device

Compliance with 4.5.3 shall be determined by inspection in accordance with ISO 80369-7, which specifies dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections with such devices, e.g. cannulae with cone and socket Luer slip connectors and Luer lock connectors.

Dimensional conformance shall be determined using any one or combination of the following:

- digital contact measurement instruments,
- optical measurement,
- three-dimensional X-ray imaging,
- analogue gauges, or
- another validated method.

Dimensional assessment may involve destructive methods to gain access to features for measurement.

5.5.4 Connectors to ancillary components

Compliance with 4.5.4 shall be determined by inspection in accordance with ISO 80369-7, which specifies dimensions and requirements for the design and functional performance of small-bore connectors intended to be used for connections with such components, e.g. hypodermic syringes with cone and socket Luer slip or lock connectors.

5.5.5 Colour coding

Compliance with 4.5.5 shall be determined by inspection.

5.5.6 Access ports

5.5.6.1 Needle access ports

Compliance with [4.5.6.1](#) shall be determined by the following procedure.

Fill the portion of the device that contains the access port with water at therapy relevant temperature range and subject the device to the maximum positive pressure that can occur in the haemodialysis system at the position of the port. Puncture the access port with a hypodermic needle, as stated by the manufacturer or, if no details are given, of outside diameter 0,8 mm (21 gauge) and in accordance with ISO 7864. Insert and withdraw the needle five times through the access port. Maintain the pressure for 6 h and visually inspect the access port for the emergence of water.

Using the same circuit, completely fill the device with degassed water at therapy relevant temperature range. Seal all ports except the port to which pressure is applied. Subject the device to the maximum sub-atmospheric pressure that can occur in the haemodialysis system unless that sub-atmospheric pressure exceeds 66,7 kPa (500 mmHg) or is not specified; in that case, apply a sub-atmospheric pressure of 66,7 kPa (500 mmHg) and seal the apparatus. Access the port in accordance with the manufacturer's instructions. Access the port an additional 10 times over a 10 min period. Maintain the pressure for 6 h and visually inspect the access port for the leakage of air into the device. The water may be circulated through the device.

5.5.6.2 Needleless access ports

Compliance with [4.5.6.2](#) shall be determined by the following procedure.

Fill the portion of the extracorporeal blood circuit that contains the access port with water at therapy relevant temperature range and subject the device to the maximum positive pressure that can occur in the haemodialysis system at the position of the port. Access the port in accordance with the manufacturer's instructions. Access the port an additional 10 times over a 10 min period. Maintain the pressure for 6 h and visually inspect the access port for the emergence of water.

Using the same circuit, completely fill the device with degassed water at therapy relevant temperature range. Seal all ports except the port to which pressure is applied. Subject the device to the maximum sub-atmospheric pressure that can occur in the haemodialysis system unless that sub-atmospheric pressure exceeds 66,7 kPa (500 mmHg) or is not specified; in that case, apply a sub-atmospheric pressure of 66,7 kPa (500 mmHg) and seal the apparatus. Access the port in accordance with the manufacturer's instructions. Access the port an additional 10 times over a 10 min period. Maintain the pressure for 6 h and visually inspect the access port for the leakage of air into the device. The water may be circulated through the device.

5.5.7 Blood pathway volume

Compliance with the [4.5.7](#) shall be verified by filling the blood pathway of the device with water and measuring the volume of the water needed to fill this pathway. The air capture chambers shall be filled to their normal operating level.

A calculation of the blood pathway volume using information from the product drawing or computer aided design (CAD) file is also valid.

5.5.8 Air capture chamber fill level

Compliance with [4.5.8](#) shall be verified by visual inspection of the existence of a marking giving the normal operating level.

5.5.9 Transducer protectors

Compliance with [4.5.9](#) shall be verified by testing the ability to withstand the maximum positive pressure that can occur at the position of the transducer protector in the haemodialysis system during normal operation and single fault condition in accordance with the outputs of the manufacturers risk management process.