



BSI Standards Publication

Implants for surgery — Active implantable medical devices

Part 5: Circulatory support devices

National foreword

This British Standard is the UK implementation of EN ISO 14708-5:2022. It is identical to ISO 14708-5:2020.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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Implants chirurgicaux - Dispositifs médicaux
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d'assistance circulatoire (ISO 14708-5:2020)

Chirurgische Implantate - Aktive
implantierbare medizinische Geräte
- Teil 5: Besondere Anforderungen an
Kreislaufunterstützungssysteme (ISO 14708-5:2020)

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European foreword

This document (EN ISO 14708-5:2022) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN-CENELEC/ JTC 16 "Active Implantable Medical Devices" the secretariat of which is held by DKE.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN-CENELEC shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 14708-5:2020 has been approved by CEN-CENELEC as EN ISO 14708-5:2022 without any modification.

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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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-5:2010), which has been technically revised. The main change compared to the previous edition is as follows:

— alignment to the revised ISO 14708-1:2014.

A list of all parts in the ISO 14708 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 specifies requirements for safety and performance of active implantable circulatory support devices. It amends and supplements ISO 14708-1:2014, hereinafter referred to as ISO 14708-1. The requirements of this document take priority over those of ISO 14708-1.

Heart failure is a major public health problem. It is estimated that worldwide more than 5 million people die per year due to heart failure. In addition, it accounts for a large portion of health care expenditure and rehospitalisation (see Reference [35]). Circulatory support devices are needed for promoting myocardial recovery following acute heart failure as well as long-term support until eventual transplantation or permanent therapy. Circulatory support devices may be fully implanted, partially implanted, or delivered by percutaneous approach. The growth of heart failure is expected to increase with the aging population (see Reference [30]).

The requirements of this document supplement or modify those of ISO 14708-1.

In this document, terms printed in italics are used as defined in [Clause 3](#). Where a defined term is used as a qualifier in another term, it is not printed in italics unless the concept thus qualified is also defined.

Information is also provided in [Annex A](#) that explains the relationship between [ISO/TR 14283](#), ISO 14708-1 and this document.

Notes on this document are provided in [Annex B](#) for information.

[Annex C](#) provides guidance on pre-clinical in vitro and in silico evaluation. [Annex D](#) provides information device hazards, associated failure modes, and evaluation methods. All annexes are informative.

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Implants for surgery — Active implantable medical devices —

Part 5: Circulatory support devices

1 Scope

This document specifies requirements for safety and performance of active implantable circulatory support devices, including type tests, animal studies and clinical evaluation requirements.

NOTE The device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify main requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

The tests that are specified in this document are type tests and are to be carried out on a sample of a device to assess device behavioural responses and are not intended to be used for the routine testing of manufactured products.

Included in the scope of this document are:

- ventricular assist devices (VAD), left or right heart support;
- total artificial hearts (TAH);
- biventricular assist devices (biVAD);
- percutaneous assist devices;
- paediatric assist devices.

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 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

[IEC 60068-1:2013](#), *Environmental testing — Part 1: General and guidance*

[IEC 60068-2-27:2008](#), *Environmental testing — Part 2-27: Tests — Test Ea and guidance: shock*

[IEC 60068-2-31:2008](#), *Environmental testing — Part 2-31: Tests — Test Ec: rough handling shocks, primarily for equipment-type specimens*

[IEC 60068-2-64:2008](#), *Environmental testing — Part 2-64: Tests — Test Fh: vibration, broadband random and guidance*

IEC 60601-1:2018, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

[IEC 60601-1-6:2010](#), *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

[IEC 60601-1-10:2007](#), *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

[IEC 62304:2006](#), *Medical device software — Software life cycle processes*

[IEC 62366-1:2015](#), *Medical devices — Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and [ISO 14971](#) and the following apply.

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

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

3.1 accessory device

separate part of a circulatory support system that is not essential to the primary function of the circulatory support system

Note 1 to entry: Examples are programming units, monitoring units and alternative *power source* ([3.18](#)) units.

3.2 artificial valve prosthetic valve

component of the circulatory support system that directs the unidirectional flow of the blood into and out of the pump

3.3 atrial cuff

connector between the right or left atrial ring after resection of the natural ventricle and the inlet of the right or left blood pump in *total artificial heart* ([3.31](#)) replacement

3.4 biVAD biventricular assist device

configuration in which two VADs are used to support both ventricles respectively

3.5 cavitation

sudden formation and collapse of low-pressure bubbles in the blood by means of mechanical forces

3.6

circulatory support device

electromechanical device that is used to partially or completely replace the left and/or right ventricular function of a failing heart

3.7

conduit

component of the circulatory support system that connects the pump to the patient's circulation

3.8

controller

component of the circulatory support system that contains the logic, circuitry and/or software to control the driving mechanism that enables the system to perform its primary function

3.9

diastolic pressure

arithmetic average of minimum pressures in a pulsatile pressure waveform over a sufficient number of cycles to filter out cyclic variation

3.10

display

component of the circulatory support system that allows data pertaining to the operation of the system to be observed

3.11

driveline

tube and/or cable that connects a driver or energy source to the pump

EXAMPLE The tube that connects a pneumatic console to a pneumatically driven pump.

3.12

durability

ability of an item to perform a required function under given conditions of use and maintenance, until a limiting state is reached

Note 1 to entry: A limiting state of an item should be characterized by the end of the useful life, unsuitability for any economic or technological reasons, or other relevant factors.

3.13

DUT

device under test

3.14

ejection/fill

E/F

ratio between the ejection time period and the filling time period of the blood pump cycle

Note 1 to entry: E/F is identical to S/D (systolic/diastolic) when related to the natural heart.

3.15

failure

termination of the ability of an item to perform a required function

Note 1 to entry: After failure, the item has a *fault* ([3.16](#)).

Note 2 to entry: "Failure" is an event, as distinguished from "fault", which is a state.

Note 3 to entry: This concept as defined does not apply to items consisting of software only.

3.16

fault

state of an item characterized by inability to perform a required function, excluding the inability during preventive maintenance or other planned actions, or due to lack of external resources

Note 1 to entry: A fault is often the result of a *failure* (3.15) of the item itself but might exist without prior *failure*.

3.17

labelling

marking

any written, printed, electronic information, or graphical matter affixed to a medical device or any of its containers or wrappers, or accompanying the medical device related to identification, technical description and use, but excluding shipping documents

3.18

power source

source of energy (battery, mains)

3.19

pulsatile flow

characteristic of the output of a pump where the flow is time dependent

3.20

pulse pressure

difference between the systolic and *diastolic pressure* (3.9) readings

Note 1 to entry: It represents the force that the heart generates each time it contracts.

3.21

pump output

performance measure for a circulatory support system indicating the volume of blood pumped into the host circulatory system per minute

Note 1 to entry: The pump output is expressed in litres per minute or its equivalent in other units.

3.22

volume displacement

pump displacement

pump that imparts its pumping action by changing the volume of the pumping chamber

EXAMPLE By displacement of a diaphragm or pusher plate.

3.23

reliability

probability that an item can perform a required function under given conditions for a given time interval (t_1 , t_2) for a specified confidence level

Note 1 to entry: It is generally assumed that the item is in a state to perform this required function at the beginning of the time interval.

Note 2 to entry: The term "reliability" is also used to denote the reliability performance quantified by this probability[1].

3.24

rotary pump

pump that imparts its pumping action directly on the blood by a rotating mechanism

3.25

safe and effective

reasonable assurance that a device will not induce harm to the recipient and that it will provide clinical benefit for the recipient for its conditions of use

3.26

safety

freedom from unacceptable risk

Note 1 to entry: See ISO/IEC Guide 51.

3.27

sales packaging

packaging that protects and identifies the device during storage and handling by the purchaser

Note 1 to entry: The sales packaging should be enclosed in further packaging, for example a “shipping package”, for delivery.

3.28

service life

period after implantation when the circulatory support system remains within stated specifications and characteristics

Note 1 to entry: The service life of the components of the system can vary (implanted components might have longer lifetimes versus the peripheral components which are replaceable).

3.29

stroke volume

amount of blood pumped by the ventricle of the heart in one contraction

3.30

transcutaneous energy transmission system

TETS

system used to send electrical energy wirelessly into a device implanted inside the body

3.31

total artificial heart

TAH

circulatory support system that replaces the pumping function of a patient's native heart

3.32

ventricular assist device

VAD

circulatory support system that augments the function of either one or both ventricles of the patient's native heart by capturing blood from the atrium(a) or ventricle(s) and providing work to pump blood into the pulmonary and/or systemic circulation

4 Symbols and abbreviations

The text in ISO 14708-1:2014, Clause 4 applies.

5 General requirements for active implantable medical devices

5.1 General requirements for non-implantable parts

The text in ISO 14708-1:2014, 5.1 applies.

5.2 General requirements for software

The text in ISO 14708-1:2014, 5.2 applies.

5.3 Usability of non-implantable parts

The text in ISO 14708-1:2014, 5.3 applies.

5.4 Data security and protection from harm caused by unauthorized information tampering

The text in ISO 14708-1:2014, 5.4 applies.

5.5 General requirements for risk management

The text in ISO 14708-1:2014, 5.5 applies.

5.6 Misconnection of parts of the active implantable medical device

The text in ISO 14708-1:2014, 5.6 applies.

5.7 Wireless coexistence and wireless quality of service

When communication with any part of an active implantable medical device is provided through wireless communication channels, the manufacturer shall evaluate wireless coexistence and wireless quality of service through the risk management process and apply the appropriate risk control measures to protect the patient from harm (see [27.6](#)).

Testing of wireless communication channels, for EMC, is performed in accordance with IEC 60601-1-2:2014.

Compliance is checked by the inspection of the risk management file.

6 Requirements for particular active implantable medical devices

6.1 Intended clinical use/indications

The intended use and indications for the device system shall be described. The intended use describes what the device system does (e.g. provides circulatory support), where it may be used safely (e.g. hospital, home, ground and/or air transport vehicles), and the intended duration of use. The indications are the disease(s) or condition(s) the device will diagnose, treat, prevent, cure, or mitigate and a description of the target population for which the device is intended without causing unreasonable risk of illness or injury associated with use of the device.

Compliance is checked by the inspection of the manufacturer's documentation.

6.2 System description

6.2.1 General

A comprehensive description of the system shall be documented, including discussions on the principles of operation, rationale for key design choices, system configurations, system components, and system performance and operating limits.

Compliance is checked by the inspection of the manufacturer's documentation.

The rationale for key design choices, for example:

- approaches taken to minimize blood component damage;
- methods for thermal management;
- choice of drive mechanisms;
- power management scheme;
- choice of connectors to prevent misuse;

- reliability considerations;
- adequacy of anatomic fit;
- electromagnetic compatibility (EMC)/ interference;
- driveline damage resistance;
- exposure to environmental conditions;
- human factors.

Design specifications for the complete system include the full range of system operating limits for each parameter, for example:

- beat rates;
- E/F ratio;
- rotation speeds;
- power consumption;
- flow rate as a function of pressure head (with varying pump rotational speed or beat rate).

Required system components, for example:

- hydrodynamic bearings;
- magnetic bearings.

System operational modes, for example:

- manual;
- automatic.

System component configurations, for example:

- hospital;
- home;
- power sources;
- optional display;
- optional subsystems;
- optional console.

Alarm thresholds, and all associated tolerances on each of these parameters.

Principle(s) of operation, for example:

- blood pumping mechanism;
- connections to the cardiovascular system;
- power system;
- control mechanisms.

6.2.2 System configuration

A detailed physical description of the system shall be given including implantation sites of various implantable components, external wearable units, and external consoles. Size, shape, weight, and volume of the components should be given, as well as the different configurations of system components that can be used to provide support.

Compliance is checked by the inspection of the manufacturer's documentation.

6.2.3 System performance and operating limits

The entire performance range of the system shall be given, even if some operating conditions are not expected to be used clinically or might cause the system to malfunction. The verified *service life* of all components shall also be documented.

Compliance is checked by the inspection of the manufacturer's documentation.

6.3 Design analysis

6.3.1 General

A comprehensive analysis shall be performed for the integrated system, the various component configurations, as well as for each system component for all safety and effectiveness issues, such as tolerance stack-up analysis, and structural analysis. Every software product should possess an adequate level of functional safety and reliability through analysis, design, implementation, system testing, quality assurance, and maintenance of the software product, all of which shall be documented and controlled. Guidance for software design and validation can be found in [IEC 62304:2006](#). The software verification and validation should not only meet requirements for the software integrity itself but should also demonstrate the software is capable of proper operation of the system according to its specifications.

6.3.2 Human factors analysis

6.3.2.1 General

Human factors analysis shall be performed for the device system, the labelling and instructions that are provided, and any training provided to mitigate the risk of harm to the patient by human error. Early stage models or prototypes should be evaluated with representative intended users during formative testing. The intended users of a circulatory support system may be divided into three categories: patients and caregivers, clinicians, and surgeons. Each user group may interact with the system in different use scenarios. Special design considerations and evaluation methods for each user group are outlined in the subclauses below.

6.3.2.2 Patients and caregivers

Patient/caregiver user scenarios are the most important types to consider as they are the ones most affected by any harms caused by human error. Patients and caregivers most commonly interact with the device system peripherals so any human factors formative studies involving all external components provided to a patient should be focused on this user group.

Alarm conditions should be simple and easily discernible so that the patient/caregiver takes the appropriate action upon noticing the alarm. Alarm type redundancy shall be considered for users with disabilities (e.g. visual, audible, and vibratory). All alarms should be distinct and easy for the patient/caregiver to comprehend. Formative studies should be conducted to demonstrate this comprehension and ability to respond with the appropriate action.

The need for patients and caregivers to connect and disconnect peripheral components, such as power sources or data cables, should be minimized as much as possible. Multiple types of connections should

be designed with separate connection configurations so that it is impossible for the patient/caregiver to make an incorrect connection. Also, all connections should be visually and/or tactilely distinct. If there is a need for repeated use in such instances as replacing a battery, use cases should be established that describe the connection interface, the number of expected cycles under normal daily use, and any locking mechanisms involved. All connector/receptacle sets should be designed such that they prevent accidental disconnection. The design may contain keyways that guide connector alignment before the electrical connection is made to prevent inadvertent damage to the pins and are made from durable materials that can withstand repeated use. As with alarms, the formative use studies should be designed to determine if the patient/caregiver subjects can perform these connections appropriately without error or inadvertently damaging connectors. Attention should be paid to training methods for cleaning exit sites during patient training sessions to also minimize infection.

These studies may be conducted with simulated and/or prototype peripherals. Simulated peripherals should have the same connection interfaces and weight as the final product configuration if the design is not complete yet. Any labelling and/or training material that is provided to the patient/caregiver should be written at an 8th grade reading level and use studies conducted to demonstrate comprehension of the instructions provided.

6.3.2.3 Clinicians

The use case considerations for clinicians (e.g. nurses, clinical engineers, first responders) should include performing the same activities as patients or caregivers as well as providing emergency response care (such as CPR) without causing harm to the patient and/or device. If the clinicians are at the hospital, they will typically utilize an external device to connect to the device controller to monitor performance, download log files, and configure device operational parameters. The usability studies for these devices are mostly focused on the controls and presentation of the information provided. If a touch screen is used, the icons, layout, and text size should be designed so that they are easily readable. Early formative studies may be conducted where the screen layouts are presented, and the subjects are studied to observe how well they interface with them.

6.3.2.4 Surgeons/interventional cardiologist

The design of the circulatory support system should take into consideration the commonly used surgical approach, technique, and surgical tools. Implant tools should be optimized for the surgical approach including intrathoracic or percutaneous. Special instructions, warnings, and training should be provided to prevent damage to the device by commonly used surgical tools, such as scalpels, cautery tools, and robotic-assist surgical systems. Formative usability studies for the implant procedure should take place in a simulated operating room or cardiac catheterization suite with either a mock patient, cadaver, or animal model and should consist of evaluations for how well the tools are used based on the instructions and training provided.

These human factors studies should be used to provide input to the design team so that the device system can be modified to reduce or eliminate use error. These modifications can take the form of physical design, software updates, labelling, training materials, user instructions, and/or packaging. The risk management file should be updated based on the results of these studies.

6.4 Risk analysis

Risk analysis, part of the risk management process, shall be performed on the system. The risk analysis should include a top-down analysis (such as a hazard analysis or fault tree analysis, FTA), a bottom up analysis (such as failure mode, effects, and criticality analysis – FMECA), as well as an analysis for potential use or user error (human factors analysis). The risk analysis should utilize a method to classify the severity of failure modes, the probability of occurrence, the risk priority number, and the detection method. The analysis should include discussion of methods used to mitigate the criticality of the failure modes and linkage to testing performed to demonstrate device safety. The hazards table in [Annex D](#) may be used as a guide for conducting this risk analysis.

NOTE For further information on risk analysis, see ISO 14971:2019.

6.5 Human factors

Human factors evaluation shall consist of both integrated system testing and subsystem testing. This evaluation shall satisfy the requirements of [IEC 62366-1:2015](#) and [IEC 60601-1-6:2010](#). The user interface, both hardware and software, shall be designed to be understandable and compatible with the intended users' anticipated capabilities (e.g. physical, mental, or sensory) to reduce the likelihood of error and/or confusion. Further, appropriate alarms and warnings are necessary and shall be designed to warn users of system or subsystem failures. Guidance for human factors can be found in IEC/TR 62366-2 and ANSI/AAMI HE75. As appropriate, these evaluations shall include but are not limited to the following scenarios:

- home/community;
- transport (air/ground);
- implant procedure (use of surgical tools and implant accessories);
- hospital environment (in-clinic check-up visit and ICU);
- emergency use.

6.6 In vitro design evaluation and system performance testing

6.6.1 Objective

In vitro testing shall include design characterization of the integrated system and its individual system subcomponents against all of its system design specifications. Test set-ups should be reasonably representative of the intended patient population in which pressures, compliances and flow should be at appropriate values (see [Annex B](#)). A description of the in vitro testing systems, including all pressures, compliances, and the location of all measurement equipment, as well as the rationale for the test set-up, shall be provided.

In both a volume displacement pump and a rotary pump VAD system, this testing includes the characterization of all-time dependent parameters as they operate with (or as a replacement for) the native heart in a pulsatile environment. In this way, the simulated performance effects of the system on the patient and the patient on the system can be understood.

6.6.2 System characterization

6.6.2.1 General

In vitro system characterization testing is a complete evaluation of the final system design in the simulated use environment.

6.6.2.2 Test set-up

All applicable parameters should be documented and reported. See [Annex B](#) for expected physiological parameters.

VAD and TAH system performance, including but not limited to, alarms, back-up systems, information displayed, measurement accuracy/precision, and failures, should be monitored and reported as specified in ISO 14708-1 and with alarms conforming to [IEC 60601-1-8](#).

6.6.2.3 Test articles

6.6.2.3.1 General

At least one clinically representative device system shall be characterized. A complete system is comprised of all system components required for that system to be operational in its intended

environment. If clinical operation of the device can utilize multiple configurations of components and accessories, then testing of each configuration is required. Where the design analysis demonstrates that critical components/sub-assemblies at the extremes of their specifications might impact overall device performance, test articles will be used which characterize that variability.

6.6.2.3.2 Pre-conditioning

The test articles shall be subjected to the following environmental conditions prior to testing, as applicable:

- sterilisation (maximum number of sterilisation cycles for implantable products or products intended for the sterile field);
- environmental (temperature and humidity), may reference ISTA Procedure 2A;
- transportation (vibration, drop, and pressure), may reference ASTM D4169;
- aging (accelerated and real-time), if device is sensitive to aging, may reference ASTM F1980;
- loads and any activity associated with the pre-implant and implant procedures that may impact device performance (e.g. mechanical forces).

6.6.2.3.3 Substitution of device components

If a device component, including but not limited to, biological prosthetic valves, vascular graft, or atrial cuff, is substituted by its alternative, a justification shall be provided.

6.6.2.4 Test equipment

6.6.2.4.1 General

Test equipment required for in vitro system characterization testing of the complete device system shall include a mock circulatory loop and all test measurement equipment.

6.6.2.4.2 Mock circulatory loop

In vitro models used to simulate the natural heart, as appropriate, and the vascular compliance and resistance, shall be documented, and justified as to the necessary physiological limits prescribed. See [Annex B](#) for expected physiological parameters.

6.6.2.4.3 Blood analogue fluid

The relevant properties of fluids used to simulate human blood shall be described. Fluids used may be Newtonian (blood analogue). Characteristics of the fluid and its chemical composition shall be given. Justification for necessary blood-matching trade-offs shall be given (e.g. viscosity, temperature, salinity and pH). See [Annex B](#) for expected physiological parameters.

6.6.2.4.4 Test measurement equipment

6.6.2.4.4.1 Transducers

All transducers used for the measurement of system parameters shall be specified in the study protocol or test procedure. Transducers shall be appropriate for measuring time dependent waveforms so that any subsequent ensemble averaging to produce representative waveforms can be achieved and any cycle-to-cycle variation can be measured. All transducer characteristics, including amplifier devices (e.g. range, resolution, error, frequency response), shall be given. Calibration schedules and calibration methods used for all transducers are required, as well as evidence that the transducers have been calibrated before use.

6.6.2.4.4.2 Use of the device system as test measurement equipment

Many device systems are capable of measuring, acquiring, manipulating, displaying, and storing desired parameters to be measured. The device system measurement and data handling systems shall be documented and validated against calibrated instruments for accuracy.

6.6.2.4.4.3 Data handling

Systems used for data acquisition, manipulation, display, and storage shall be documented. Data acquisition methods and equipment used shall be specified (e.g. real time, triggering methods, sampling rate, filters, amplification). If any data manipulation (e.g. averaging, smoothing) is performed prior to display and storage of final information, this should be clearly explained, including the algorithms used and documenting evidence of system consistency. Characteristics for the display shall be documented (e.g. accuracy, precision, and error).

6.6.2.5 Test conditions

A matrix of test conditions should be generated in order to characterize the system over the full range of operational limits using all possible component configurations against all of the design specifications of the device. The VAD system algorithms, if configurable by the clinician, should also be tested in the ON and OFF states to demonstrate they meet their specifications. The testing should simulate the effects of changes in system performance on the patient and the effects of patient changes on system performance. The effects of extremes of operation on both the device and the patient (e.g. test set-up) should be determined. The extremes of operation include the minimum blood flow and maximum blood flow, hypertension, hypotension, responses to changes in flow, pressure and possible inflow/outflow restrictions.

The relevant conditions used to characterize the system should be selected according to the type of the system (e.g. volume displacement or continuous flow, total artificial heart or ventricular assist system). See [Annex C](#) for more information.

6.6.2.6 Parameters to be measured

The pump should be characterized over the full operating range with the following parameters as appropriate (see [Annex C](#) for more information):

- a) blood pump inlet and outlet pressure waveforms;
- b) blood pump outlet flow waveform;
- c) average outlet pressure from the pump;
- d) average inlet pressure to the pump;
- e) average pump outlet flow.

6.6.2.7 Data analysis

Data analysis shall be performed to show that the system performance meets the design specifications for the system. This shall include statistical significance calculations comparing actual in vitro system performance to the expected design specification. Further, data analysis of system performance and the expected clinical effects of the system, based upon a review of the literature, should be provided.

6.6.2.8 “Worst case” operating conditions

System characterization data should be evaluated to determine the worst-case modes of operation (e.g. power input, pump flow, pressures, battery life) within the design input specification. A discussion should provide the rationale for the selection of the conditions determined to be worst case and what effect they might have on the device.

6.6.3 Subsystem component testing

6.6.3.1 Design evaluation of the pump subsystem

6.6.3.2 Fluid dynamic analysis

A fluid dynamic characterization of the device should be conducted, and its results should be discussed in terms of how these characteristics relate to the design specification and the results of other *in vitro* and *in vivo* design evaluations including haemolysis, cavitation, and thrombus formation. Such studies include computational fluid dynamics (CFD) or experimental flow characterization (see [Annex C](#)). These study results should be used for justification of design improvement of the device. The contribution of the native heart to the total pump flow should be considered during the analysis or test method development.

6.6.3.3 Cavitation

The device shall not exhibit cavitation under any operating conditions. As applicable, the critical cavitation conditions [e.g. net positive suction head required (NPSHR)] should be provided.

Compliance is checked by the inspection of the design verification record.

6.6.3.4 Control and drive units

6.6.3.4.1 External units

Blood pump controlling and driving units that are carried by patients shall be tested against the design requirement specifications. At a minimum, these units should be qualified by verifying the following requirements.

- a) Electrical input (voltage range, ripple, current range, and power requirements).
- b) Electrical and/or mechanical output (e.g. voltage, current, power, torque, and pressure).
- c) Electrical safety requirements, as specified in IEC 60601-1:2018 shall be met.
- d) Software used in the controlling and driving units shall be verified as specified in [IEC 62304:2006](#).
- e) The unit alarms should meet the requirements of [IEC 60601-1-8](#) and include multiple types of alarms (e.g. auditory, visual, and vibratory).
- f) The external control and drive unit qualification shall also include testing as specified in the following documents:
 - 1) [IEC 60068-1:2013](#);
 - 2) [IEC 60068-2-64:2008](#);
 - 3) [IEC 60068-2-27:2008](#);
 - 4) [IEC 60068-2-31:2008](#);
 - 4) [IEC 60601-1-10:2007](#) (for closed-loop controller);
 - 5) IEC 60601-1-11:2015.
- g) Unit enclosure temperature shall be as specified in IEC 60601-1:2018.
- h) Biocompatibility of materials that might be in contact with the patient's skin shall also be verified according to the biocompatibility documents within ISO 10993-1:2018.

This list of documents is not all-inclusive, and others may be used as applicable.

6.6.3.4.2 Implantable controllers and drivers

Implantable devices shall comply with the safety, marking and supplied information requirements specified in ISO 14708-1.

6.6.3.4.3 Programming and monitoring units

Peripheral/accessory devices are for the programming of the system, collecting, storing and displaying information in hospitals and/or home environment. As a part of the circulatory support system, programming and monitoring units shall be tested as described in [6.6.3.4.1](#) External units. Where appropriate, the test levels shall be documented for the intended use environment (e.g. hospital, home, and air/ground transport). See ISO 14708-1. If testing is not to be performed (e.g. the use of qualified off-the-shelf laptops), an equivalency rationale shall be provided.

6.6.3.4.4 Power supplies

Power supplies (including battery chargers) for the circulatory support devices shall meet safety requirements for medical devices as specified in IEC 60601-1:2018, such that at no time is there total loss of power. Electrical input and output (voltage range, ripple, current, and power) as well as overload capabilities and protection shall be verified.

Where appropriate, the test levels shall be documented for the intended use environment (e.g. hospital, home, and air/ground transport).

6.6.3.4.5 Batteries

Battery-powered circulatory support systems should be considered for testing the following:

- a) battery voltage from full capacity to the depleted state;
- b) effect of current (load) on battery performance (voltage, capacity, and case temperature);
- c) effect of time, temperature, load, and cycles on the battery's capacity (aging);
- d) battery preventive maintenance and replacement schedule (based on cycles or time);
- e) emergency back-up procedure if the battery fails;
- f) recharge specifications, for example, charge current, end of charge determination, and recharge time;
- g) method to measure battery depletion;
- h) method to control hazard from potential gases produced while charging;
- i) battery status indicator that gives advance warning of battery depletion. The manufacturer shall define the time interval between the activation of this indicator and the point at which the battery will cease to support the normal operation of the device;
- j) auditory, visual, and vibratory warning alarms in the event of battery depletion;
- k) appropriateness of parallel redundancy for battery sources;
- l) method to measure/identify high discharge temperatures;
- m) protection against battery explosion or burst;
- n) ease of battery exchange process especially if the battery is implanted.