

American National Standard



ANSI/AAMI/ ISO 8637-1: 2017

Extracorporeal systems
for blood purification—
Part 1: Haemodialysers,
haemodiafilters, haemofilters
and haemoconcentrators

Extracorporeal systems for blood purification—Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

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AAMI

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American National Standards Institute, Inc.

Abstract: Specifies safety and performance requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Keywords: biological, labelling, mechanical, non-pyrogenicity, sterility, test

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Committee representation

Association for the Advancement of Medical Instrumentation

Renal Disease and Detoxification Committee

This standard was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Renal Disease and Detoxification Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of AAMI adoption of ISO 8637-1:2017

The International Organization for Standardization (ISO) published ISO 8637-1:2017, *Extracorporeal systems for blood purification - Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators* as a revision of ISO 8637:2010 and ISO 8637:2010/AMD1-2013. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, Subcommittee 2, Cardiovascular implants and extracorporeal systems, to fill a need for safety and performance requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators. The dimensions of the blood ports and the dialysis fluid or filtrate ports have been specified to ensure compatibility of the device with the extracorporeal blood circuit specified in ISO 8637-2:2018. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 150/SC 2 supports the guidance provided in this document.

NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 8637-1:2017.

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 on 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 the following URL: 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*.

This first edition of ISO 8637-1:2017 cancels and replaces the third edition of ISO 8637:2010 and ISO 8637:2010/Amd1:2013, which has been technically revised. The following changes have been done:

— Figure 1, Figure 2, and Figure 3 have been revised.

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

Introduction

This document is concerned with devices intended for haemodialysis, haemodiafiltration, haemofiltration and haemoconcentration in humans. The requirements specified in this document 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 used 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.

The dimensions of the blood ports and the dialysis fluid or filtrate ports have been specified to ensure compatibility of the device with the extracorporeal blood circuit specified in ISO 8637-2. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

This document reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use. Conformance with this document is voluntary and it does not supersede any national regulation.