

This is a preview of "ISO 11140-6:2022". [Click here to purchase the full version from the ANSI store.](#)

First edition
2022-11

Sterilization of health care products — Chemical indicators —

Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 6: Indicateurs de type 2 et dispositifs d'épreuve de procédé destinés à être utilisés pour les essais de performances relatifs aux petits stérilisateur à la vapeur d'eau



Reference number
ISO 11140-6:2022(E)

© ISO 2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "ISO 11140-6:2022". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Requirements	3
4.1 General.....	3
4.2 Porous devices.....	3
4.2.1 Reference porous device (RPD).....	3
4.2.2 Detector for reference porous device (RPD).....	4
4.2.3 Alternative porous indicator system (APIS).....	5
4.2.4 Reference porous device (RPD) response.....	6
4.3 Hollow devices.....	6
4.3.1 Reference hollow device (RHD).....	6
4.3.2 Detector for reference hollow device (RHD).....	7
4.3.3 Reference hollow indicator system (RHIS).....	8
4.3.4 Reference hollow indicator system (RHIS) performance determination.....	8
4.3.5 Leakage test.....	9
4.4 Alternative hollow indicator system (AHIS).....	9
4.4.1 General.....	9
4.5 Alternative hollow devices intended for multiple use.....	10
4.6 Test procedure for validation of conformance of the alternative hollow device to the reference hollow device (RHD).....	12
5 Chemical indicator dry heat performance	13
5.1 General.....	13
5.2 Test 1.....	13
5.3 Test 2.....	14
6 Marking and labelling	14
6.1 Device labelling.....	14
6.2 Additional labelling requirements for hollow devices.....	14
6.3 Chemical indicators for use in hollow devices.....	15
Annex A (normative) Test method for performance of reference hollow indicator system (RHIS)	16
Annex B (normative) Test method for performance of alternative porous indicator system (APIS)	24
Annex C (normative) Test method for performance of alternative hollow indicator system (AHIS)	27
Annex D (informative) Relationship between chemical indicator components	28
Annex E (normative) Reference hollow device (RHD)	30
Annex F (informative) Accelerated ageing of test samples	32
Annex G (informative) Evaluation of reference hollow devices (RHDs) — Interlaboratory results	33
Bibliography	40

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 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 11140 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.

This is a preview of "ISO 11140-6:2022". [Click here to purchase the full version from the ANSI store.](#)

Introduction

This document includes a description of both hollow and porous process challenge devices (PCDs) and their performance requirements, along with methods by which an alternative PCD can be shown to have equivalent performance to that of the reference PCD. Small sterilizers unable to accommodate a sterilization module [rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)] cannot be tested using the tests described in EN 285 for large sterilizers for wrapped goods and porous loads because

- the chamber size of a small steam sterilizer according to EN 13060 is unable to accommodate the standard test pack from EN 285, and
- the efficacy of the tests is impaired when the test pack occupies a large proportion of the chamber volume (>20 % chamber volume).

Indicators described in this document are intended to be used in conjunction with appropriate PCDs to show penetration of steam into the PCD. The reference indicator systems and alternative indicator systems pose specified challenges to air removal and steam penetration.

The devices described in this document are intended for use only in small steam sterilizers conforming to EN 13060 to monitor steam penetration in type B cycles and some type S cycles.

NOTE Even though the hollow load was originally designed as a type test in EN 867-5 (withdrawn standard replaced by this document) to test the performance of small steam sterilizers conforming with EN 13060, the same test is also used in other standards, for example, EN 285.