BS ISO 16971-1:2024

BSI Standards Publication

Ophthalmic instruments — Optical coherence tomographs

Part 1: Optical coherence tomographs for the posterior segment of the human eye

Documents
Document Sharing Hub

Full document details: BS ISO 16971-1:2024

National foreword

This British Standard is the UK implementation of ISO 16971-1:2024.

The UK participation in its preparation was entrusted to Technical Committee CH/172/6, Ophthalmic instruments.

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

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2024
Published by BSI Standards Limited 2024

ISBN 978 0 539 21078 1

ICS 11.040.70

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2024.

Amendments/corrigenda issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: BS ISO 16971-1:2024

International Standard

ISO 16971-1

First edition
2024-11

Ophthalmic instruments — Optical coherence tomographs —

Part 1: Optical coherence tomographs for the posterior segment of the human eye

Instruments ophtalmiques — Tomographe à cohérence optique —

Partie 1: Tomographe à cohérence optique du segment postérieur de l'oeil humain

Reference number
ISO 16971-1:2024(en)

© ISO 2024

Documents
Document Sharing Hub

Full document details: BS ISO 16971-1:2024

COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

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

Documents
Document Sharing Hub
Full document details: BS ISO 16971-1:2024

Contents

Page

Foreword ... **v**
Introduction ... **vi**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms, definitions and symbols ... **1**
3.1 General ... 2
3.2 Optical properties ... 3
3.3 Signal characteristics ... 4
3.4 Optical coherence tomography angiography ... 5
3.5 Anatomy and physiology ... 5
3.6 Data processing ... 5
3.7 Symbols ... 5
4 Requirements ... **5**
4.1 General ... 5
4.2 Construction and function ... 6
4.2.1 Optical properties and specifications ... 6
4.2.2 Tolerance requirements ... 6
4.2.3 Co-alignment of fundus image and OCT hardware ... 6
4.2.4 Light hazard protection ... 6
4.3 Analysis and presentation of results ... 7
4.3.1 Presentation of structural OCT images ... 7
4.3.2 Retinal thickness measurement ... 7
4.3.3 Reference database ... 7
4.4 Data exchange ... 7
5 Recommended test methods ... **8**
5.1 General ... 8
5.2 Measurement setups ... 8
5.3 Test methods for optical properties ... 8
5.3.1 Transverse optical resolution ... 8
5.3.2 Axial optical resolution ... 9
5.3.3 Axial range ... 9
5.3.4 Angular field of view ... 9
5.4 Test methods for signal quality ... 9
5.4.1 Sensitivity ... 9
5.4.2 Axial signal roll-off ... 9
5.5 Co-alignment of fundus image and OCT scan ... 9
5.5.1 General ... 9
5.5.2 En-face method ... 10
5.5.3 Line scan method ... 10
6 Information to be supplied by the manufacturer ... **11**
6.1 General ... 11
6.1.1 Warnings and safety-related information ... 11
6.1.2 Maintenance ... 12
6.2 Technical description ... 12
6.2.1 Imaging parameters ... 12
6.2.2 Acquisition and scan modes ... 12
6.2.3 Measurements and data analysis ... 12
6.2.4 Data exchange ... 13
6.3 Information available on request ... 13
7 Marking ... **13**
Annex A (informative) **Example for test devices** ... **14**

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 16971-1:2024

Bibliography **15**

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 16971-1:2024

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 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments.*

This first edition of ISO 16971-1 cancels and replaces the first edition (ISO 16971:2015), which has been technically revised.

The main changes are as follows:

— revision of the dated references;

— document restructured;

— definitions added with particular emphasis on performance parameters;

— added example performance parameters;

— clarified requirements for presentation of OCT images;

— clarified minimum requirements for data exchange; DICOM required;

— test methods not mandatory anymore; added additional test methods;

— extended requirements for the information to be supplied by the manufacturer;

— deleted annex on *Minimum requirements for a normative database;*

— Annex A *Example for test device* added.

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.

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 16971-1:2024

Introduction

Until the early 21st century, it was impossible to obtain clinically relevant depth-resolved information of the inner structures of the human eye, including those of the retina. With optical coherence tomography (OCT), eye care practitioners now have an available non-invasive method that allows the rapid generation of high-resolution three-dimensional in vivo images of the eye. Before the first edition of ISO 16971 was published, there were no well-defined and widely accepted requirements for either OCT instruments or the data collected and displayed with them. Consequently, it was very difficult to compare the instruments, their measurement results, and clinically relevant diagnostic findings based on them.

The first edition of ISO 16971 was an important first step towards defining the necessary terminology and performance requirements for OCT instruments and to establishing standardized framework conditions for the application of OCT technology to ophthalmic imaging.

This edition continues the task by extending the requirements of ISO 16971 and specifying a more comprehensive set of characteristics for OCT instruments. To facilitate this, ISO 16971 has been divided with this document serving as the first part addressing OCT instruments for the posterior segment of the human eye.

© ISO 2024 – All rights reserved

Documents
Document Sharing Hub
Full document details: BS ISO 16971-1:2024