

ISO 16971-1:2024-11 (E)

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

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
Bibliography		15