

ISO 16971:2015-04 (E)

Ophthalmic instruments - Optical coherence tomograph for the posterior segment of the human eye

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	3
4.1	General	3
4.1.1	General requirements	3
4.1.2	Light hazard protection	3
4.2	Retinal thickness measurement	3
4.2.1	General	3
4.2.2	Presentation of retinal thickness maps	3
4.3	Angular field of view	4
4.4	Depth scaling	4
4.5	Image quality	4
4.6	Axial resolution	4
4.7	Signal-to-noise ratio (SNR)	4
4.8	Calibration co-alignment of fundus image and OCT scan	4
4.9	Normative database	4
4.10	Data export	5
5	Test methods	5
5.1	General	5
5.2	Test device	5
5.3	Co-alignment of preview and OCT scan	6
5.3.1	Test device	6
5.3.2	Procedure	6
5.4	Retinal thickness measurement	6
6	Information to be supplied by the manufacturer	7
7	Marking	7
Annex A (informative)	Minimum requirements for a normative database	8
Bibliography		9