ISO 15004-1:2006-06 (E)

Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instru ments

Contents

Page

Foreword iv

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Fundamental requirements (for non-active and active ophthalmic instruments) 2
4.1 General 2
4.2 Design 2
4.3 Performance 2
4.4 Combination of different devices 2
4.5 Materials 3
4.6 Protection against contaminants 3
4.7 Scales and displays 3
4.8 Thermal hazards 3
4.9 Mechanical hazards 3

5 Environmental conditions (for non-active and active ophthalmic instruments) 3
5.1 Environmental conditions of use 3
5.2 Storage conditions 4
5.3 Transport conditions 4

6 Particular requirements for active ophthalmic instruments 5
6.1 Electrical safety 5
6.2 Inapplicable clauses of IEC 60601-1:2005 5
6.3 Optical radiation hazard 5

7 Test methods 5
7.1 Ignitability 5
7.2 Surface temperatures 5
7.3 Environmental conditions 5
7.4 Checking electrical safety 7

8 Information supplied by the manufacturer 7
8.1 Accompanying documents 7
8.2 Marking 7

Annex A (informative) Product-related International Standards for ophthalmic instruments 8