

Template for comments and secretariat observations

Date: October 23, 2017

Document: **ANSI Z80.35 Annex A and Annex C changes**

Project:EDF IOL

MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Original version	Changed version	Reason for change
		A.1	4 th paragraph	ed	In particular, this characterization will assess the optical performance of the EDF IOL and the comparison monofocal IOL and multifocal IOL when used to view distant objects. It will assess the optical resolution of the EDF IOL and the comparison monofocal IOL and multifocal IOL when viewing objects at increasing near distances.	In particular, this characterization will assess the optical resolution performance of the EDF IOL and the comparison monofocal IOL and multifocal IOL when used to view distant objects at different distances . It will assess the optical resolution of the EDF IOL and the comparison monofocal IOL and multifocal IOL when viewing objects at increasing near distances.	Simplify language without changing meaning
		A.2	title	ed	A.2 'Optical characterization'	A.2 'Theoretical evaluation'	Theoretical evaluation is a separate issue from optical testing and so is given its own clause
		A.2.1	title	ed	A.2.1 Theoretical evaluation	A.2.1 is made into the separate clause A.2	See above
		A.2.1	2 nd paragraph	ed	Reference to A.2.2.1 and A.2.2.4	Reference to A.3.2 and A.3.3	New clause structure and numbering
		A.2.2.1			A.2.2.1 Modulation transfer function testing	A.3.1 MTF through-focus testing	New clause structure and numbering and division of optical testing into several sub-sections as per H. Weeber suggested revision
		A.2.2.1	Paragraphs 1 through 5			Changed to be essentially as the proposed revision of H. Weeber. Reference to Annex C. C.2 for suitable model eyes is explicitly made. Type 2 ISO 11979-2 model is indicated as suitable with instruction to refer to Annex C. C.8 for proper use.	This version concisely includes instruction on the light source to use and the inclusion of proper chromatic and spherical aberration characteristics of the model eye.
		A.2.2.1				A.3.1 has a note informing the user that in addition to using the specified polychromatic light for testing, testing may also be done using monochromatic light at wavelength 550 nm .	The group consensus is that MTF measurements shall be made using 'white' light, as specified in clause A.6 but that if so desired, addition measurement may be made – and reported – using monochromatic light

¹ **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

² **Type of comment:** **ge** = general **te** = technical **ed** = editorial

Template for comments and secretariat observations

Date: October 23, 2017

Document: **ANSI Z80.35 Annex A and Annex C changes**

Project:EDF IOL

MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Original version	Changed version	Reason for change
							at a wavelength of 550 nm.
		A.2.2.1	6 th paragraph		The original version included tilt and decentration testing	Tilt and decentration testing moved to sub-clause A.3.2	In accordance with proposed revision of H. Weeber
		A.2.2.2	title		A.2.2.2 Depth of focus	A.3.4 Depth of focus range	Revision of clause structure as per suggested revision of H. Weeber. The title now more clearly describes the
		A.2.2.2			The reported depth of focus value shall be the vergence of light entering the model eye when the expected visual acuity, as found using the method of A.2.2.4, has the logMAR value 0.2 when measurements of the MTF are taken with the image set as specified in A.4	The reported depth of focus value shall be the <u>defocus range for which</u> the expected visual acuity, as found using the method of A.3.3, has the logMAR value 0.2 <u>or better</u> .	This revision simplifies the text and properly references the renumbered clause for expected visual acuity.
		A.2.2.3	title		A.2.2.3 Unwanted optical visual effect testing	A.4 Unwanted optical visual effect testing	Renumbering of the sub-clause and making it separate clause as per H. Weeber suggested revision
		A.2.2.3.1	title		A.2.2.3.1 Testing conditions	A.4.1 Testing conditions	Renumbering of the sub-clause
		A.2.2.3.2			A.2.2.3.2 Light source	A.4.2 Light source	Renumbering of the sub-clause
		A.2.2.3.2	1 st paragraph		Reference to A.6	Reference to 4.3.1 a) and b)	Slightly clearer reference material
		A.2.2.3.3	title		A.2.2.3.3 Procedure	A.4.3 Procedure	Renumbering of the sub-clause
		A.2.2.4	title		A.2.2.4 Expected visual acuity	A.3.3 Expected visual acuity	Renumbering of the sub-clause while keeping it within Optical testing clause A.3.
		A.3			A.3 Model eye specifications	This clause is removed and all reference to model eyes is to informative Annex C.	Annex A only will contain normative clauses whereas the model eye specifications are generally informative.

¹ **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

² **Type of comment:** **ge** = general **te** = technical **ed** = editorial

Template for comments and secretariat observations

Date: October 23, 2017

Document: **ANSI Z80.35 Annex A and Annex C changes**

Project:EDF IOL

MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Original version	Changed version	Reason for change
		A.3.1			A.3.1 Physiological cornea	This section is moved to Annex C, C.9	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		A.3.2			A.3.2 Model eye	This clause is removed and the text moved to Annex C C.2	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		A.4			A.4 Modulation transfer function measurement method	This clause is removed. Information on the details of performing suitable MTF measurements to fulfil the requirements of ANSI Z80.35 is already to be found informative Annex C in the revised clause C.5	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		A.4.1			A.4.1 Point spread method	This sub-clause is removed. Information on these details of performing suitable MTF measurements to fulfil the requirements of ANSI Z80.35 is already to be found informative Annex C in the revised clause C.5.1	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		A.4.2			A.4.2 Point spread method	This sub-clause is removed. Information on these details of performing suitable MTF measurements to fulfil the requirements of ANSI Z80.35 is already to be found informative Annex C in the revised clause C.5.1	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		A.7			A.7 Target creation optical model	This clause is removed. Information on the details of a suitable target system for performing MTF measurements to fulfil the requirements of ANSI Z80.35 is already to be found informative Annex C in the revised clause C.3	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		C.1	1 st paragraph		Within this annex are found methods and devices that can be successfully used to fulfill the optical characterization requirements for EDF	Within this annex are found methods and devices that can be successfully used to fulfill the imaging quality verification requirements of 5.2.3 and the optical	Reference to applicable clauses of the main body of ANSI Z80.35 are added as they contain the requirements that need to be fulfilled.

¹ **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

² **Type of comment:** **ge** = general **te** = technical **ed** = editorial

Template for comments and secretariat observations

Date: October 23, 2017

Document: **ANSI Z80.35 Annex A and Annex C changes**

Project:EDF IOL

MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Original version	Changed version	Reason for change
					IOLs set forth in Annex A. Other methods and/or devices that can be shown to successfully perform the tests required by Annex A can be used instead of the methods and devices given in this annex if so desired.	characterization requirements for EDF IOLs set forth in 5.2.1 and specified in Annex A. Other methods and/or devices that can be shown to successfully perform the tests required by 5.2.3 and by 5.2.1 as specified in Annex A can be used instead of the methods and devices given in this annex if so desired.	
		C.2				Text from A.3.2 that listed the characteristics needed in a model eye has been removed from Annex A and inserted here.	Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.
		C.2.1			C.2.1 Physiological model eye	C.2.2 Physiological model eye	The placement of the Fluid cell model eye and the Physiological model eye have been changed because it is likely that the Fluid cell model eye will be preferred by users for a variety of reasons
		C.2.1	2 nd paragraph		Reference to A.2.2.1	Reference to A.3.1 and to A.3.2	Changed numbering in Annex A
		C.2.1	3 rd paragraph		Reference to A.2.2.1	Reference to A.3.2	Changed numbering in Annex A
		C.2.1	Table C.1		Table C.1	Table C.2	Renumbered due to change in clause sequence
		C.2.1	Figure C.1		Figure C.1	Figure C.2	Renumbered due to change in clause sequence
		C.2.1	Figure C.1		Reference to C.1.2 and to A.3	Reference to A.3.1 and to A.5	Changed numbering in Annex A
		C.2.1	Figure C.2		Figure C.2	Figure C.3	Renumbered due to change in clause sequence
		C.2.1	Figure C.3		Figure C.3	Figure C.4	Renumbered due to change in clause

¹ **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

² **Type of comment:** **ge** = general **te** = technical **ed** = editorial

Template for comments and secretariat observations

Date: October 23, 2017	Document: ANSI Z80.35 Annex A and Annex C changes	Project:EDF IOL
------------------------	--	-----------------

MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Original version	Changed version	Reason for change
							sequence
		C.2.2	title		C.2.2 Simple Fluid Filled Eye Model	C.2.1 Fluid Cell Model Eye	The placement of the Fluid cell model eye and the Physiological model eye have been changed because it is likely that the Fluid cell model eye will be preferred by users for a variety of reasons. , "Simple Fluid Filled Eye Model, is now called "Fluid Cell Model eye" because this more accurately describes it.
		C.2.2	1 st paragraph		Reference to A.3	Reference to 5.2.1, 5.2.3 and A.3.1 (now in C.2.1)	Inclusion of main body requirement clauses and changed numbering in Annex A
		C.2.2	Table C.2		Table C.2	Table C.1	Renumbered due to change in clause sequence
			New figure		No figure	Figure C.1	Addition of a figure illustrating the construction of the fluid cell model eye.
		C.4	Figure C.4		Figure C.4	Figure C.5	Renumbered due to addition of the figure illustrating the fluid cell model eye.
		C.4	3 rd paragraph		Reference to figure C.4	Reference to figure C.5	The figure has been renumbered.
		C.4 (2 nd)			C.4 Modulation transfer function measurement method (MTF)	C.5 Modulation transfer function measurement method (MTF)	Incorrect numbering corrected.
		C.4 (2 nd)			Information on MTF measurement methods suitable testing IOLs of all types is found in mis-numbered clauses C.4 (2 nd) and C.5(2 nd) .	New clause C.5 has an initial paragraph text moved from A.4 (a deleted clause). New sub-clause C.5.1 contains information on MTF measurements using point or line target and has text from deleted sub-clauses A.4.1 and A.4.2 and from C.4 (2 nd). New sub-clause C.5.2 contains information on MTF measurements made using targets with known spatial frequency elements and contains text from C.5 (2 nd).	Consolidate information on methods to measure the MTF of IOLs and move non-normative information from Annex A a per agreed decision (10/20/2017 teleconference) s

1 **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

Template for comments and secretariat observations

Date: October 23, 2017	Document: ANSI Z80.35 Annex A and Annex C changes	Project:EDF IOL
------------------------	--	-----------------

MB/NC ¹	Line number	Clause/Subclause	Paragraph/Figure/Table/	Type of comment ²	Original version	Changed version	Reason for change
		C.5 (1 st)	title		C.5 Depth of focus measurement method	C.6 Depth of focus measurement method	Renumbered to correct numbering errors
		C.5(1 st)	1 st paragraph		Reference to A.2.2.1	Reference to A.3.4	Changed numbering in Annex A
		C.5(2 nd)	title		C.5 Modulation transfer method methods	Removed clause and combined with newly numbered clause C.5. This number was incorrect.	There were 2, somewhat duplicating clauses on MTF measurement, C.4 and mis-numbered C.5. They have been combined.
		C.6	title		C.6 Expected visual acuity	C.7 Expected visual acuity	Renumbered to correct numbering errors
		C.6	Equation C.10		$VA(\log MAR) = ax^b + c$	$VA(\log MAR) = ax^b + c$ C.10	Inserted missing equation number
		C.7	Title		C.7 Use of ISO 11979-2 type 2 model	C.8 Use of ISO 11979-2 type 2 model eye	Renumbered to correct numbering errors
		C.7	1 st and 2 nd paragraphs		Reference to A.2.2.1	Reference to A.3.1	Changed numbering in Annex A
		New clause				C.9 Physiological cornea	Moved from Annex A. A.3.1. Done per agreed decision (10/20/2017 teleconference) to place non-normative but useful material in Annex C, an informative annex.

¹ **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g. CN for China; comments from the ISO/CS editing unit are identified by **)

² **Type of comment:** **ge** = general **te** = technical **ed** = editorial