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Global RA Manager

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Certifie la matérialité de la
signature de M. Monsieur
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apposée ci-contre.
~~ci-dessus.~~

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USER MANUAL

Spectacle lenses made of plastic and glass material: clear, tinted, photochromic, afocal, bifocal, progressive, single vision, trifocal, lenticular, polarized with anti-reflective coating, hard coating or uncoated

Manufacturer: Essilor International Société par Actions Simplifiée, I47, rue de Paris, 94220 Charenton Le Pont, France

1. DESIGN AND PURPOSE OF MEDICAL PRODUCT.

Spectacle lenses made of polymeric and organic material: clear, tinted, photochromic, afocal, bifocal, progressive, single vision, trifocal, lenticular, polarized with anti-reflective coating, hard coating or uncoated (hereinafter called lenses, product) are optical products intended for manufacturing of corrective glasses used for correction of any degree of ametrophia.

In case of **amblyopia** all the variety of lenses are paired with afocal lenses (delivered in pairs optical lens + afocal lens).

Application: ophthalmology departments of hospitals, clinics, healthcare institutions.

Indications for Use

- amblyopia
- anisometropia
- aphakia
- keratoconus
- astigmatism
- ametrophia, including high level ametrophia

Contraindications

- non ability of vision correction with spectacle lens
- allergy for used materials

Side effects: The only potential physical danger is risk of avulsed wound caused by lens fracture.

Lenses are characterised with high shatterproof, however, fracture is possible under severe physical impact. Broken lenses are subject to utilisation in an orderly manner.

1.1.Design:

Линза отрицательная

Minus lens

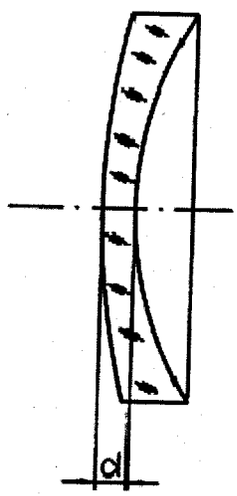


Рис. 1

Fig. 1

Plus lens

Линза положительная

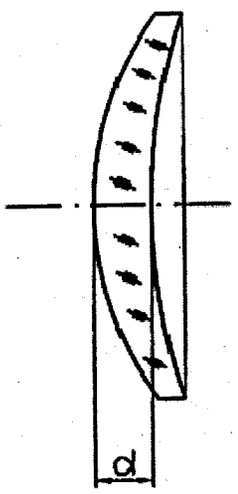


Fig. 2

Рис. 2

1.2.Configuration

1	Organic clear afocal spectacle lenses
2	Organic clear single vision spectacle lenses
3	Organic clear bifocal spectacle lenses
4	Organic clear progressive spectacle lenses
5	Organic tinted afocal spectacle lenses
6	Organic tinted single vision spectacle lenses
7	Organic tinted bifocal spectacle lenses
8	Organic tinted progressive spectacle lenses
9	Organic photochromic afocal spectacle lenses
10	Organic photochromic single vision spectacle lenses
11	Organic photochromic bifocal spectacle lenses
12	Organic photochromic progressive spectacle lenses
13	Organic polarized afocal spectacle lenses

14 Organic polarized single vision spectacle lenses
15 Organic polarized bifocal spectacle lenses
16 Organic polarized progressive spectacle lenses
17 Organic polarized photochromic afocal spectacle lenses
18 Organic polarized photochromic single vision spectacle lenses
19 Organic polarized photochromic progressive spectacle lenses
20 Organic polarized photochromic bifocal spectacle lenses
21 Organic clear lenticular spectacle lenses
22 Organic tinted lenticular spectacle lenses
23 Organic lenticular photochromic spectacle lenses
24 Organic clear trifocal spectacle lenses
25 Organic tinted trifocal spectacle lenses
26 Organic trifocal photochromic spectacle lenses
27 Organic polarized tinted afocal spectacle lenses
28 Organic polarized tinted single vision spectacle lenses
29 Organic polarized tinted progressive spectacle lenses
30 Organic polarized tinted bifocal spectacle lenses
31 Polymeric polarized tinted lenticular spectacle lenses
32 Polymeric polarized tinted trifocal spectacle lenses
33 Mineral clear lenticular spectacle lenses
34 Mineral tinted lenticular spectacle lenses
35 Mineral lenticular photochromic spectacle lenses
36 Mineral lenticular polarized photochromic spectacle lenses
37 Mineral lenticular tinted photochromic spectacle lenses

Instruction for Use

2. SPECIFICATIONS

2.1. Optical requirements:

Lens power range for single vision, lenticular and multifocal lens: from -108,00 to +90,00 dptr.

Back vertex power
When verified according to 5.2.1, spectacle lenses shall comply with the tolerances on the power of each principal meridian (see Table 1,second column), and with the tolerances on the cylindrical power (see Table 1, third to sixth column) using the method specified in 6.2.
Values in dioptres (D)
Table 1 [dioptre]

Surface refraction on *the second* principal meridian	Tolerances on *the first* principal meridian	Tolerances for astigmatic difference (cylinder) absolute value			
		0.00 through 0.75	0.75 through 4.00	4.00 through 6.00	over 6.00
0.00 through 3.00	±0.09	±0.09	±0.12	±0.18	-
3.00 through 6.00	±0.12	±0.12	±0.12	±0.18	±0.25
6.00 through 9.00	±0.12	±0.12	±0.18	±0.18	±0.25
9.00 through 12.00	±0.18	±0.12	±0.18	±0.25	±0.25
12.00 through 20.00	±0.25	±0.18	±0.25	±0.25	±0.25
over 20.00	±0.37	±0.25	±0.25	±0.37	±0.37

Direction of the cylinder axis

The cylinder axis shall be specified in accordance with ISO 8429.
These tolerances apply to multifocal lenses and to single-vision lenses with a predetermined orientation, e.g. prism base setting and/or position-specific single-vision lenses.

Table 2 — Tolerances on the direction of the cylinder axis

Absolute cylindrical power dioptres (D)	<0,12	≥0,12 and ≤0,25	>0,25 and ≤0,50	>0,50 and ≤0,75	>0,75 and ≤1,50	>1,50
Tolerance on the direction of the cylinder axis degrees (°)	No requirement	±14	±7	±5	±3	±2

Addition power for multifocal lenses

The addition power shall comply with the tolerances specified in Table 3.
Values in dioptres (D)

Table 3 — Tolerances on the addition power for multifocal lenses

Value of the addition power	≤4,00	>4,00
Tolerance	±0,12	±0,18

Prismatic power

The total prism (including ordered and thickness reduction prism) shall comply with the tolerance(s) given in Table 4. Lenses with no ordered prism are also included.

To determine the prismatic power tolerances, find the value S of the higher absolute principal power. Then:

a. for single-vision lenses with no specific orientation, the row in Table 4 is chosen according to the value of the total prism and the tolerance selected from the second column;

b. for position-specific single-vision lenses and multifocal lenses:

1. if ordered as an oblique prism, resolve any ordered prism into its horizontal and vertical components;

2. determine the horizontal prism tolerances in the row in Table 4 according to the total horizontal prism component using the third column;

3. determine the vertical prism tolerances in the row in Table 4 according to the total vertical prism component using the fourth column.

Values in prism dioptres

Table 4 — Prismatic tolerance

Higher total prism component value	Type of lens		
	Single-vision	Multifocal and position-specific single-vision lenses	
		Horizontal component	Vertical component
≥0,00 and ≤2,00	±[0,25 + (0,1 × *S*)]	±[0,25 + (0,1 × *S*)]	±[0,25 + (0,05 × *S*)]
>2,00 and ≤10,00	±[0,37 + (0,1 × *S*)]	±[0,37 + (0,1 × *S*)]	±[0,37 + (0,05 × *S*)]
>10,00	±[0,50 + (0,1 × *S*)]	±[0,50 + (0,1 × *S*)]	±[0,50 + (0,05 × *S*)]
Table 4 :			
S is the focal power, in dioptres, in the meridian of higher absolute principal power.			
Table 4 :			
(0,1 × *S*) corresponds to the prismatic effect of 0,1 cm (1 mm) displacement, while (0,05 × *S*) corresponds to the prismatic effect of 0,05 cm (0,5 mm) displacement.			

NOTE : An example of applying the tolerances in Table 4 to a distance power of +0,50 D sphere /–2,50 D cylinder axis 20° in a multifocal prescription with a prismatic power of not greater than 2,00 Δ is as follows:

For this prescription, the principal powers are +0,50 D and –2,00 D so that higher absolute principal power is 2,00 D. For a power of 2,00 D, the horizontal tolerance is ±[0,25 + (0,1 × 2,00)] = ±0,45 Δ. The vertical tolerance is ±[0,25 + (0,05 × 2,00)] = ±0,35 Δ.

For position-specific single-vision and multifocal lenses, the tolerances on the base setting of any prism shall be determined by verifying that the horizontal and vertical components comply with Table 4.

2.2. Geometric requirements

Lens diameter is from 45mm to 90 mm.

Requirements for size and thickness

Lens sizes are classified as follows:

1. à. nominal size (d_n): dimension(s), in millimetres, indicated by the manufacturer;
2. b. effective size (d_e): actual dimension(s), in millimetres, of the lens;
3. c. usable size (d_u): dimension(s), in millimetres, of the area that is optically usable.

For lenses specified by diameter, the tolerances on size shall be as follows:

- effective size, d_e:
  - $d_n - 1\ \text{mm} \leq d \leq d + 2\ \text{mm}$

  usable size, d :
  - $d_u \geq d_n - 2\ \text{mm}$

The tolerance on usable size does not apply for lenses with a carrier curve such as lenticulars.
The thickness of the lens may be specified by the manufacturer or be agreed between the orderer and the supplier.
The thickness shall be verified at the reference point of the front surface and normal to this surface. It shall not deviate from the ordered or agreed value by more than ±0,3 mm.
As the size and thickness of lenses worked for a particular shape and size will inevitably be subject to the requirements of the spectacle frame into which the lenses are to be mounted, the tolerances on size and thickness are not applicable to these lenses. Such tolerances may be agreed between the orderer and supplier.

Requirements on segment dimensions for multifocal lenses

When using one of the methods specified in 6.6, each of the segment dimensions (width, depth and intermediate depth) shall not deviate from its nominal value by more than ±0,5 mm.
If sold as a matched pair, each of the segment dimensions (width, depth and intermediate depth) shall not differ by more than 0,7 mm.

2.3. Quality requirements:

Cosmetic requirements

The refractive surface finish of lens shall comply with the following requirements:
- Deviations of the lens surface configuration (waves), which distort an object image, are not allowed.
- Thickness (b) and overall length (l) of scratches shall not exceed the values specified in Table 5:

Table 5

Lens area	b [mm]	l [mm]
Centre, 30-mm diameter	Over 0.006 through 0.01	10
Edge	Over 0.006 through 0.02	10

Scratches up to 0.006 mm wide and spots up to 0.05 mm in diameter are considered allowable if their area over the limited extent of 5 mm in diameter is no more than 0.1 mm^2.

- The number of bubbles, spots and other foreign inclusions (N) considered permissible if only an in-between distance is greater than 5 mm, whilst their diameter (d) not exceeding the values indicated in the Table 6:

Table 6

Lens area	d [mm]	N, no more than
Centre, 30-mm diameter	0.05 through 0.1	1
Edge	0.1 through 0.2	2

- defects in 2 mm annular area around the lens edge, except for cracks, are not subject to limitations. No cracks are allowable.

Lenses shall withstand the static load test of 22-mm steel ball which carries a force (100 ± 2) N

Organic materials used for lenses manufacturing shall be optically-homogeneous, colourless and shall have refractive index within the limit from 1.49 to 1.74.

Luminous transmittance

Lenses material shall ensure UV absorption: UVB-100%.

Luminous transmittance factor of lens in design reference point (for colourless coated lenses) shall be at least 3%.

Luminous transmittance factor for night driving spectacle lenses shall be at least 75%.

Categories for luminous transmittance and the related permissible transmittance in the ultraviolet solar spectral range

		Visible spectral range		Ultraviolet spectral range	
		Range of luminous transmittance τV		Maximum value of solar UV-A transmittance $\tau SUVA$	Maximum value of solar UV-B transmittance $\tau SUVB$
Tint description	Luminous transmittance category	from over %	to %	> 315 nm to 380 nm UV-A	> 280 nm to 315 nm UV-B
Clear or very light tint	0	80,0	100	τV	0,05 τV
Light tint	1	43,0	80,0	τV	0,05 τV
Medium tint	2	18,0	43,0	0,5 τV	1,0 % absolute or 0,05 τV, whichever is greater
Dark tint	3	8,0	18,0	0,5 τV	1,0 % absolute
Very dark tint	4	3,0	8,0	1,0 % absolute or 0,25 τV, whichever is greater	1,0 % absolute

It is recommended that a tint should be ordered by reference to a manufacturer's sample. Such a tint shall not be obviously dissimilar from the tint of the sample and its assessment is not restricted by its luminous transmittance τV measured by spectrophotometer.

For a lens ordered by a specific luminous transmittance τV shall have a measured τV at the design reference point within ± 8 % absolute of that ordered. The tint of the two lenses of a pair should not be obviously dissimilar.

Depending on tinting strength lenses are divided into the following categories 0,1,2,3,4. Following recommendations for driving are applied:

Not recommended for driving	●
Not recommended for night driving	●
Neither	●

LUMINOUS TRANSMITTANCE FACTOR	RESTRICTIONS OF USE		
	●	●	●
Lenses in category 0	X		
Lenses in category 1		X	
Lenses in category 2		X	
Lenses in category 3 if Tv>8.0%		X	
Lenses in category 4 if Tv<8.0%			X
Photochromic lens	X		

The following materials shall be used for manufacturing of the lenses:

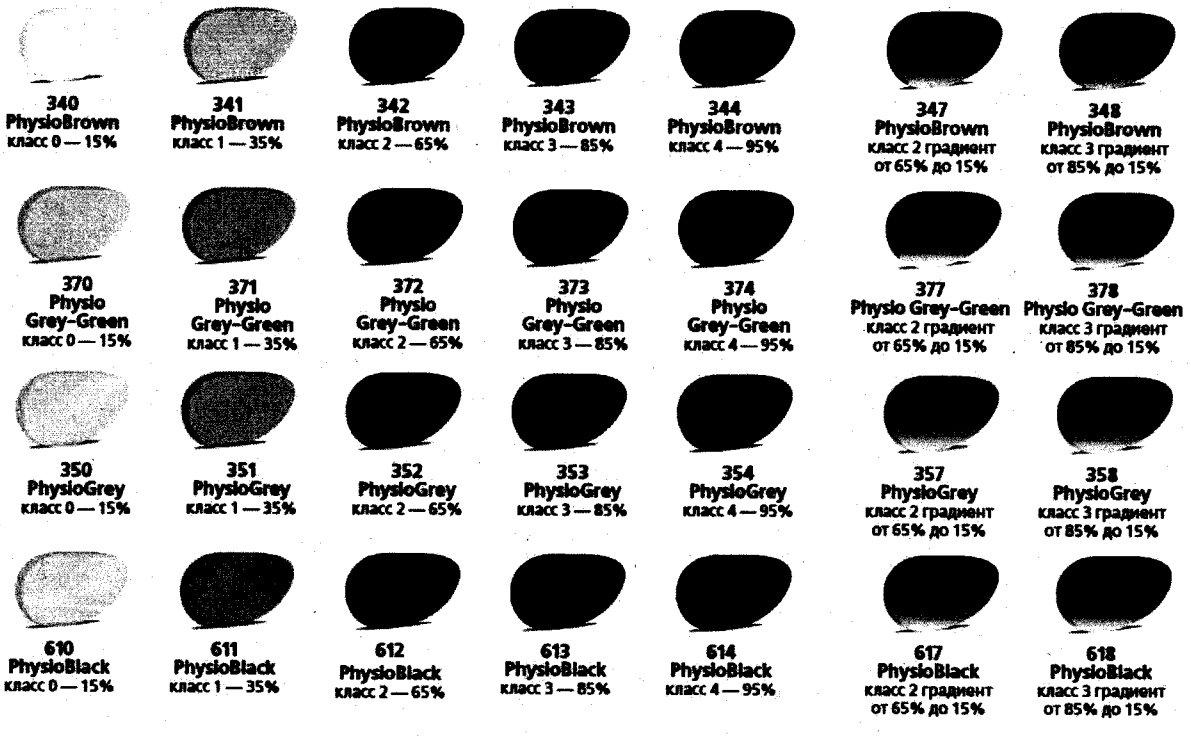
ORGANIC LENS

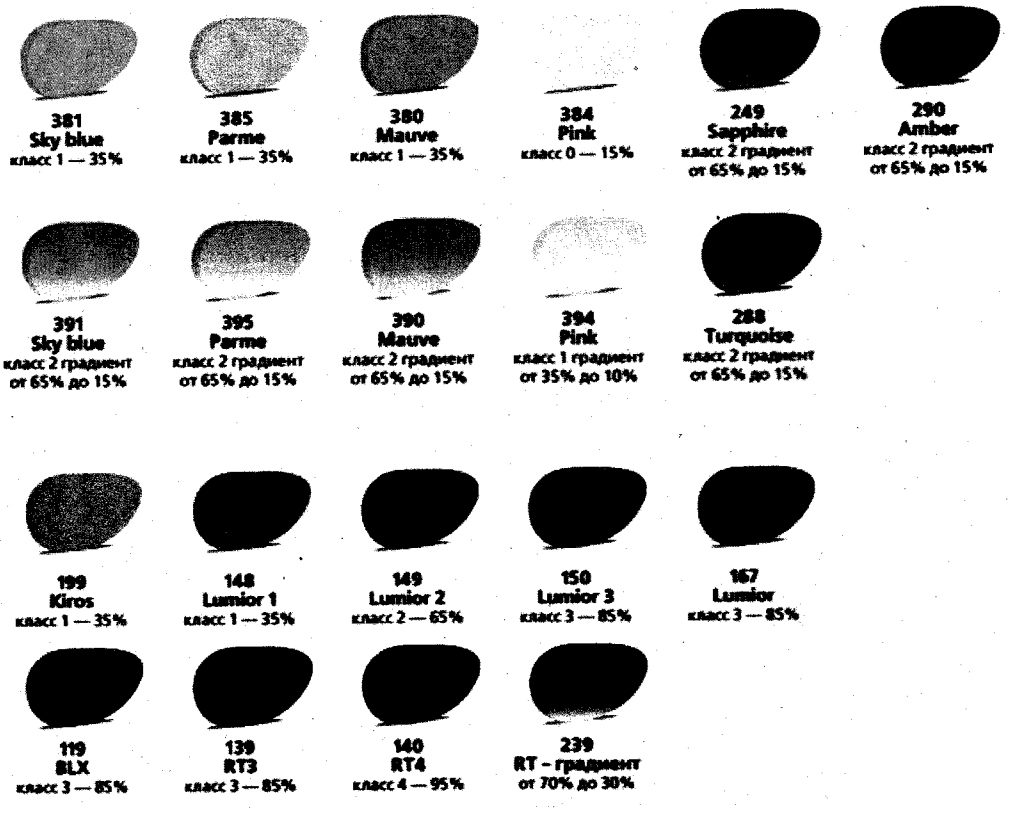
Material	Index	Abbe ne	Specific gravity	UV cut	Chemical components
1.5 (CR39)**	1.502	58	1.31 g/cm3	355nm	diethylene glycol bis (allyl carbonate)
1.5 Photocromic (CR607)**	1.499	60	1.27 g/cm3	383nm	
1.5 Photochromic (CR39)	1.502	58	1.31 g/cm3	393nm	
1.5 Polarized (CR39)	1.502	58	1.31 g/cm3	380nm	
1.6 (MR8)	1.601	42	1.30 g/cm3	398nm	polythiourethanes produced by a reaction of a polythiol with di-isocyanates
1.6 Photochromic (MR8)	1.601	42	1.30 g/cm3	400nm	
1.6 Polarized (MR8)	1.601	42	1.30 g/cm3	400nm	
1.67 (MR7)	1.665	32	1.36 g/cm3	395nm	
1.67 Photochromic (MR7)	1.665	32	1.36 g/cm3	400nm	
1.74 (N19)	1.736	31	1.46 g/cm3	400nm	episulphides
1.74 Photochromic (N19)	1.736	31	1.46 g/cm3	400nm	
Polycarbonate (PC)	1.591	31	1.20 g/cm3	380nm	polycarbonate
Polycarbonate Photochromic (PC)	1.591	31	1.20 g/cm4	390nm	
Polycarbonate Polarized (PC)	1.591	31	1.20 g/cm5	390nm	

MINERAL LENS

1.5 UV CLEAR	1,5	59	2.48 g/cm3	silicon dioxide (SiO2), sodium oxide (Na2O) from sodium carbonate (Na2CO3), calcium oxide (CaO)
1.5 UNICROWN	1,5	58	2.61 g/cm3	
1.6/41 White	1,6	42	2.63 g/cm3	
1.7/35 White	1,7	34	3.21 g/cm3	
1.7/42 White	1,7	42	3.21 g/cm3	
1.8/35 White	1,8	34	3.65 g/cm3	
1.9/31 White	1,9	30	3.99 g/cm3	
UV DG 37	1,5	60	2.48 g/cm3	
PHOTOGRAY EXTRA	1,5	57	2.41 g/cm3	
PHOTOBROWN EXTRA	1,5	46	2.41 g/cm3	
FUSIBLE PHOTOGRAY 16	1,6	42	2.70 g/cm3	
XDF DARK GRAY	1,5	56	2.41 g/cm3	
XDF LIGHT GRAY	1,5	57	2.41 g/cm3	

AVAILABLE TINTS:



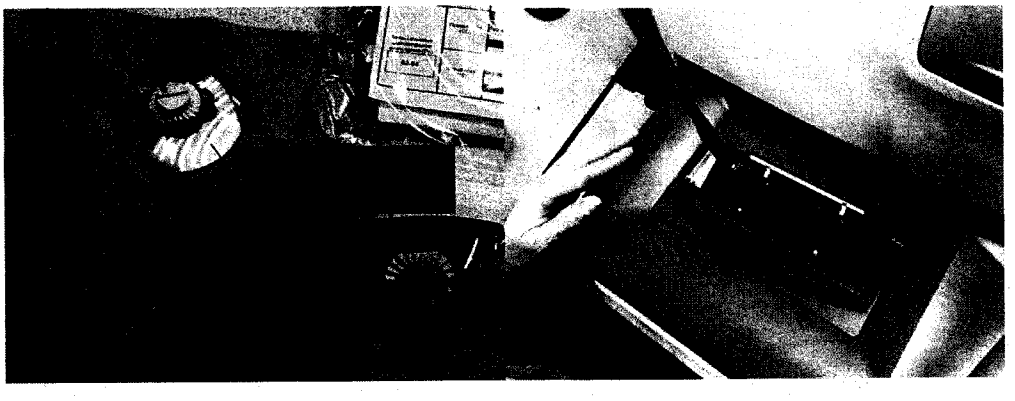


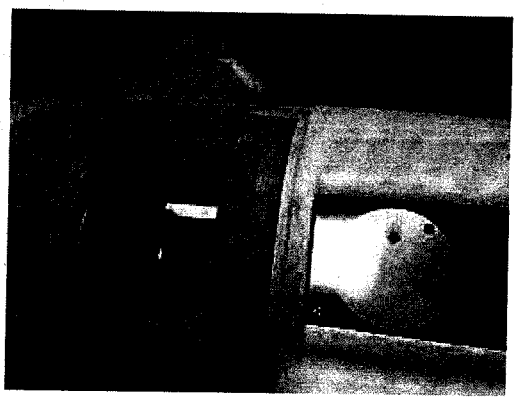
3. USAGE CONDITIONS. INSTRUCTION FOR USE. CARE INSTRUCTIONS.

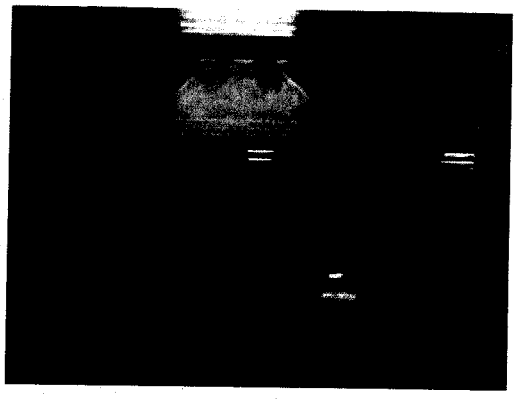
3.1 Lenses shall fit for use at ambient temperature of -45°C to +40°C and relative humidity up to 80%.

3.2. Instruction for use:

Spectacle lenses are processed by means of edging a round lens in an electronic finishing machine until it fits a frame.







After that, a frame is shaped according to STB GOST standards and anthropological data of the patient.

Spectacles are manufactured following the prescription of ophthalmologist.

The process is verified by an automatic dioptrimeter. It prints a cheque to warrant that spectacles have been manufactured according to the prescription.