



Unisil was developed following feedback from leading eye care practitioners, who shared their desire for a wider range of silicone hydrogel options to meet the needs of their custom soft lens patients. Unisil offers outstanding surface wettability, and the increased oxygen permeability of a silicone hydrogel, combined with a higher modulus to enable more complex lens designs, improving visual acuity and supporting corneal health.

Please Note: Regulatory requirements and standards vary from country to country, and are constantly evolving. As a global company we want to be sure we provide you with detailed technical information, specific to your market, where appropriate, rather than using the condensed and simplified technical information on the website. If you need to use technical data for quality paperwork, or for a regulatory submission, please contact your account manager to obtain this precise and detailed information to support your regulatory requirements, we will be happy to help.

### **Material Characteristics**

PROPERTY	UNISIL	
Oxygen Permeability (ISO) at 35°C (Barrer)	50	
Water Content at 20°C by Weight (%)	62	
Swell Factor at 20°C	1.41	
Refractive Index at 20°C - Hydrated	1.40	
Refractive Index at 20°C - Dry	1.51	
Modulus - Elasticity (MPa)	0.80	
Tensile Strength (MPa)	0.88	
Elongation to Break (%)	200	
UV Blocker	Standard	
Classification (ISO)	Filcon 5B (50) [62%]	

Please note: Some values may have been rounded for presentation purposes. Please contact your account manager for further details.

## **Manufacturing Consumables**

Low Melt Black Wax Contapol 3 Polish

Delrin Polishing Cup **Delrin Polishing Sponge** 

### **Accessories**

Tweezers Glass Vial Siloprene Bung

Tear Off Aluminium Seal DMV Soft Lens Handler/Remover

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## **Material and Lathing Recommendations**

DAC	REM	OPTOFORM	
INCHES/MINUTE	p/second	mm/MINUTE	
0.50	0.50	0.50	
(0.30 - 0.50)	(0.30 - 0.50)	(0.30 - 0.50)	
4	1666	100	
(3 - 4)	(1250 - 1666)	(75 - 100)	
8000	8000	8000	
(7000 - 9000)	(7000 - 9000)	(7000 - 9000)	
0.15	0.15	0.15	
(0.10 - 0.20)	(0.10 - 0.20)	(0.10 - 0.20)	
2	1066	50	
(1.5 - 2.5)	(633- 1066)	(38 - 64)	
8000	8000	8000	
(7000 - 9000)	(7000 - 9000)	(7000 - 9000)	
2	833	50	
(1.5 - 2.5)	(633- 1066)	(38 - 64)	
7500	7500	7500	
(7000 - 8000)	(7000 - 8000)	(7000 - 8000)	
0.05	0.05	0.05	
(0.05 - 0.10)	(0.05 - 0.10)	(0.05 - 0.10)	
	0.50 (0.30 - 0.50) 4 (3 - 4) 8000 (7000 - 9000) 0.15 (0.10 - 0.20) 2 (1.5 - 2.5) 8000 (7000 - 9000) 2 (1.5 - 2.5)	INCHES/MINUTE p/SECOND   0.50 (0.30 - 0.50) 0.50 (0.30 - 0.50)   4 (3 - 4) 1666 (1250 - 1666)   8000 (7000 - 9000) 8000 (7000 - 9000)   0.15 (0.10 - 0.20) 0.15 (0.10 - 0.20)   2 (1.5 - 2.5) 1066 (633-1066)   8000 (7000 - 9000) 8000 (7000 - 9000)   2 (1.5 - 2.5) 833 (633-1066)   7500 (7000 - 8000) 7500 (7000 - 8000)   0.05 0.05	INCHES/MINUTE     p/SECOND     mm/MINUTE       0.50 (0.30 - 0.50)     0.50 (0.30 - 0.50)     0.50 (0.30 - 0.50)       4 (3 - 4)     1666 (1250 - 1666)     100 (75 - 100)       8000 (7000 - 9000)     8000 (7000 - 9000)     8000 (7000 - 9000)     8000 (7000 - 9000)       0.15 (0.10 - 0.20)     0.15 (0.10 - 0.20)     0.15 (0.10 - 0.20)     0.15 (0.10 - 0.20)       2 (1.5 - 2.5)     1066 (633 - 1066)     50 (38 - 64)     38000 (7000 - 9000)     8000 (7000 - 9000)     8000 (7000 - 9000)     7000 (7000 - 9000)     7500 (7000 - 8000)     7500 (7000 - 8000)

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## **HYDRATION PROTOCOL**

Unisil is a silicone hydrogel material and will need to be hydrated differently to normal hydrogels. Silicone is naturally hydrophobic and will resist hydration at normal temperatures. Additional energy in the form of heat will need to be used during the process in order to achieve full hydration. Failure to do this will result in lenses failing to meet target powers as the refractive index of partially hydrated lenses will be higher than anticipated from the certificate of conformity.

### **Protocols**

Contamac suggests the following protocols to ensure the complete hydration process of contact lenses manufactured from Unisil silicone hydrogel material.

Contamac recognises two types of incubation ovens common in the manufacturing of contact lenses. Isothermal and Ramp Program incubation ovens.

The advantage of using a ramped protocol is that the temperature in the oven can be increased and reduced gradually, thus avoiding the possibility of thermal stresses being introduced into lenses due to too rapid heating or cooling.

Depending on the type used in the manufacturing operation, follow the relevant protocol below.

If you require further advice our experts can assist.

#### 1. Isothermal Incubation:

- Place dry lens in vial containing Buffered Saline (BS) with a pH 6.8 - 7.5 @ room temperature
- Cap vial and shake for 30-seconds to prevent lens 11. sticking to walls of vial
- III.Hydrate in BS @ room temperature for a minimum of 2-hours
- IV. Place in an Oven at 95°C and incubate overnight (>16
- ٧. Allow lenses to cool to room temperature for a minimum of 2-hours (after 95°C incubation)
- VI. Change BS for fresh solution
- Measure hydrated lens parameters upon change of BS solution
- VIII. Package lenses
- Autoclave lenses for a minimum of 20 minutes

### 2. Ramp Program Incubation:

- Place dry lens in vial containing Buffered Saline (BS) with a pH 6.8 - 7.5 @ room temperature
- Cap vial and shake for 30-seconds to prevent lens 11. sticking to walls of vial
- Hydrate in BS @ room temperature for a minimum of 2-hours
- IV. Place in an oven and implement the following program conditions:
  - A. START TEMPERATURE 23°C
  - B. RAMP up to 95°C in 'STEP' mode
  - C. HOLD at 95°C for 15-hours1
  - D. RAMP down to 23°C in 'STEP' mode
  - E. END program
- Once the oven has cooled to <40°C remove lenses and allow to settle at room temperature for at least 1-hour
- VII. Change BS for fresh solution
- VIII. Measure hydrated lens parameters upon change of BS solution VIII Package lenses
- Autoclave lenses for a minimum of 20 minutes IX.

<sup>1</sup>The 95°C HOLD can be reduced if necessary but to not less than 12-hours. However, it is generally considered beneficial to HOLD the lenses at 95°C for as long as possible to ensure that they are fully hydrated.

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