

# User's Manual





Document No: 7000043 Rev. A(0)

08/2013

# **Table of Contents**

1.	Introduction	1
2.	Technical Specifications	2
3.	Terms of Use	3
4.	Warranty and Service	6
5.	System Description	7
	5.1. Valon 5G	
	5.2. PC and Touch screen	
	5.3. Foot switch	
	5.4. Slit Lamp Adapter	10
	5.4.1. SLA - Revolver	10
	5.5 Smart Wheel	
	5.6 Laser Aperture	11
	5.7. Optical beam path	
	5.7.1. Laser	12
	5.7.2. System (normal)	اں۔۔۔۔۔ 14
	5.8.1 Eve Safety Filter	1 <del>4</del> 1 <i>1</i>
	5.8.2 Eve safety goggles	<del>ب</del> ا 1 <i>4</i>
	5.8.3. Cables	15
6.	Using Valon	16
	6.1 Before Use	16
	6.1.1. Ensuring the Basic Safety	16
	6.1.2. Turning the System on	
	6.1.3. Adjusting the Binocular Lenses	18
	6.1.4. Selecting the Spot Size	18
	6.2. Using the software	19
	6.2.1. Graphical user interface (GUI)	19
	6.2.2. Adjusting the Settings	_20
	(1) Pulse Duration	20
	6.2.3. Treatment Mode	22
	6.2.4 Before treatment	24
	6.2.5 Connecting / disconnecting the fiber	24
	6.2.7 Treatment Instructions	24 24
	6.2.8 Einisching the treatment	24 25
	6.2.9 Applications of the Smart wheel	20 25
	6 2 9 1 Changing the pattern	25 25
	6 2 9 2 Changing the pattern size	20 25
	6.2.9.3. Using the micromanipulator	25
	6.2.9.4. Adjusting the Orientation of the Pattern	26
	6.2.9.5. Changing the power	27

### **Table of Contents**

6.2.10. Treatment Information	28
6.2.11. Lens Selection	_29
6.2.12. Setup	_30
6.2.13. Service	31
6.3 Instructions for After Use	32
6.3.1. Turning off the system	
7. Patterns	_33
7.1. Square	34
7.2. Sector	
7.3. Circle	35
7.4. Arc	35
7.5. Line	36
7.6. Spot repetition	
8. Safety	37
8.1. Emergency Stop Button	37
8.2. Double Control	37
8.3. Eye Safety Instructions	38
8.3.1. Eye Safety Filter (OD > 5)	38
8.3.2. Laser Safety Eyewear Requirements	38
8.4. Caution for High Power	38
8.5. Prevention of unauthorized use	39
8.6. Requirements for the treatment room	
9. Maintenance	40
9.1. User Maintenance	40
9.2. Essential performance and maintenance	40
10. Errors	41
10.1. Confirmable Errors	41
10.2. Non-confirmable Errors	42
10.3. Laser Heatsink Overtemperature	42
10.4. Warnings caused by the RTC4 card	42
10.5. Warnings caused by Spot Recognition	42
11. Troubleshooting	44
11.1. System does not turn on	44
11.2. Aiming beam not visible	44
11.3. Aiming beam not in focus	44
11.4. Aiming beam not correctly centered	45
11.5. Smart wheel not active	45
11.6. Foot switch not active	45
11.7. Error messages	45

# **Table of Contents**

12. System Labeling	46
12.1. System type label and serial numbers	46
12.2. Label and symbol definitions	47
13. Disposal of Waste	.50
14. Electromagnetic compatibility	
Revision history	.55

### 1. Introduction

Valon Multispot Laser, Valon 5G, is a semi-automated laser system that enables fast and effective treatment of retinal diseases. Connected to most popular microscopes it offers variable functions for transpupillary laser photocoagulation. Aside from standard single shot photocoagulation Valon also offers varied laser scanning patterns enabling a faster and high-quality treatment.

The system is composed of a slit lamp adapter integratable with compatible microscopes. With computer controllable scanners it produces a variety of different predefined spot patterns to suit several treatment applications. The slit lamp adapter (SLA) also allows the adjustment of the spot size: available sizes are (50 µm,) 100 µm, 200 µm, 300 µm and 400 µm. The 532 nm laser beam is produced by a laser installed in the console and transmitted to SLA by an optical fiber. The system itself is controlled by a PC connected to a monitor with a touch screen enabling the physician to adjust suitable settings for the treatment. The available settings are the shape and size of the figure formed by the single spots, the duration and intensity of the laser pulse, the mutual distance of spots and the intensity of the aiming beam. The program also produces a preview of the spot pattern to visualize the area to be coagulated in the target tissue.

To ease the control of the system during treatment, a smart wheel is also included for manual control. It enables the physician to change between figures, figure sizes and the positioning of the figure and also changing the power without looking away from the microscope. The system is designed to suit hospital environment.

Valon provides a safe and costefficient treatment by shortening the treatment time and making it more effective. The short period of time required for the coagulation of a large amount of spots makes the treatment also more bearable for the patient. Valon has been developed in collaboration with medical experts to ensure the optimal properties for safe and efficient use. Caution! Valon should only be used for treatment purposes

**Caution!** This medical elecrical equipment is intended for use by healthcare personnel only

**Caution!** U.S. Federal law restricts this device to sale by or on the order of a physician

### **2. Technical Specifications**

Treatment wavelength	532 nm
Spot size	50 μm, 100 μm, 200 μm, 300 μm and 400 μm
Slit Lamp	Integrateable to various uppert light source type slits-lamps e.g. Haag- Streit BM and BQ and CSO SL 990
Laser	Frequency doubled Nd-YVO 532 nm
Laser Power	0-2000 mW (nom. 3000 mW limited to 2000 mW), maximum available power depends on the spot size
Accuracy of internal pow- er measuring	±5 %
Laser class (treatment)	IV
Pulse duration	10-650 ms, 10-30 ms in pattern mode
Aiming laser	635 nm, adjustable brightness
Laser class (aiming)	3R, limited to class I
Available Patterns	Square, Circle, Line, Sector, Arc, Spot
User Interface	Touch screen or smart wheel
Risk classification	llb
Electrical classification	Туре 1
NOHD (nominal ocular hazard distance)	5.2 m
NA (numerical aperture)	0.075-0.125
Operating room tempe- rature	+10°C - +35°C humidity 30-90 % (non-condensing) 800-1060 hPa
Condition of transport and storage	-10°C - +55°C humidity 10-95 % (non-condensing) 800-1060 hPa
Mains input specification	100/115-120/220-240 V~ 50/60 Hz 600 W (supported voltages, the de- vice is configured for one voltage)

# 3. Terms of Use

The device is designed only for treatment purposes that are described below.

#### Functional purpose of the device (intended use)

The Valon-laser proposes a radically different way to perform **photocoagulation**. A concept introduced by Meyer-Schwickerath for the treatment of diabetic retinopathy in the 1950s.

Photocoagulation entails the delivery of a laser beam to the fundus of the eye with the assistance of a slit lamp (microscope) and a contact lens. A certified physician places several hundred laser burns ("spots") in selected areas of the patients fundus. The burns are used to destroy the abnormal blood vessels that form in the retina of the diabetic patient. This treatment has been shown to reduce the risk of severe vi-sion loss for eyes at risk by 50%.

The treatment parameters for retinal photocoagulation have remained relatively constant since the first description of an argon laser coupled to a slitlamp delivery system in 1970. The three separate but interdependent variables available to the clinician are the **beam size**, **power**, **and duration of the pulse**. Typically, for diabetic retinopathy, retinal vascular applications, and the treatment of retinal breaks, the retinal laser spot sizes range from 100 to 500  $\mu$ m, the pulse durations from 100 to 200 milliseconds, and the power from 100 to 750 mW.

#### Intended patient population and medical condition (indication for use)

Photocoagulation has been shown to be effective in the treatment of **proliferative diabetic retinopathy and advanced forms of nonproliferative diabetic retinopathy** associated with macular edema in large, prospective, multicenter, randomized trials—the DRS and ETDRS. **Caution!** This medical electrical equipment is inteded for use by professional healthcare personnel only

**Caution!** Mobile RF communications equipment can effect medical electrical equipment

#### **Caution!**

Medical electrical equipment needs special precautions regarding EMC and need to be installed according to EMC information

# 3. Terms of Use

In addition to proliferative and non proliferative diabetic retinopathy, other treatments and pathologies that may benefit from laser photocoagulation include:

- Choroidal neovascularization
- Branch and central retinal vein occlusion
- Age-related macular degeneration
- Lattice degeneration
- Retinal tears and detachments
- Iridotomy
- Iridectomy
- Trabeculoplasty in angle closure and open angle glaucoma

Valon is solely intended for treating the lesions mentioned above.

#### Complications (reasonable foreseeable)

Properly conducted laser photocoagulation rarely causes serious complications. The adverse effects of PRP include visual field constriction, night blindness, color vision changes, inadvertent laser burn, macular edema exacerbation, acute glaucoma, and traction retinal detachment.

#### **Contraindications**

Contraindications for using the laser include opacities in the cornea or lens, or blood in the vitreous humor that may interfere with the delivery of laser energy to the desired structure. Warning! Do not use this device in the presence of flammable anesthetics, vapors or liquids.

### 3. Terms of Use

#### Explanation of any novel features

Valon delivers patterns of several laser spots with a pulse duration that is five times shorter than that of a conventional laser. The Valon method of photocoagulation has the following advantages when compared to a conventional, single spot treatment:

- Minimized thermal damage leading to homogenous and predictable burns.
- Less total energy required
- · Less discomfort for the patient

In addition to the conventional single shot setting, Valon can deliver several **different patterns** including sectors, squares, arcs and circles.

These modes of operation are a new approach to the treatment of diabetic retinopathy, retinal tears, vascular occlusions and other retinal pathologies.

The laser is operated via a touch screen and a smart wheel wheel, which gives the physician the freedom to choose a pattern without removing their eyes from the oculars.

The user is allowed to perform only the maintenance or service operations that are described in this manual. Further operations might damage the device and the user. Such service operations may be performed solely by qualified maintenance personnel.

Before performing treatment operations with Valon, the user must receive user training.

# 4. Warranty and Service

The warranty of Valon is 12 months for the entire system excluding fiber and optics. Painted surfaces are not covered by warranty if the system is left in direct sunlight or subjected to other UV radiation for long periods of times.

System does not contain components that could be serviced by the user. In case the system needs service, please contact the manufacturer or an authorized service representative.

Manufactured by:

Valon Lasers Oy Merimiehenkuja 5 01670 Vantaa FINLAND tel. +358 9 894 61600

#### 5.1. Valon 5G

The Valon MultiSpot Laser 5G consists the laser console and slit lamp adapter. The console includes the laser source, computer, touch screen display and all the electronics. The console is on wheels and is easily movable. Use the integrated handle when moving the device. The foot switch is connected to the console. Functions and connections between different parts of the trolley are described in the following sections.

#### Warning!

Handle with extreme care when moving the system to protect especially the optical fiber



Warning! The system should not be stacked or located too close to other equipment

Warning! Do not move the system during treatment

Warning! Do not lean into the system not to tip it

#### 5.2. PC and Touch screen

The system is equipped with a computer, touch screen monitor and MultiSpot software. Key specifications are presented below.

Industrial PC

#### PC specifications

Computer type

**Display** type

Native screen resolution

**Operating** system

Software

10.4" touch screen 1024 x 768 Windows XP embedded + sp2 MultiSpot 1.07 d2x Driver versio 3.01.0 RBC9 driver for smart wheel Touch screen monitor driver Scanner controller drivers Cute PDF 2.8

GPL Ghostscript 8.15

SLP 440 driver

Warning!

Never use the PC for any other purpose than treatment purposes. Do not connect to the internet. The PC contains no antivirus software. Also, the use of any external equipment or accessories is not allowed.

#### 5.3. Foot switch

When the foot switch is pressed the system starts the process of coagulating the defined spot pattern with the 532 nm laser beam. The laser emission can always be interrupted by releasing the foot switch if the patient's eye



has moved or there is any doubt about the function of the system. The system terminates the drawing of the pattern instantly when the foot switch is released.

If the foot switch stays pressed after the pattern is drawn, the system does not continue the coagulation. To produce a new laser pattern, the foot switch must be released and repressed.

The foot switch is solidly connected to the laser console box.

Connecting the foot switch:



#### 5.4. Slit Lamp Adapter

The slit-lamp adapter (SLA) contains the scanners that deflect the laser beam delivered from the laser console by an optical fiber. The SLA case envelopes the focusing optics and the scanner electronics. The SLA is intergratable to various upper light source type slit lamps e.g. Haag-Streit slit lamp models 900BM and 900BQ and CSO SL 990. The connection of the SLA to the console iw shown below.





#### 5.4.1. SLA - Revolver

The SLA also includes a focusing unit that enables the adjustment of the spot size. The spot size is changed by rotating the revolver on the SLA. Available spot sizes are 50µm, 100µm, 200µm, 300 µm and 400µm.

Connect one end of the fiber to the slit-lamp adapter and the other end to the SMA connector on the front panel of the device.



Slit lamp adapter and revolver

#### **Caution!**

Do not bend the fiber cable tighter than to the minimum bending radius of 100 mm. Bending the cable too sharp may break the cable.

#### **Caution!**

Make sure the fiber is properly connected to the console and slit-lamp adapter before operating the device.

#### **Caution!**

Secure any excess cables or fiber cable to the handle of the device or to the slit-lamp table to make sure the cables are not lying on the floor.

#### 5.5 Smart Wheel

The smart wheel is a manual control button that allows the user to change figure, figure size, figure position, figure orientation and power during the treatment without having to use the touch screen.

The smart wheel is connected to the USB-port on the front panel of the console.



#### 5.6 Laser Aperture

Laser aperture is situated on the slit lamp and it is marked with laser aperture sticker.



#### Note

The applications of the smart wheel are presented in section 6.2.8.

#### 5.7. Optical beam path

#### 5.7.1. Laser



- 1. Green power laser generator 532nm
- 2. Green beam path 532nm
- 3. Collimating lens
- 4. Red aiming beam path 635nm
- 5. Red aiming beam laser diode 635nm
- 6. Beam combiner
- 7. Coupling lens
- 8. Fiber connector
- 9. Fiber of delivery device
- 10. Output beam 532 nm + 635 nm aiming beam
- 11. Green power laser measuring diode
- 12. Frequency doubling crystal
- 13. Laser crystal (Nd:YVO)
- 14. Laser Diode

#### 5.7.2. System (normal)



- 1. Laser unit
- 2. Fiber
- 3. Collimating lens
- 4. Scanner No 1
- 5. Slit lamp adapter
- 6. Transferring lenses

- 7. Scanner No 2
- 8. Focusing lens
- 9. Slit lamp
- 10. Beam combiner
- 11. Slit lamp optics
- 12. Slit lamp mirror

#### 5.8. Accessories

#### 5.8.1. Eye Safety Filter

The eye safety filter protects the eyes of the user. The optical density of the filers is OD>5 which is a standard value in this field.

The shape and location of the filter depends on the slit lamp model. In Haag-Streit BM the filter is located as shown in image below.





In Haag-Streit BQ (left) and CSO 990 (right) the ringshaped filter is located between microscope and binoculars.



#### Warning!

Use of any other accessories may result in noncompliance of standards

Warning! Never use any other eye safety filters with the system

#### Caution!

Do not touch the filter plates! The plates may become scratched

**Caution!** Do not use accessories other

than the ones approved by Valon.

#### 5.8.2. Eye safety goggles

A pair of goggles (OD > 5 for 532nm) is delivered with each Valon unit.



#### 5.8.3. Cables

Cable	Length	Shielded	Туре
Power cable	2 m	No	AC
Foot switch cable	2 m	No	I/O
Slit lamp power cable	2 m	No	AC
Scanner cables	3 m	No	I/O
Smart wheel cable	1.7 m	Yes	DC
Spot size recognizion cable	3 m	Yes	I/O
Fiber cable	3 m		optical

#### Warning!

Use of cables other than the ones supplied with the system or sold as replacement parts by the manufacutrer, may result in increased EMC emission or decreased EMC immunity.

#### 6.1 Before Use

#### 6.1.1. Ensuring the Basic Safety



1. Check that the eye safety filter is installed.

2. Ensure the eye safety of all personnel in the treatment room: Laser safety eyewear (OD > 5 for 532nm) is required.

#### Warning!

Never use Valon if there is any doubt about the presence of the eye safety filter

#### Warning!

Dot not remove the eye safety filter under any circumstances

#### Warning!

Never look directly into the laser light source or laser light scattered from reflective surfaces!

#### Note

See section 8. Safety for further safety instructions

#### 6.1.2. Turning the System on

• Plug the power cable into the electrical outlet

• Turn the system on by turning the key switch clockwise

• The system starts automatically and the graphical user interface (GUI) of the MultiSpot software appears on the touch screen



**Note** If the screen is not active even though the system is started, ensure that the monitor is on (see page 11).

The key switch



The GUI of the software

#### 6.1.3. Adjusting the Binocular Lenses

- 1. Adjust the focus of one eyepiece by checking if the focusing stick is seen in focus (laser is not active). If the focusing stick is not in focus, adjust the diopter settings of the eyepieces to a suitable position.
- 2. Then focus the other eyepiece similarly.

#### 6.1.4. Selecting the Spot Size

- 1. Choose the suitable spot size by rolling the revolver. A larger spot size is chosen by turning the revolver clock-wise.
- 2. Available spot sizes are 50 μm, 100 μm, 200 μm, 300 μm and 400 μm.
- 3. The resulting spot size is shown on yellow background on the revolver and as a field on the GUI when the program is on setting mode.



In case the lenses are not adjusted, the focus of the image and the spots are not on the same plane. Thus the coagulations may exceed or undershoot the correct depth in the retina.



Changing the spot size



The spot size indicator

#### 6.2. Using the software

#### 6.2.1. Graphical user interface (GUI)

- 1. When the computer is on, the GUI of the program appears on the touch screen.
- 2. The black bar (1) on the top of the GUI shows the current laser status. ("Laser standby") The pilot laser and the treatment laser are both inactive.
- 3. The available settings are described on the following pages.



#### 6.2.2. Adjusting the Settings



#### (1) Pulse Duration

Choose a setting for the duration of the laser pulse at Pulse Duration (1) by pressing the + and – buttons. Available settings are 10-30 ms for patterns and 10-650 ms for single spot.

#### (2) Laser Power

Adjust the power of the laser pulse at Laser Power (2) similarly by pressing the + and – buttons. Available settings depend on the spot size.

#### (3) Aiming Beam

Use the + and – buttons to adjust suitable power for the aiming beam.

#### (4) Selected Pattern

Select the shape of the figure at Selected Figure (4) by pressing the image of the desired

#### (5) Interval

The single spot mode allows repeated laser pulses to the target tissue at a specified interval, adjustable on the Interval menu. Available intervals are 200-640 ms. The Interval field is active only in case single spot mode is selected.

Note More on the applications of patterns can be read at section 7

#### Attention!

The maximum power for 50 µm spot is 800 mW, for 100 µm spot is 1200 mW and for all others 2000 mW.

#### Warning!

Do not use smart wheel micromanipulator with interval mode.

#### (6) Figure Size / Radius

Select the size of the figure at Figure Size (6). The size is displayed as the number of spots on one edge of the figure. The available scale depends on the figure type. For arcs the figure size can be changed using smart wheel or by touching the pattern on the screen. Figure size changes to Radius when the radius of the arc is adjustable.

#### (7) Distance

The spacing between the spots can be chosen at Distance (7). The values for the distance are scaled as multiples of the spot size.

#### (8) Selected Spot Size

The spot size installed by the revolver is displayed at Selected Spot Size (8). To change the spot size, see section 6.1.4.

#### (9) Real Spot Size

The size of the spot on the retina depends on the used contact lens. When the lens is selected the real spot size on the retina is displayed on the screen.

#### (10) Fluence

Displays the fluence on the retina. Fluence depends on the power, pulse duration and real spot size and is calculated as follows

where *P* is the laser power, *t* is the pulse duration and *r* is the real spot size

$$F = \frac{Pt}{\pi r_{real}^2}$$

#### (11) Entering Treatment Mode

After the settings are made, press the top bar (11) to enable both pilot laser and treatment laser and to enter the treatment mode.

#### (12) Fixation light (optional feature)

Fixation light is available with 100  $\mu$ m and 200  $\mu$ m arc pattern. When fixation light is ON, aiming beam draws a small cross in the center point of the arc.

#### 6.2.3.Treatment Mode



When the laser is enabled, the pilot laser is active and draws the outline or shows all spots of the chosen pattern. The treatment laser is ready and controllable via foots-witch.

Settings can be changed without disabling the laser by using the touch screen or the smart wheel (see section 6.2.9).

#### (1) Laser status

The top bar (1) shows the laser status. Currently the status is "Laser enabled". If the the treatment is over or there is a longer pause in treatment, disable the laser by pressing the laser status button.

#### (2) The Laser emission warning

The Laser emission warning (2) is shown on the top bar when the treatment laser is active.

#### (3) Outline / Spots

From Outline / Spots button (3) user can choose whether the aiming beam shows the outline of the selected pattern or the spots of the selected pattern.

#### (4) Laser Counter

The Laser Counter field (4) shows the number of the coagulated spots. It can be reseted by pressing the Reset button. Attention If the spot is not in focus try adjusting the oculars or contact Valon Lasers service for help

#### 6.2.4 Before treatment

Before treatment, it is essential to ensure the spot is in focus and the pattern produced by the aiming beam matches exactly to the figure on the GUI preview.

#### 6.2.5 Connecting / disconnecting the fiber

When a fiber is disconnected from the device, an error message is displayed on the graphical user interface and laser output is disabled. When a fiber is reconnected, the software asks for type of fiber connection. The used can choose SLA (slit-lamp adapter), LIO (laser indirect ophthalmoscope) or Endo fiber.

Also, every time the device is started, the fiber type must be selected.

#### 6.2.6 Checking the Spot Focus

- 1. When the system is on treatment mode, the red pilot laser is active.
- 2. Check the spot focus on the focusing stick.
- 3. Check also the beam alignment by ensuring the spot is placed in the middle of the slit of the slit lamp.

#### 6.2.7. Treatment Instructions

- 1. Ensure the position of the patient is correct
- 2. Ensure that the figure drawn to the retina is completely visible. Otherwise the microscope has to be moved before starting the treatment.
- 3. Coagulate the figure by pressing the foot switch. The treatment laser coagulates a set of pulses to the target tissue. The program begins to coagulate the spots from the outer edge of the figure and continues to the center to ensure the safety of the treatment. A warning sound is produced when the treatment laser is active.
- 4. Each press of the footswitch produces one scanned pattern to the target tissue unless the treatment is interrupted prematurely by releasing the foot switch.

#### **Attention!**

As the aiming beam passes down the same delivery system as the working beam it provides a good means of checking the integrity of the system. If the aiming beam is not present, its intensity is reduced or it look diffused. this is a possible indication of a damaged or malfunctioning delivery system.

Warning!

Do not use the system if the pattern produced by the aming beam differes in any way from the pattern on the user interface!

#### 6.2.8. Finishing the treatment

- 1. After the treatment press the top bar to deactivate the treatment laser.
- 2. The program returns to the setting mode.

#### 6.2.9. Applications of the Smart wheel

#### 6.2.9.1. Changing the pattern

- Press the button once to change to another figure
- The figures change in the following order:

Square  $\rightarrow$  Triangle  $\rightarrow$  Circle  $\rightarrow$  Arc  $\rightarrow$  Line  $\rightarrow$  Single spot

#### 6.2.9.2. Changing the pattern size

Tilt the smart wheel left or right to increase or decrease the size of the pattern.

#### 6.2.9.3. Using the micromanipulator

The smart wheel can be used as a micromanipulator by moving the button in a plane.







More on the selection and applications of the patterns can be read at section 7.

#### 6.2.9.4. Adjusting the Orientation of the Pattern

Turn the smart wheel clockwise or counterclockwise to equivalently change the orientation of the pattern to suit the selected location.



By turning the manual control button the physician can e.g. produce a figure composed of several sectors to the retina.





#### 6.2.9.5. Changing the power

The laser power can be changed by pressing the smart wheel buttons. To increase the power press right button and to decrease the power press the left button.





When the power is changed with the smart wheel, it is shown by the aiming beam for 1 s. During this time, the foot switch and the smart wheel are inactive to lower associated risks. The font size depends on the spot size.



#### 6.2.10. Treatment Information

	LASER STANDBY						
LASER		TREATI	MENT REPORT		×		
Pulse Duration	PULSES		area 1,50 mm²	energy <b>0,04</b> j			
Laser Power	SPOTSIZE	PULSES	AVE. POWER	AVE. PULSE DURATION			
	400	0 0%	0mW	0ms			
Interval	300	0 0%	0mW	0ms			
—	200	48 100%	100mW	10ms			
	100	0 0%	0mW	0ms			
AIMING BEAM	50	0 0%	0mW	0ms			
Brightness	LENSE:	Maister Wie	de field				
Spots Outline	RESET		PRINT LABEL	PRINT PDF			
С	atment Info	Lens Sele	ction	Setup	Service		

The Treatment Information window details the used treatment parametres:

- The total number of coagulated spots
- The number of spots coagulated with each spot size (as chosen from SLA, without lens magnification) and the percentage of all spots
- The average power and pulse duration for each spot size
- The total area on the retina (calculated with the real spot size)
- The total energy delivered to the target tissue
- The selected lens

•

The treatment information can be printed to a label by pressing the "print label" button (optional)

#### 6.2.11. Lens Selection

	LASER STAN	DBY	
LASER	Select Lens	Magnification	×
Pulse Duration	NO LENS	1.0	
	VOLK AREA CENTRALIS	1.0	
Laser Power	GOLDMANN THREE MIRROR	1.08	
	VOLK TRANSEQUATOR	1.4	
Interval	RODENSTOCK PANFUNDUS	1.4	
—	MAINSTER WIDE FIELD	1.47	
	VOLK QUADRASPHERIC	2.0	
AIMING BEAM	MAINSTER 165	2.0	
Brightness	VOLK H-R WIDE FIELD	2.0	
	VOLK SUPERQUAD 160	2.0	
Spots Outline			Distance
🕑 Shut Down Tre	Lens Selection		

Select the proper contact lens to see the real spot size on the retina. The real spot size also affects the values of fluence and total treated area. Available lenses are presented below.

Spot size 200 μm	Spot size on the retina	Magnification
Volk Area Centralis	200	1
Goldmann Three Mirror	216	1.08
Volk Transequator	286	1.4
Rodenstock Panfundus	286	1.4
Mainster Wide Field	294	1.47
Volk Quadraspheric	400	2.0
Mainster 165 PRP	400	2.0
Volk H-R Wide Field	400	2.0
Volk Superquad 160	400	2.0

#### 6.2.12. Setup



Setup menu can be used for changing the settings of the smart wheel and language.

The micromanipulator and power adjustement features available on the smart wheel can be turned off by unmarking the boxes in the upper section of the setup screen. Select the language of the software by pressing the corresponding language button.

After changing any settings press save to enable new settings.

#### 6.2.13. Service

LASER Pulse Duration Laser Power Laser Power Interval	Write correct password to enter service mode DK CLEAR 1 2 3 4 X
AIMING BEAM. Brightness Spots Outline	- + +
🕁 Shut Down Treat	tment Info Lens Selection Service

The service window is meant only for trained service personnel and it is therefore protected with a password.

#### 6.3 Instructions for After Use

#### 6.3.1. Turning off the system

- 1. Ensure the laser is disabled.
- Turn off the software by selecting shut down from the menu and then by pressing ok.
- When the computer has shut down, turn the key switch and remove the key.

	LASER S	TANDBY		
LASER Pulse Duration	Are you sure you want to	shut down the system?	×	
Laser Power	ОК	CANCEL		
Interval				
AIMING BEAM				
Brightness			e	
Spots Outline	r igure	- 012G	Dist	
		+		+
🕹 Shut Down	Lens Selection			

#### **Attention!**

Make sure windows has shut down before turning the key switch!

#### Attention!

Make sure the key is not available to unauthorized people

The software enables the use of six different patterns and thereby makes the system multifunctional and flexible. It provides the ability to choose a pattern, pattern size and orientation of the pattern optimal for the target tissue. These settings can be changed both with the GUI by pressing the +/- or by touching the pattern on the screen and with the smart wheel (see section 6.2.9).

In the following pages the patterns are presented in all available sizes, both in the form that is drawn to the retina and on the GUI.



#### 7.1. Square

The square pattern with 5 spots on the edge and the equivalent settings on the GUI. The available figure sizes are 1-5 for spot sizes (50  $\mu$ m,) 100  $\mu$ m and 200  $\mu$ m and 1-4 for spot sizes 300  $\mu$ m and 400  $\mu$ m.



#### 7.2. Sector

On Sector mode the laser draws a triangular shaped figure which can be used as a sector of a circle by turning it. The vertex point of the sector is left unburned. Available sizes are 1-4 for spot sizes (50  $\mu$ m,) 100  $\mu$ m and 200  $\mu$ m and 1-2 for spot sizes 300  $\mu$ m and 400  $\mu$ m





#### 7.3. Circle

On circle mode the system emits a circle-shaped figure of laser spots. In this case the distance between all adjacent spots is equal. Available sizes are 1-4 for spot sizes (50  $\mu$ m,) 100  $\mu$ m and 200  $\mu$ m and 1-3 for spot sizes 300  $\mu$ m and 400  $\mu$ m





#### 7.4. Arc

The arc-shaped pattern is resizable by quadrants. The radius is resizable from 600  $\mu$ m to 1600  $\mu$ m. Size can be adjusted using the touch screen or the Smart wheel. Radius is adjustable on the user interface. Arcs are delivered one by one from the inner arc to the outer arc.





#### 7.5. Line

The available figure sizes are 1-7 for all spot sizes.



#### 7.6. Spot repetition

On single-spot mode the system emits repeated laser pulses to the target tissue at a specified interval as long as the foot switch is pressed down. If interval is set to 0 the laser emits only one pulse. This mode corresponds to the standard photocoagulation treatment.





+

# 8. Safety

#### 8.1. Emergency Stop Button

- The emergency stop button is situated on the front panel of the laser console above the key switch.
- In case of an emergency you can shut down the system by pressing the button down.
- To continue the normal use the button needs to be released.
- Release the button by pulling and turning it clockwise according to the white arrows.



The emergency stop button

#### 8.2. Double Control

To increase treatment safety, the laser emission is ensured with double control: to emit the laser beam the laser must be enabled and the footswitch must be pressed down. Through this double control the physician can interrupt the treatment at any point by releasing the foot switch.

# 8. Safety

#### 8.3. Eye Safety Instructions

#### 8.3.1. Eye Safety Filter (OD > 5)

The eyes of the operating physician are protected by the eye safety filter installed to the slit lamp. The filter ensures that all laser radiation coming through the binoculars has been attenuated below class 1 limit. Thus, the physician should never look past the binoculars during treatment.



The location of the eye-safety filter

#### 8.3.2. Laser Safety Eyewear Requirements

Use of appropriate laser safety eyewear (OD>5 for 532nm laser radiation) is required for all personnel in the treatment room.

#### 8.4. Caution for High Power

The system enables treatment with a high laser power, even up to 2000 mW. Therefore it is essential to proceed carefully during treatment, that is to start with low power in single spot mode and increase the power gradually until the coagulated spots become visible. By using the lowest power required for the treatment, the patient is protected from possible retinal damage. Warning! Never, under any circumstances remove the eye safety filter from the slit lamp

#### Warning! To avoid severe eye damage, never look straight into the laser-

beam or reflections from reflecting surfaces

### 8. Safety

#### 8.5. Prevention of unauthorized use

The Valon is designed for use by qualified physicians only. Ensure this by turning off the system and removing the key at the end of the treatment.

#### 8.6. Requirements for the treatment room

A risk of fire and/or explosion exists when the laser output is used in the presence of flammable materials solutions or gases or in an oxygen enriched environment. The high temperatures produced in normal use of the laser equipment may ignite some materials for example cotton wool when saturated with oxygen. The solvents of adhesives and flammable solution used for cleaning and disinfectiong should be allowed to evaporate before laser equipment is used. Attention should also be drawn to the danger of ignition of endogenous gases.

Reflecting material near the laser can cause reflection hazards possibly harmful for your eyes. Before treatment make sure all reflective materials (mirrors, metal objects etc.) are removed from the treatment area.

The treatment room temperature should not be over 30 degrees Celcius. High temperature can cause over heating of the system

# 9. Maintenance

It is the user's responsibility to ensure that the Valon laser is operated and maintained in accordance with local regulations.

If the user notices any abnormal functioning of the unit, the laser must be immediately taken out of use and certified Valon service personnel must be contacted.

#### 9.1. User Maintenance

#### **Cleaning the Slit Lamp Mirror**

The slit lamp mirror should be cleaned periodically. Clean the mirror with 100% ethanol using a lens tissue.

#### Inspecting the SLA

Inspect the SLA frequently for dirt, damage or change in the spot quality.

#### Cleaning the Touch Screen

In case you need to clean the touch screen of the monitor, turn it off by pressing the power button and wipe the screen with a dry cloth. Avoid liquids near the monitor.

#### Changing the Fuses

The main fuses for Valon STA are placed next to the mains input plug. The values for fuses are presented below. Fuse must be selected according to the mains voltage.

220-240V:T315L250V 5x20mm100-120V:T5L250V 5x20mm

#### 9.2. Essential performance and maintenance

The essential performance should be checked yearly by authorized service personnel. Essential performance includes calibration, alignment of SLA and full capability of producing and controlling patterns. Warning!

Avoid all possible exposure to laser radiation. Wearing laser safety goggles is required

#### **Caution!**

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure

# 10. Errors

This section presents the possible error message types that are shown to the user in case the program recognizes an error. The possible error messages are divided to five categories, that are specified below. All error codes are listed in the service manual.

#### 10.1. Confirmable Errors

Confirmable errors can basically be influenced by the user. In case a confirmable error occurs, a text box declaring the character of the error appears on the screen area that usually presents the pattern preview. The message contains instructions for solving the program and a "Confirm" button. With the button the user confirms having followed the instructions. While the confirmable error message is displayed, all other buttons are inactive and the laser is disabled.

When the "Confirm" button is pressed, the system controls whether the error is solved. If this is not the case, the confirmable error message reappears on the screen.



Possible confirmable error message

# 10. Errors

#### 10.2. Non-confirmable Errors

In case a non-confirmable error message appears on the screen, a serious error has occurred and the entire system has to be shut down. A non-confirmable error message replaces the pattern preview and requests the user to press the OK button that shuts down the program. While the non-confirmable error message is displayed, all other buttons are inactive and the laser is disabled.

#### 10.3. Laser Heatsink Overtemperature

In case the heatsink is overheated the program disables the laser and advises the user to wait while the temperature is being decreased. This may take a few minutes. When the heatsink is cooled down the message disappears.

#### **10.4.** Warnings caused by the RTC4 card

The RTC4 card that controls the scanners in the revolver may also produce error messages. In this case the program operates similarly to the case of a non-confirmable error: the laser is disabled, the buttons of the GUI are inactivated and the user is requested to press the OK button that shuts down the program.

#### **10.5.** Warnings caused by Spot Recognition

There are two possible error messages caused by an error in the spot recognition:

The system may detect more than one spot. This may be caused by problems in the electronics of the spot recognitions system. In such case the program declares that multiple spots are recognized and the service should be contacted.

### 10. Errors

In case os spot recogniziotn error, the laser is disabled, the buttons of the GUI are inactivated and the user is requested to press the OK button that shuts down the program.

If the revolver somehow remains between two spot size modes or one of the reed switches of the spot recognition is defected, the system may not recognize any spots. An error message appears on the screen.

If changing the spot size on the slit lamp adapter helps, the program returns automatically to normal state. However, if it does not help, the system should be shut down or the user should contact service.



Error message caused by possible spot recognizion problem

# **11. Troubleshooting**

In case the system seems to operate improperly, this section will help you to locate and repair the defect. If the troubleshooting instructions below do not correct the problem, contact the manufacturer or an authorized service representative for further assistance.

#### 11.1. System does not turn on

- Ensure the power cable is plugged in.
- Check that the key switch is in correct position.
- Ensure the monitor is switched on.
- Ensure that the emergency switch is not pressed

#### 11.2. Aiming beam not visible

- Check the system is on
- Ensure you have pressed the laser ready button. When laser is enabled, the aiming beam should be visible.
- If the aiming beam is not visible turn the aiming beam to maximum power.
- Ensure the spot size is correctly selected.
- Restart the system by shutting down the PC and starting it again.
- Check the optical fiber is connected to SLA. If not, call
   an authorized Valon service representative
- If problems still occur, contact an authorized Valon service representative

#### 11.3. Aiming beam not in focus

- Check the focusing stick is in focus. If not, adjust the binocular lenses to meet your diopters. Set the left eye first and then the right eye.
- Check whether the slit is correctly in focus on the focusing stick. If the slit is in order contact Valon Lasers or local distributor's service for help. For advanced slit lamp service contact your local Haag-Streit or CSO representative.

Reference See also slit lamp's operation manual for help

# **11. Troubleshooting**

#### 11.4. Aiming beam not correctly centered

- Press reset on the treatment information window
- If the aiming beam is still not centered contact Valon Lasers or local distributor's service for help.

#### 11.5. Smart wheel not active

- If smart wheel is not, active try restarting the system. The smart wheel needs to be connected to the system be-fore the system starts. Otherwise it doesn't work
- If the smart wheel does not work after restarting the system, contact Valon Lasers or local distributor's service for help.

#### 11.6. Foot switch not active

- Set the system to "Laser disabled"- mode and enable the laser again.
- Check that the foot switch cable is connected to the laser console
- Restart the system.
- If the foot switch still doesn't work, contact Valon Lasers Service.
- •

#### 11.7. Error messages

In case the program displays an error message:

- See section 10 for more detailed information about the error messages.
- If the error is confirmable, try fixing it and press confirm
- Shut the computer down and restart it.
- If the error message is still on the screen, contact Valon Lasers or local distributor's service and declare the number of the error message.

#### 12.1. System type label and serial numbers



Type label



The label showing the serial number of the eye safety filter is placed on the eye safety filter

#### 12.2. Label and symbol definitions

The warning symbols of the system are defined in the following arrays (see also next page).



#### 12.2. Warning symbol definitions

The warning symbols of the system are defined in the array below.



#### 12.2. Warning symbol definitions

The warning symbols of the system are defined in the array below.



# **13. Disposal of Waste**

The product contains electrical components and therefore cannot be disposed as normal waste. Different materials and components (plastic, metal, electronics..) should be taken apart and recycled/disposed in accordance with local regulations.

Guidance and manufacturer's declaration – elecromagnetic emissions					
Valon and Valon TT are intended for use in the electromagnetic environment specified below. The customer or the user of Valon and Valon TT should assure that it is used in such an envi- ronment.					
RF emissions CISPR 11	Group 1	Valon and Valon TT use RF energy only for its internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.			
RF emissions CISPR 11	Class B	Valon and Valon TT are suitable for use in all establishments other than domestic, and may			
Harmonic emissions IEC 61000-3-2	Class A	be used in domestic establishments and those directly connected to the public low-voltage power			
Voltage Fluctuations / flicker emissions IEC 61000-3-3	Complies	domestic purposes, provided the following warn- ing is heeded: <b>Warning</b> : This equipment/system is intended for use by healthcare professionals only. This equip- ment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating Valon and Valon TT or shielding the location.			

Guidance and manufacturer's declaration – elecromagnetic immunity						
Valon and Valon TT are intended for use in the electromagnetic environment specified below. The customer or the user of Valon and Valon TT should assure that it is used in such an environment.						
IMMUNITY TEST	IEC 60601 test level	Compliance level	Elecromagnetic environment guidance			
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact	Floors should be wood, con- crete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.			
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines		Mains power quality should be that of a typical commer- cial or hospital environment.			
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth		Mains power quality should be that of a typical commer- cial or hospital environment.			
Power frequency (50/60 Hz) mag- netic field IEC 61000-4-8"	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commer- cial or hospital environment.			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11(>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s)NOTE UT is the a c mains voltage prior to application of the test level						
NOTE OT is the a.c. mains voltage prior to application of the test level.						

Guidance and manufacturer's declaration – elecromagnetic immunity						
Valon and Valon TT The customer or the ronment.	are intended for user of Valon	or use in the el and Valon TT	ise in the electromagnetic environment specified below. d Valon TT should assure that it is used in such an envi-			
IMMUNITY TEST	IEC 60601 test level	Compliance level	Elecromagnetic environment guidance			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equip-ment should be used no closer to an part of Valon or Valon TT including cables,			
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2,5 Ghz	3 V/m than the recommended separation dista calculated from the equation applicable frequency of the transmitter.				
			Recommended separation distance			
			$d = 1.17 * \sqrt{P}$			
			$d=1.17*\sqrt{P}_{80}$ MHz to 800 MHz			
			$d=2.23*\sqrt{P}_{ m 800}$ MHz to 2.5 GHz			
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmit- ters, as determined by an electromagnetic site survey, a should be less than the compli- ance level in each frequency range. b Inter- ference may occur in the vicinity of equip- ment marked with the following			
NOTE 1 At 80 MHz NOTE 2 These guid fected by absorptior	0 MHz and 800 MHz, the higher frequency range applies. se guidelines may not apply in all situations. Electromagnetic propagation is af- sorption and reflection from structures, objects and people.					
Field strengths from ephones and land m cannot be predicted due to fixed RF tran ured field strength in RF compliance leve abnormal performan ing or relocating the b Over the frequence	fixed transmitt nobile radios, a theoretically w smitters, an ele the location ir l above Valon o vce is observed Valon or Valor sy range 150 kH	transmitters, such as base stations for radio (cellular/cordless) tel- radios, amateur radio, AM and FM radio broadcast and TV broadcast retically with accuracy. To as-sess the electromagnetic environment ers, an electromagnetic site survey should be considered. If the meas- ocation in which Valon or Valon TT are used exceeds the applicable <i>v</i> e Valon or Valon TT should be observed to verify normal operation. If observed, additional measures may be necessary, such as reorient- n or Valon TT. ge 150 kHz to 80 MHz, field strengths should be less than 3 V/m.				

#### Recommended separation distances between portable and mobile RF communications equipment and the Valon or Valon TT

The Valon and Valon TT are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Valon or Valon TT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Valon or Valon TT as recommended below, according to the maximum output power of the communications equipment.

Rated maximum out- put power	Separation distance according to frequency of transmitter m				
of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz		
vv	$d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	$d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	$d = \left[\frac{7}{E1}\right]\sqrt{P}$		
0.01	0.12	0.12	0.23		
0.1	0.37	0.37	0.74		
1	1.17	1.17	2.33		
10	3.69	3.69	7.36		
100	11.7	11.7	23.3		
The two we like a set of the second device a set that a second second second second second second second in					

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and

reflection from structures, objects and people.

### **Revision history**