



VALON 5G USER MANUAL

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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.

Caution!

Valon should only be used for treatment purposes

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.

Caution!

This medical electrical equipment is intended for use by health-care personnel

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.

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 upper light source type slit 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 power measuring	±5 %
Laser class (treatment)	IV
Pulse duration	10-650 ms, 10-30 ms in pattern mode
Aiming beam	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	IIb
Electrical classification	Type 1
NOHD (nominal ocular hazard distance)	5.2 m
NA (numerical aperture)	0.075-0.125
Operating room temperature	+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 VA (supported voltages, the device 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 vision 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 slit lamp 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 μm , 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 intended for use by professional health-care 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 nonproliferative 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

Warning!

Do not use this device in the presence of flammable anesthetics, vapors or liquids.

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.

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, 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 5G is 24 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



5. System Description

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 and when going over a threshold. The footswitch 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 over.

5. System Description

5.2. PC and Touch screen

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

PC specifications

Computer type	Industrial PC
Display type	10.4" touch screen
Native screen resolution	1024 x 768
Operating system	Windows XP embedded + sp2
Software	MultiSpot 1.0.xx 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 anti-virus software. Also, the use of any external equipment or accessories is not allowed.

Warning!

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Note!

Position the device so that the mains plug is easily accessible in case the device needs to be disconnected from the supply mains.

5. System Description

5.3. Footswitch

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

The footswitch is solidly connected to the laser console box.

Connecting the footswitch:



5. System Description

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 Haag-Streit slit lamp models 900BM and 900BQ, CSO SL 990 and Keeler Symphony 40H. Connect the SLA to the console as shown below.



SLA connections to the console

5.4.1. SLA - Revolver

The SLA also includes a focusing unit that enables selection 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.

One end of the fiber is connected to the slit lamp adapter. Connect the fiber to the SMA connector on the front panel of the device and align the fiber as shown below.



SLA and revolver



Correct fiber alignment

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. System Description

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.

Note

The applications of the Smart Wheel are presented in section 6.2.9.



5.6 Laser Aperture

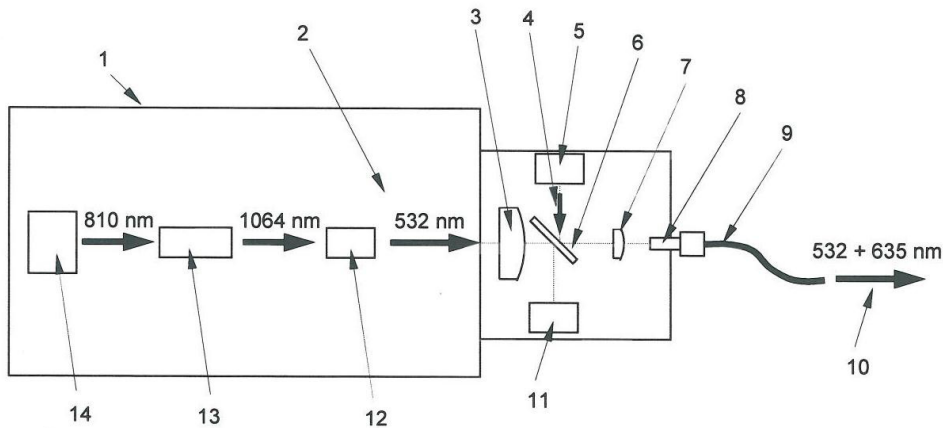
Laser aperture is situated on the slit lamp and it is marked with laser aperture sticker.



5. System Description

5.7. Optical beam path

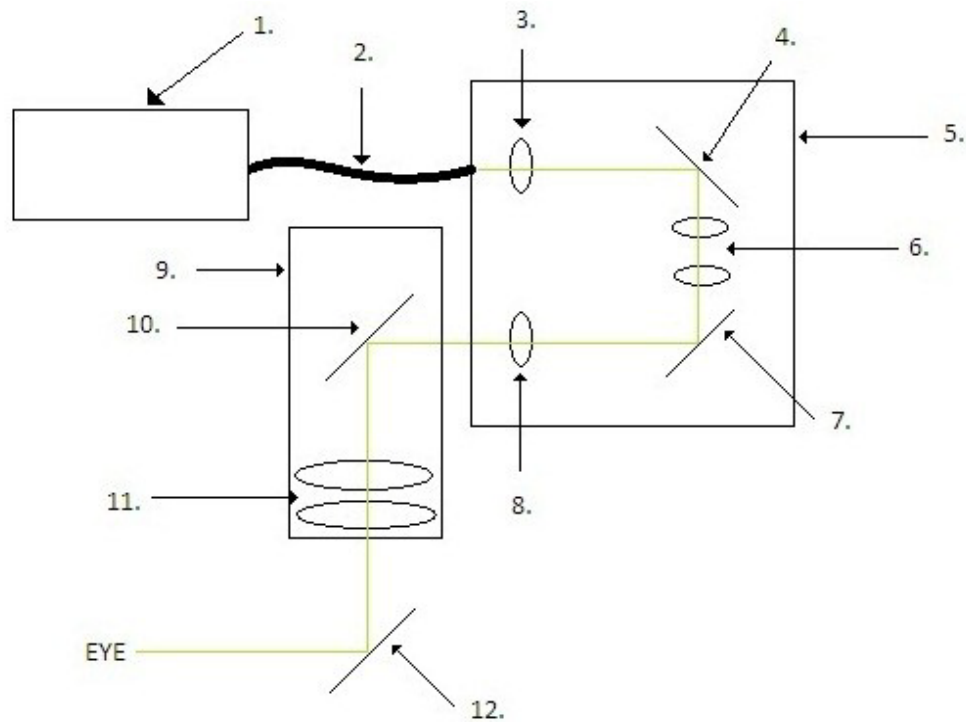
5.7.1. Laser



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. System Description

5.7.2. System (normal)



- | | |
|------------------------|----------------------|
| 1. Laser unit | 7. Scanner No 2 |
| 2. Fiber | 8. Focusing lens |
| 3. Collimating lens | 9. Slit lamp |
| 4. Scanner No 1 | 10. Beam combiner |
| 5. Slit lamp adapter | 11. Slit lamp optics |
| 6. Transferring lenses | 12. Slit lamp mirror |

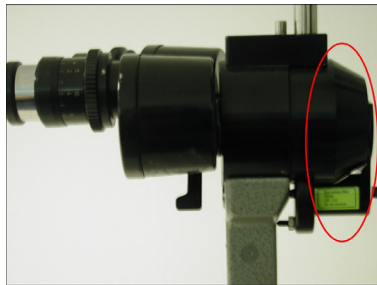
5. System Description

5.8. Accessories

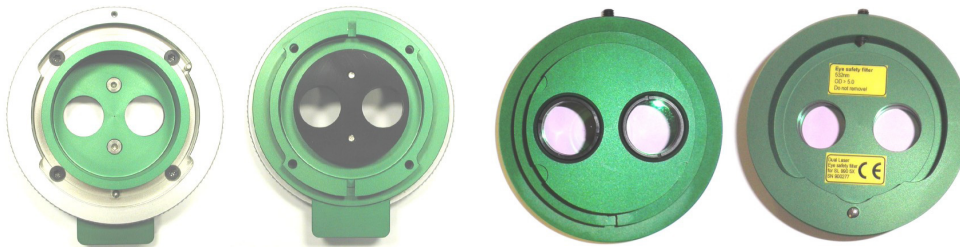
5.8.1. Eye Safety Filter

The eye safety filter protects the eyes of the user. The optical density of the filters 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 ring-shaped filter is located between microscope and binoculars.



5.8.2. Eye safety goggles

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



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. System Description

5.8.3. Cables

Cable	Length	Shielded	Type
Power cable	2 m	No	AC
Footswitch 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 recognition cable	3 m	Yes	I/O
Fiber cable	3 m	-	optical

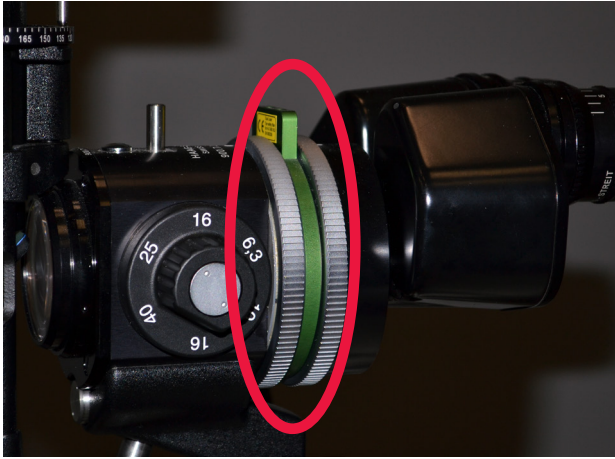
Warning!

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

6. Using Valon

6.1 Before Use

6.1.1. Ensuring the Basic Safety



Warning!

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

Warning!

Do 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

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.

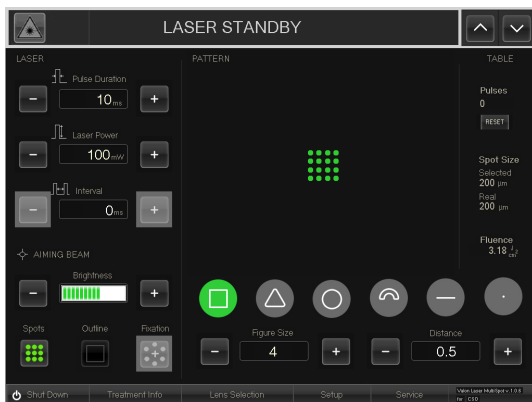
6. Using Valon

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



Key switch



The GUI of the software

Note

When the software starts it asks to confirm that the eye safety filter is in place and to select the connected fiber type (SLA, Endo or LIO)

6. Using Valon

6.1.3. Adjusting the Binocular Lenses

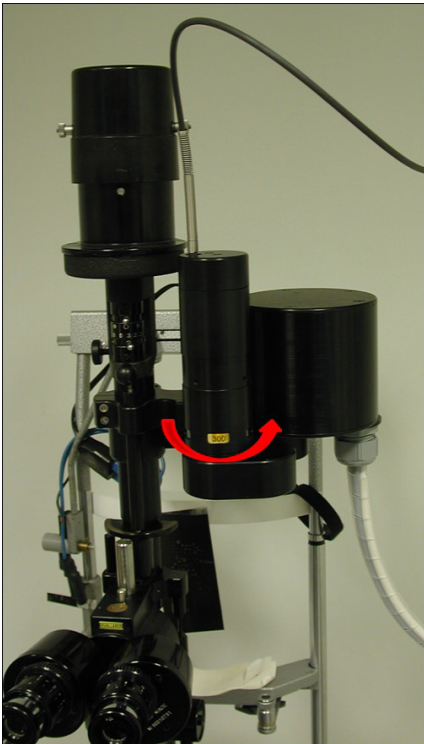
1. Adjust the focus of one eyepiece by checking if the focusing stick is seen in focus (laser is not active). If the focusing stick is not in focus, adjust the diopter settings of the eyepieces to a suitable position.
2. Then focus the other eyepiece similarly.

6.1.4. Selecting the Spot Size

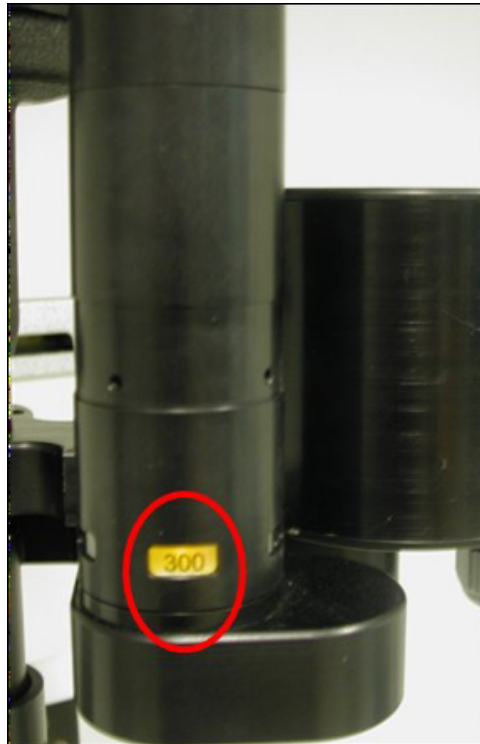
1. Choose the suitable spot size by rolling the revolver. A larger spot size is chosen by turning the revolver clockwise.
2. Available spot sizes are 50 μm , 100 μm , 200 μm , 300 μm and 400 μm .
3. The resulting spot size is shown on yellow background on the revolver and as a field on the GUI when the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

Warning!

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



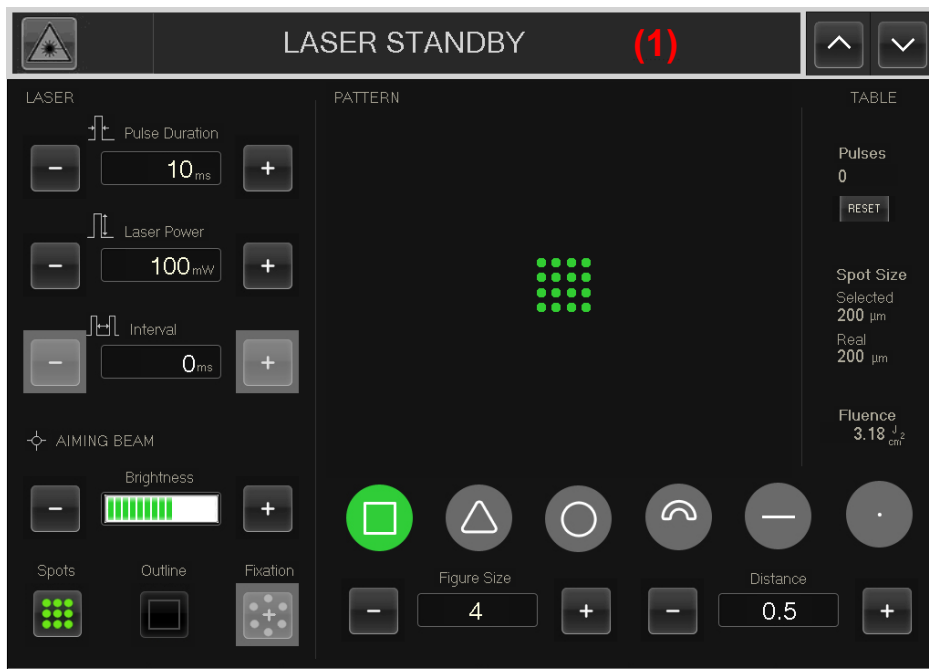
The spot size indicator

6. Using Valon

6.2. Using the software

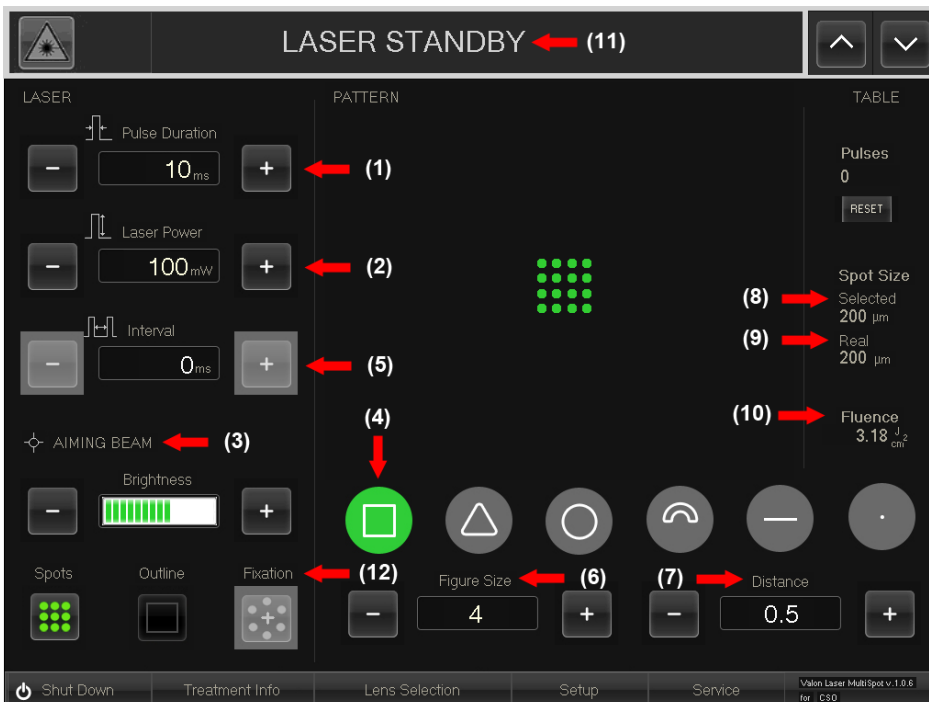
6.2.1. Graphical user interface (GUI)

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 aiming beam and the treatment laser are both inactive.
3. The available settings are described on the following pages.



6. Using Valon

6.2.2. Adjusting the Settings



Note

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

(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 100-640 ms. The Interval field is active only in case single spot mode is selected.

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. Using Valon

(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

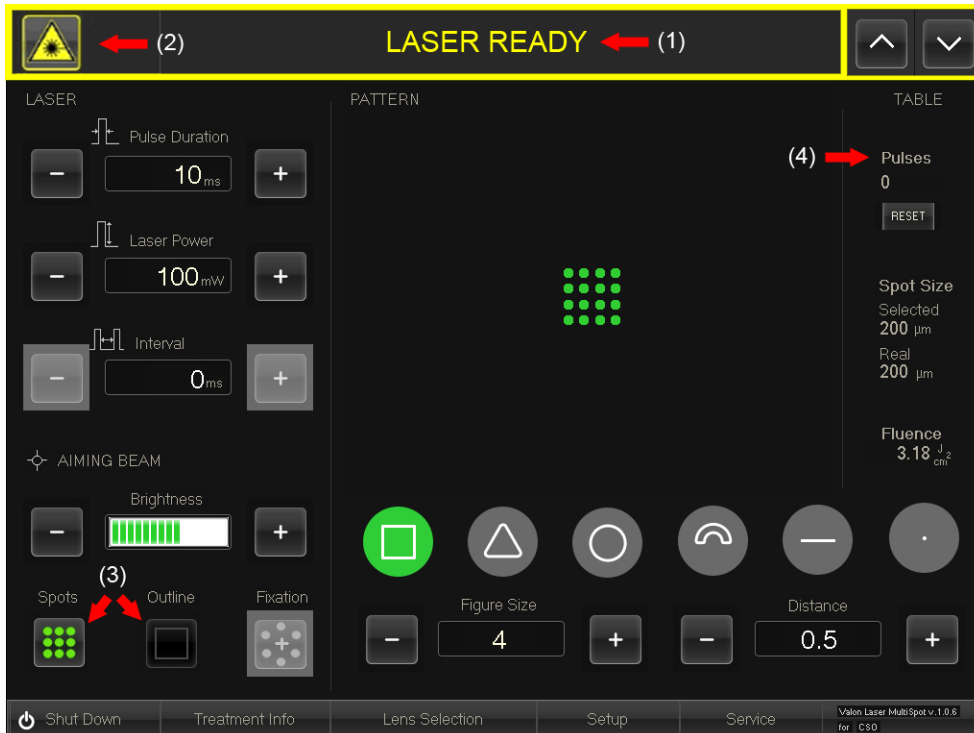
After the settings are made, press the top bar (11) to enable both aiming beam and treatment laser and to enter the treatment mode.

(12) Fixation light (optional feature)

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

6. Using Valon

6.2.3. Treatment Mode



When the laser is enabled, the aiming beam is active and draws the outline or shows all spots of the chosen pattern. The treatment laser is ready and controllable via foot-switch.

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 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.

Note

Aiming mode spots available only in selected countries.

6. Using Valon

(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

Note

Aiming mode spots available only in selected countries.

6. Using Valon

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 user can choose SLA (slit lamp adapter), LIO (laser indirect ophthalmoscope) or endoprobe.

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 aiming beam 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 footswitch. 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 footswitch.

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 aiming beam differs in any way from the pattern on the user interface!

6. Using Valon

6.2.8. Finishing the treatment

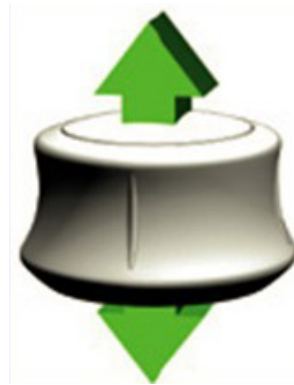
1. After the treatment press the top bar to deactivate the treatment laser.
2. The program returns to the setting mode.

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 → Triangle → Circle →
Arc → Line → Single spot



Note!

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

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

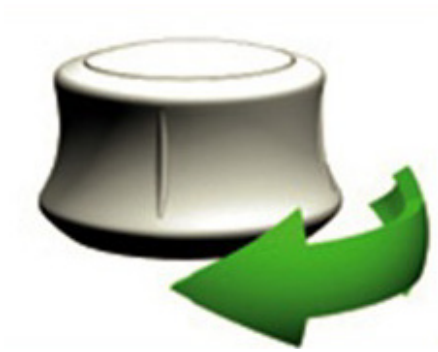
The Smart Wheel can be used as a micromanipulator by moving the button in a plane.



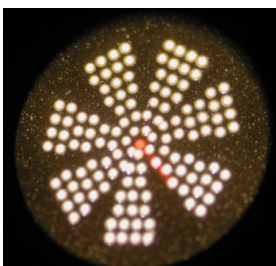
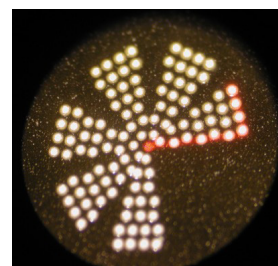
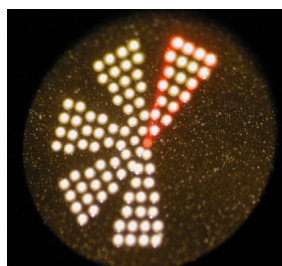
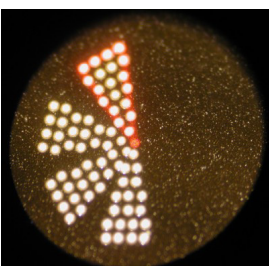
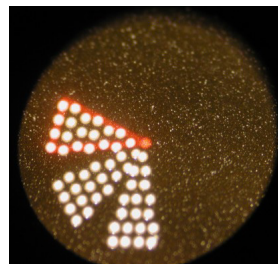
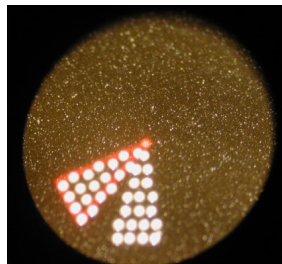
6. Using Valon

6.2.9.4. Adjusting the Orientation of the Pattern

Turn the Smart Wheel clockwise or counterclockwise to rotate 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.



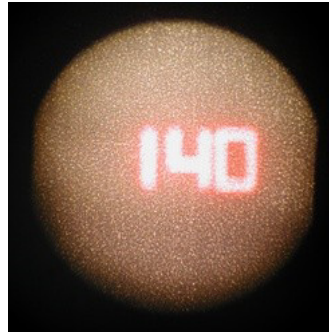
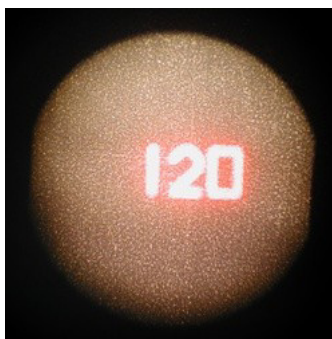
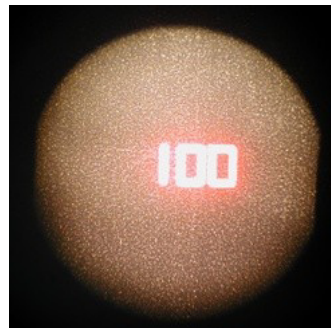
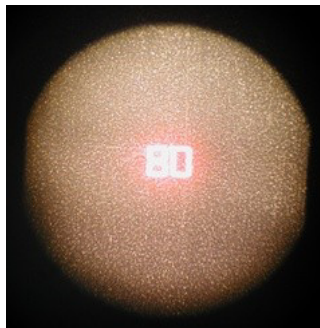
6. Using Valon

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.

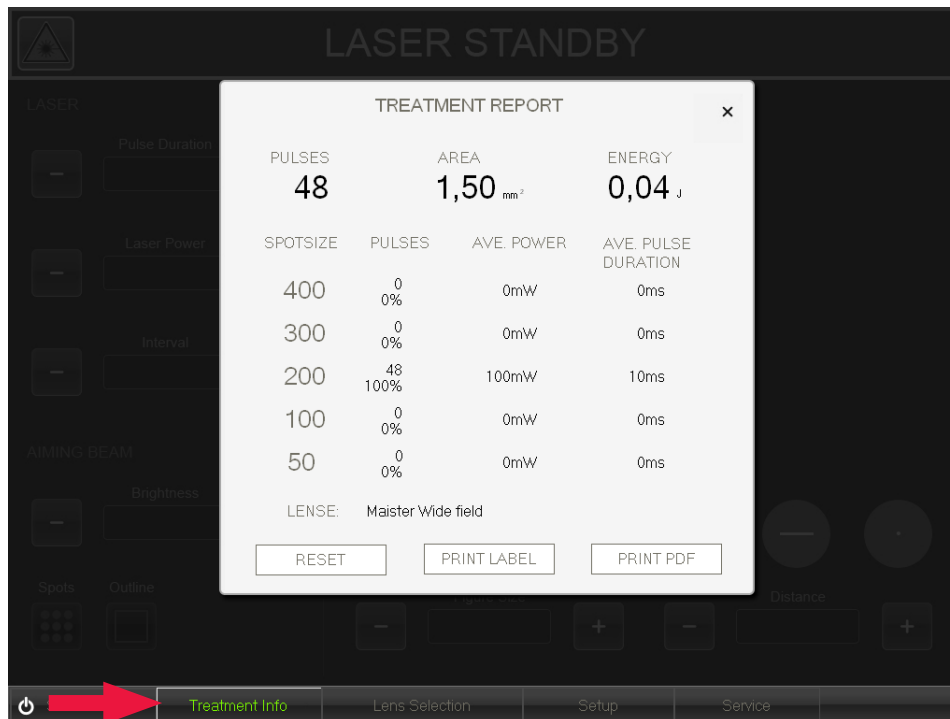


When the power is changed with the Smart Wheel, it is shown by the aiming beam for 1 s. During this time, the footswitch and the Smart Wheel are inactive to lower associated risks. The font size depends on the spot size.



6. Using Valon

6.2.10. Treatment Information



The Treatment Information window details the used treatment parameters:

- 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. Using Valon

6.2.11. Lens Selection

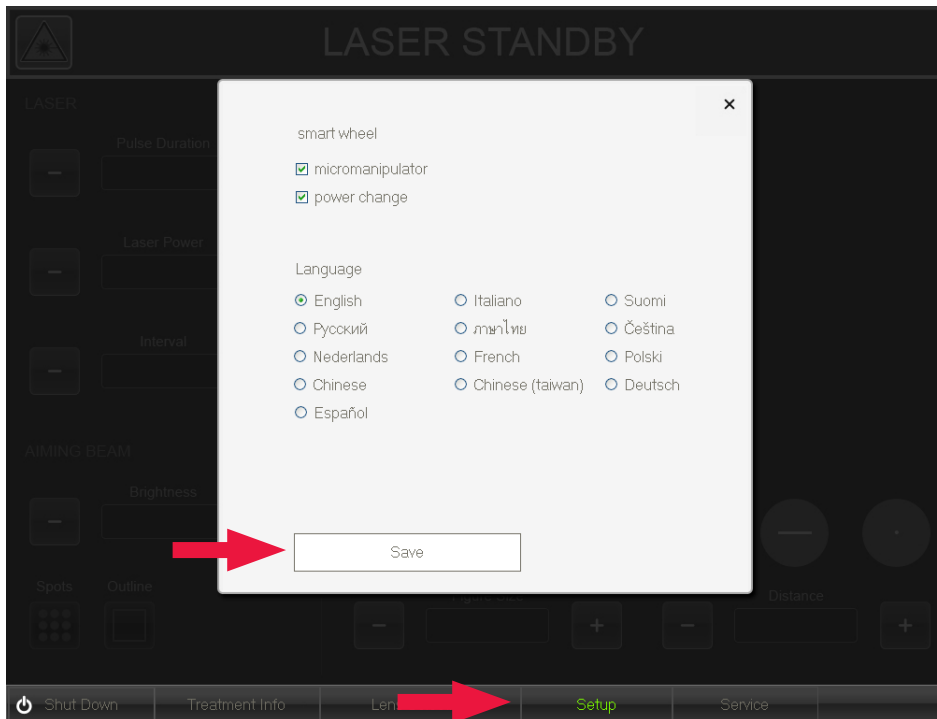


Select the proper contact lens to see the real spot size on the retina. The real spot size also affects the values of fluence and total treated area. Available lenses are presented below.

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. Using Valon

6.2.12. Setup



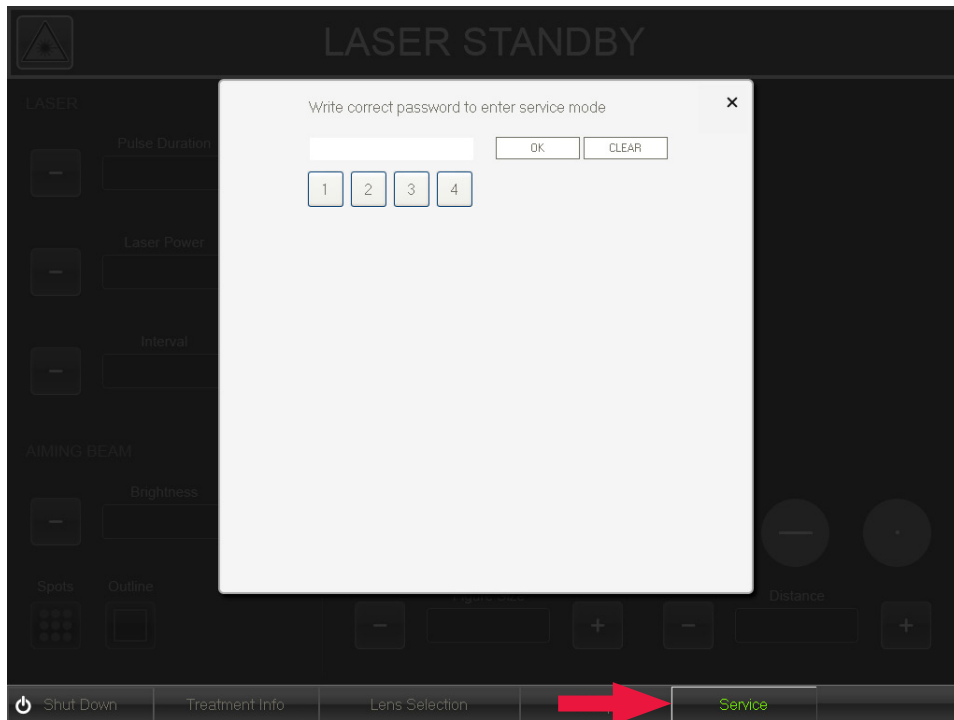
Setup menu can be used for changing the settings of the Smart Wheel and language.

The micromanipulator and power adjustment 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. Using Valon

6.2.13. Service



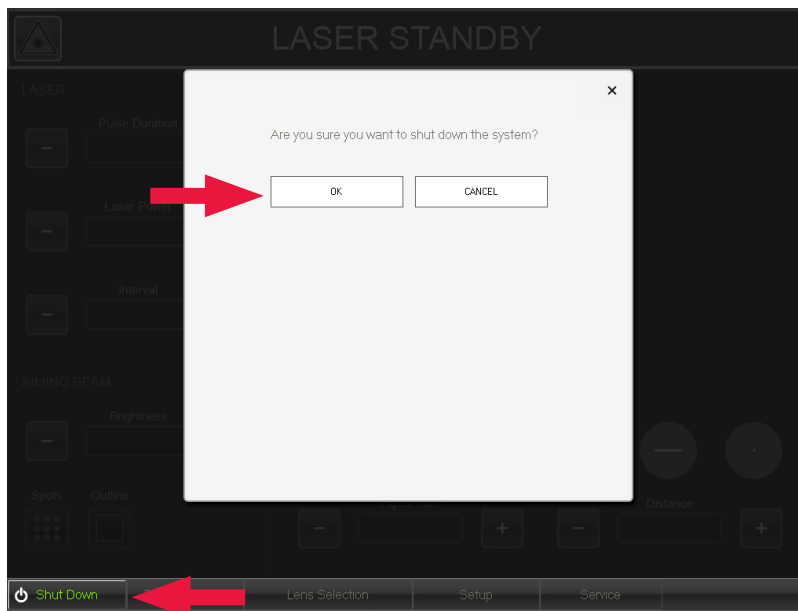
The service window is meant only for trained service personnel and it is therefore protected with a password.

6. Using Valon

6.3 Instructions for After Use

6.3.1. Turning off the system

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



Attention!

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

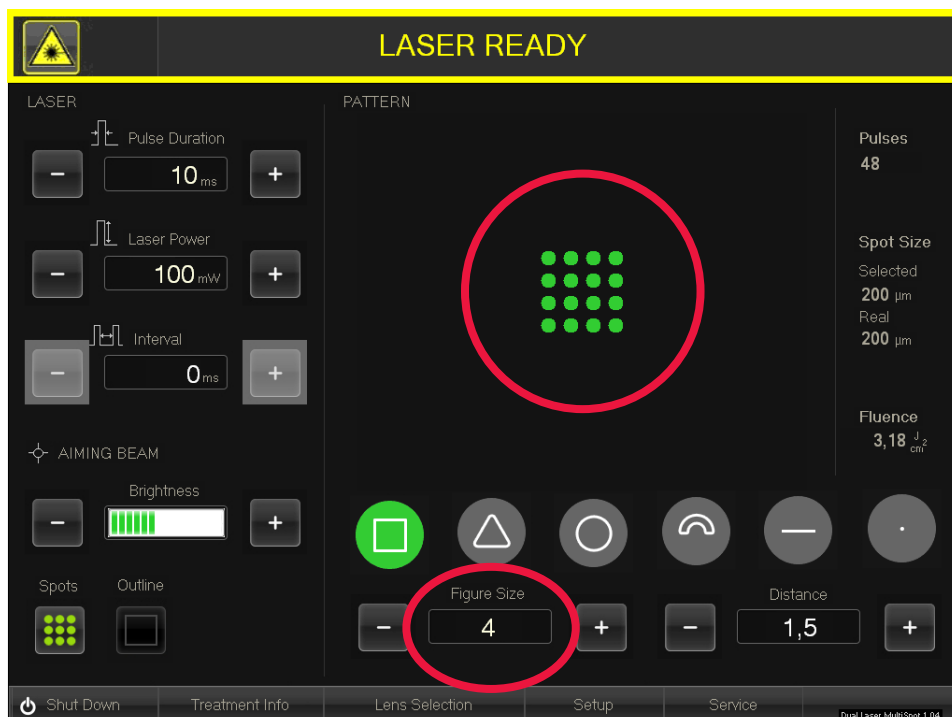
Attention!

Make sure the key is not available to unauthorized people

7. Patterns

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).

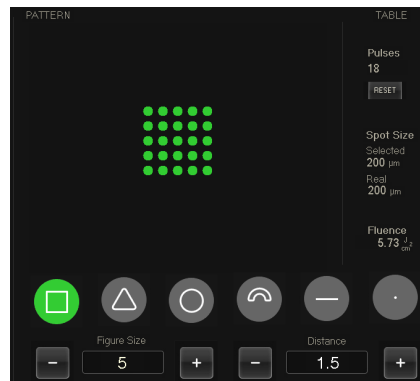
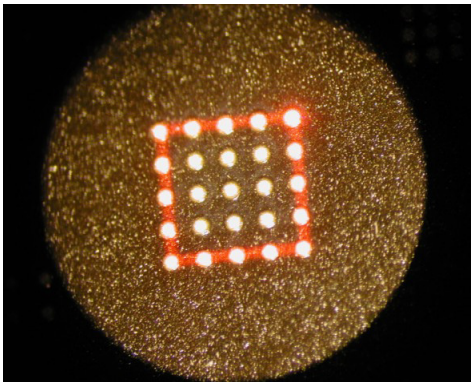
In the following pages the patterns are presented in all available sizes, both in the form that is drawn to the retina and on the GUI.



7. Patterns

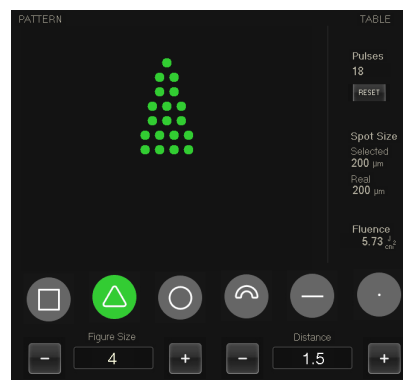
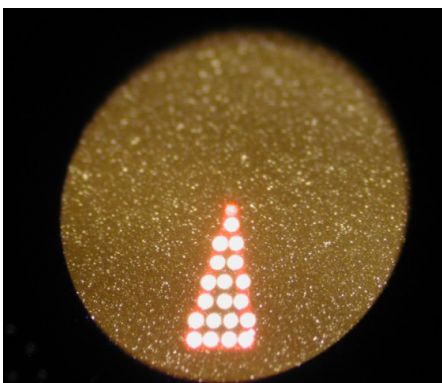
7.1. Square

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 µm, 100 µm and 200 µm and 1-4 for spot sizes 300 µm and 400 µm.



7.2. Sector

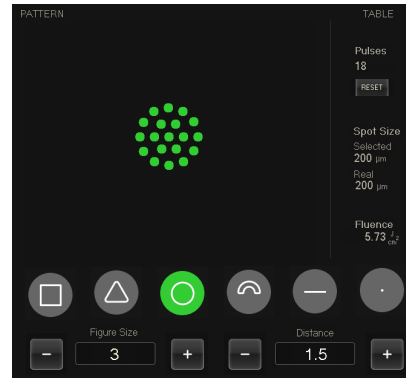
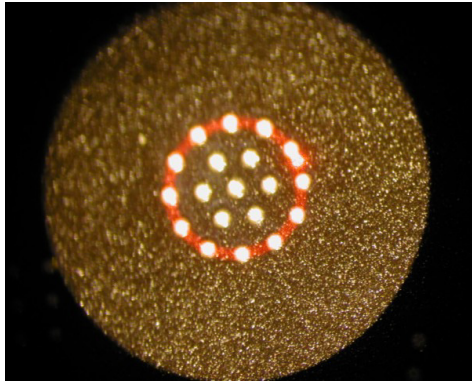
On Sector mode the laser draws a triangular shaped figure which can be used as a sector of a circle by turning it. The vertex point of the sector is left unburned. Available sizes are 1-4 for spot sizes 50 µm, 100 µm and 200 µm and 1-2 for spot sizes 300 µm and 400 µm



7. Patterns

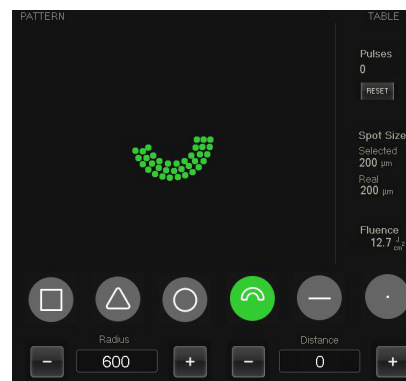
7.3. Circle

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 1-3 for spot sizes 50 μm , 100 μm and 200 μm and 1-3 for spot sizes 300 μm and 400 μm



7.4. Arc

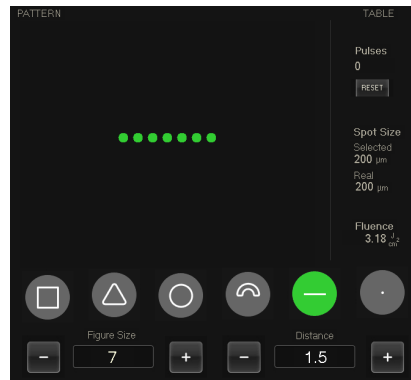
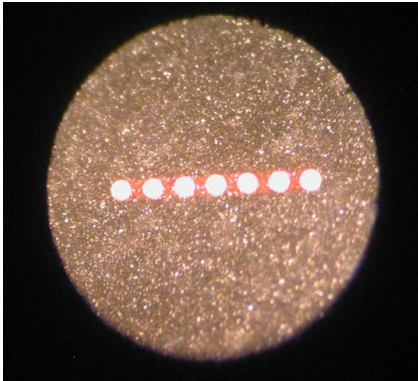
The arc-shaped pattern is resizable by quadrants. The radius is resizable from 600 μm to 1600 μm . Size can be adjusted using the touch screen or the Smart Wheel. Radius is adjustable on the user interface. Arcs are delivered one by one from the inner arc to the outer arc.



7. Patterns

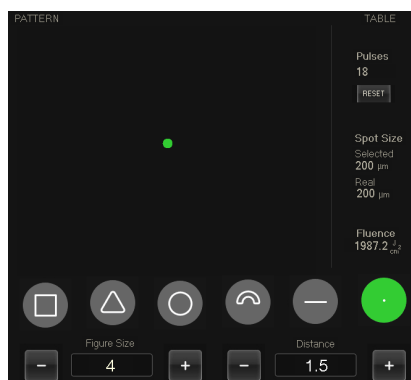
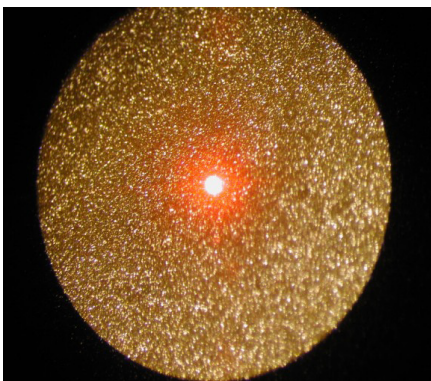
7.5. Line

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 footswitch 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 device console next to 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 (laser stop)

8.2. Double Control

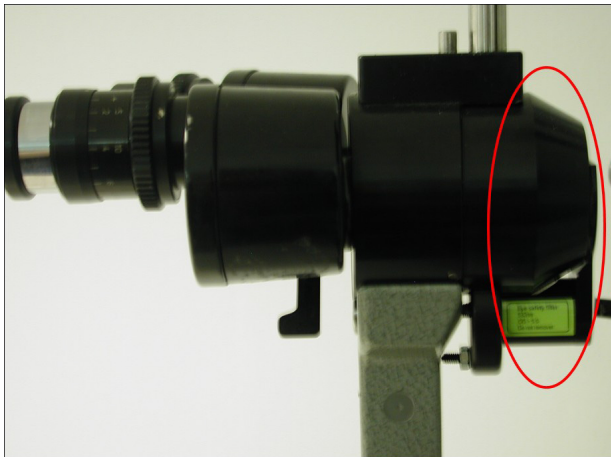
To increase treatment safety, the laser emission is ensured with double control: to emit the laser beam the laser must be enabled and the footswitch must be pressed down. Through this double control the physician can interrupt the treatment at any point by releasing the footswitch.

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

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 laserbeam or reflections from reflecting surfaces

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.

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 disinfection 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 cleaning wipe.

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 5x20mm

100-120V: 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

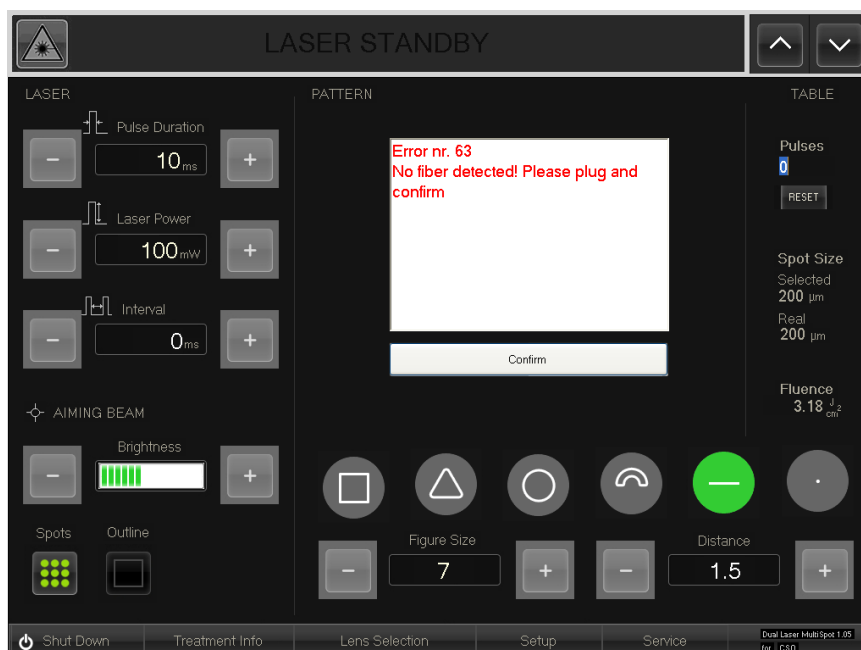
10. Errors

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:

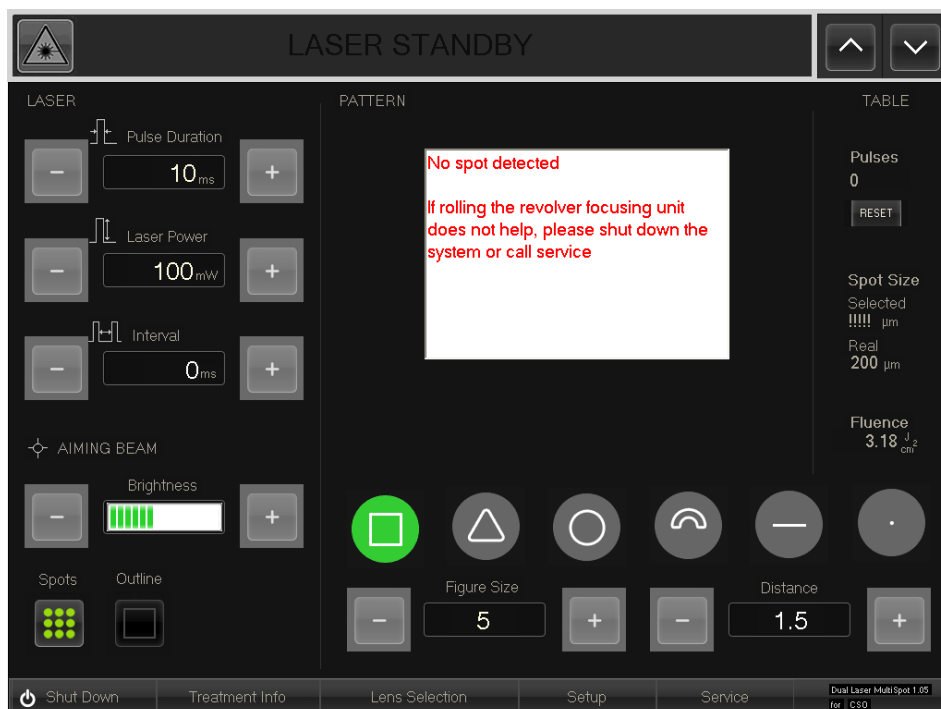
The system may detect more than one spot. This may be caused by problems in the electronics of the spot recognitions system. In such case the program declares that multiple spots are recognized and the service should be contacted.

10. Errors

In case of spot recognition 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 recognition 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.

Reference

See also slit lamp's operation manual for help.

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.

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 device. Make sure Smart Wheel is connected to the system before restarting the device.
- If the Smart Wheel does not work after restarting the system, contact Valon Lasers or local distributor's service for help.

11.6. Footswitch not active

- Set the system to "Laser standby"- mode and enable the laser again.
- Check that the footswitch cable is connected to the laser console.
- Restart the system.
- If the footswitch 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. System Labeling


12.1. System type label and serial numbers






Valon 5G

Valon Lasers Oy
Merimiehenkuja 5
FI-01670 Vantaa
Finland
Made in Finland



0537






REF 10510-1
SN

220-240 V~
50/60 Hz 600 VA



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).	
	Eye safety filter label on the slit lamp.
	Eye safety filter label on the slit lamp (other side).
	Laser stop button.
I / O	The switch symbols at the key switch. ON/OFF

12. System Labeling



The type label declaring the part number, serial number and date of manufacture (see previous page).



Consult instructions for use



Follow instructions for use



Caution

REF

Part number

SN

Serial number



Manufacturer



Date of manufacture



Electrical and Electronic
Equipment - Do not dispose
of with normal waste.



No pushing

240V~ 50Hz 600VA

Mains input label

~

a.c. (alternating current)



CE marking

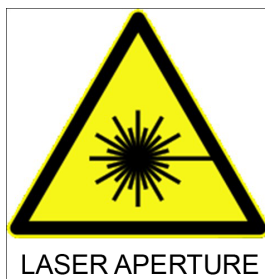
12. System Labeling

12.2. Warning symbol definitions

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



The laser emission warning on the top bar of the GUI.



The laser aperture warning is placed at the laser output on the slit lamp mirror.



The laser radiation warning is placed behind the console. Valon is rated as class 4 laser.



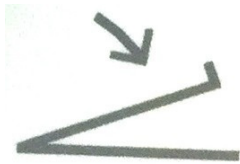
12. System Labeling

12.2. Warning symbol definitions

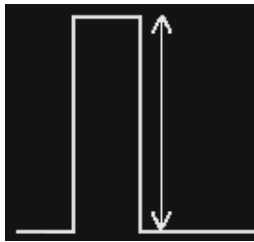
The warning symbols of the system are defined in the array below.



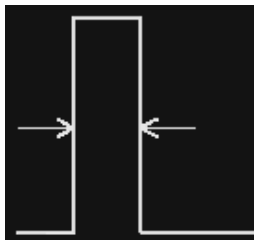
Door interlock



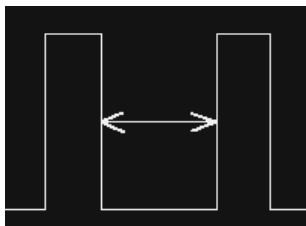
Footswitch



Laser power



Laser pulse duration



Interval between pulses
(available only in single spot mode)



Aiming beam

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.


14. Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic 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 environment.		
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 be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / flicker emissions IEC 61000-3-3	Complies	

14. Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic 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	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact	Floors should be wood, concrete 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 commercial 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 commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial 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.			

14. Electromagnetic compatibility

Guidance and manufacturer's declaration – electromagnetic 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	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Valon or Valon TT including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17 * \sqrt{P}$ $d = 1.17 * \sqrt{P}$ 80 MHz to 800 MHz $d = 2.23 * \sqrt{P}$ 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 transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following 
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2,5 Ghz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, 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.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To as-sess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Valon or Valon TT are used exceeds the applicable RF compliance level above Valon or Valon TT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorient-ing or relocating the Valon or Valon TT. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

14. Electromagnetic compatibility

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 output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E1} \right] \sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E1} \right] \sqrt{P}$
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

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

A(0) First version

B(0) Updated device photos, new photo showing correct fiber orientation, type label pictures updated, typos fixed

B(1) Note added about aiming beam modes

B(2) Software version changed

C(0) Fixed typos, new labels, warnings required by 60601-1 3rd edition

C(1) Terminology corrections