ellex
BY LUMIBIRD MEDICAL

integre® pro scan

LP6G | LP6Y| LP6RY

OPERATOR MANUAL

8449430EN-13

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Drag Finger, Single Tap, Pinch Out, Pinch In, Rotate Clockwise, Rotate Counter-clockwise, Vertical Drag symbols were designed by Gary Lim from the thenounproject.com.

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These instructions are compatible with devices using system version 2.3 or higher.

This manual describes how to operate the Integre® Pro Scan photocoagulator laser (LP6G, LP6Y, and LP6RY.

[US ONLY] Caution: U.S. federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

[CANADA ONLY] This device must be installed and operated according to CAN/CSA Z386:2020 Laser Safety in Health Care Facilities.

Always review documentation supplied with software upgrades for information about new features.

IMPORTANT READ CAREFULLY BEFORE USE
KEEP FOR FUTURE REFERENCE

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Contents

Document revision history

Version	ECR	Date	Description
1.0	05344	December 2016	Document released.
02	05611 05659	March 2017	Revised for introduction of the Generation 4 iDISPLAY tablet and presentation of electromagnetic tables. Laser safety labels updated for 2014 edition.
03	05729		Cancelled.
04			Overridden.
05	06185	August 2018	Updates related to Fluence Assist and minimum power setting.
	06143		Updated compliance label.
06	06286	September 2018	Address update.
07	06770	November 2019	Corrected port numbers on Table 9-1 in chapter 9 Alarms, updated year in copyright info and corrected grammar in “Cautions”
08	06849	August 2020	Updated the FCC and manufacturer labels. This was an immediate requirement prompting trackpad updates (started in June 2020) to be pushed to 09 issue release.
09	06869	September 2020	Updated documentation to include content on new Wired trackpad and Treatment settings memory. Moved Assembly chapter to Service manual.
10	07047	November 2020	Updating document to remove Fluence Assist content.
11	07353	June 2022	Updated Accessory table. Removed LP6RG variant. Removed all wireless function and battery charging description to match the current device configuration
12	07407	September 2022	Updated document with Integre® Pro Scan instead of non-register mark Integre Pro Scan.
13	07726	Sep 2024	Company Logo updated. Updates Notified Body number, CE mark, and related label and icon changes.

1 Warnings and Cautions

All warnings and cautions used in this manual are listed below. You must read and understand all warnings and cautions before using this device.

1.1 Warnings

If you clinically rely on fluence and ‘true’ spot size, ensure the correct lens is selected before treatment.

This equipment/system is intended for use only by qualified ophthalmic physicians. 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 reorienting or relocating this device or shielding its location.

Ensure that you understand the lens data sheet and enter the correct magnification value into this device. Retain the lens data sheet for future reference.

Do not use the device if there are no audible indications. Contact your Authorised Ellex Distributor.

Place the delivery head and slit lamp assembly upright, supporting it from underneath to avoid crushing the optical fibre and power cable.

Avoid trapping your fingers when placing the console on the top plate.

Always support the console from underneath if you are placing it on a flat surface. This avoids crushing the bottom exhaust fan grilles.

Do not position the foot switch more than two metres from the console. A long cable is provided for convenient and safe positioning only.

The safety interlock socket is a switched input type circuit. Do not connect external power connections to this socket.

This information is a guide only and is not intended to present complete or thorough instructions. It does not replace the judgement of a qualified ophthalmic physician.

Do not aim, focus or fire this device in, on or near the fovea; on corneal structures; on the patient's lens (natural or artificial); or on any other structure of the human body that is not related to the treatment of an eye disorder.

Use of controls or adjustments, or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.

This device is designed for use with a range of Ellex approved attachments. The use of unapproved attachments may result in serious injury to the patient and/or physician and voids the warranty. In no event shall Ellex, its employees, officers, directors, representatives or affiliates, be held liable for any injury occurring through such use.

Do not operate the device until you are familiar with all the precautions.

Do not use the device if you experience an abnormal operating condition. Contact your Authorised Ellex Distributor.

Do not modify this device. Unauthorised modifications may create a safety hazard.

The device is not intended to be a patient or operator support system.

Do not lean on the device.

To ensure adequate electrical safety you must connect this device to a mains power outlet that has a reliable protective earth conductor.

To protectively earth the device, the power lead from the mains power outlet to this device must incorporate an earth terminal and earth conductor.

Do not use liquids with this device.

Do not fire the laser if you cannot see the aiming beam (or beams).

Do not look into the aiming beam (or beams) unless under the control of a qualified ophthalmic physician.

Do not look into the treatment beam unless under the control of a qualified ophthalmic physician.

Safety glasses, or safety filters providing protection from other wavelengths, may not offer any protection from the treatment wavelength and should not be used. Ordinary spectacles offer no protection.

Never look directly into the path of a laser beam. Correctly selected safety glasses offer protection against accidental exposure to a direct laser beam for a maximum exposure of 5 seconds.

Objects that reflect visible light will reflect treatment laser light. Avoid placing reflective materials such as glass, metal and polished plastic in the path of the laser beam.

Some materials (for example, cotton wool saturated with oxygen) may be ignited by the high temperatures produced by the treatment laser. Before using the device, allow

the solutions of adhesives and flammable solutions (used for cleaning and disinfecting) to evaporate.

Ignition of endogenous gases may occur.

Do not use the device unless you understand the potential hazards inherent in laser technology.

Do not place your hands, arms, or any other body parts or tissue in the path of the treatment laser.

The patient's head must not move during laser treatment.

To protect the patient from possible retinal damage, use the lowest practical aiming beam intensity during treatment.

Leave the slit lamp at minimum intensity to reduce heat build-up. Do not leave the illumination intensity at maximum for more than 10 minutes.

Always select the lowest power and duration settings required to perform a procedure.

Do not use the device if the treatment beam is visible. Contact your Authorised Ellex Distributor.

Do not fire the laser if the aiming beam is not present.

Do not fire the laser if the pattern displayed on the tablet differs from that of the aiming beam.

Do not change any settings or move any controls while the treatment laser is firing.

Dangerous laser radiation is emitted from the laser aperture when the treatment laser is fired.

Do not administer fluids to the patient while they are seated at the device.

Do not allow the ingress of any fluid into the device.

Do not leave the device unattended in READY.

Do not turn the device off and on rapidly. Wait at least 10 seconds after turning off before turning the device on again to allow the device to restart properly.

Turn the device off and remove the mains plug from the wall socket to avoid possible exposure to hazardous laser radiation during user maintenance.

Do not immerse any part of the device in liquid or place opened containers holding liquids on the device.

Do not use the device if the external optics are scratched. Contact your Authorised Ellex Distributor.

Use one tissue or swab per wipe and then discard it. Do not use dry tissues or swabs as they may damage the surface of the optic.

Do not use the device if the eye safety filter is damaged or discoloured. Contact your Authorised Ellex Distributor.

Ensure that there are no reflective surfaces behind the target.

Do not use the device if you can move the aiming beam out of the field of view. Contact your Authorised Ellex Distributor.

Do not use the device if the aiming beam is not centred in the burn mark. Contact your Authorised Ellex Distributor.

Dispose of console batteries according to your local environmental laws and guidelines.

The globe may be hot. Wait until the globe cools before replacing it.

Do not use the patient handles, chinrest, slit lamp, delivery head or the tablet mount to move the device.

If you raise the table too high, it may overbalance.

Only Authorised Ellex Distributors should perform this procedure.

Do not use the device if the measured values are not within ± 15% of the power setting that appears on the device. In such cases, investigation by your Authorised Ellex Distributor is necessary to determine if the device requires recalibration or if the delivery device has poor transmission.

Non-ionising electromagnetic radiation. Equipment includes RF (radio frequency) transmitters. Interference may occur in the vicinity of equipment marked with this symbol.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Integre® Pro Scan — including LIO and foot switch cables — otherwise, degradation of the performance of this equipment could result.

Only use Ellex approved consumables and accessories. Using unauthorised parts may result in injury, increased electromagnetic emissions, or decreased immunity to such emissions and result in improper operation of the device. Use of unapproved parts will void the warranty.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally prior to using it in a surgical procedure.

Do not use the tablet for any other purpose than for which it has been provided. It is an integral part of the device.

1.2 Cautions

The illumination light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument, when operated at maximum intensity, will exceed the safety guideline after 4 minutes and 52 seconds.

2 Overview

2.1 About this manual

This manual describes how to operate the Integre® Pro Scan ophthalmic laser.

This device is available in the models listed below.

Table 2–1

Model	Model Number	Wavelengths
Green	LP6G	532 nm (Green)
Yellow	LP6Y	561 nm (Yellow)
Red-Yellow	LP6RY	561 nm (Yellow) and 670 nm (Red)

This device is classified as a Class 4 laser with Class 1 Type B electrical protection. This device is a surgical laser instrument designed for use by qualified ophthalmic physicians to perform iridectomies, iridotomies, retinal photocoagulation, pan-retinal photocoagulation, photocoagulation for wet age-related macular degeneration and laser trabeculoplasty. This device is designed for use in clinics or outpatient facilities, or in the retinal specialist's practice but not near active HF (high frequency) surgical equipment and the RF (radio frequency) shielded room of a medical system for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.

2.1.1 Who should read this manual

Owners and operators of this device should read this manual.

2.1.2 Providing feedback to Ellex

Ellex welcomes your feedback on the accuracy and effectiveness of this document. Please send feedback to documentation@ellex.com or forward it to your Authorised Ellex Distributor. Ensure the document name and part number (see the footer of each page) are clearly identified and refer to page numbers where appropriate.

2.1.3 Document conventions

When used without qualification, the term 'physician' refers to a qualified ophthalmic physician.

The phrase 'Integre® Pro Scan' refers to the Integre® Pro Scan family that comprises devices identified as LP6G, LP6Y, and LP6RY.

A dashed callout line in a graphic refers to an object that is obscured.

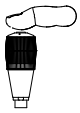
The following images may be used to highlight the use of specific input devices and gestures.

Joystick

Trackpad

Tablet

Delivery Head



Press joystick button

Single Tap

Single finger swipe

Three finger swipe

Spread

Pinch

Rotate clockwise

Rotate counter clockwise

2.2 Carton labelling

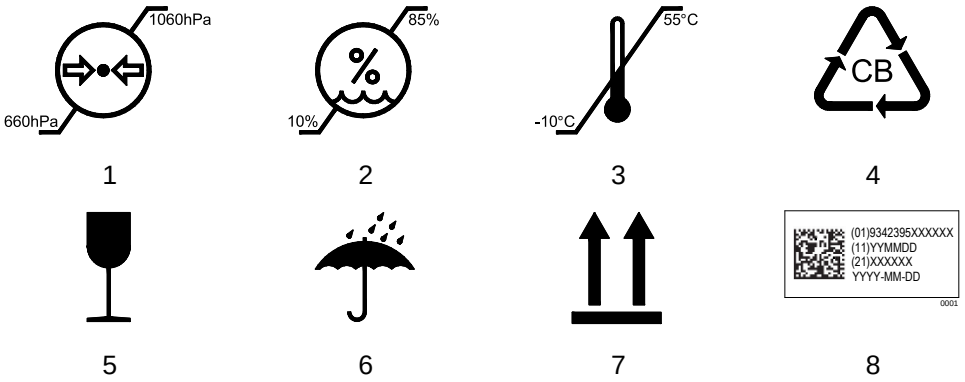


Figure 2-1

Table 2–2

1	Atmospheric pressure limitation
2	Humidity limitation
3	Temperature limitation
4	Corrugated board (package may be recycled)
5	Fragile, handle with care.
6	Keep dry
7	This way up
8	Unique device identification (UDI). For more information about this label refer to 2.5.10 Unique device identification (UDI) on page 47.

2.3 Assembling the device

Your authored Ellex Distributor/ Service Technician will install/assemble and check the device. The Distributor/Service technician will complete a Product Acceptance and Fault (PAF) report which formally documents this assembling process.

Packing cartons opened by unauthorised personnel may void the warranty.

If you need to contact Ellex: Check the packing list and contact Ellex immediately if any item is missing or damaged. Short and long power cables are included with the device. Retain all packing cartons in case you need to transport the device.

2.4 Training

Ellex shall supply device training during the installation process. Training is based on material from this operator manual.

Training may be repeated upon request. Please discuss your training needs with your Authorised Ellex Distributor.

2.5 Device description

User accessible controls, connectors and labels are described below. Some controls are available on both sides of the delivery head and may also be duplicated on the tablet.

Frequently used functions are described in this section.

2.5.1 Delivery head and chinrest

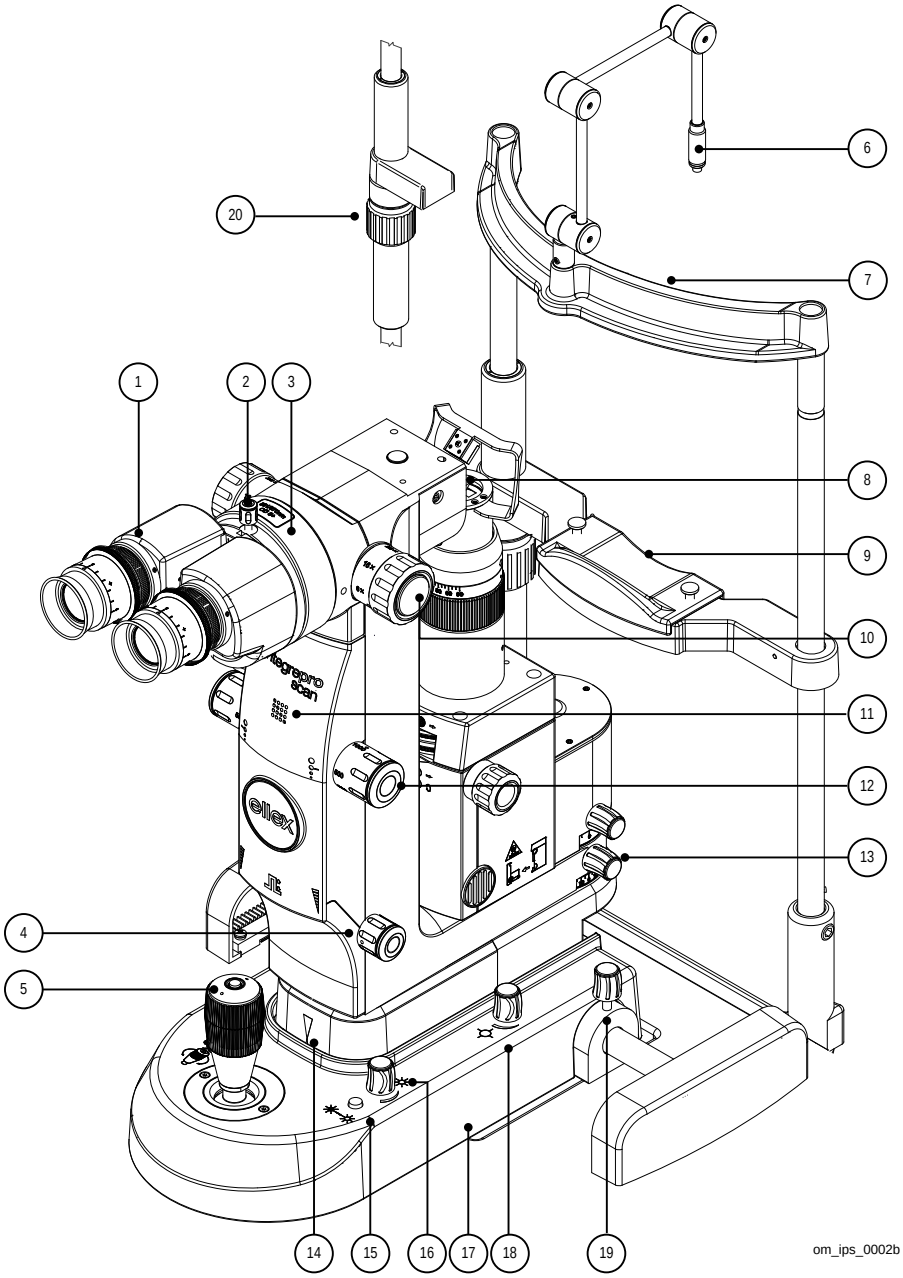
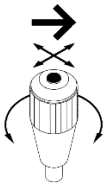


Figure 2-2

Table 2–3

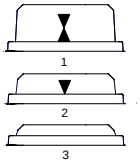
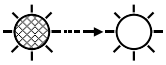
1		Binocular Adjustable to suit the operator's interpupillary distance. The focus of each eyepiece may be individually adjusted. One ocular incorporates crosshairs (a reticle).
2		Binocular thumbscrew Secures the binocular to the delivery head.
3		Motorised safety filter. Model specific label indicates wavelength and optical density.

Model	**Wavelength OD**
Green (LP6G)	532 nm OD5+
Yellow (LP6Y)	561 nm OD5+
Red-Yellow (LP6RY)	561/670 nm OD5+

4		Power Slowly rotate this control to incrementally adjust the power value. Quickly rotate this control to jump between larger power values.
5		Joystick

	Press the button on top of the joystick to move to the next pattern. If you have selected favourite patterns press this button to move to the next favourite pattern. For more information refer to Favourites on page 37.
	Move the joystick in the XY axis to move the delivery head and slit lamp backward, forward, left and right.
	Rotate the joystick to adjust the height of the slit lamp and delivery head.

6		Fixation lamp
7		Headrest
8		Objective lens
9		Chinrest
10	6×, 10×, 16×, 25×, 40×	Magnification changer
11	Model logo	 Integre® Pro Scan Green LP6G
		Integre® Pro Scan Yellow LP6Y
		 Integre® Pro Scan Red-Yellow LP6RY

12		Spot Size Adjusts the treatment laser spot size. Detents are at 50 µm, 100 µm, 200 µm, 300 µm, 500 µm and 1000 µm. You may also select intermediate positions. If you have selected a pattern you are limited to spot sizes between 100 µm and 500 µm.
13		Delivery head locking screw Stops the delivery head from moving.
14		(Obscured) Slit lamp height reference mark 1 Maximum (highest) 2 Midway 3 Minimum (lowest)
15		Illumination Boost Press and hold to boost illumination intensity.
16		Illumination Intensity Turn knob counter clockwise fully to turn off slit lamp illumination. For cautionary information about optical radiation hazards refer to 4.3.2 Slit lamp illumination on page 55.
17		[Underneath] Label indicating the country of manufacture
18		Aiming Beam Intensity The aiming beam is turned off in STANDBY and the minimum intensity position is visible (not off) in READY. When an LIO delivery device is selected this physical control is ignored and the aiming beam intensity is controlled by software on the tablet.
19		Cross slide locking screw (one on either side of the delivery head) stops the delivery head from moving.
20		Chinrest height adjustment

2.5.2 Slit lamp

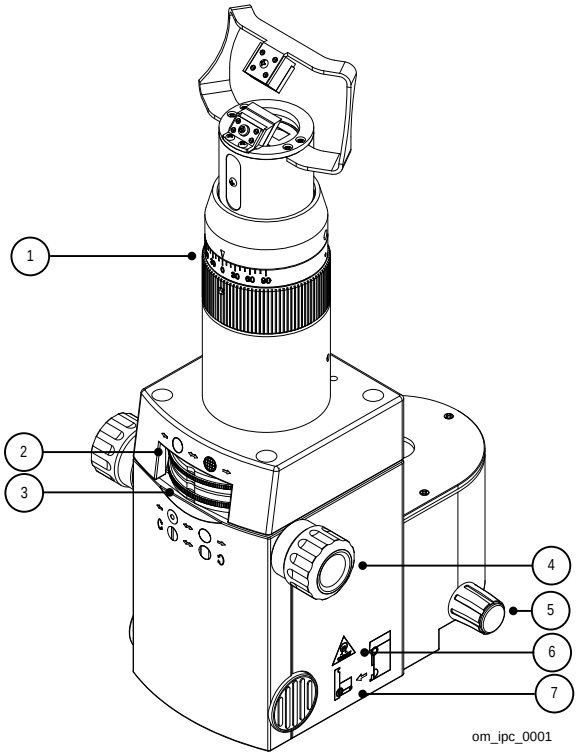
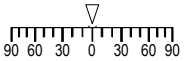
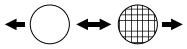
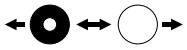
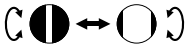
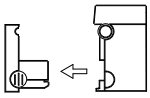


Figure 2-3

Table 2–4

1		Slit Rotation Adjust slit rotation through 90° either side of vertical (0°).
2		Filters Select from blue-green, violet-blue, heat absorbing and none.
3		Aperture Adjusts the illumination aperture between 0.5 mm, 3.0 mm, 8.0 mm and 12.0 mm.
4		Slit Width Continuously variable between closed and 12 mm.
5		Slit lamp locking screw Stops the slit lamp from moving.
6		Type of globe fitted to the slit lamp (halogen).
7		Graphic illustrating how to access the globe holder.

2.5.3 Console

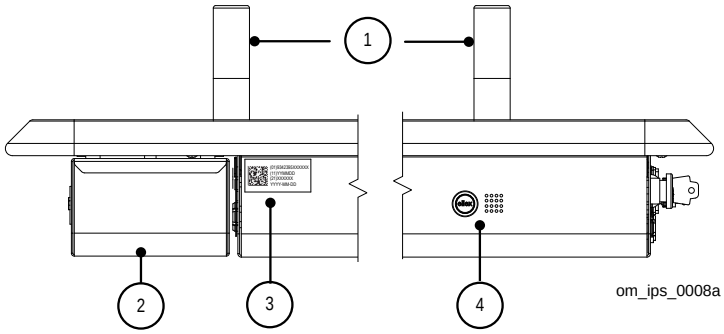


Figure 2-4

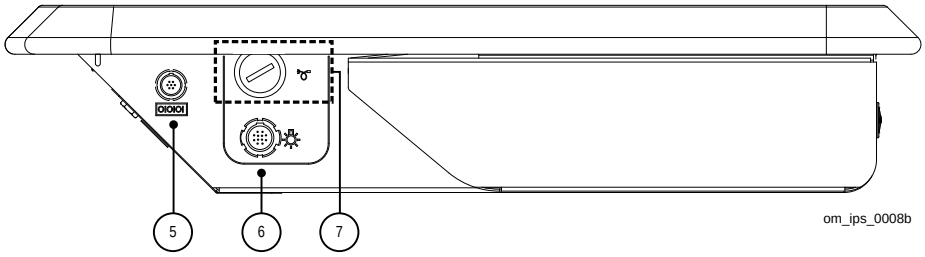


Figure 2-5

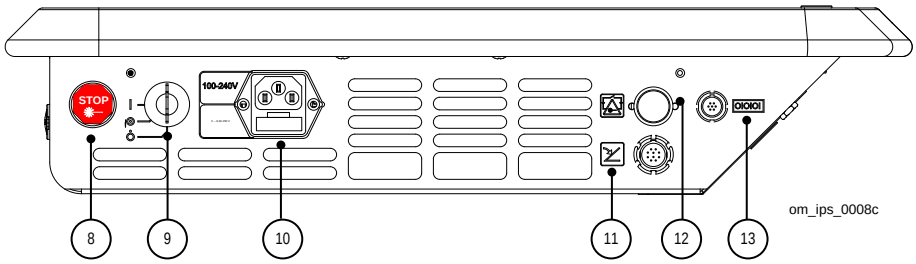


Figure 2-6

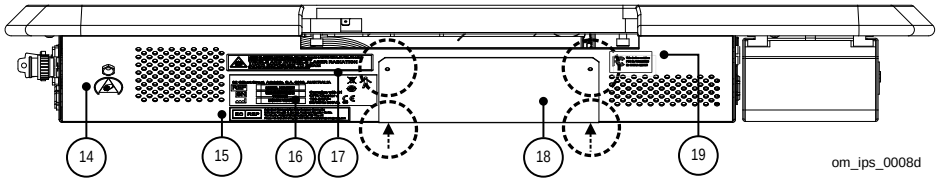
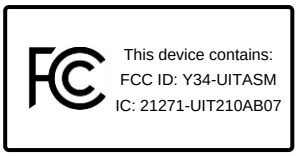
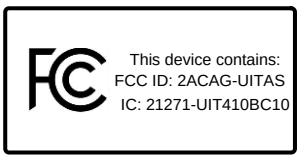


Figure 2-7

Table 2–5

1		Patient handles
2		Drawer
3		Unique device identification (UDI). For more information about this label refer to 2.5.10 Unique device identification (UDI) on page 47.
4	ellex	Manufacturer's logo and product logo. Logo is illuminated in white when mains power is supplied to the device.
		Integre® Pro Scan Green LP6G
		Integre® Pro Scan Yellow LP6Y
		Integre® Pro Scan Red-Yellow LP6RY
5	O|O|O|	Not used.
6		LIO power connector
7		LIO optical fibre connector with protective cap. Attach the cap to the connector when you are not using the LIO.
8	STOP	Emergency Stop switch Press to activate (immediately cuts power to the device, ceasing operation). Rotate clockwise to release the switch.
9		Key switch The main power switch for the device. Key cannot be removed unless it is in the Off position. The device cannot be turned on if the Emergency Stop switch has been activated. Off Slit Lamp | Laser
10	**100–240 V~** **F – 6.3 A 250 V**	Mains power (with mains supply voltage, fuse type and rating label)
11		Foot switch connector
12		Safety interlock connector
13	O|O|O|	Not used
14		(Service use) Earth point for antistatic wrist strap.

15	EC REP	European authorised representative label Authorised Representative in the European Community: E C Rep Ltd, 5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland Phone +353 1 2 544 944 Email: info@ecrep.ie
16		Compliance label (for more information refer to 2.5.9 Compliance label on page 46).
17		Laser safety label Indicates laser radiation hazard and class of treatment and aiming beam lasers (for more information refer 2.5.11 Laser safety labels on page 47).
18		Service bay (see below)
19		FCC label
		Generation 3 iDISPLAY 
		Generation 4 iDISPLAY 
		Generation 4b iDISPLAY 
		Service bay panel screws (two are located on the console base, indicated by arrows).

Service bay

Access the service bay by removing the four screws that secure the panel to the console. The bay contains wiring and cabling.

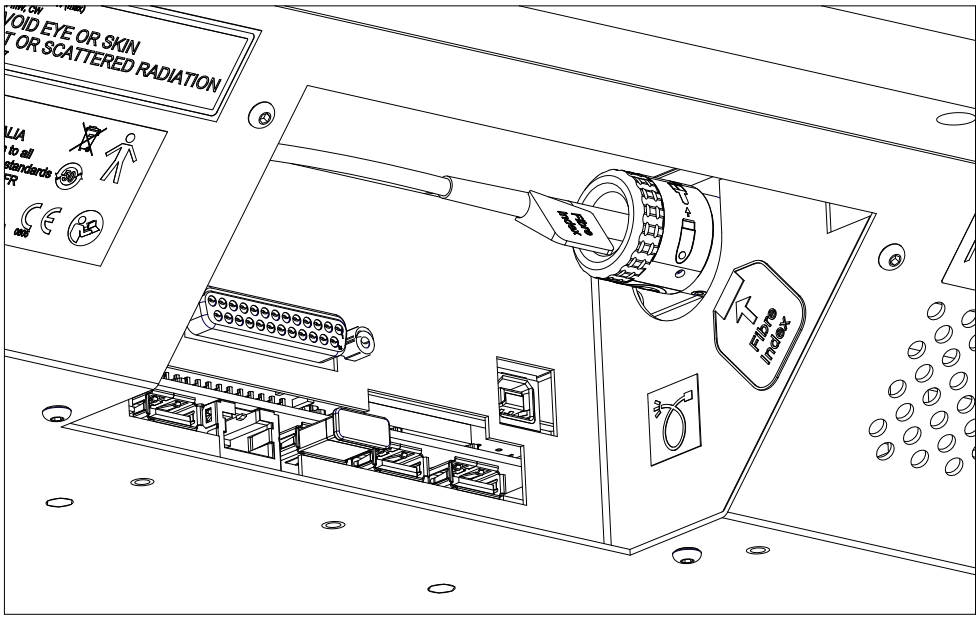
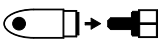


Figure 2-8

The optical fibre connector includes four labels.

Table 2–6

	Read the operator manual before use
	Do not touch the fibre tip
	Always place a cap on the exposed fibre tip to protect it
Fibre Index	Fibre index (on optical fibre)

On the inside right of the service bay, two labels are placed near the optical fibre port.

	Optical fibre port
	Fibre index The same label is also placed on the optical fibre.

The label describing connector use is placed on the inside of the service bay cover plate.

Devices using iDISPLAY tablets

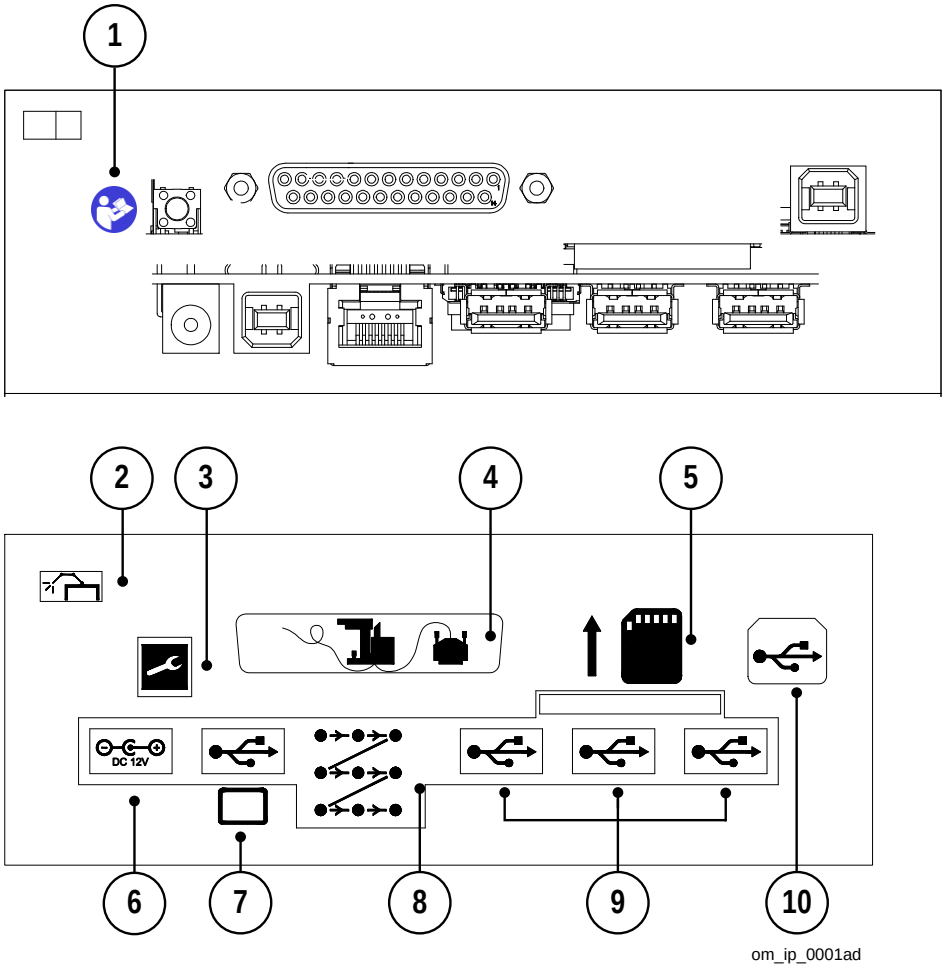


Figure 2-9

Table 2–7

1		(Service only) Refer to the Service Manual for more information.
2		Fixation lamp
3		(Service only)
4		Slit lamp
5		(Service only) SD card
6	iDISPLAY tablet	DC connector for tablet use only.
7	Generation 3 iDISPLAY tablet	USB type B connector for Generation 3 iDISPLAY tablet use only.
8		Scanner connection

9		Low power USB connections Connectors for Generation 4 iDISPLAY tablet.
10		USB type B connector for firmware updates. Service use only.

2.5.4 Tablet

WARNING! Do not use the tablet for any other purpose than for which it has been provided. It is an integral part of the device.

You do not need to operate any of the physical controls on the tablet. The tablet turns on when you turn the console key switch to On and the tablet turns off when you turn the key switch to Off.

Power

Tablets derive their power from the console to which they are connected through a power cable.

Start-up screen sequence

Start-up screens display before the STANDBY treatment screen appears. Apart from responding to the alarms described below, you should not need to interact with the device during the normal start-up process.

Low battery

A low battery alarm displays if the battery inside the console (not the tablet) must be replaced. If you see this alarm, please contact your Ellex Authorised Distributor to schedule a service visit. This alarm repeats each time the device is started until the battery is replaced.

Service reminder

If the device has not been serviced within a period of 12 months a reminder alarm displays during start-up. Tap the button to acknowledge the alarm and the start-up process will continue. If you see this alarm, please contact your Ellex Authorised Distributor to schedule a service visit. This alarm repeats each time the device is started until the device is serviced.

Treatment screen STANDBY

Pattern (slit lamp)

Where displayed, tap the plus or minus symbols to increment or decrement the value for that control.

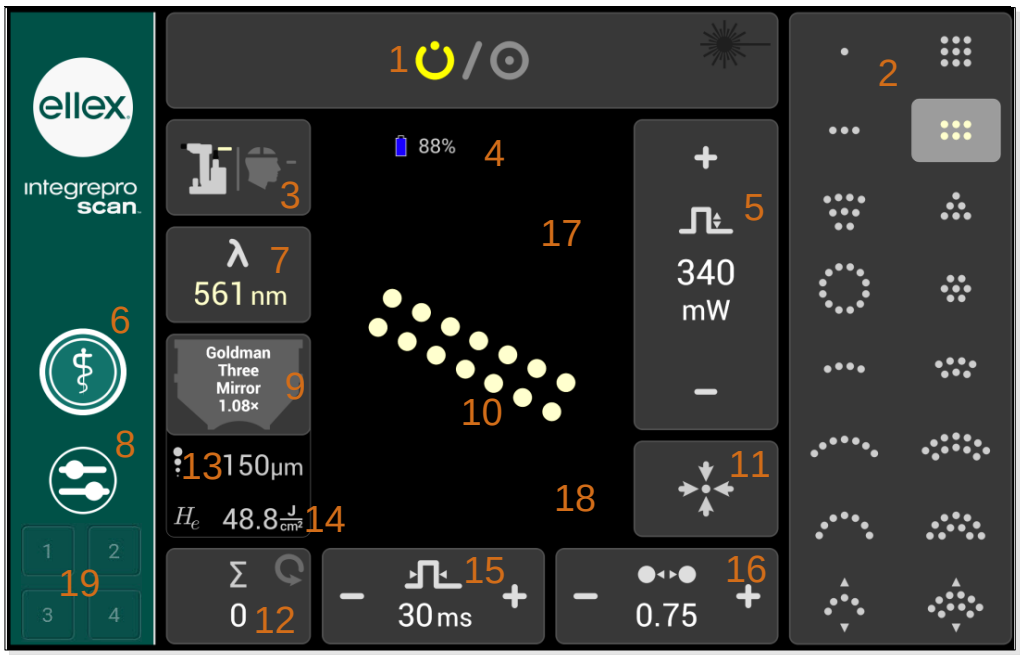


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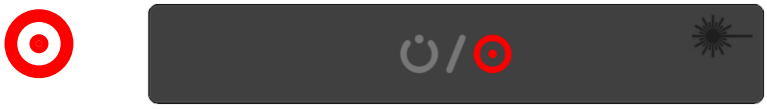
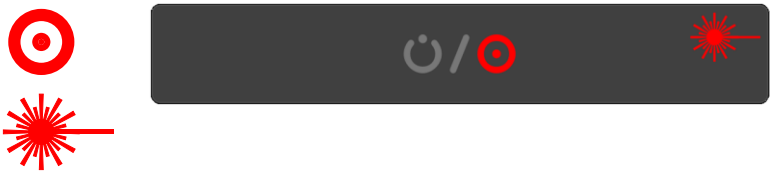
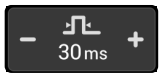
Figure 2-10

Table 2–8

1	STATE Select between STANDBY (laser cannot fire) and READY (laser may be fired). The device emits a tone confirming the change.
	STANDBY (laser cannot be fired) 
	READY (laser may be fired but is not currently firing). Note the laser emission symbol at right is black (inactive). 
	READY (laser is firing) Note the laser emission symbol at right is bright red (active). The device emits a tone when you fire the laser. The volume for this tone is adjustable: for more information refer to Preferences on page 41. 
2	Pattern Gallery Tap a pattern to select it. A selected pattern has a light grey background and appears in the pattern workspace. Only one pattern can be selected at a time. Repeatedly press the joystick button to cycle one-by-one through the patterns. The device emits a tone confirming the change in pattern and the laser is locked from firing for ½ second. For information about manipulating patterns refer to Manipulating patterns on page 35.
3	Delivery Device Tap the button to toggle between the slit lamp delivery system (SDS) or LIO. If LIO is selected the treatment screen displays LIO specific controls. For more information refer to LIO on page 30. The laser beam symbol on the button indicates the colour of the laser. The device emits a tone confirming the change in delivery device.

		SDS selected 	LIO selected 
4	***Battery power***	***Not used***	
5		Power The device emits a tone confirming the change in value.	
6		Treatment Tap this button to access the treatment screen. The outer ring white ring of this button becomes thicker when this button is selected. The device emits a tone confirming this selection.	
7		Wavelength (Single wavelength devices) Display only. (Multiple wavelength devices) Tap this button to toggle between wavelengths; the device emits a tone indicating the change in wavelength. The selected wavelength is also indicated by the colouring of the spot in the pattern workspace, the colour of the wavelength value and as part of the graphic on the delivery device button.	
8		Preferences Tap this button to access device preferences. The outer white ring of this button becomes thicker when this button is selected. The device emits a tone confirming this selection. For more information refer to Preferences on page 41.	
9	 	Lens If you select a lens the device calculates both the spot size at the target (the ‘true’ spot size) and the fluence. This additional information may assist you clinically but does not change the behaviour or operation of the device. By default, no lens is selected when you start the device. No lens is indicated by a circle with a line through it. Tap the lens symbol to select from a list of lenses or to create a custom lens.	
10		Pattern Workspace The selected pattern displays in this area. The spots are shown in the colour of the selected wavelength. You can rotate and resize patterns by touching this central area of the tablet screen. For more information about manipulating patterns refer to Manipulating patterns on page 35.	

11		Pattern Reset Re-centres the pattern or spot within the field of view. The device emits a tone confirming the change and the laser is locked from firing for ½ second.
12		Shot Count and Reset button (Multiple wavelength devices) Shot counts for each wavelength are stored and displayed when you change the wavelength. They must also be individually reset. Tap the button to reset the Shot Count to 0 for the current wavelength.
13		Spot Size (µm) If no lens is chosen the spot size displayed is the value selected using the delivery head Spot Size control. If a lens is chosen the spot size displayed is the result of the spot size selected using the delivery head Spot Size control as magnified by the lens (the ‘true’ spot size).
14		Fluence (J/cm2) The energy delivered per unit area (radiant exposure). Fluence only displays if you have selected a lens and the ‘true’ spot size is used in the calculations to determine the fluence value.
15		Pulse Duration Tap the + and – to change the duration to the next value. The device emits a tone confirming the value has changed.
16		Spot Separation Distance between spot edges in pattern mode. Unit of measure is by spot diameter (for example 1.0 means the distance between spots is the diameter of one spot). Tap the + and – to change the separation to the next value. The device emits a tone confirming the value has changed. For more information refer to Spot separation on page 34.
17		Appear when a pattern is selected. Rotate the pattern clockwise or anti-clockwise.
18		Appear when a pattern is selected. Increase or decrease the pattern size.
19		Treatment settings memory. Stores up to 4 unique treatment settings for easy recall and use. Can use alphabets or numbers to name these settings. See Treatment Settings on page 59

Single spot (slit lamp)

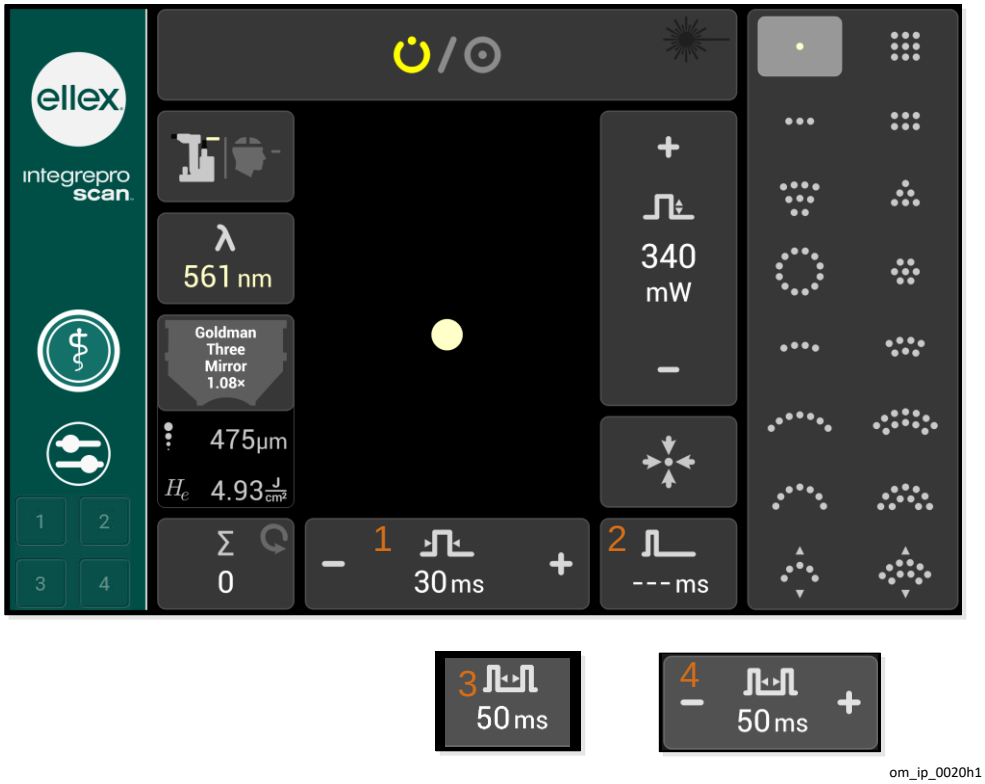
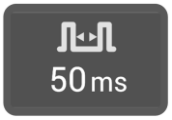
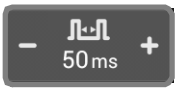


Figure 2-11

Table 2–9

1		Note the Pulse Duration control becomes wider in single spot mode (as shown above).
2		Pulse Interval (default) The default is no interval (--- ms) which means the device only fires a single shot. This is depicted by a single pulse symbol. To change the pulse interval tap the button to activate the button, tap the − or + symbols that are now displayed on the now larger button to select a value, then tap the centre of the button to deactivate it. Once a value is selected the symbol on the button changes from a single to pulse to two pulses. The device emits a tone confirming the change in value.
3		Pulse Interval (value selected)
4		Example of the Pulse Interval button when it has been activated (showing the − and + symbols)

LIO

When you select the LIO delivery device the Pattern Gallery and Spot Separation controls are replaced by the Aiming Beam Intensity and Pulse Interval controls. The Pattern Reset button is also removed. You can only fire single spots (not patterns) using an LIO.

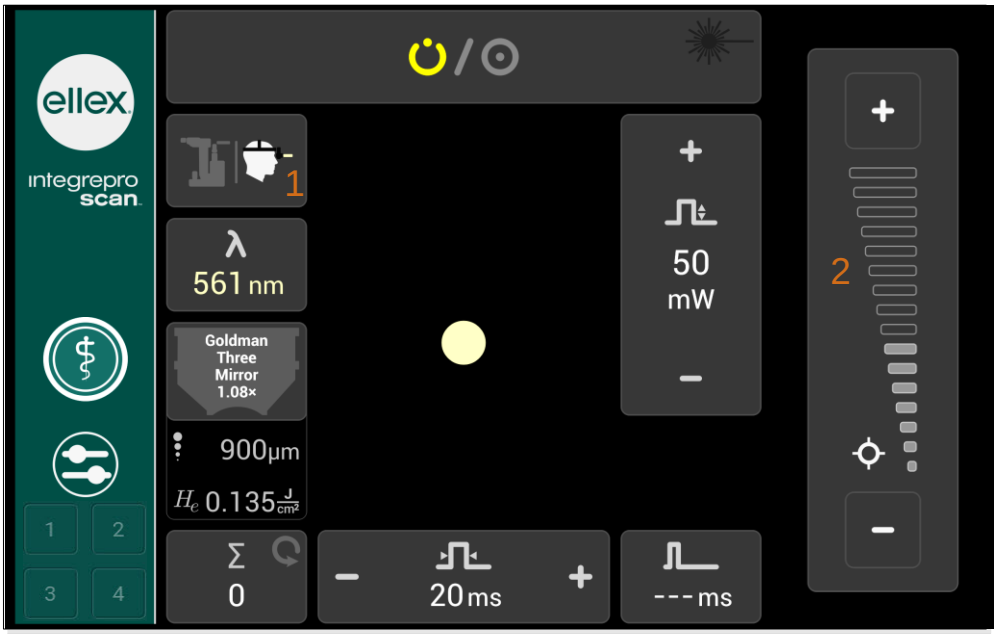


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Figure 2-12

Table 2–10

1		Delivery Device button with LIO accessory highlighted
2		Aiming Beam To increase intensity tap the + button. To decrease intensity tap the – button. The aiming beam is turned off in STANDBY.

Treatment screen READY

An example READY screen is shown below. This illustration highlights the State button with a bright red READY symbol and a bright red active laser emission symbol indicating that the laser is firing.

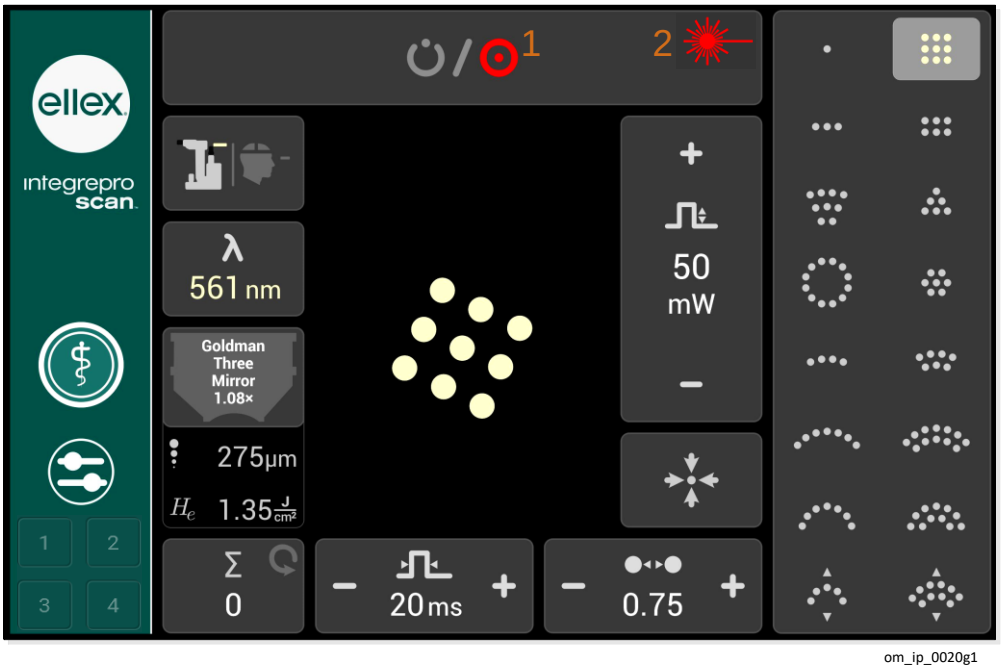


Figure 2-13

Table 2–11

1		READY state indicator laser may be fired but is not currently firing
2		Laser emission indicator (bright red) Laser beam is emitted by the device through the laser aperture.

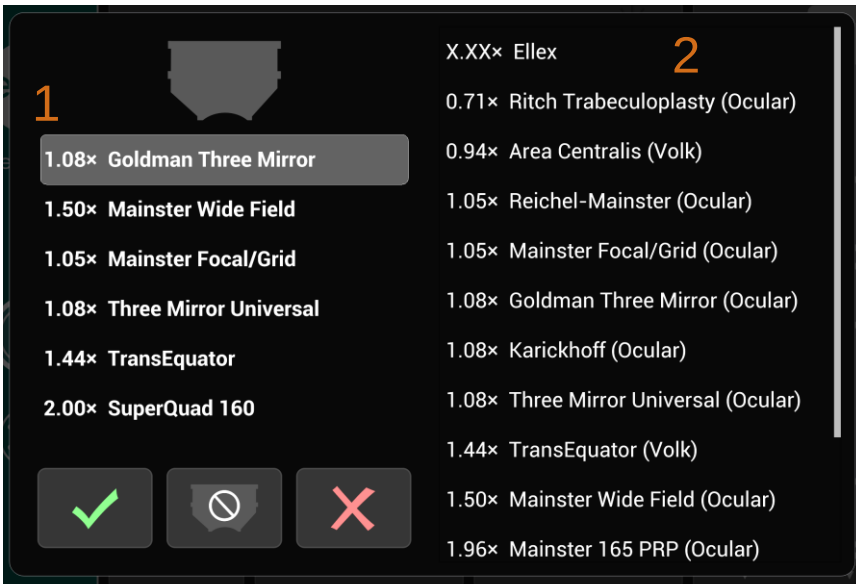
Selecting lenses

You can choose a lens when the device is in STANDBY or READY.

WARNING! If you clinically rely on fluence and 'true' spot size, ensure the correct lens is selected before treatment.

Selecting a lens

1 At the treatment screen tap the **Lens** button. (The lens button shows the last selected lens or the no lens symbol.)



7023a1

Figure 2-14

Table 2–12

1	Recent lens list
2	List of all lenses

2 Tap to select a lens from the either the **Recent Lenses** list at the left or the list of all lenses at the right.

Recent Lenses will be empty if this is the first time a lens has been selected.

3 Tap the **Tick** button.

4 The six most recently selected lenses are shown at the left with the most recently selected lens at the top of the list. Custom lenses only appear in the **Recent Lenses** list.

Selecting no lens

- Tap the **No Lens** button.

Selecting no lens has no effect on the **Recent Lenses** list.

Adding a custom lens

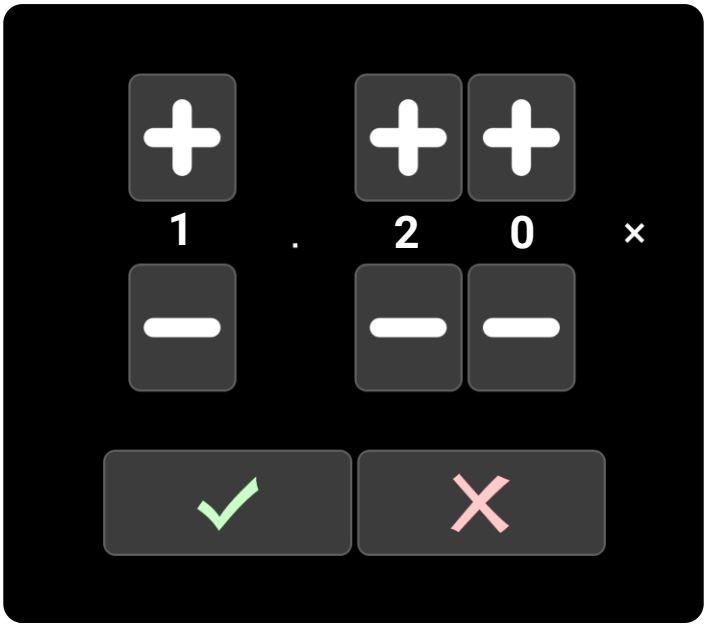
Define a custom lens if the list of lenses does not include a lens you want to use.

1 Ensure the device is in STANDBY.

2 Tap the **Lens** button.

3 Tap **X.XX× ELLEX** from the list of all lenses on the lens selection screen. This lens is permanently located at the top of the list.

4 At the input screen define the magnification and tap the **Tick** button to return to the lens selection screen.



om_ip_0020h

Figure 2-15

WARNING! Ensure that you understand the lens data sheet and enter the correct magnification value into this device. Retain the lens data sheet for future reference.

The newly added lens is added to the top of the **Recent Lenses** list and automatically selected.

5 Tap the **Tick** button to confirm your lens selection and return to the treatment screen.

You can define up to six custom lenses (the number of recent lenses).

Custom lenses only appear in the list of **Recent Lenses** and are not listed in the full list of lenses. This means if you frequently use more than six lenses, or if multiple operators of this device use different lenses, you may need to recreate custom lenses.

Patterns

Pattern scanning is available for spot sizes between 100 µm to 500 µm.

All patterns may be rotated.

The number of spots and pulse duration settings limit the total exposure time for any pattern to 750 ms or less. If you modify a pattern and exceed this threshold, the device will show an error.

Resetting the pattern

- Tap **Pattern Reset** to centre the pattern within the binocular field of view in its default orientation.

This is only available if the slit lamp delivery device has been selected.

Aiming beam display

The aiming beam only displays when the device is in READY.

Spot separation

The distance between spots may be adjusted for all patterns except the single spot and is measured from edge to edge of adjacent spots. The unit of measurement is one spot diameter.

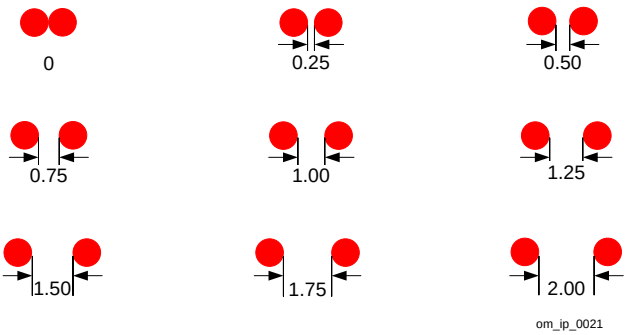
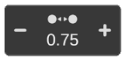


Figure 2-16

Adjusting spot separation



- Using the **Spot Separation** button, tap **+** or **–** to increase or decrease the distance between the spots.

Selecting patterns

There are two ways to select a pattern:

- Use a finger to tap the symbol for the pattern on the tablet.
- Press the joystick button repeatedly to navigate pattern-by-pattern through the pattern gallery.

If you have selected favourites then using the joystick button only works within this operator-selected group of patterns. To select favourite patterns, refer to the section Favourites on page 37.

Manipulating patterns

You can manipulate patterns using the trackpad or tablet (where noted).

Use the trackpad by lightly touching the surface with your finger (or fingers where instructed) in a series of one or more gestures.

Use the tablet by lightly touching the centre of the tablet (the workspace area) with your fingers in a series of one or more gestures. Avoid touching the buttons outside the workspace when manipulating patterns using the tablet.

Changing pattern size

These instructions apply to all patterns.

To make a spot larger use the Spot Size control on the delivery head.

1 Select a pattern.

2 Place the device in READY.

The aiming beam (and therefore the pattern) is only visible in READY.

3 Look through the binocular.

4 Place two fingers on the trackpad or in the pattern workspace area of the tablet and slowly spread them apart to make the pattern larger. Bring the two fingers together (pinch) to make the pattern smaller.

For the Sector pattern, these gestures add or remove outer arcs of spots (outer diameter). The tablet also shows the change in pattern size.

Changing inner diameter of the Sector pattern

1 Select the Sector pattern.

2 Place the device in READY.

The aiming beam (and therefore the pattern) is only visible in READY.

3 Look through the binocular.

4 Place three fingers on the trackpad or in the pattern workspace area of the tablet and move them up or down to change the inner diameter of the pattern (to add or remove inner arcs of spots).

Moving patterns (micromanipulation)

You can only move the pattern or spot within the binocular field of view when the device is in READY.

1 Select a pattern or single spot.

2 Place the device in READY.

The aiming beam (and therefore the pattern) is only visible in READY.

3 Look through the binocular.

4 Swipe one finger across the surface of the trackpad to move the pattern or spot within the field of view.

The tablet will not display micromanipulation.

Rotating patterns

This feature applies to all patterns but not the single spot.

You can only move the pattern within the binocular field of view when the device is in READY.

1 Select a pattern.

2 Place the device in READY.

The aiming beam (and therefore the pattern) is only visible in READY.

3 Look through the binocular.

4 Place two fingers on the trackpad on in the pattern workspace area of the tablet and rotate your fingers in the direction of rotation.

The tablet will display the pattern rotation.

In the diagram below (not to scale), the Triangle pattern has been sequentially rotated to the right by 90 degrees. Notice the shape pivots from the centre of the pattern.

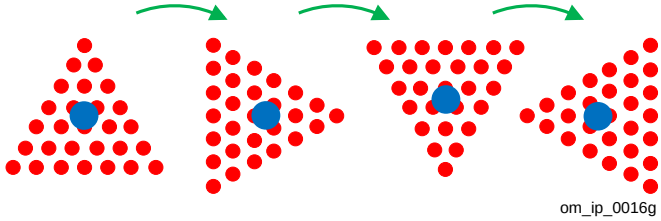


Figure 2-17

This means if you need to rotate the Sector pattern to treat a circular or semi-circular area you must use a combination of rotation and micromanipulation gestures to place the pattern around an imaginary pivot as illustrated below in green.

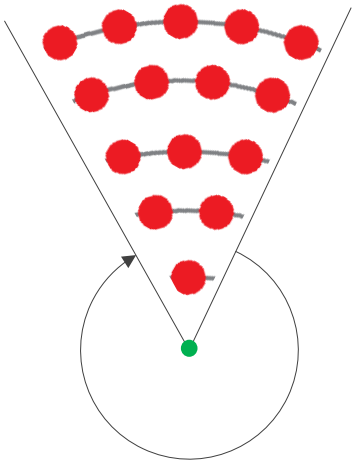
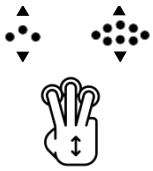


Figure 2-18

Adjusting the Flex pattern



The Flex pattern is a one or two row arc with an adjustable radius.

1 Select a Flex pattern.

2 Place three fingers on the trackpad or in the pattern workspace area of the tablet and move all three fingers individually to adjust the pattern.

As you have a wide range of flexibility practise manipulating the pattern before applying it clinically.

Favourites

If you only use a few patterns, consider making them your favourites.

Favourites are patterns you select and navigate between as a small group rather than having to navigate through all the patterns in the pattern gallery. Define favourites to apply regularly used patterns easier and quicker without losing the option of selecting from the full range of patterns.

Favourite patterns are only available in slit lamp delivery mode and remain selected until you manually delete them or turn the device off.

Saving favourites

1 On the tablet press (tap and hold) a pattern to select it.

The device emits a tone and encloses the pattern in a dashed white border confirming your choice.

2 Repeat this action for other patterns as needed.

You can add a pattern to your favourites at any time using this method.

Note you are only saving the pattern as a favourite and not the current treatment settings such as power or duration.

Deleting favourites

- On the tablet press (tap and hold) a favourite pattern to remove it.

  The device emits a tone and the dashed white border around the pattern is removed.

Favourites are cleared when the device is turned off.

Selecting favourites

During an examination session, you can easily jump between your favourite patterns without having to look away from the binocular.

- Press the joystick button once to sequentially move through your favourite patterns.

Pattern size is the value last selected for this pattern and all other treatment settings are as they were last set.

Using other patterns

If you need to use another pattern (that is, one you have not defined as a favourite) tap its symbol on the tablet.

To return to your favourites press the joystick button once and the next favourite in the pattern gallery will be selected.

Gallery

Table 2–13

Type	Example		Spots per pattern grouped by maximum duration		
	Pattern	Name	30 ms	20 ms	10 ms
Line		7	2, 3, 4, 5, 6, 7		
Rectangle *		2×6	2×2, 2×3, 2×4 2×5, 2×6, 2×7		
Square *		6×6	2×2, 3×3, 4×4	5×5	6×6
Sector (45° or $\frac{1}{8}$ of a circle)		15	3, 6, 10, 15, 21		
Triangle		28	3, 6, 10, 15, 21	28	
Circle		37	3, 7, 12, 19	27	37
Ring		12	12, 18	24, 30	
60° arc (open shape)					
Single		6	3,4,5,6,7		
Double		13	5,7,9,11,13		
120° arc (open shape)					
Single		11	5, 7, 9, 11		
Double		20	8, 12, 16, 20		
180° arc (open shape)					
Single		10	4,7,10		
Double		17	11,17, 23		
Flex (open shape)			This is a single or double row pattern with an adjustable radius.		
Single		4	3, 4, 5, 6, 7, 8		
Double		4	3, 4, 5, 6, 7, 8	The number of spots in the inner radius. The outer radius adjusts to complete the arc.	

The number of spots available for selection for a specific pattern is also a factor of the selected spot size.

* The number of spots is the result of the calculation shown. For example, for the 2×3 rectangle the result is 6 spots, for a 4×4 square the result is 16 spots.

Gesture summary

Place the device in READY so you can observe the aiming beam and see the changes to the pattern in the field of view.

Note: Trackpad mentioned in Input Device is a Wired trackpad.

Table 2–14

To …	Do this …	Gesture	Input Device
Select a pattern	Tap the symbol for the pattern on the tablet.		Tablet
Move a pattern	Swipe one finger across the trackpad in the desired direction.		Trackpad
Rotate a pattern	Use the two finger rotate gesture on the trackpad or tablet.		Tablet Trackpad
Make a pattern **larger**	Use the two-finger spread gesture on the trackpad or tablet.		Tablet Trackpad
Make a pattern **smaller**	Use the two-finger pinch gesture on the trackpad or tablet.		Tablet Trackpad
Add a Favourite	Press (tap and hold) the symbol for the pattern on the tablet.		Tablet
Select a Favourite	Press the button on the top of the joystick.		Joystick
Remove a Favourite	Press (tap and hold) the symbol for the pattern on the tablet.		Tablet
 **Adjust** the Flex pattern	Swipe three fingers in the direction of the pattern.		Tablet Trackpad
 **Adjust** the **outer diameter** of the Sector pattern	Use the two-finger pinch and spread gestures on the trackpad or tablet.		Tablet Trackpad
Adjust the **inner diameter** of	Swipe three fingers in the direction of the pattern.		Tablet Trackpad

the Sector pattern	

Preferences

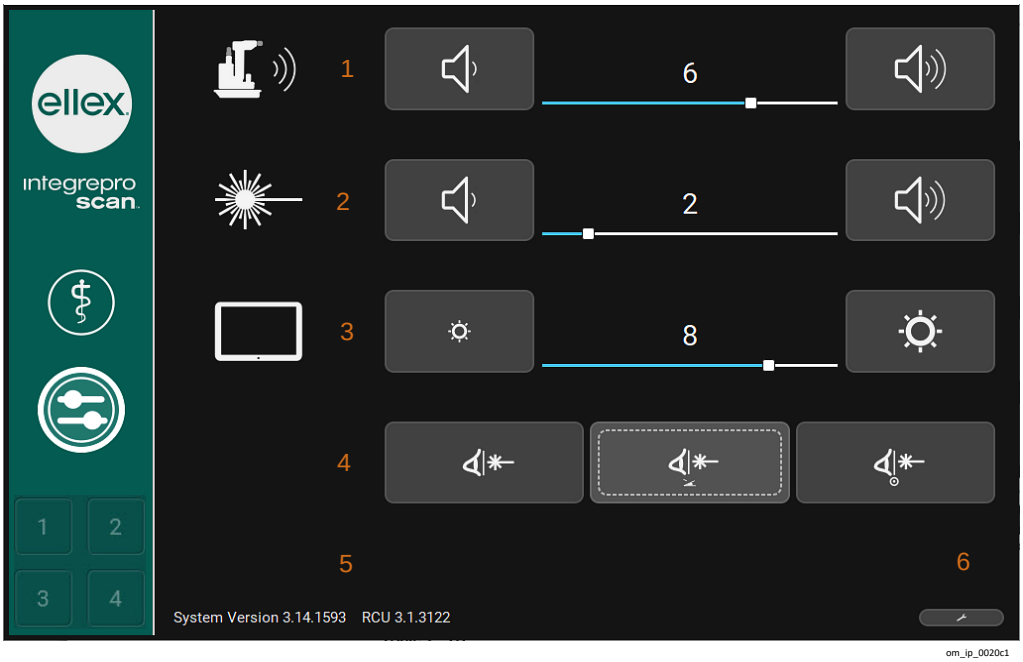
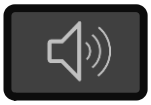
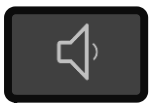
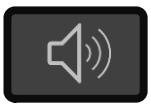
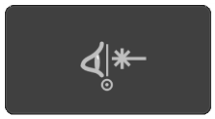


Figure 2-19

Table 2–15

1		System volume The range is from quiet (left) to loud (right).  Tap this button to decrease the volume.  Tap this button to increase the volume.
2		Laser emission warning volume The range is from quiet (left) to loud (right).  Tap this button to decrease the volume.  Tap this button to increase the volume.
3		Tablet brightness Only displays on tablets without automatic brightness control.
4		Eye safety filter (ESF) Every time the device is started the ESF preference is set to Foot switch Activated.

		Fixed in Place The eye safety filter is permanently in the viewing path.
		Foot switch Activated The eye safety filter moves into the viewing path when the foot switch is activated and prior to laser emission.
		READY Activated The eye safety filter moves into the viewing path when the device is placed in READY.
5		Software version information
6		(Service use) Tablet menu

Alarms

A visual alarm displays if an error has occurred. To dismiss this alarm, tap the tick button.

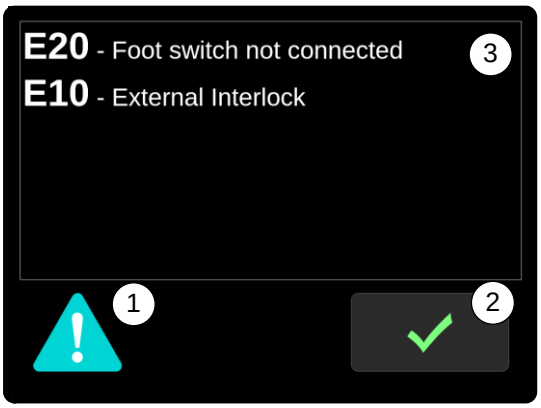


Figure 2-20

Table 2–16

1		Alarm symbol
2		Tick button
3		Error code and message display

If any faults remain the fault symbol appears in the State button. Tap the State button to display the alarm screen and list all the current faults. These faults must be resolved before the device can be used. Restarting the device may clear some or all of the faults.

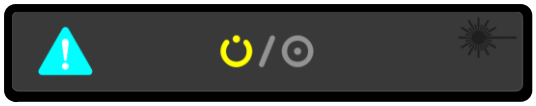


Figure 2-21

2.5.5 Trackpad – Wired

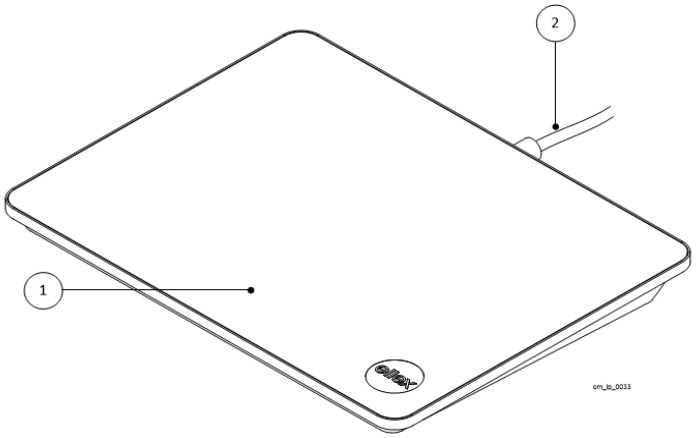


Figure 2-22

Table 2–17

1	Touch surface
2	Cable

This trackpad allows you to finely adjust the position of the pattern (micromanipulation).

For more instructions about how to use the trackpad refer to Manipulating patterns on page 35.

The trackpad is hard wired to the console at the time of installation; by default placed on the right hand side. If you want to use it on the left hand side, then go to the rear section of the console. Look for the trackpad cable under the tabletop. Unhook the cable from the clip (retainers) and move the trackpad to the left.

2.5.6 Audible indicators

The console and tablet emit warning sounds and other audible indications to confirm actions, such as tapping buttons and to indicate laser emission. An error code appears on the tablet if an error occurs.

Always check the volume setting if you cannot hear the audible indications.

WARNING! Do not use the device if there are no audible indications. Contact your Authorised Ellex Distributor.

2.5.7 Foot switch

Standard Folding (A) and optional Power Control (B) foot switches are shown below.

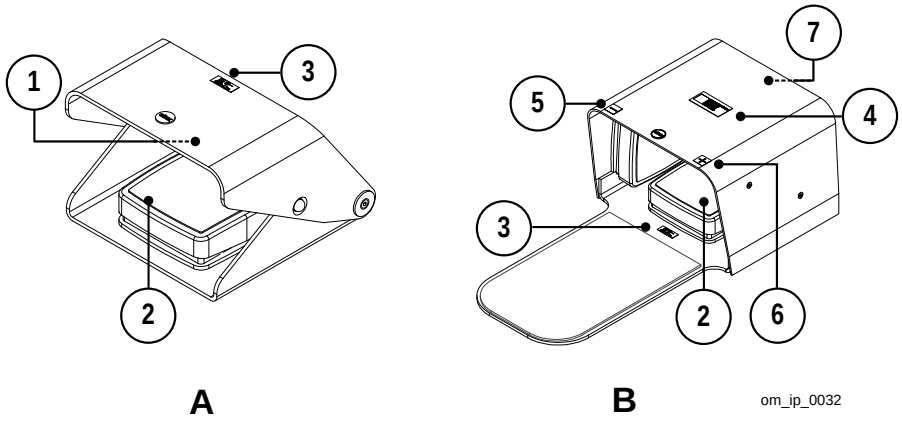
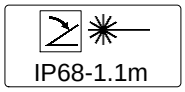


Figure 2-23

Table 2–18

1		Serial number label and recycling symbol Recycling symbol in compliance with EU Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) indicating the use of separate collection and recycling methods when disposing of this product.
2		Pedal (triggers laser emission)
3		Foot switch and laser emission labels. IP68 indicates that the foot switch is protected from total dust ingress and against the ingress of water during continuous immersion to a maximum depth of 1.1 metres. Depressing the foot switch when the device is in READY triggers laser emission.
4		Unique device identification (UDI). For more information about this label refer to 2.5.10 Unique device identification (UDI) on page 47.
5	_	(Power Control foot switch) Power decrement switch Decreases laser power in single step increments. Power Control on the delivery head remains functional.

6	+	(Power Control foot switch) Power increment switch Increases laser power in single step decrements. Power Control on the delivery head remains functional.
7		Serial number

2.5.8 Laser aperture

The location of the laser aperture is shown below. The laser aperture label is placed immediately below the aperture.

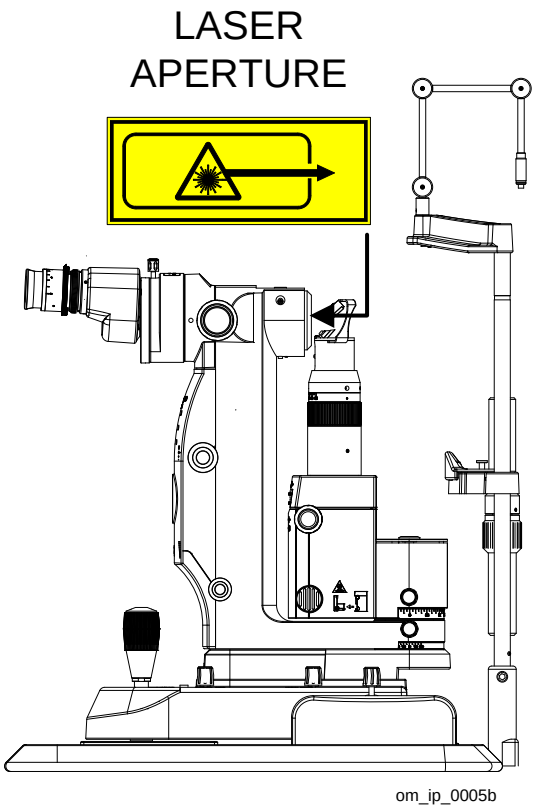


Figure 2-24

2.5.9 Compliance label

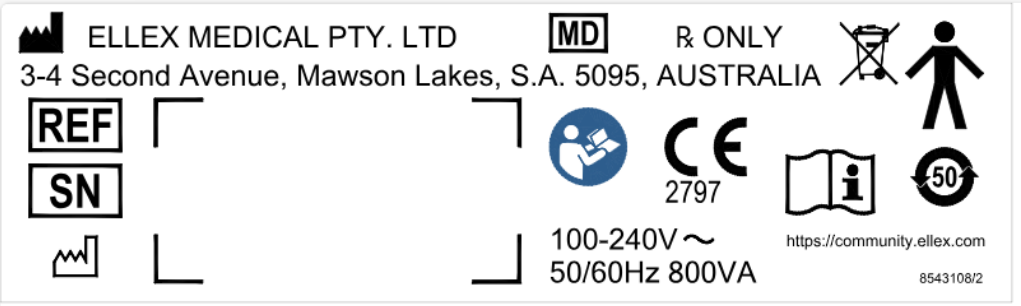


Figure 2-25

Table 2–19

	Manufacturer
REF	Device model designation (LP6G, LP6Y, and LP6RY)
SN	Serial number as text and barcode
	Date of manufacture
	Recycling symbol Symbol in compliance with EU Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) indicating the use of separate collection and recycling methods when disposing of this product.
	Type B equipment symbol The equipment provides protection against electric shock through the limiting of leakage current and the provision of a protective earth connection.
50	Pollution control label in compliance with People's Republic of China (PRC) standards.
CE 2797	CE mark in compliance with the EU Medical Device Directive (MDD).
	The user must read and comprehend the operator manual before use.
℞ ONLY	PRESCRIPTION ONLY ⚠ **CAUTION:** U.S. federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
MD	Medical Device: Indicates the item is a medical device.
	Consult electronic *instructions for use,*
https://community.ellex.com	Website address: eIFU indicator

2.5.10 Unique device identification (UDI)

Figure 2-26

Table 2–20

(01)	Global trade item number (GTIN)
(11)	Date of manufacture in YYMMDD format
(21)	Serial number
YYYY-MM-DD	Full date of manufacture in YYYY-MM-DD format

2.5.11 Laser safety labels

Integre® Pro Scan Green LP6G

Figure 2-27

Integre® Pro Scan Yellow LP6Y

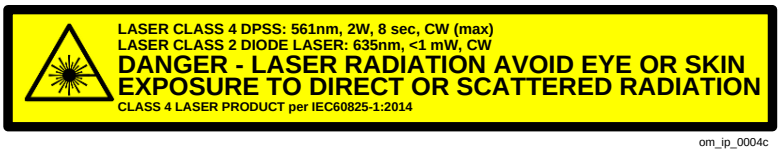


Figure 2-28

Integre® Pro Scan Red-Yellow LP6RY

Figure 2-29

2.5.12 Treatment Settings Memory

The device allows you to store treatment settings (See label 19 on Figure 2-10). These setting(s) can then be recalled by tapping a button on the main screen, thereby saving time.

For more details see 5.1 Treatment Settings on page 59

3 Clinical Use

WARNING! This information is a guide only and is not intended to present complete or thorough instructions. It does not replace the judgement of a qualified ophthalmic physician.

Ellex accepts no responsibility for negligent medical practices, or for any event that results from the improper use of this equipment.

Only use this device in accordance with the purpose, indications and contraindications described below.

WARNING! Do not aim, focus or fire this device in, on or near the fovea; on corneal structures; on the patient's lens (natural or artificial); or on any other structure of the human body that is not related to the treatment of an eye disorder.

A range of laser contact lenses may be used with the device. Each contact lens:

- has a different field of view, to suit optimal treatment of different ocular structures
- changes the spot diameter related to the lens magnification.

Read the contact lens documentation to determine the magnification factor and indications for use. Always use the appropriate handheld laser lens recommended in peer reviewed literature for the appropriate treatment of an eye disorder or disease.

Treatment should be performed prudently following the principle of ALARA (As Low as Reasonably Achievable).

The information provided under the General purpose, Indications and Contraindications headings (see below) has been cleared by the US Food and Drug Administration (FDA). This information is generally valid for other countries.

3.1 General purpose

This device is intended to be primarily used in ophthalmic photocoagulation procedures.

3.2 Operating principle

3.2.1 Clinical concept

The operating principle of ophthalmic photocoagulation is that absorption of energy by ocular tissue results in heating, which causes a photo-thermal reaction resulting in photocoagulation. Photocoagulation is used to cauterise blood vessels in the retina to stop them from growing and leaking, and to destroy dead areas of the retina where blood vessels have been closed. In response, the eye ceases producing new blood vessels and existing vessels decrease or disappear. The extent of heating, and thus photocoagulation, is dependent on the laser (wavelength, power, duration, spot size) and the target ocular tissue (pigmentation).

3.2.2 Device operation

When you turn the device on using the key switch the internal power supply converts alternating current (AC) mains power to the required internal voltages.

The device has two modes of operation: STANDBY and READY. The device is placed in STANDBY when it has successfully completed starting up.

In STANDBY you may safely select various treatment laser parameters without the ability to fire the treatment laser. Treatment settings are controlled using physical controls on the device and virtual ones present on the tablet. Operator feedback is delivered using visual and audio cues such as tones for virtual setting changes, visual changes (numbers and/or graphics) on the tablet, as values are adjusted or options selected. The treatment laser parameters available to the operator are:

- power
- duration
- interval
- spot size
- pattern

Parameters are typically selected prior to commencing treatment and may be altered as treatment progresses to best meet the unique treatment requirements of each patient.

In STANDBY you can also use the slit lamp to conduct an ophthalmic examination.

The diode aiming module (DAM) is also energised in STANDBY. The DAM is a low power 635 nm red laser located in the sealed optics bench in the console. This red light is directed through a fibre port to a fibre optic cable that terminates at the top of the delivery head. The emitted laser beam is reflected 90 degrees and exits the device at the laser aperture towards the patient. The beam is coaxial with the operator’s viewing axis.

Only when the device is in READY can you fire the treatment laser. If the device detects a problem in this state, it will immediately drop to STANDBY.

In READY, when you press the foot switch to fire the treatment laser, the device passes current to the laser engine and regulates laser output to the set power level. Treatment settings selected by the operator are controlled by electronics and software.

The optical output from the aiming beam and treatment laser engine are directed via an optical fibre to the delivery device. In the case of the slit lamp delivery device, the spot size at the treatment plane is adjusted by a zoom assembly built into the delivery device. The LIO delivery device has a fixed non-adjustable spot size.

When pattern scanning mode is selected, the aiming and treatment beams are deflected in the slit lamp optical pathway in order to create the required pattern. The system electronics and software control the creation of the pattern and the dwell time in each spot location of the pattern is held before continuing to the next spot.

If an LIO delivery device is chosen a port selector inside the optics bench redirects laser output to the external optical fibre port.

3.3 Indications

This device is indicated for use in the photocoagulation of both anterior and posterior segments of the eye including:

- retinal photocoagulation and pan-retinal photocoagulation of vascular and structural abnormalities of the retina and choroid including:
    - proliferative and non-proliferative diabetic retinopathy
    - choroidal neovascularisation
    - retinal vein occlusion
    - wet age-related macular degeneration (AMD)
    - retinal tears and detachments
    - retinopathy of prematurity.

Iridotomy, iridectomy, suturelysis and trabeculoplasty in angle closure glaucoma and open angle glaucoma are also indicated.

3.4 Contraindications

Laser surgery is contraindicated if an appropriate procedure cannot be performed safely, such as if tissue targets cannot be visualised properly. Under such circumstances, tissue adjacent to the target tissue might be photocoagulated inadvertently. Corneal opacities, cataract formation, and vitreous haemorrhage, can all interfere with the physician’s view of appropriate target structures.

Treatment should be delayed until the ocular media problem is resolved. If it is not possible to delay treatment or correct the ocular media problem, an alternative form of therapy should be implemented, if available and medically indicated.

This device must not be used to treat patients with minimal retinal pigmentation.

3.5 Precautions

As with any surgical procedure, there are risks involved. Potential complications accompanying photocoagulation surgery may include, but are not limited to anterior segment complications such as corneal or lenticular opacification, transient visual

loss, permanent vision loss, macular edema, haemorrhage, choroidal effusion, colour vision alterations, pain, visual field defects and night vision problems, hemeralopia. Secondary surgical interventions include, but are not limited to, vitrectomy and additional photocoagulation.

3.6 Operational indications and contraindications

For operational indications and contraindications refer to the Warnings chapter on page 7 and the Operation chapter on page 59.

3.7 Further reading

Visit the Ellex website for whitepapers and other educational material. A small selection of relevant publications is listed below.

Boyd S. Laser surgery of the eye. Highlights of Ophthalmology; 2005.

Fankhauser F, Kwasniewska, S, editors. Lasers in ophthalmology: basic, diagnostic and surgical aspects: a review. The Netherlands: Kugler Publications; 2003.

Hora HJ, Schwarz H. Laser interaction and related plasma phenomena: volume 3a. Massachusetts: Kluwer Academic Publishers; 1974.

Hora H, Schwarz H. Laser interaction and related plasma phenomena: volume 3b. New York: Plenum Press; 1974.

Joffe SN, Goldman L, Muckerheide MC, editors. Neodymium: YAG laser in medicine and surgery. Elsevier Science; 1983.

Lim ASM. A colour atlas of posterior chamber implants. Philadelphia: W.B. Saunders; 1985.

Niemz, MH. Laser-tissue interactions: fundamentals and applications. Berlin: Springer-Verlag; 2007.

Pattnaik NK. Laser in ophthalmology: principles and techniques. Jaypee Brothers; 1995.

Sliney DH, Wolbarsht ML. Safety with lasers and other optical sources. New York: Springer-Verlag; 1980.

4 Safety

Only qualified ophthalmic physicians may operate this device.

WARNING! Use of controls or adjustments, or performance of procedures other than those specified in this manual may result in hazardous radiation exposure.

WARNING! This device is designed for use with a range of Ellex approved attachments. The use of unapproved attachments may result in serious injury to the patient and/or physician and voids the warranty. In no event shall Ellex, its employees, officers, directors, representatives or affiliates, be held liable for any injury occurring through such use.

This device is a safe instrument when used correctly. However, like all laser surgical equipment, it can cause injury if not used in accordance with the correct safety procedures and operating instructions.

4.1 Before first use

Read this document in its entirety before using the device for the first time.

Ensure the equipment is correctly installed and all safety devices are operational.

Anyone likely to use, or assist in the use of the device, should read this document and undertake basic laser safety training. You should designate a laser safety officer to be responsible for coordinating laser safety.

4.2 Precautions during use

Follow these precautions when you use the device:

- Do not operate the laser unless it is correctly positioned on a level, stable surface.
- Do not adjust or change settings when the laser is fired.
- Remove the key from the console when the laser is not in use, to protect the device from unqualified use.
- Do not operate the laser unless the eye safety filter is in place in the delivery device.
- The eye safety filter is a mandatory safety mechanism yet when positioned in the optical path it reduces target illumination. To lessen this impact on visualisation, you may select the filter to be activated only when the foot switch is pressed (which is also the system default). In addition, you may temporarily increase illumination using the Illumination Boost and Illumination Intensity controls but note the relevant caution (refer to 4.3.2 Slit lamp illumination on page 55) and consider using these controls only when the laser is fired.
- Carefully handle optical fibres and delivery systems and regularly inspect them for damage.
- Ensure delivery devices and optical fibres are correctly connected before using the device.
- Regularly inspect the safety filter.

4.3 Warnings

WARNING! Do not operate the device until you are familiar with all the precautions.

WARNING! Do not use the device if you experience an abnormal operating condition. Contact your Authorised Ellex Distributor.

WARNING! Do not modify this device. Unauthorised modifications may create a safety hazard.

WARNING! The device is not intended to be a patient or operator support system.

WARNING! Do not lean on the device.

4.3.1 Electrical safety

WARNING! To ensure adequate electrical safety you must connect this device to a mains power outlet that has a reliable protective earth conductor.

WARNING! To protectively earth the device, the power lead from the mains power outlet to this device must incorporate an earth terminal and earth conductor.

WARNING! Do not use liquids with this device.

Turn the device off as normal to isolate the equipment from the mains supply.

4.3.2 Slit lamp illumination

CAUTION The illumination light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater is the risk of ocular damage. Exposure to light from this instrument, when operated at maximum intensity, will exceed the safety guideline after 4 minutes and 52 seconds.

4.3.3 Aiming laser

WARNING! Do not fire the laser if you cannot see the aiming beam (or beams).

WARNING! Do not look into the aiming beam (or beams) unless under the control of a qualified ophthalmic physician.

WARNING! Do not fire the laser if the pattern displayed on the tablet differs from that of the aiming beam.

The blink reflex is considered sufficient protection from the aiming laser. Take precautions to protect people whose normal aversion responses are impaired or disabled.

Check the aiming beam spot shape regularly to ensure the device is aligned and to verify that the optical fibre is not damaged.

Always use the lowest practical aiming beam intensity and minimise exposure time.

For more information refer to 9.5 Aiming laser on page 99.

4.3.4 Treatment laser

WARNING! Do not look into the treatment beam unless under the control of a qualified ophthalmic physician.

A safety shutter blocks the optical path until you fire the treatment laser. A sensor monitors the shutter and if the shutter fails, the fire switch is disabled and an error code displays on the device.

For more information refer to 9.6 Treatment laser on page 99.

4.3.5 Eye safety

Everyone attending the procedure (except the physician and patient) must wear safety glasses, goggles or masks designed to prevent transmission of the treatment beam. Safety glasses, with a minimum optical density (OD) value as listed below, are required for the treatment wavelengths.

Table 4–1

Ellex device	Minimum optical density (OD)	EN 207 resistance to laser radiation minimum scale number
Photocoagulator	3.5 @ 532 nm, 561 nm, 670 nm	D LB3

Appropriate safety glasses should be made available close to the door outside the treatment room.

WARNING! Safety glasses, or safety filters providing protection from other wavelengths, may not offer any protection from the treatment wavelength and should not be used. Ordinary spectacles offer no protection.

(European customers) Safety eyewear must have a minimum resistance to laser radiation scale number as outlined in the table above to meet the EN 207 specification.

Cover windows and viewing ports in the room while the device is in use.

Safety glasses

WARNING! Never look directly into the path of a laser beam. Correctly selected safety glasses offer protection against accidental exposure to a direct laser beam for a maximum exposure of 5 seconds.

Power density E_D incident on the laser safety glasses at a distance of 1 metre from the laser aperture, with the smallest delivery device beam divergence Φ and highest output power P, is summarised in the table below.

Table 4–2

Delivery Device	Use	P(W)	Φ (Radians)	E_D (W/m^2)	Scale Number
SDS	Normal	1.5	0.035	1.89×10^3	LB3
LIO†	Normal	1.5	0.026	6.49×10^3	LB3
LIO‡	Normal	1.5	0.037	2.69×10^3	LB3

† For LIO serial numbers 4Cxxxx/5Cxxxx/6Cxxxx/7Cxxxx.

‡ For LIO serial numbers 4Nxxxx/5Nxxxx/6Nxxxx/7Nxxxx.

Safety glasses only protect the wearer. All personnel within the work area should wear appropriate eye protection against possible exposure to reflected beam energy.

Increased work area lighting may be required if eye protection luminous transmittance is less than 20%.

NoIR Laser Company LaserShields Model LLX (OD 3.5+ @ 532 nm, 561 nm and 670 nm) safety glasses with 11% luminous transmittance are supplied with Ellex photocoagulators.

These safety glasses are clearly marked with wavelength (nm) and absorption (Optical Density). Absorption curves are available upon request.

Colour recognition, for example of warning lights, may be impaired by tinted filters.

Symbols used on glasses

Table 4–3

Symbol	Description
532 + 561 + 670	Wavelengths for which the safety glasses provide protection
DIRM	Test conditions
	D Continuous wave laser
	I Pulse laser
	R Q-switched pulsed laser
	M Mode-coupled pulse laser
LB3	Resistance to laser radiation scale number
NOIR	Manufacturer
CE	CE Mark approval

Refer to EN 207 specification for further details of eye protection marking and test conditions.

Caring for your safety glasses

- Place the glasses in their protective case when not in use.
- Store the glasses in an area not exceeding 26 °C.
- Discard the glasses if they are damaged, faded or if scratches reduce vision.
- Clean the glasses with a mild detergent or any other over the counter lens/sunglasses cleaner (non-alcohol) and wipe with a non-abrasive cloth.

4.3.6 Reflection

WARNING! Objects that reflect visible light will reflect treatment laser light. Avoid placing reflective materials such as glass, metal and polished plastic in the path of the laser beam.

All surfaces in the room should be matt finished to prevent possible reflection of the treatment laser. Avoid using reflective instruments.

4.3.7 Fire hazard

WARNING! Some materials (for example, cotton wool saturated with oxygen) may be ignited by the high temperatures produced by the treatment laser. Before using the device, allow the solutions of adhesives and flammable solutions (used for cleaning and disinfecting) to evaporate.

WARNING! Ignition of endogenous gases may occur.

4.3.8 Electromagnetic compatibility

Radio frequency sources (for example, mobile phones) may affect the device. Make sure all mobile phones in the treatment room are turned off while the device is in use.

The device has been certified to be compliant to the emission limits of EMI (electromagnetic interference) for medical devices and must be connected to an earthed power outlet to ensure compliance and reduce the risk of interference to other devices.

4.3.9 Physical safety

WARNING! Do not use the device unless you understand the potential hazards inherent in laser technology.

WARNING! Do not place your hands, arms, or any other body parts or tissue in the path of the treatment laser.

4.3.10 Warning signs

You should display safety signs outside the treatment room warning of the type of laser being used. Consider installing warning lamps outside the treatment room to indicate that a laser is in operation.

4.4 Safety interlock

A safety interlock connection is provided for connection to a theatre or clinic door. When connected, if the door is opened:

- the treatment laser is immediately disabled and the device is placed in STANDBY
- a warning sounds
- an interlock warning icon is displayed on the device.

A separate fibre interlock detects the presence of an optical fibre connection. The treatment laser is disabled if an optical fibre is not connected.

4.5 Laser safety monitoring

A hardware safety system monitors the power and safety functions of the device and ensures that software failure does not affect the safety of the device.

5 Operation

Frequently used functions are described in this chapter.

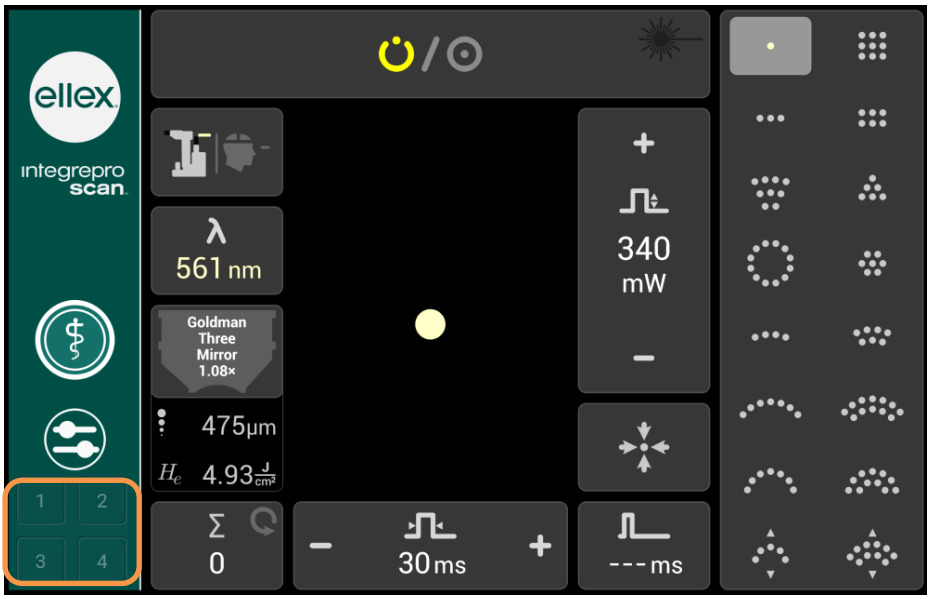
The patient must be under the control of the operator at all times during surgery.

Use an LIO if the patient is unable to use the chinrest.

For younger patients and those who are unable to keep their head still, Ellex suggests some form of sedation may permit safe treatment if clinically acceptable.

5.1 Treatment Settings Memory

The system now allows for treatments parameters to be set and stored for easy recall. The treatment screen displays 4 buttons (see figure below), each of which can store a treatment setting.



om_ip_0020h2

Figure 5-1

5.1.1 Storing treatment parameters

To store a treatment setting, perform the following steps:

1 On the treatment screen, select the desired parameters for the treatment (See Firing the treatment laser procedure on page 64)

2 Press and hold any of the 4 Store buttons (see Figure 5-1). A pop-up appears with the treatment parameters checked by default.

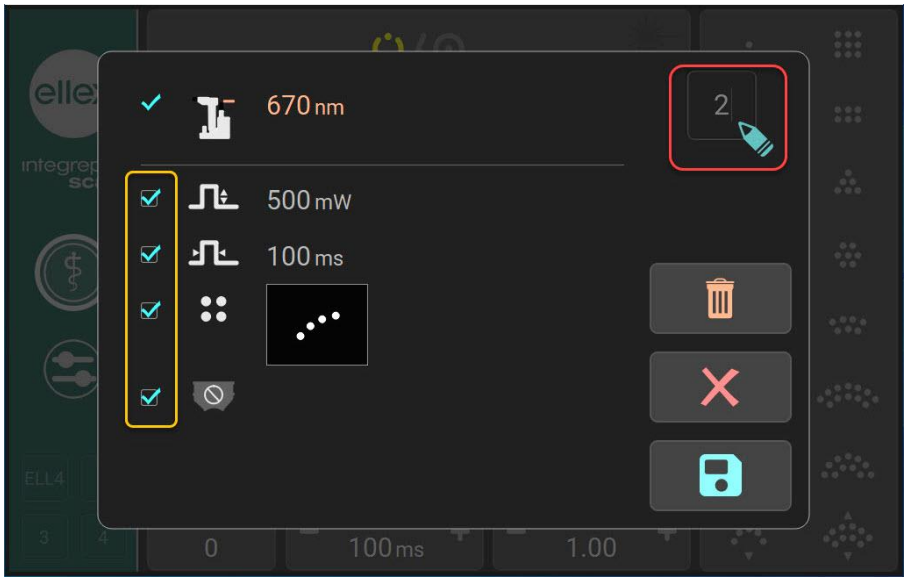


Figure 5-2

3 Except Wavelength and Delivery device you can uncheck the parameters. Wavelength and delivery device are mandatory to the treatment and hence cannot be unchecked.

4 (Optional) By default these treatment memory settings are stored as Numbers. If you wish to provide a name, then click on the number (highlighted red box in Figure 5-2). A keyboard pop–up appears. Enter up to 4 alpha numeric characters and tap to register the name.

5 Tap to save your settings and close the pop-up window. The system will move into its current mode.

Note: Tap if you want to cancel storing the settings. Tap to delete all the settings in the store pop-up window.

5.1.2 Recalling stored treatment setting

To recall a stored treatment setting, perform the following steps:

1 On the main screen, tap the desired memory button (highlighted in an orange box in Figure 5-1). A pop-up window with the settings appears.

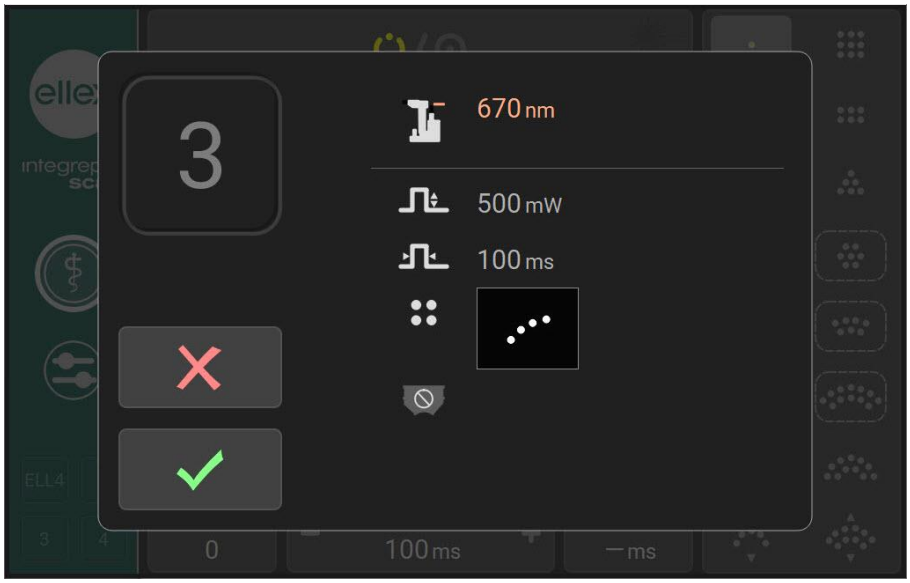


Figure 5-3

2 If you approve of the settings, tap .

3 The system will move into the standby mode.

Note: If you don't approve of the setting then tap . The system will stay in its current mode.

4 Tap Ready mode icon to begin the laser fire.

5.2 Slit Lamp

Turn the key to Slit Lamp to turn on the slit lamp (Slit Lamp mode). In this mode the:

- slit lamp is turned on
- slit lamp controls are available, including the joystick
- aiming beam is turned off
- treatment laser cannot be fired
- laser controls (including the foot switch) do not work.

5.3 Laser On

To turn the laser on, turn the key to Laser (Laser On mode). In this mode, the device has two states: STANDBY and READY.

5.3.1 STANDBY

The device is in STANDBY when you turn the key to Laser. In STANDBY you can select treatment settings, aim and focus the device, knowing that the treatment laser cannot be accidentally fired.

Table 5–1

Where indicated?	How indicated?
Tablet	State button displays the yellow STANDBY icon

5.3.2 READY

You can only enter READY by tapping the State button. You can only fire the treatment laser when the device is READY. Tap the State button to return to STANDBY.

(Multiple wavelength devices) If you change the treatment mode (wavelength) the device automatically returns to STANDBY.

The device automatically switches to STANDBY if left unattended in READY for more than five minutes (time out mechanism).

Table 5–2

Where indicated?	How indicated?
Tablet	The State button displays the red READY icon

5.4 Treatment workflow

Refer to the Laser Indirect Ophthalmoscope (LIO) operator manual if you are using an LIO with this device.

For information about how to respond to errors or abnormal operating conditions refer to 6 Troubleshooting on page 69.

Before starting the device

1. Ensure the safety interlock (or emulation plug) is connected.
2. Ensure all observers are wearing appropriate eye safety glasses and are aware of the device's safety requirements.

Preparing the patient

1. Ensure all patient contact surfaces have been cleaned.
2. Seat the patient.
3. Adjust the patient's and operator's chairs to position both comfortably.
4. Adjust the height of the chinrest until the patient's chin sits comfortably in the chinrest and their forehead rests firmly against the headrest.
5. Lock the castors (or wheels) if the device is mounted on a mobile table.

WARNING! The patient's head must not move during laser treatment.

6 Position the fixation lamp and ask the patient to focus on it (it will become illuminated when the device is turned on).

Turning the device on

If you are restarting the device wait until the tablet has powered down for at least 10 seconds before turning the device on.

1 Turn the mains power supply on.

2 If the Emergency Stop switch was activated, turn it clockwise to release it.

3 Insert the key and turn it to Slit Lamp.

Using the slit lamp

WARNING! To protect the patient from possible retinal damage, use the lowest practical aiming beam intensity during treatment.

1 Adjust the binocular for a clear view of the focal plane. To do this:

- Look into the right ocular with your left eye.
- Adjust the ocular until the reticle is in focus.
- Adjust the left ocular to the right ocular setting.
- Look into the right ocular with your right eye.
- Adjust the ocular until the reticle is in focus.

2 Adjust slit width.

3 Adjust illumination Intensity (use the lowest useful setting).

4 Select a filter.

5 Move the slit lamp so that it is in approximately the correct position.

6 Use the joystick to finely position the slit lamp.

7 Rotate the joystick to adjust slit lamp height.

WARNING! Leave the slit lamp at minimum intensity to reduce heat build-up. Do not leave the illumination intensity at maximum for more than 10 minutes.

You can move the illumination tower to be either on-axis in the centre of the slit lamp (without obstructing the aiming or treatment beams) or place it off-axis.

Firing the treatment laser

1 Turn the key to Laser.

The device uses the last used power and duration settings.

2 (Multiple wavelength devices) Select the treatment mode (wavelength).

The default start-up wavelength will be yellow (Red/Yellow devices).

3 Select the lens being used for treatment.

4 (Single spot) Set the pulse interval.

Leave this at --- if you want to fire a single pulse.

5 Set the power.

WARNING! Always select the lowest power and duration settings required to perform a procedure.

6 Set the pulse duration.

7 Set the spot size.

8 Set the aiming beam intensity.

9 Set the magnification.

10 Check the focus of the slit lamp. With the slit lamp in focus, the aiming (and treatment) beams are focused, and their diameter is indicated by the spot size.

11 (Multiple wavelength devices) Confirm you have selected the correct mode (wavelength).

12 Tap the State button to put the device in READY.

13 Place the contact lens into position.

14 Select and position a pattern.

15 Set the spot separation.

16 At the start of a treatment session reset the shot count.

17 Verify the pattern displayed on the tablet matches that of the aiming beam.

18 When you are satisfied that the device is correctly configured press the foot switch to fire the laser.

WARNING! Do not use the device if the treatment beam is visible. Contact your Authorised Ellex Distributor.

WARNING! Do not fire the laser if the aiming beam is not present.

WARNING! Do not fire the laser if the pattern displayed on the tablet differs from that of the aiming beam.

WARNING! Do not change any settings or move any controls while the treatment laser is firing.

WARNING! Dangerous laser radiation is emitted from the laser aperture when the treatment laser is fired.

WARNING! Do not administer fluids to the patient while they are seated at the device.

WARNING! Do not allow the ingress of any fluid into the device.

When the treatment laser fires:

- the laser emission symbol briefly appears on the tablet
- the laser emission indicator tone sounds
- changes to power, pulse duration and interval are ignored
- the shot counter and total energy are updated.

You can stop laser emission at any time by releasing the foot switch.

Fluorescence from the burn is normal and is not blocked by the safety filter. Ensure you can distinguish the treatment beam from tissue fluorescence during the burn (for more information, refer to 5.8 Fluorescence on page 68).

19 When you have finished treating this patient, tap the State button to put the device in STANDBY.

WARNING! Do not leave the device unattended in READY.

The device automatically returns to STANDBY if:

- you leave the device idle in READY for longer than the idle timeout period
- an error occurs
- the safety interlock is triggered
- you change the treatment mode (wavelength)
- you access Preferences.

Turning the device off normally

WARNING! Do not turn the device off and on rapidly. Wait at least 10 seconds after turning off before turning the device on again to allow the device to restart properly.

1 If the device is in READY tap the State button to select STANDBY.

2 Turn the key to Off.

3 Remove the key and store it in a safe place to prevent unauthorised use.

4 Disconnect attachments.

5 Cover the device with a dust cover.

Turning the device off in an emergency

- Press the Emergency Stop switch.

Resuming normal operation after an emergency

- Turn the Emergency Stop switch clockwise to release it.

5.5 Using a laser indirect ophthalmoscope (LIO)

Apart from the integrated slit lamp microscope, the only compatible delivery device is an Ellex laser indirect ophthalmoscope (LIO). Read the LIO manual to learn how to use that delivery device.

An LIO may only be used to deliver single consecutive treatment shots. It cannot be used to deliver a pattern.

Using an LIO

1 Connect the LIO to the console.

2 Once the device is in STANDBY tap the Delivery Device button to highlight the LIO symbol on the button. The device now displays LIO specific functions and directs laser output to the LIO optical fibre port. For an example of the LIO treatment display refer to LIO on page 30).

5.6 Power and duration settings

The minimum selectable interval (ms) is shown below as a function of power and duration.

Table 5–3

	Power range (mW)			
Maximum duration (s)	**50–500**	**550–750**	**800–1000**	**1050–1500**
8.00	0.05			
4.00	0.05			
3.00	0.05	1.00		
2.00	0.05	0.70	1.00	
1.50	0.05	0.50	0.80	
1.00	0.05	0.40	0.50	
0.90	0.05	0.40	0.50	
0.80	0.05	0.30	0.40	
0.70	0.05	0.30	0.40	
0.60	0.05	0.20	0.30	
0.50	0.05	0.20	0.30	
0.40	0.05	0.20	0.20	
0.30	0.05	0.10	0.20	0.30
0.25	0.05	0.10	0.20	0.30
0.20	0.05	0.10	0.10	0.20
0.15	0.05	0.05	0.10	0.20
0.10	0.05	0.05	0.05	0.10
0.09	0.05	0.05	0.05	0.10
0.08	0.05	0.05	0.05	0.10
0.07	0.05	0.05	0.05	0.10
0.06	0.05	0.05	0.05	0.10
0.05	0.05	0.05	0.05	0.05
0.04	0.05	0.05	0.05	0.05
0.03	0.05	0.05	0.05	0.05
0.02	0.05	0.05	0.05	0.05
0.01	0.05	0.05	0.05	0.05

5.7 Thermal warning

A flashing thermal mitigation symbol will appear on the tablet if the temperature of the device becomes too high. If you see this symbol, place the device in STANDBY for a few minutes to allow the device to cool.

If you do not let the device cool, the thermal warning will display as a static image and the device will automatically revert to STANDBY. You will not be able to select READY until the temperature returns to a safe level.

5.8 Fluorescence

During photocoagulation, you may see laser induced fluorescence from the patient's crystalline lens near the aiming beam. When seen through one eyepiece, this fluorescent area appears as an out of focus patch of light close to the treatment spot. When viewed through both oculars, the area appears out of focus and anterior to the retina. This is normal but, because it is almost the same colour as the treatment beam, it only appears when the treatment laser is fired and is relatively bright, so you may confuse it with the treatment beam.

To shift fluorescence away from the field of view, move the slit lamp illumination, microscope and contact lens.

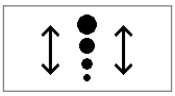
6 Troubleshooting

Contact your Authorised Ellex Distributor if you cannot resolve a problem. Always quote the entire error code or message.

Table 6–1

Problem	Probable cause	Resolution
Device does not start	Power cable is not connected	Check the power cable is connected to the local supply and to the stand, and from the stand to the device
	No mains power	Check the local supply is functioning and switched on. Check with another appliance to be certain.
	Emergency Stop switch activated	Release the switch
	Blown fuse	Replace the fuse
No slit lamp illumination	Slit closed	Open slit
	Slit lamp globe incorrectly seated	Reseat globe

Problem	Probable cause	Resolution
	Slit lamp illumination control in off position	Turn control on
	Slit lamp globe blown	Replace globe
Blurred illumination	Slit lamp globe incorrectly seated or faulty	Reseat globe. If illumination is still blurred, replace the globe.
Aiming beam out of focus	Eyepieces incorrectly set	Adjust eyepieces
	Dirty objective lens	Clean objective lens
	Internal misalignment	Contact your Authorised Ellex Distributor
Aiming beam not visible or intensity too low	Incorrect illumination setting	Increase the aiming beam illumination intensity
	Internal laser failure	Contact your Authorised Ellex Distributor
	Device in STANDBY	Place the device in READY to see the aiming beam
Low aiming beam when set to maximum intensity	Dirty optics	Clean external optics
	Optical fibre is damaged, misaligned or dirty	Contact your Authorised Ellex Distributor
No treatment beam and no aiming beam	Internal laser failure	Contact your Authorised Ellex Distributor
No treatment beam, aiming beam is present	Foot switch not pressed or not connected	Press or connect foot switch
	Defective foot switch	Contact your Authorised Ellex Distributor
	Internal laser alignment error or failure	Contact your Authorised Ellex Distributor
No controls operate, no aiming beam, tablet is illuminated, a continuous audible tone may be heard	Safety interlock has been activated	Correct safety interlock condition (close door or fit emulation plug)
	Fibre interlock activated	Fit optical fibre to console fibre port
Treatment and aiming beams not aligned	Internal misalignment	Contact your Authorised Ellex Distributor

Problem	Probable cause	Resolution
Treatment beam ineffective	Dirty objective lens	Clean objective lens
Spot size does not change when new spot size is selected	Damaged internal movement	Do not use the device. Contact your Authorised Ellex Distributor
Only one treatment pulse is delivered	Foot switch held down when device in single pulse mode	Release foot switch
	Device not in repeat mode	Select an interval greater than 0
Aiming beam movement is restricted	Damaged or sticky movement	Contact your Authorised Ellex Distributor
Zoom warning appears 	Spot Size control was moved while the laser was firing	Do not touch or adjust any control while the device is firing
Flashing thermal warning indicator appears, device will automatically revert to STANDBY if indicator appears but is not flashing 	Laser cavity temperature too high	Put the device in STANDBY and allow it to cool for a few minutes before continuing. If device automatically switched to STANDBY, READY cannot be selected until the temperature has returned to a safe level.
Change in laser emission audible tone	Power delivered is 20% less than or more than set value	Device is automatically placed in STANDBY. The device may continue to be used normally however if this occurs frequently contact your Authorised Ellex Distributor as the device may need to be recalibrated.
Display is frozen and the control panel buttons do not work	Device turned on too quickly after being turned off	Turn the device off. Wait 10 seconds and turn it on.

6.1 Alarms

If a fault is detected the device disables the firing mechanism, reverts to STANDBY and an alarm is displayed. The device cannot be used until the alarm is dismissed and the fault is rectified.

For a list of alarm codes refer to 8 Alarms on page 85.

Resolving the fault

1 Tap the State button once.

If the error code clears, you may use the device normally.

If the error condition remains, the original message will display. Follow the next step.

2 Turn the device off.

3 Wait 10 seconds and turn the device on.

If the error code no longer appears and the device functions normally you may continue to use the device. If the error code appears again contact your Authorised Ellex Distributor.

6.2 Mains power fluctuations

If mains power drops below the minimum specified operating voltage, the device shuts down in an orderly manner without malfunction or permanent loss of data. The device remains shut down until the mains power rises to the nominal operating range and then restarts automatically to STANDBY.

7 User Maintenance

WARNING! Turn the device off and remove the mains plug from the wall socket to avoid possible exposure to hazardous laser radiation during user maintenance.

Also refer to the documentation supplied with the delivery device or adapter for specific maintenance instructions.

7.1 Cleaning

This device is categorised as a non-critical medical device according to the Spaulding Classification scheme (instruments and other devices whose surfaces contact only intact skin and do not penetrate it, including devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil during patient care).[1]

Patient skin contact occurs for Ellex laser devices that include a chinrest.

Patient contact surfaces include the:

- chinrest
- headrest
- patient handles.

[1] Spaulding, EH The role of chemical disinfection in the prevention of nosocomial infections. In: Brachman PS, Eickoff TC, eds Proceedings of the International Conference on Nosocomial Infections, 1970. Chicago: American Hospital Association, 1971:254-274.

7.1.1 Your responsibilities

As the operator of the device, you must:

- Train staff how to clean and disinfect the device.
- Ensure cleaning and disinfection methods do not damage the instrument.
- Ensure the device is routinely cleaned and disinfected.

7.1.2 Contact areas

Operator and patient contact areas are designed for use with unbroken skin.

You must:

- Clean all contact areas (operator and patient) prior to first use and between patients. Ellex recommends using neutral mild hospital-grade detergent or neutral hospital-grade disinfectant.
- Ensure any open wounds that are likely to come into contact with the device (for example those located on the chin and forehead) are covered before contact with the device occurs.
- Use disposable chinrest papers and change them between patients.

7.2 Routine maintenance

This device is designed to provide trouble-free operation and requires very little user maintenance. There are four routine maintenance tasks:

- general cleaning including tablet and trackpad
- cleaning the external optics
- checking the safety filters
- checking optical alignment.

Cleaning frequency should follow clinic protocol.

7.2.1 Cleaning the device

General cleaning

1. Turn the device off and disconnect mains power.
2. Wipe external surfaces (except the optics) using a damp (not wet) cloth with a neutral mild hospital-grade detergent or a neutral hospital-grade disinfectant.
3. Dry with a clean cloth or allow to air dry.

WARNING! Do not immerse any part of the device in liquid or place opened containers holding liquids on the device.

Cleaning the external optics

The delivery head objective lens and the oculars must be kept free of dust, fingerprints and other contamination. Performance is compromised if the external optics are dirty.

Periodically inspect and clean the external optics.

WARNING! Do not use the device if the external optics are scratched. Contact your Authorised Ellex Distributor.

1 Turn the device off and disconnect mains power.

2 Moisten lint free optical tissue with pure or AR grade ethanol.

3 Gently wipe the tissue or swab across the optical surface in a linear stroke.

WARNING! Use one tissue or swab per wipe and then discard it. Do not use dry tissues or swabs as they may damage the surface of the optic.

4 After cleaning, check that the coating is not scratched, chipped, or has lifted from the optic surface.

7.2.2 Checking the eye safety filter

An eye safety filter is fitted to this device, or to the accessories used with this device. This filter prevents transmission of treatment laser light to the physician's eyes while allowing the aiming beam to remain visible. The filter is located in the binocular mount of the delivery head and in the optical path of adapters and delivery devices.

The eye safety filter must be checked at least every six months to ensure there are no surface imperfections or deterioration of the coating.

Checking the safety filter for delivery device or adapter

- Refer to the documentation supplied with the delivery device or adapter.

Checking a delivery head safety filter

1 Select fixed filter mode if the device has a motorised safety filter.

2 Place the device in STANDBY.

3 Remove the binocular and external magnification changer (where fitted).

4 Carefully check the safety filters (the two glass windows in the mounting plate) for imperfections, cracks or discolouration.

WARNING! Do not use the device if the eye safety filter is damaged or discoloured. Contact your Authorised Ellex Distributor.

7.2.3 Checking optical alignment

The aiming beam follows the same optical path as the treatment beam. Checking the aiming beam is a good method of checking the integrity of the optical path of the treatment beam. The delivery system may be damaged or compromised if the aiming beam spot is not present, or its intensity is reduced or diffused. Do not fire the laser under these conditions. Contact your Authorised Ellex Distributor.

Check optical alignment:

- after the device has been assembled or reassembled
- before using the device on a patient
- at least every three months.

Checking optical alignment

1 Turn the treatment laser on (if it is separately controlled).

2 Attach the supplied target plate to the chinrest and affix fundus to the side facing the laser aperture.

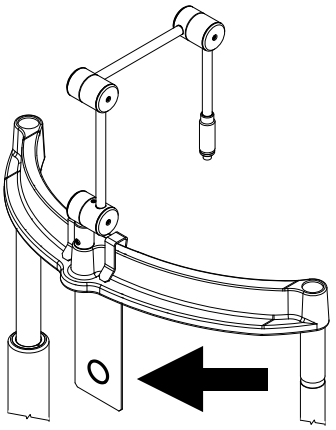


Figure 7-1

3 Select the largest spot size (where possible) and low aiming beam intensity.

4 Fire the laser at the fundus on the target plate.

WARNING! Ensure that there are no reflective surfaces behind the target.

5 Compare what you see through the binocular to the illustrations below. Illustration A is optimal. Consider contacting your Authorised Ellex Distributor if you observe B. Contact your Authorised Ellex Distributor immediately if you observe C).

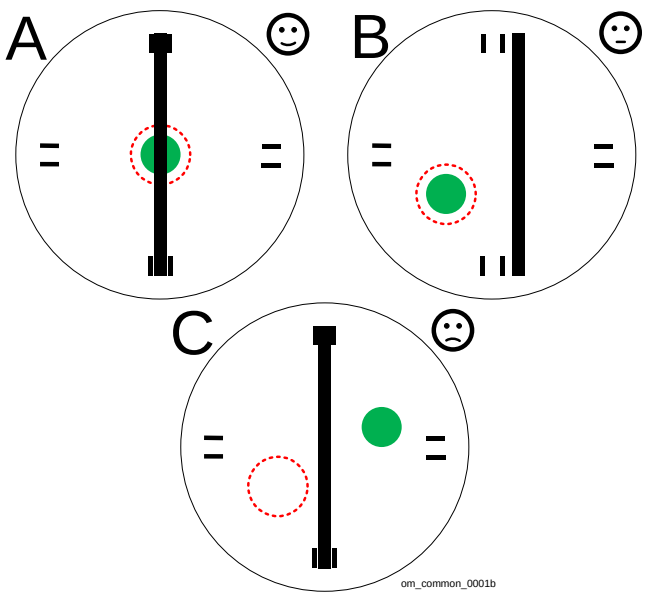


Figure 7-2

Table 7–1

	Slit (vertical line)	Aiming beam/s (dashed red circle)	Laser burn (green spot)	Recommendation
A	Aligned	Aligned	Aligned	Device may be used.
B	Misaligned	Misaligned	Centred to aiming beam	Device may be used but schedule a maintenance visit by your Authorised Ellex Distributor.
C	Aligned	Misaligned	Not centred to aiming beam	Do not use the device. Contact your Authorised Ellex distributor immediately.

WARNING! Do not use the device if you can move the aiming beam out of the field of view. Contact your Authorised Ellex Distributor.

WARNING! Do not use the device if the aiming beam is not centred in the burn mark. Contact your Authorised Ellex Distributor.

7.3 Additional maintenance

7.3.1 Checking delivered laser output

You may check the delivered laser output at any time.

Checking delivered laser output

Ensure that a burn mark is created on the fundus for each test shot fired. Contact your Authorised Ellex Distributor if a burn mark is not created for any test fire.

1 Attach a fundus to the target and place the target on the slit lamp.

2 Turn the device on.

3 (Dual wavelength devices) Select the desired wavelength.

4 Select a single spot.

5 Set energy to 50 mW.

6 Set a pulse duration of 0.05 s.

7 Set the spot size to 50 µm.

8 Aim the device at an unused section in the black area of the fundus and fire the laser.

9 Set energy to 400 mW.

10 Set pulse duration to 0.1 s.

11 Set the spot size to 1000 µm.

12 Aim the device at an unused section in the black area of the fundus and fire the laser.

13 (Dual wavelength devices) Repeat these steps for the other wavelength but fire instead at the red area of the fundus.

7.3.2 Replacing fuses

The mains power socket includes a fuse holder. Always keep a spare fuse on hand. Fuses rarely need replacing and a blown fuse may indicate an internal fault. Contact your Authorised Ellex Distributor if you need to replace a fuse. Fuses are also located in the mains power socket on Total Solution tables.

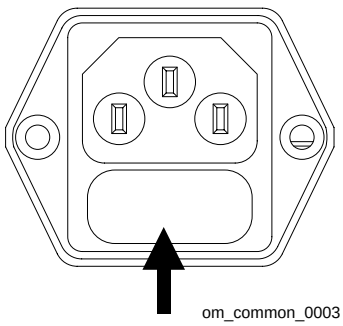


Figure 7-3

Replacing a fuse

1 Turn the device off.

2 Turn mains power off to the device.

3 Disconnect the power cable from the device.

4 Pull out the fuse holder.

5 Replace the fuse with one of the same type.

6 Push the fuse holder back.

7 Reconnect the power cable and turn mains power on.

8 Turn the device on.

7.3.3 Replacing the slit lamp globe

Ensure a spare globe is always available. Do not touch the glass surface of the globe with your fingers as this may shorten the life of the globe. Clean the new globe with a cotton swab dipped in ethanol if necessary.

The globe holder is located at the front of the slit lamp.

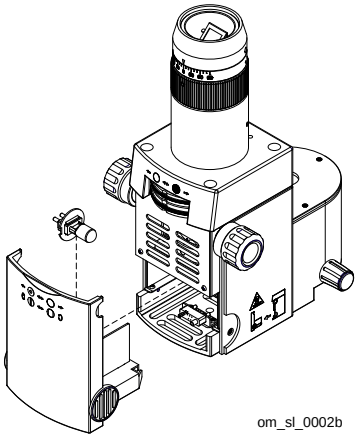


Figure 7-4

Replacing the globe

1 Turn the device off.

2 Move the slit lamp to one side.

3 Pull off the lower front of the slit lamp illumination box.

4 Open the restraining clip and pull the globe holder out.

WARNING! The globe may be hot. Wait until the globe cools before replacing it.

5 Replace the globe.

6 Insert the globe holder with the notch facing right and lower the restraining clip.

7 Reattach the lower front of the slit lamp illumination box.

8 Turn the device on and check slit lamp illumination.

7.4 Moving the device

Treat the device with care to maintain its accuracy and to ensure trouble free operation.

WARNING! Do not use the patient handles, chinrest, slit lamp, delivery head or the tablet mount to move the device.

Moving the device a short distance

1 Lower the table to its minimum height.

2 Turn the device off.

3 Disconnect the power cable from mains power.

4 Disconnect the interlock cable (where fitted).

5 Disconnect the foot switch (where fitted).

6 Move the arm and tablet so they do not overhang the tabletop.

7 Lower the slit lamp.

8 Tighten all locking screws on the slit lamp and delivery head.

9 (Total Solution Mobile and Wheelchair Accessible, Mobile tables) Unlock the castors.

10 (Total Solution Wheelchair Accessible table) Stand in the patient's position and raise the table so the base pads are only just clear of the floor. The device can then be moved using the wheel in the base.

WARNING! If you raise the table too high, it may overbalance.

11 Move the device.

If a Total Solution table is not in use, remove the table extensions (where fitted) and have two people lift the device from the left and right sides.

12 (Total Solution Mobile and Wheelchair Accessible, Mobile tables) Lock the castors.

13 Reconnect the safety interlock (where used), foot switch (where used), table extensions (if removed) and mains power cable.

7.4.1 Transporting the device

This device is tough and durable but contains complex optical and mechanical systems that may become damaged if the unit is mishandled or subjected to excessive shock or vibration.

Ensure the environmental requirements for storage are maintained during storage and transportation.

Ellex is not responsible for damage to the device caused by mishandling during use, storage or transportation.

Pack the device in the original packaging to protect it against damage during transportation.

7.5 Service visits

Contact your Authorised Ellex Distributor at least every 12 months to arrange a preventive maintenance visit. At each visit the Distributor will (as applicable for the device):

- clean the external optics
- check the eye safety filters
- optically align the device
- verify calibration
- check the performance of the device
- check ground resistance and earth leakage

Service work must only be performed by fully trained and qualified Ellex Service Technicians.

When used in relation to servicing an Ellex device, the phrase Ellex Authorised Distributor refers to suitably qualified Ellex Service Technicians who are fully trained by Ellex and who have access to the appropriate Ellex Service Toolkits and service information.

Service information is only available to Ellex Service Technicians. Service information includes:

- circuit diagrams
- list of components
- descriptions
- alignment instructions
- calibration instructions.

7.6 Verifying calibration

WARNING! Only Authorised Ellex Distributors should perform this procedure.

The accuracy of the externally delivered laser emission from this device must be verified at least annually. This is a routine part of the service visit performed by your Authorised Ellex Distributor.

The calibrated laser power/energy meter used to verify calibration accuracy must be traceable to the US National Institute of Standards and Technology (NIST) or another international standard.

The power/energy meter must be able to measure the full laser power/energy range at the treatment wavelengths that this device emits. For specifications of the treatment laser refer Treatment laser on page 99.

Verifying calibration of the laser output

1 Ensure all observers are wearing appropriate eye protection. For more information about eye protection refer to 4.3.5 Eye safety on page 55.

2 Follow the laser energy meter instructions to measure the output from this device at all power settings.

WARNING! Do not use the device if the measured values are not within ± 15% of the power setting that appears on the device. In such cases, investigation by your Authorised Ellex Distributor is necessary to determine if the device requires recalibration or if the delivery device has poor transmission.

7.7 Product lifetime

This device has a normal use lifetime of at least seven years from the date of manufacture (recorded on the compliance label).

7.8 Product disposal

7.8.1 Correct disposal of this product

(Waste Electrical and Electronic Equipment) (Applicable in the European Union and other European countries with separate collection systems). This marking on the product, accessories or literature indicates the product and its electronic accessories should not be disposed of with other household waste at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate these items from other types of waste and recycle them responsibly to promote the sustainable reuse of material resources. Business users should contact their supplier and check the terms and conditions of the purchase contract. This product and its electronic accessories should not be mixed with other commercial wastes for disposal. This EEE is compliant with RoHS.

7.8.2 Correct disposal of batteries in this product

Console

The console contains a battery. If you intend to discard the product, contact your Authorised Ellex Distributor for instructions on how to remove the battery.

7.9 Restriction of hazardous substances (China RoHS)

Table 7–2

部件名称	有害物质或元素					
	铅 (Pb)	汞 (Hg)	镉 (Cd)	六价铬 ($Cr6^{+}$)	多溴联苯 (PBB)	多溴二苯醚 (PBDE)
外壳和机械部件	O	O	O	O	O	O
电缆及电气部件	O	O	O	O	O	O
印刷电路板组件	O	O	O	O	O	O
主机电源	O	O	O	O	O	O
光学部件	O	O	O	O	O	O
电力线	O	O	O	O	O	O

本表格依据 SJ/T 11364 的规定编制。

○：表示该有害物质在该部件所有均质材料中的含量均在 GB/T 26572 规定的限量要求以下。

×：表示该有害物质至少在该部件的某一均质材料中的含量超出 GB/T 26572 规定的限量要求。

注解:迄今为止，未能发现标有＂Ｘ＂的有害物质或元素的替代品，但是本仪器可以有效安全使用。

8 Alarms

All alarms are classified as technical and are low priority. They are grouped in ascending order in the table below by alarm code.

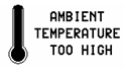
During normal operation, if a warning condition is detected and the device is in READY the system controller places the device in STANDBY (except for alarms E016, E017, E018 and E060 which are informative).

All alarms are accompanied by an audible tone.

For information about how to respond to alarms, refer to 6 Troubleshooting on page 69 and 6.1 Alarms on page 72.

Table 8–1

Code	Symbol or text	Description
E010		External Interlock External interlock is not connected, or the cable is faulty.
E012		Fibre Interlock A delivery device is not connected to the fibre port.
E013	Accessory Interlock	LIO or ESF are not connected.

Code	Symbol or text	Description
E016	 Spot Size Change During Laser Fire	The spot size control was moved by more than 2% from its current position during a treatment laser fire.
E017	Spot size too Small for Pattern	Selected spot size is too small for the pattern
E018	Spot size too Large for pattern	Selected spot size is too large for the pattern
E020		Foot switch not connected The foot switch is not connected to the console.
E022	No Delivery Device on Port 1	Fibre nut not properly connected or is not programmed
E023	No Accessory on Port 1	Loose slit lamp electrical connection to system control board.
E024	No Delivery Device on Port 2	Fibre nut not properly connected or is not programmed
E025	No Accessory on Port 2	Loose LIO electrical connection.
E040	Energy Deviation Warning (Low)	The total energy delivered for entire pulse duration is less than the expected energy by more than 18%.
E042	Energy Deviation Warning (High)	The total energy delivered during a single pulse rises above the expected energy by more than 18%.
E044		PM & SM differ more than 5%. Recalibration needed The power level from the power monitor does not agree with the power level reported by the safety monitor by more than 5%.
E050		The ambient temperature sensor indicates an ambient temperature <5 °C.
E052		The ambient temperature sensor indicates an ambient temperature >40 °C.
E060	 (flashing)	Thermal Mitigation Warning Thermal mitigation warning temperature has been reached (first threshold).
E062	 (static)	Thermal Mitigation Active Thermal mitigation active temperature has been reached (critical threshold).
E063	Out of Thermal Regulation	Temperature regulation error, temperature gauge icon displays in main service menu.

Code	Symbol or text	Description
E070		(Non-Volatile Memory) NVM Back up Battery Low The NVM battery power level is less than 2.5 V (3.0 V when new).
E072	Annual service required	Annual service is due (tablet-based devices) Appears after 52 weeks have elapsed since the last service.
E080	Colour not supported by delivery device or ESF	The combination of cavity and delivery device does not allow an available laser colour to be used.
E081	Fibre port 1 data checksum error	The CRC value stored on the port 1 fibre 1-wire bus device does not equal the CRC value calculated for the device data.
E082	Fibre Port 1 Data Configuration Not Found	The port 1 fibre 1-wire device is not detected so configuration data cannot be found. This occurs when the 1-wire device is not present or not programmed while a fibre connection is detected.
E083	Fibre Port 1 Data Out of Range	The port 1 fibre 1-wire device is detected but the configuration data is not valid.
E084	Fibre Port 1 Device is not supported	The port 1 fibre 1-wire device is detected but the configuration data is for an incompatible device.
E085	Fibre Port 2 Data Checksum Error	The CRC value stored on the port 2 fibre 1-wire device does not equal the CRC value calculated for the device data. The data is corrupted.
E086	Fibre Port 2 Data Configuration Not Found	The port 2 fibre 1-wire device is not detected so configuration data cannot be found. This occurs when the 1-wire device is not present or not programmed while a fibre connection is detected.
E087	Fibre Port 2 Data Out of Range	The port 2 fibre 1-wire device is detected but the configuration data is not valid.
E088	Fibre Port 2 Device is not supported	The port 2 fibre 1-wire device is detected but the configuration data is for an incompatible device.
E104	RCU Comms Failure	Connection issue with the RCU
E120	Foot Switch Pressed	Both foot switch contacts are grounded with foot switch connected.

Code	Symbol or text	Description
E122	Foot Switch Fault	Both foot switch contacts read active voltage with foot switch connected.
E124	Foot Switch Receive Fault	One or more foot switch contacts are grounded with no foot switch connected.
E130	External Interlock Signal Fault	Although connected, the external interlock does not return the expected signal and is deemed faulty.
E140	Spot size control fault	The spot size control pot reading is outside the expected limits, indicating that the spot size pot is either broken or not present.
E200	NVM Checksum Error	The CRC value stored non-volatile data area (FLASH/EEPROM) does not equal the CRC value calculated for the non-volatile memory.
E212	NVM watchdog timeout	The watchdog timer has expired due to a software fault and the unit has reset itself.
E213	FPGA NVM Watchdog Timeout	Software process has hung.
E214	Internal ARM Watchdog Timeout	The watchdog timer has expired due to a software fault and the unit has reset itself.
E216	Internal DSP Watchdog Timeout	The internal DSP watchdog has timed out (default timeout is 60 ms).
E218	DSP System Error	The DSP has responded incorrectly.
E221	Inadvertent Laser Emission	The safety FPGA has detected that a laser emission has occurred when none was expected.
E223	Laser Off Time Exceeded	The safety FPGA has detected that the time between the foot switch or external interlock opening, and the laser being commanded to turn off, has exceeded 10 ms.
E224	Laser Diode Power Feedback Fault	The laser diode drive feedback does not match the control value.
E230	Safety FPGA Not Detected	The safety FPGA is not detected within 10 seconds of configuration.
E231	Safety FPGA Write Attempt	The safety FPGA has detected that a write has been attempted to its protected registers
E232	Safety FPGA Failed to Detect Error condition	The safety FPGA has failed to detect an error condition during the Power On Self-Test (POST), which is usually related to low or unstable laser output.
E233	FPGA Fault	FPGA has reported an unknown error.

Code	Symbol or text	Description
E240	Laser Power Over 150% of Treatment Setting	The measured treatment power >150% of the selected treatment power during a laser fire.
E241	FPGA Laser Power Over 150% of Treatment Setting	The safety FPGA has detected that the delivered laser power has exceeded 150% of the selected treatment power.
E242	Pulse Duration Over 110% of Treatment Setting	The measured laser pulse duration is >110% of the selected pulse duration.
E243	FPGA Pulse Duration Over 110% of Treatment Setting	The safety FPGA has detected that the delivered laser pulse exceeded 110% of the selected pulse duration.
E244	Pulse Interval Under 80% of Treatment Setting	The measured laser pulse interval is <80% of the selected pulse interval.
E245	FPGA Pulse Interval Under 80% of Treatment Setting	The safety FPGA has detected that the time between delivered laser pulses is <80% of the selected pulse interval.
E246	Laser Power Under 12.5% of Treatment Setting	The measured treatment power <12.5% of the selected treatment power and the selected treatment power is over 50 mW, during a laser emission.
E247	Safety FPGA detects Laser Power Under 12.5%	The safety FPGA has detected that the measured treatment power <12.5% of the selected treatment power and the selected treatment power is over 50 mW, during a laser emission.
E250	Cavity TEC Driver Over Current	A cavity TEC power driver chip indicates an over current condition.
E252	Cavity TEC Driver Under Voltage	A cavity TEC power driver chip indicates an under-voltage condition.
E254	Cavity TEC Driver Temperature too High	A cavity TEC power driver chip indicates an over temperature condition.
E256	System Control Board Module Checksum Error	The CRC value stored on system control board does not equal the CRC value generated on start-up.
E258	System Control Board Module Data Out of Range	The system control board 1-wire device is detected but the configuration data is not valid.
E260	System Control Board Module 1-wire Device Not Found	The system control board 1-wire device has not been found on the 1-wire bus.

Code	Symbol or text	Description
E270	Laser Power Deviation 20% High (FPGA)	The FPGA has detected that the output laser power measured by the Safety Monitor was 20% above the power level set by the user.
E271	Laser Power Deviation 20% High	The DSP has detected that the output laser power measured by the Power Monitor was 20% above the power level set by the user
E272	Laser Power Deviation 20% Low (FPGA)	The FPGA has detected that the output laser power measured by the Safety Monitor was 20% below the power level set by the user.
E273	Laser Power Deviation 20% Low	The DSP has detected that the output laser power measured by the Safety Monitor was 20% below the power level set by the user.
E300	Laser Cavity 1 Module Checksum Error	The CRC value stored on cavity 1-wire device does not match the one generated on start-up.
E302	Cavity Selector Position Sensor Fault	Cavity selector has not detected an open or closed position.
E303	Laser Cavity 2 Module Checksum Error	The CRC value stored on cavity 1-wire device does not match the one generated on start-up.
E304	Cavity Selector Jammed Midway	Cavity selector jammed between cavities.
E306	Cavity Selector Jammed Red	Cavity selector jammed on red cavity.
E308	Cavity Selector Jammed Green	Cavity selector jammed on green cavity.
E310	Cavity Selector Jammed Yellow	Cavity selector jammed on yellow cavity.
E311	FPGA Detected Cavity Selector Fault	The FPGA has detected that the cavity selection logic is in an invalid state.
E312	Cavity Selector Fault Selecting Red cavity	Cavity selector failed when selecting red cavity.
E314	Cavity Selector Fault Selecting Green Cavity	Cavity selector failed when selecting green cavity.
E316	Cavity Selector Fault Selecting Yellow Cavity	Cavity selector failed when selecting yellow cavity.
E318	Cavity Selector Moved Whilst Firing	The cavity selection logic changed state while laser emission was occurring.
E320	Red Cavity Temperature Not Stabilised Timeout	Red cavity temperature does not reach operating temperature within 45 seconds.

Code	Symbol or text	Description
E322	Red Cavity Temperature TEC Regulation Fail	Red cavity temperature is not within 0.5 °C of the normal operating temperature for more than 10 seconds or not within 4.0 °C during regulation.
E324	Red Cavity Thermistor Reading Out of Range	Red cavity temperature sensor reading out of range.
E330	Green Cavity Temperature Not Stabilised Timeout	Green cavity temperature does not reach green cavity operating temperature within 45 seconds.
E332	Green Cavity Temperature TEC Regulation Fail	Green cavity temperature is not within 0.5 °C of the green cavity normal operating temperature for more than 10 seconds or not within 4.0 °C during regulation.
E334	Green Cavity Thermistor Reading Out of Range	Green cavity temperature sensor reading out of range.
E340	Yellow Cavity Temperature Not Stabilised Timeout	Yellow cavity temperature does not reach yellow cavity operating temperature within 45 seconds.
E342	Yellow Cavity Temperature TEC Regulation Fail	Yellow cavity temperature is not within 0.5 °C of the normal operating temperature for more than 10 seconds or not within 4.0 °C during regulation.
E344	Yellow Cavity Thermistor Reading Out of Range	Yellow cavity thermistor is reporting a temperature less than 8 °C or greater than 35 °C.
E345	Cavity Thermal Interlock (FPGA)	Cavity temperatures are out of range.
E352	Laser Cavity 1 Module Configuration Not Found	The cavity 1 1-wire device has not been found on the 1-wire bus.
E353	Laser Cavity 2 Module Configuration Not Found	The cavity 2 1-wire device has not been found on the 1-wire bus.
E354	Laser Cavity 1 Module Data Out of Range	The cavity 1 1-wire device is detected but the configuration data is not valid.
E356	Laser Cavity 2 Module Data Out of Range	The cavity 2 1-wire device is detected but the configuration data is not valid.
E418	Safety Filter Invalid Colour Configuration	The ESF does not filter any wavelength that may be generated.
E420	Accessory Port 1 Checksum Error	The CRC value stored on the port 1 ESF 1-wire bus device does not equal the CRC value calculated for the device data.

Code	Symbol or text	Description
E422	Eye Safety Filter Port 1 Closure Failed Timeout	The external eye safety filter on port 1 does not close within 250 ms.
E424	Eye Safety Filter Port 1 Release Failed Timeout	The external eye safety filter on port 1 has not moved from the closed position within 250 ms after the solenoid is instructed to de-energise.
E426	Eye Safety Filter Port 1 Position Sensor Error	The external eye safety filter on port 1 is in the incorrect position, or the sensor has failed, while the solenoid is not energised.
E428	Eye Safety Filter Port 1 Open Whilst Energised	The external eye safety filter on port 1 has opened while energised and the selected delivery port = 1.
E430	Port 1 Eye Safety Filter Solenoid is Broken	The external eye safety filter on port 1 has a broken solenoid (open circuited) and the selected delivery port = 1. A valid 1-wire device has been detected.
E432	No Eye Safety Filter Detected on Port 1	The external eye safety filter on port 1 has not been connected to the system and the selected delivery port = 1. No ESF 1-wire device has been detected.
E434	Accessory Port 1 Data Out of Range	1-wire programmed configuration values are not within acceptable range
E435	Accessory Port 1 Configuration Not Found	The Port 1 Accessory Device 1-wire device is not detected, so configuration data cannot be found. This occurs when the 1-wire device is not present or not programmed when an accessory connection is detected.
E436	Accessory Port 1 Device is not supported	The Port 1 Accessory Device 1-wire device is detected and valid but is not supported by the system.
E440	Accessory Port 2 Checksum Error	The CRC value stored on the port 2 ESF 1-wire bus device does not equal the CRC value calculated for the device data.
E442	Eye Safety Filter Port 2 Closure Failed Timeout	The external eye safety filter on port 2 does not close within 250 ms.
E444	Eye Safety Filter Port 2 Release Failed Timeout	The external eye safety filter on port 2 has not moved from the closed position within 250 ms after the solenoid is instructed to de-energise.
E446	Eye Safety Filter Port 2 Position Sensor Error	The external eye safety filter on port 2 is in the incorrect position, or the sensor has failed, while the solenoid is not energised.

Code	Symbol or text	Description
E448	Eye Safety Filter Port 2 Open Whilst Energised	The external eye safety filter on port 2 has opened while energised and the selected delivery port = 2.
E450	Port 2 Eye Safety Filter Solenoid is Broken	The external eye safety filter on port 2 has a broken solenoid (open circuited) and the selected delivery port = 2. A valid 1-wire device has been detected.
E452	No Eye Safety Filter Detected on Port 2	The external eye safety filter on port 2 has not been connected to the system and the selected delivery port = 2. No ESF 1-wire device has been detected.
E454	Accessory Port 2 Data Out of Range	1-wire programmed configuration values are not within acceptable range
E455	Accessory Port 2 Configuration Not Found	The Port 2 Accessory Device 1-wire device is not detected, so configuration data cannot be found. This occurs when the 1-wire device is not present or not programmed when an accessory connection is detected.
E456	Accessory Port 2 Device is not supported	The Port 2 Accessory Device 1-wire device is detected and valid but is not supported by the system.
E460	Port Selector Position Sensor Fault	Port selector has not detected an open or closed position.
E462	Port Selector Jam Midway	The port selector did not complete a change to the correct position within 80 ms and both position sensors are inactive.
E464	Port Selector Jam port 1	The port selector has jammed in the port 1 position during self-test.
E466	Port Selector Jam port 2	The port selector has jammed in the port 2 position during self-test.
E468	Port Selector Fault	The port selector has either moved while firing or took too long to get into position.
E470	Galvanometer Feedback Fault	The galvanometer position feedback for both axes does not match the expected value.
E471	Galvanometer Feedback Fault X Axis	The galvanometer position feedback for the X axis does not match the expected value.
E472	Galvanometer Feedback Fault Y Axis	The galvanometer position feedback for the Y axis does not match the expected value.
E474	Galvanometer Position Fault	A galvanometer has moved from the correct position.
E475	Pattern Pulse Quality Error	The number of pattern pulses does not match the requested amount.

Code	Symbol or text	Description
E476	Galvanometer Settling Timeout	The galvanometer has not reached the requested position in the allowed time.
E500	Optics Bench Module Checksum Error	The CRC value stored on the optics bench 1-wire device does not equal the CRC value calculated for the device data. The data is corrupted.
E501	Optics Bench Module Data Out of Range	The optics bench 1-wire device is detected but the configuration data is not valid
E502	Safety Shutter Position Sensor Fault	An open or closed shutter position has not been reported by the sensors.
E503	Optics Bench Module 1-wire Device Not Found	The optics bench 1-wire device has not been found on the 1-wire bus.
E504	Safety Shutter Jammed Open	The safety shutter does not change from the open position within 80 ms of de-energising the solenoid control state.
E506	Safety Shutter Jammed Closed	The safety shutter does not change from the closed position within 80 ms of energising the solenoid control state.
E508	Safety Shutter Fault	The safety shutter does not complete a change to the correct position within 80 ms and both position sensors are inactive.
E510	Power Monitor Not Zero Whilst Laser Is Not Firing	The power monitor reads more than 5 mW when the laser is not firing.
E512	Power Monitor Does Not Detect Power	The power monitor photodiode fails to measure any power or the associated signal conditioning circuitry on the system control board does not produce a voltage, in response to the detected power.
E516	Power Monitor Interlock Fault	The safety FPGA detects that the power monitor interlock is open (the power monitor is not connected properly).
E520	Aim Intensity Control Open Circuit Fault	Slit lamp DAM input control is open circuit.
E522	Aiming Light Feedback Error	There is an excessive ADC reading from the internal power monitor in the DAM, with the DAM DAC set to maximum.
E524	Aiming Light Over Power	The ADC reading from the internal power monitor in the DAM is above the DAM operating power, with the DAM DAC set to the lowest value.

Code	Symbol or text	Description
E526	Aiming Light Under Power	The ADC reading from the internal power monitor in the DAM is below the DAM operating power, with the DAM DAC set to the highest value.
E528	Aiming Light Power Below Comparator Set Limit	The DAM power output is below the comparator set limit (0.5 mW) during DAM on time.
E530	Optics Bench Temperature Not Stabilised Timeout	Optics bench has not reached operating temperature within 150 seconds.
E532	Optics Bench Temperature TEC Regulation Fail	During regulation, the optics bench temperature is not within 2 °C of the optics bench operating temperature for more than 20 seconds or not within 4 °C
E534	Optics Bench Thermistor Reading Out of Range	The optics bench thermistor is reporting a temperature less than 8 °C or greater than 45 °C
E600	Pump Diode Module Checksum Error	The CRC value stored on the pump diode 1-wire bus device does not equal the CRC value calculated for the device data.
E602	Pump Diode 1 Temperature Not Stabilised Timeout	Laser diode temperature does not reach pump diode operating temperature within 45 seconds.
E604	Pump Diode 1 Temperature TEC Regulation Fail	During regulation, the pump diode temperature is not within 4 °C of the pump diode operating temperature for more than 10 seconds or not within 6 °C.
E605	Pump Diode Current Exceeds Limit While Off	The FPGA detects a pump diode current greater than 5 amps while the diode is turned off.
E606	Pump Diode 1 Thermistor Reading Out of Range	The FPGA detects a pump diode current greater than 5 amps while the diode is turned off.
E608	Pump Diode 2 Temperature Not Stabilised Timeout	Laser diode temperature does not reach pump diode operating temperature within 45 seconds.
E609	Pump Diode 2 Temperature TEC Regulation Fail	During regulation, the pump diode temperature is not within 4 °C of the pump diode operating temperature for more than 10 seconds or not within 6 °C.
E610	Pump Diode 2 Thermistor Reading Out of Range	The pump diode 2 thermistor is reporting a temperature less than 8 °C or greater than 45 °C.

Code	Symbol or text	Description
E612	Pump Diode 1-wire Device not found	The pump diode 1-wire device is not detected so configuration data cannot be found. This occurs when the 1-wire device is not present or not programmed.
E614	Pump Diode 1-wire Data out of Range	The pump diode 1-wire device is detected but the configuration data is not valid.
E615	Pump Diode Thermal Interlock (FPGA)	Pump diode temperatures are out of range.
E706	Software Internal Error	Software failure causing the system to shut down.
E710	Software Device Driver Fail	Software failure in accessing an external device driver.
E720	Configuration Mismatch. Check Hardware Components	Bad combination of 1-wire devices.
E721	Invalid FPGA configuration	The system was unable to load a valid configuration into the FPGA.
E722	Incompatible RCU version	An RCU with an incompatible software version has been connected to the system.
E802	Power failure	Power supply has failed.

9 Specifications

9.1 General

Table 9–1

Weight (kg) [2]	35
Dimensions (mm)	
Height	615
Width	755
Depth	470
Operating conditions	+15 °C to +35 °C (5 hours typical operation) 35% to 85% relative humidity @ +35 °C non-condensing 660 hPa to 1060 hPa atmospheric pressure
Storage and transport conditions	−10 °C to +55 °C 10% to 85% relative humidity @ +35 °C non-condensing 660 hPa to 1060 hPa atmospheric pressure

[2] Including all accessories, manual and top plate. Excludes the Total Solution column and base.

9.2 Power supply

Table 9–2

Voltage (V_{AC})	100–240 single phase
Frequency (Hz)	50/60
Power consumption (VA)	800
Fuses	6.3 A 250 V, Type F Fast Acting, High Breaking Capacity

9.3 Audio

Table 9–3

Tone	**Frequency (Hz)**	**Volume (dB)**
Emission	1084	49–52
Input Accepted Rejected	 1624 664	 45–52
Alarm	430	53 ±2
	The alarm volume is not user adjustable and automatically compensates for the operator selected emission and input volume levels to ensure that the alarm tone is louder than other tones. The alarm volume is at least 2 dB louder over the range of selectable volume levels for all tones.	

9.4 Slit lamp

Table 9–4

Type	Galilean stereoscopic microscope with converging optics
Eyepiece lens	12.5× dioptre adjustable in the range of ±5 D & one lens includes a KOWA style crosshair reticle
Magnification changer	Removable five position (6×, 10×, 16×, 25×, 40×)
Interpupillary distance adjustment (mm)	55–88
Working distance (mm)	55
Focal length (mm)	92
Slit width (mm)	0–12

Illumination view field (mm)	0.5, 3.0, 8.0 and 12.0
Slit rotation	±90°
Illuminating angle	180° at horizontal plane (90° for right/left)
Filters	Blue-green, violet-blue, heat absorbing (28% attenuation) and none
Globe	12 V pre-centred halogen
Fixation lamp	Yellow or green LED

9.5 Aiming laser

Table 9–5

Type	Visible laser diode
Wavelength (nm)	635 (red)
IEC Class	2
Operation	Continuous wave
Power	Adjustable between 5 µW and < 0.95 mW

9.6 Treatment laser

Table 9–6

Type	Diode pump solid state (DPSS)
Wavelength	LP6RY 561 nm (Yellow) 670 nm (Red) LP6Y 561 nm (Yellow) LP6G 532 nm (Green)
IEC Class	4
Operation	Continuous wave
Available Patterns	Spot, line, square, rectangle, triangle, sector, circle, ring, single 60° arc, double 60° arc, single 120° arc, double 120° arc, single 180° arc, double 180° arc, single flex, double flex. For more information refer to Gallery on page 38.
Pattern Total Exposure Time	The number of spots to be delivered & available pulse duration settings for each spot limit the total exposure time for any pattern to no longer than 750 ms.

<table>
<tr><td>Spot size</td><td colspan="3">Continuously variable between 50 µm and 1000 µm. Detents are at 50 µm, 100 µm, 200 µm, 300 µm, 500 µm and 1000 µm. Spot size at the target site depends upon the lens selected during treatment Refer to your lens manufacturer’s information sheet for more information.</td></tr>
<tr><td></td><td colspan="2">Pattern mode*</td><td>Continuously variable between 100 µm and 500 µm.</td></tr>
<tr><td>Power range (delivery head)</td><td>Spot size (µm)</td><td colspan="2">Maximum power (mW)</td></tr>
<tr><td>Green (532 nm) & Yellow (561 nm)</td><td>≥ 200
100
75
50</td><td colspan="2">1500
1000
1000
1000</td></tr>
<tr><td>Red (670 nm)</td><td>≥ 200
100
75
50</td><td colspan="2">1000
700
340
340</td></tr>
<tr><td>Power range (LIO) (mW)</td><td colspan="2">Green (532 nm) & Yellow (561 nm)</td><td>Red (670 nm) (where wavelength is supported)</td></tr>
<tr><td></td><td colspan="2">50 to 1500</td><td>50 to 1000</td></tr>
<tr><td>Factory calibrated accuracy of delivered energy</td><td colspan="3">The laser energy delivered from the objective lens, measured in the treatment plane over the full power and pulse duration ranges, does not exceed the following limits.
Power tolerance ≤ ±9.5% of treatment power setting
Pulse duration tolerance≤ ±9.5% of treatment pulse duration setting
These equate to a delivered energy tolerance of < 20%.</td></tr>
<tr><td>Pulse duration</td><td colspan="3">Range is from 10 ms to 8.0 s, incrementing in steps as described below.
10 ms to 100 ms in 10 ms steps (0.01 s to 0.1 s in 0.01 s steps)
100 ms to 300 ms in 50 ms steps (0.1 s to 0.3 s in 0.05 s steps)
300 ms to 1000 ms in 100 ms steps (0.3 s to 1.0 s in 0.1 s steps)
1000 ms to 2000 ms in 500 ms steps (1.0 s to 2.0 s in 0.5 s steps)
2000 ms to 4000 ms in 1000 ms steps (2.0 s to 4.0 s in 1.0 s steps)
8000 ms setting</td></tr>
</table>

Pulse repetition interval	OFF / --- (single pulse, non-repeating), 50 ms and 100 ms to 1.00 s in 100 ms steps. 150 ms and 250 ms intervals are also included.				
Safety filters	Motorised OD 5+ @ 532 nm OD 5+ @ 561 nm OD 5+ @ 670 nm				
Maximum permissible exposure (J/m^2)	6.36 (for NOHD calculations using an assumed exposure duration of 0.25 seconds)				
Nominal ocular hazard distance (NOHD) under normal use conditions	Type	Spot size (µm)	Beam divergence Φ (Rad)	NOHD (m)	
				λ 532 nm & 561 nm Power 1.5 W	λ 670 nm Power 1.0 W
	SDS	50	0.199	1.5	1.2
		100	0.100	2.8	2.3
		200	0.062	4.5	3.7
		300	0.042	6.6	5.4
		400	0.038	7.2	5.9
		500	0.038	7.2	5.9
		1000	0.035	8.0	6.5
	LIO†	900	0.026	10.8	8.8
	LIO‡	1100	0.037	7.7	–

* Pattern mode only selectable for spot sizes between 100 µm and 500 µm.

† For LIO serial numbers 4Cxxxx/5Cxxxx/6Cxxxx/7Cxxxx.

‡ For LIO serial numbers 4Nxxxx/5Nxxxx/6Nxxxx/7Nxxxx.

9.7 Wired connectivity

Devices using any iDISPLAY tablet and Wired trackpad

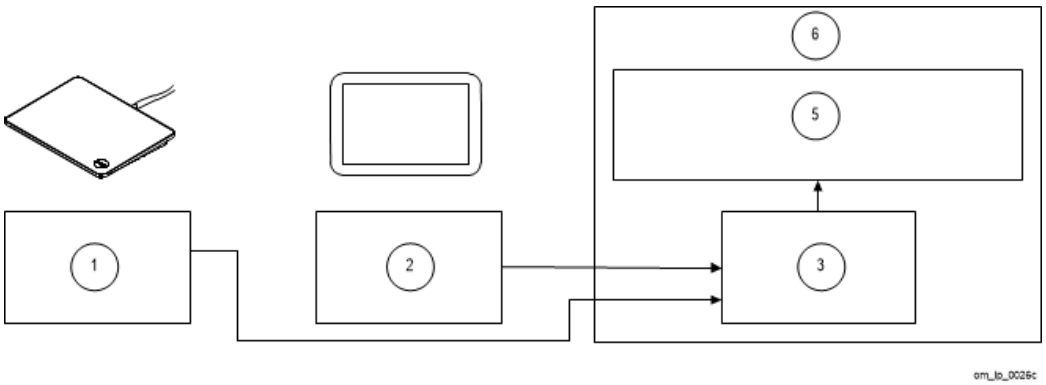


Figure 9-1

Table 9–7

1	Trackpad (wired)
2	Tablet (iDISPLAY 3/4/4b)
3	Daughterboard
5	System control board
6	Console

9.8 Consumables and accessories

WARNING! Only use Ellex approved consumables and accessories. Using unauthorised parts may result in injury, increased electromagnetic emissions, or decreased immunity to such emissions and result in improper operation of the device. Use of unapproved parts will void the warranty.

Contact your Authorised Ellex Distributor for the consumables and accessories mentioned in this section, for this device.

Category	Accessories Description	Accessories code
Total Solution Table	Total Solution Mobile Base (h-base)	TS_MOBILE
	Total Solution Wheelchair Accessible Base (u-base)	TS_ACCESS
	Total Solution Wheelchair Accessible, Mobile Base (v-base)	TS_ACCESS-MOBILE
	Low Voltage (110-120V) Column	COLUMN_LV
	High Voltage (220-240V) Column	COLUMN_HV
Slit Lamp accessories	Co-observation Tube (Includes Eyepiece) - Silver colour Requires Beam Splitter part	6334995
	Beam Splitter (2 Ports) - Silver Colour	6334990
	35 mm Camera Adapter - Silver Colour Requires Beam Splitter part	6348005

Category	Accessories Description	Accessories code
	Video Camera Adapter - Silver Colour (To suit 'C' Mount Video Cameras) Note: Also requires the purchase of a Beam Splitter part #6334990	6348006
Magnification changer	5 Position Magnification Changer (with Enhanced view) - Silver Colour	6334980
Safety Glasses	Triple Wavelength OD>3.5 at 532 nm, 561 nm & 670 nm	6340802
Safety Glasses	Single Wavelength OD5 at 561 nm	6347800
Footswitch	ACC. FOOTSWITCH, POWER, LP4532	6328535
LIO	ACCESSORY, LIO, KEELER, L2RG (for Pro/Pro Scan G, R/G)	6341610
	ACCESSORY, LIO, KEELER, L2RY (for Pro/Pro Scan Y, R/Y)	6341615
Photocoagulator Laser lenses	Three Mirror Universal Lens (18 mm)	3800026
	Mainster PRP 165 Lens	3800028
	Reichel-Mainster 1x Retina Lens	3800029
	Mainster (Standard) Focal Grid Lens	3800030
	Ritch Trabeculoplasty Lens	3800032
Posterior Laser lenses	Lens, Laser, HR Centralis	6338110
	Lens, Laser, Area Centralis	6338111
	Lens, Laser, Super Quad 160	6338112
	Lens, Laser, HR Wide Field	6338113
	Lens, Laser, QuadAspheric	6338132
LIO Lens	Lens 20 Dioptre Ocular Maxlight Indirect	3800034
	Lens 28 Dioptre Ocular Maxlight Indirect	3800035

Category	Accessories Description	Accessories code
	Lens, Ocular Maxlight High Mag 78D, 29mm	3800069
	Lens, Ocular Maxlight STD 90D, 19mm	3800070

10 Electromagnetic Compatibility

WARNING! Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally prior to using it in a surgical procedure.

Fixed, portable and mobile radio frequency communications equipment can affect the performance of this equipment. For recommended separation distances between the radio equipment and the device refer to 10.1.3 Recommended separation distance on page 109.

The emission characteristics of this equipment make it suitable for use in a professional healthcare facility environment. If it is used in a residential environment this equipment might not offer adequate protection to radio-frequency communication services. The operator might need to take mitigation measures such as relocating or reorienting the equipment.

10.1 Guidance and manufacturer’s declarations

This information is provided in compliance with *IEC 60601-1-2 Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*.

This device is intended for use in the electromagnetic environment specified below. The owner and operator should ensure that the device is used in such an environment.

10.1.1 Electromagnetic emissions

Table 10–1

Class	Level	Notes
RF emissions CISPR 11	Group 1	This device uses radio frequency (RF) energy only for its internal function. This means that RF emissions are very low and unlikely to cause any interference in nearby electronic equipment.
	Class A	This device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations / flicker emissions IEC 61000-3-3	Complies	**WARNING!** This equipment/system is intended for use only by qualified ophthalmic physicians. 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 reorienting or relocating this device or shielding its location.

10.1.2 Electromagnetic immunity

Table 10–2

Test condition	IEC 60601 test level	Compliance	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	As for IEC 60601 test level column	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 100kHz for power supply lines; ±1 kV 100kHz for input/ output lines	As for IEC 60601 test level column	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	As for IEC 60601 test level column	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	As for IEC 60601 test level column	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions & voltage variations on power supply input lines IEC 61000-4-11	0% U_T * (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°. 0% U_T (100 % dip in U_T) for 1 cycle at 0°. 70% U_T (30 % dip in U_T) for 25/30 cycles at 0°. 0% U_T (100 % dip in U_T) for 250/300 cycles	As for IEC 60601 test level column	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Test condition	IEC 60601 test level	Compliance	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands and amateur radio bands	As for IEC 60601 test level column	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, it could result in the degradation of the performance of this equipment.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 9 - 28 V/m Spot frequencies 385MHz to 5.785 GHz Pulse modulation	As for IEC 60601 test level column	Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. (continued) Recommended separation distance $d = 6/E \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the immunity test levels in volt per meter (V/m), and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 

* U_T is the AC mains voltage prior to application of the test level

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 television broadcast cannot be predicted theoretically with accuracy. To assess 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 this device is used exceeds the applicable RF compliance level above the device should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the device.

Over the frequency range 150 kHz to 80 MHz field strengths should be less than 3 V/m.

10.1.3 Recommended separation distance

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

Table 10–3

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**						
	380MHz - 390MHz $d = 0.22\sqrt{P}$	**430MHz - 470MHz** $d = 0.22\sqrt{P}$	**704MHz - 787MHz** $d = 0.67\sqrt{P}$	**800MHz - 960MHz** $d = 0.22\sqrt{P}$	**1.7GHz - 1.99GHz** $d = 0.22\sqrt{P}$	**2.4GHz - 2.57GHz** $d = 0.22\sqrt{P}$	**5.1GHz - 5.8GHz** $d = 0.67\sqrt{P}$
0.01	0.02	0.02	0.07	0.02	0.02	0.02	0.07
0.10	0.07	0.07	0.21	0.07	0.07	0.07	0.21
100	0.22	0.22	0.67	0.22	0.22	0.22	0.67
100	0.70	0.70	2.12	0.70	0.70	0.70	2.12
100	2.20	2.20	6.70	2.20	2.20	2.20	6.70

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.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

10.1.4 Federal Communications Commission (FCC) notice

All radio frequency modules have been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC ID: Y34-UITASM (Generation 3 iDISPLAY tablet)

FCC ID: 2ACAG-UITAS (Generation 4 iDISPLAY tablet)

FCC ID: 2AO9X-T410 ((Generation 4b iDISPLAY tablet)