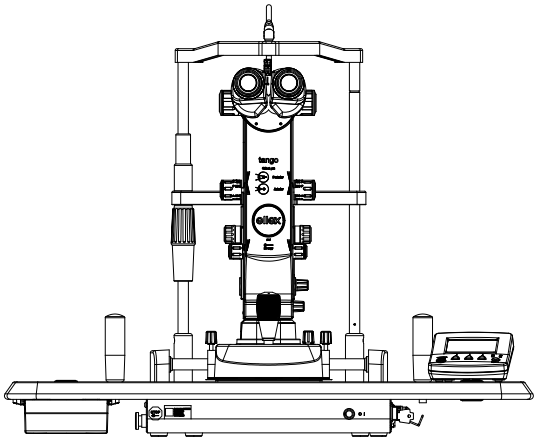
OPERATOR MANUAL

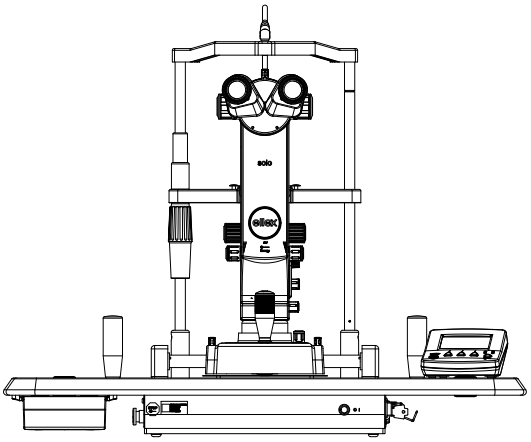
tango™

LT5106-T



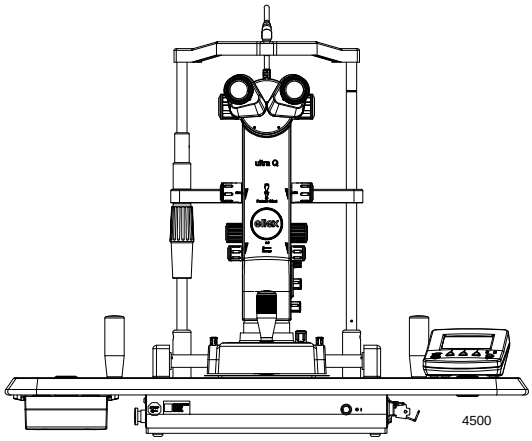
solo™

LT5106-S



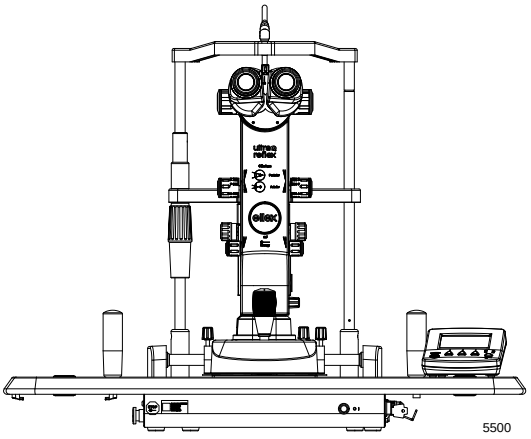
ultraQ™

LQP3106-U



ultraQ reflex™

LQP3106-U



Nov 2022

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The Eye symbol included as part of the illustration on page 68 was designed by Katie M Westbrook from The Noun Project.

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Information in this document is compatible with software release 12 and higher.

This manual describes how to operate the Solo LT5106-S, Tango LT5106-T, and UltraQ LQP3106-U and UltraQ Reflex LQP3106-U lasers. These devices are manufactured by Ellex Medical Pty Ltd.

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

Note: Vitreolysis indication is not cleared for use in the United States of America.

IMPORTANT

READ CAREFULLY BEFORE USE
KEEP FOR FUTURE REFERENCE

CE 0805

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Contents

Document revision history

Version	ECR #	Date	Description
1.0	07159	May 2021	Initial release
2.0	07205	August 2021	Incorporated Takagi related updates to Ultra Q; edits to Specifications chapter
3.0	07331	March 2022	Updated Safety filter/glasses data
4.0	07411	Nov 2022	Updates the trademark name format and changes the product name Ultra Q to UltraQ. Figure 2.2 updates Delivery Head images to include both UltraQ models with CSO and Takagi Slit Lamps. Corrects text in footers.

1 Warnings

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

Overview

Do not use the device if segments of the remote control display are absent or unclear. Contact your Authorised Ellex Distributor.

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

Assembly

During assembly place the slit lamp upright and support it from underneath to avoid crushing the electrical cable.

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

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

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.

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

Clinical Use

This information is provided as a guide only and is not intended to present complete or thorough instructions. It is not meant to replace the judgment of a trained 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.

If the user finds the plasma burst doesn't occur where expected, the clinical treatment should be immediately terminated until the device is serviced by the Ellex Service technician.

Safety

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 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 physician.

Do not use liquids with this device.

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

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.

Operation

Refer to the Operation chapter (from page 57).

Troubleshooting

No warnings exist in this chapter.

User Maintenance

Device intended to be in contact with intact skin.

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 when checking optical alignment.

Do not use the device. Contact your Authorised Ellex Distributor immediately.

Do not use the device if you cannot make the aiming spots converge, or 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.

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

Do not use the patient handles to move the device.

If you raise the table too high the device may overbalance when it is being moved.

Only Authorised Ellex Distributors should verify calibration.

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.

Alarms

No warnings exist in this chapter.

Specifications

No warnings exist in this chapter.

Electromagnetic Compatibility

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.

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as reorienting or relocating this device or shielding its location.

2 Overview

2.1 About this document

2.1.1 Product description

This guide describes how to operate the devices listed in the table below.

Table 2–1 Devices described in this manual

Device	Laser
Solo	532 nm green laser (SLT)
Tango	532 nm green and 1064 infra-red laser (SLT and YAG)
UltraQ and UltraQ Reflex	1064 nm infra-red laser (YAG)

These devices are classified as Class 3B lasers with Class 1 Type B electrical protection. They are surgical laser instruments designed for use by ophthalmologists in clinics or an outpatient facility in a hospital or surgery except for 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.

The UltraQ Reflex includes a Reflex Coaxial Illumination (RCI) mirror (Reflex Technology) mounted on top of the slit lamp to provide illumination that is coaxial with

the viewing path. This mirror automatically moves out of the way when the treatment beam is fired.

2.1.2 Who should read this manual

Owners and operators of this device should read this manual.

2.1.3 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 that the document name and part number (see the footer of each page) are clearly identified, and refer to page numbers where appropriate.

2.1.4 Document conventions

Where information is only relevant to a specific device or devices, those devices are indicated by parentheses. For example: (Tango, UltraQ Reflex).

(Tango) Where information is only relevant to a specific treatment mode (SLT or YAG), the mode is indicated in brackets. For example: (Tango [YAG]).

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

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

A reference number at the lower right of an illustration is for document maintenance purposes only.

2.2 Training

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

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

2.3 Carton labelling

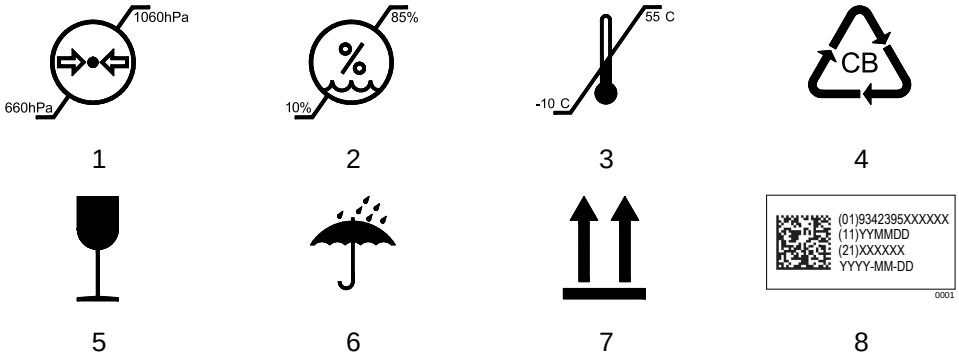


Figure 2–1 Carton labelling

Table 2–2 Explanation of the carton labels

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 refer to 2.4.9 Unique device identification (UDI) on page 32.

2.4 Device description

User accessible controls, connectors and labels are described below.

Due to product variations the main subcomponents are separately illustrated and described.

2.4.1 Delivery head

You can move the delivery head approximately 20 degrees either side of centre.

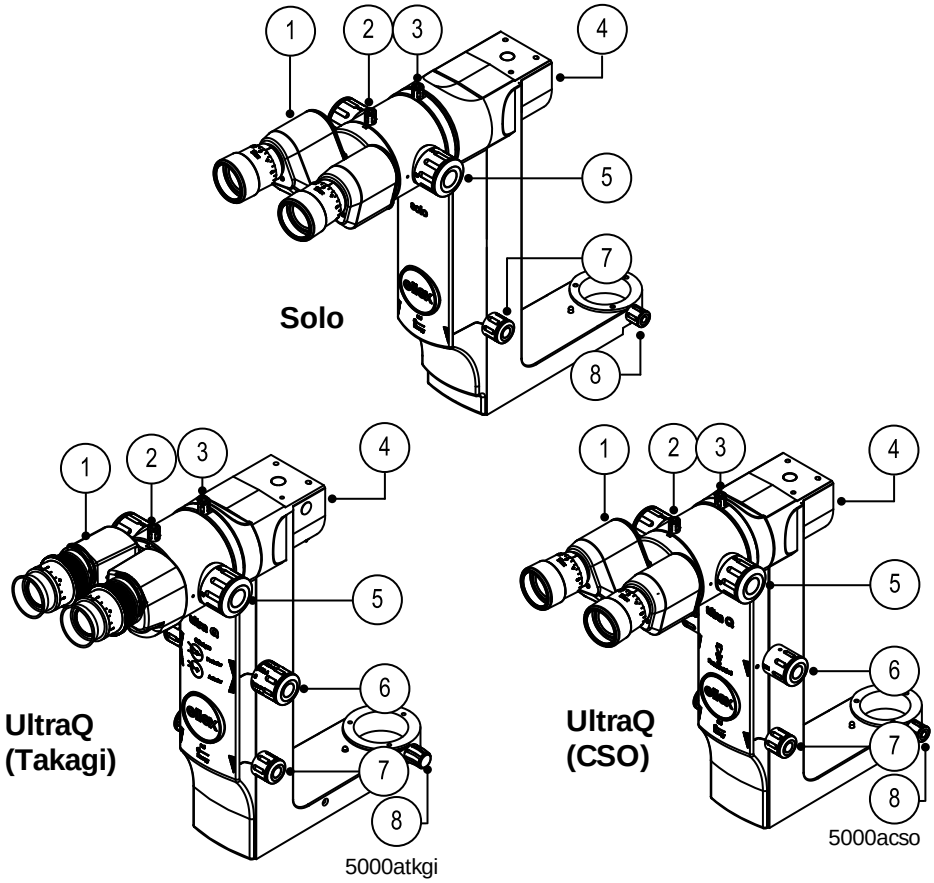


Figure 2-2 Delivery head — Solo and UltraQ

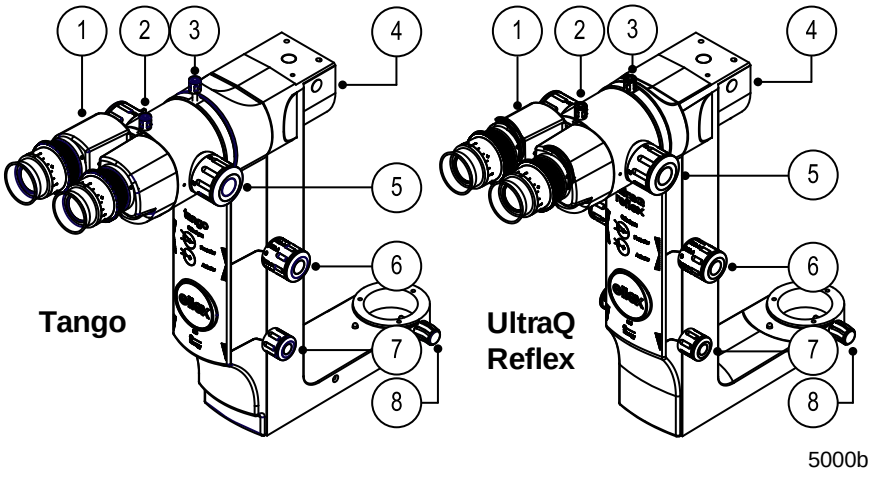
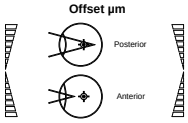
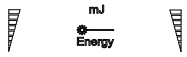


Figure 2-3 Delivery head — Tango and UltraQ Reflex

Table 2–3 Parts of the delivery head

1		Binocular Adjustable to suit the operator's interpupillary distance. The focus of each eyepiece may be individually adjusted.	
2		Binocular thumbscrew	
3		Magnification changer thumbscrew	
4		Objective lens	
5		Magnification changer (ambidextrous control)	
6	UltraQ 	Posterior Offset	Ambidextrous control. Adjusts the focus of the treatment laser relative to the aiming lasers (posterior offset means that the YAG beam is focussed behind the focus point of the aiming beams). Continuously variable, with detents at MIN, +150 µm and +250 µm. For more information refer to 6.5 Posterior Offset (UltraQ) on page 66.
	Tango and UltraQ Reflex 	Offset	Ambidextrous control. Adjusts the focus of the treatment laser relative to the aiming lasers. Continuously variable with detents at 0 and at defined anterior and posterior positions. On the control knobs anterior detent positions are coloured orange and are indicated by the letter A; posterior positions are coloured blue and are indicated by the letter P. For more information refer to 6.6 Offset (Tango and UltraQ Reflex) on page 67.

7		Energy (ambidextrous control) Turn the control slowly to finely adjust the energy; turn the control quickly to adjust the energy in larger steps.
8		Delivery head locking screw Prevents the delivery head from moving.

2.4.2 Slit lamp

(Tango [YAG]) If the slit lamp is in line with the objective lens, you will not be able to fire the treatment laser. The device will also:

- beep
- display a warning message
- flash the aiming laser beam until the slit lamp is moved out of the treatment beam path.

Slit lamp base

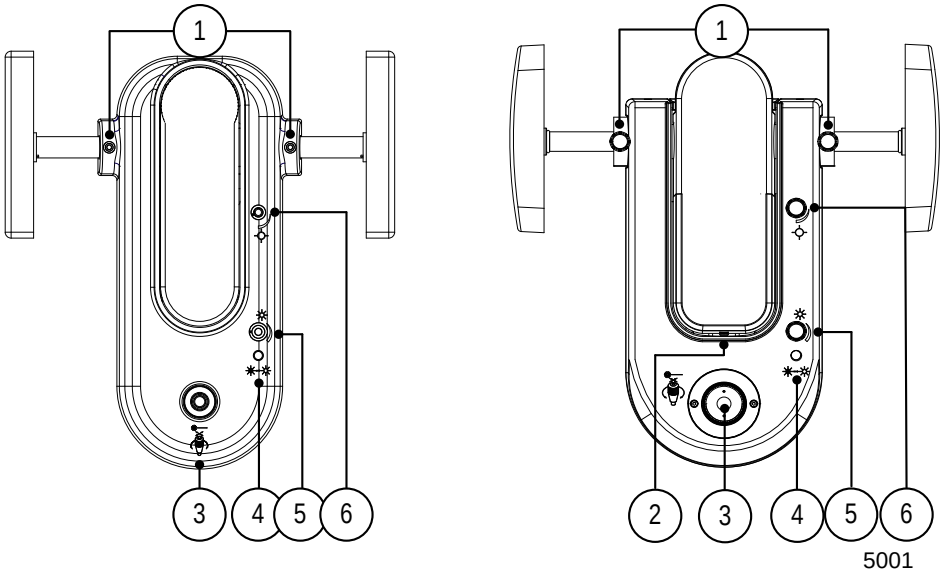
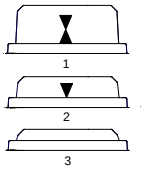
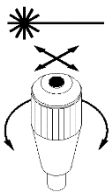
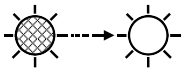


Figure 2-4 Slit lamp base

Table 2–4 Parts of the slit lamp base

1		Cross slide locking screw (one on either side of the delivery head) Prevents the delivery head from moving on the tabletop.
2		(Obscured) Slit lamp height reference mark 1 Maximum (highest) 2 Midway 3 Minimum (lowest)

3		Joystick with fire button Moves the delivery head and slit lamp backwards, forwards, left and right. Rotating the joystick adjusts the height. The fire button only operates when the device is in READY. The fire button fires the treatment laser unless a foot switch has been connected to the console and is selected as the firing mechanism.
4		Illumination Boost Press and hold to boost illumination intensity to maximum
5		Illumination Intensity Turn knob fully anticlockwise to turn slit lamp illumination off
6		Aiming Beam Intensity

Chinrest

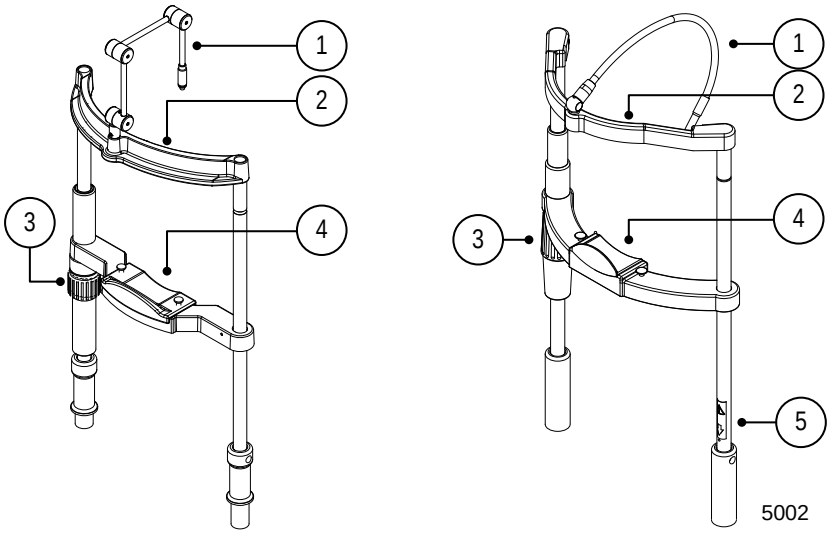


Figure 2-5 Chinrest

Table 2–5 Parts of the chinrest

1		Fixation lamp
2		Headrest
3		Chinrest height adjustment (collar on chinrest support)
4		Chinrest
5		Fixation lamp power connection label The power connector for the fixation lamp is located at the base of this chinrest support.

Illumination tower and prism

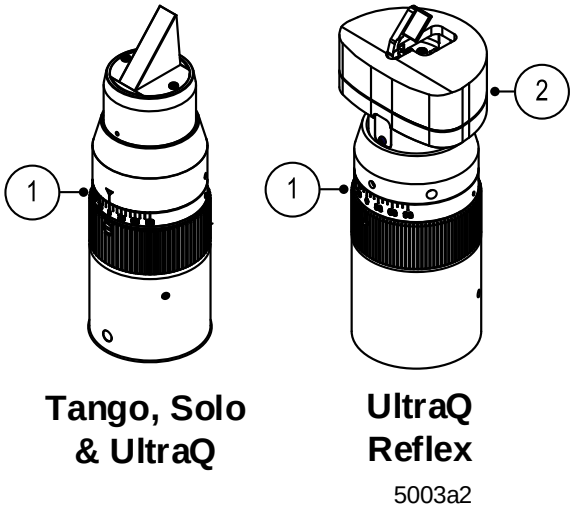
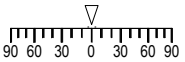


Figure 2-6 Illumination tower and prism

Table 2–6 Parts of the illumination tower and prism

1		Slit Rotation Adjusts slit rotation through 90º either side of vertical.
2		Reflex Coaxial Illumination (RCI) module (Reflex Technology). A motorised mirror provides enhanced eye illumination. Moving part: the mirror automatically moves out of the path of the treatment beam during the firing sequence.

Slit lamp body

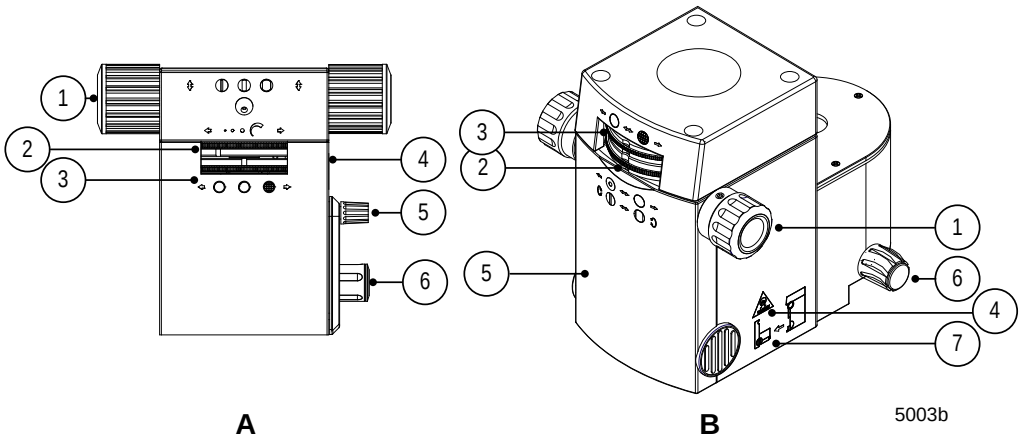
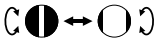
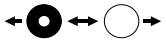
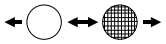
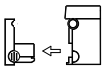


Figure 2-7 Slit lamp body

Table 2–7 Parts of the slit lamp body

	A	B	
1			Slit Width (ambidextrous control) Continuously variable between closed and 12 mm.
2			Aperture Adjusts the illumination aperture.
3			Filters Blue-green, violet-blue, heat absorbing (28% attenuation), none.
4			Type of globe fitted to the slit lamp
5			Globe holder access
6			Slit lamp locking screw Prevents the slit lamp from moving.
7			Illustration describing how to access the globe.

2.4.3 Console

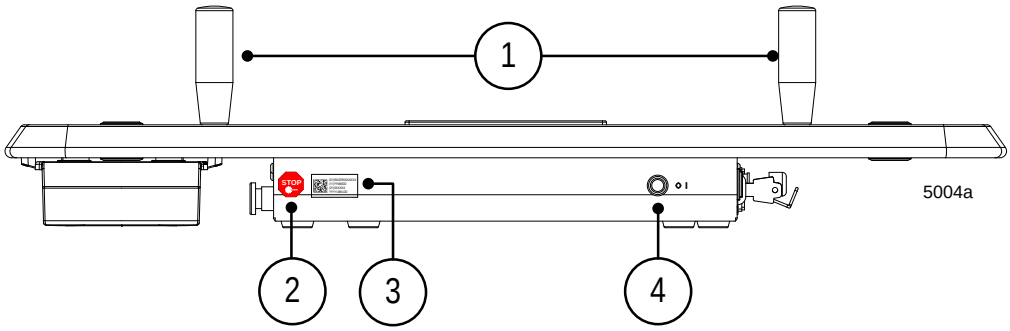


Figure 2-8 Console — Front

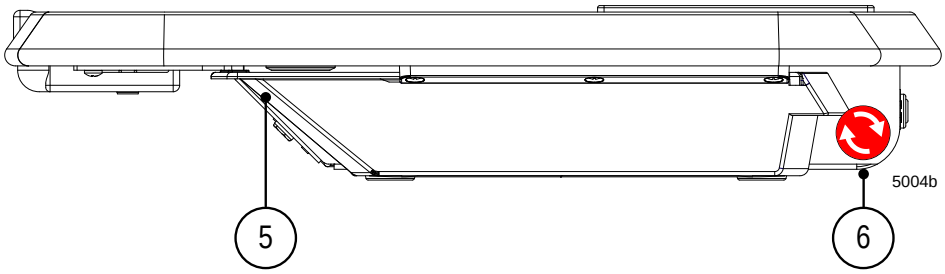


Figure 2-9 Console — Left

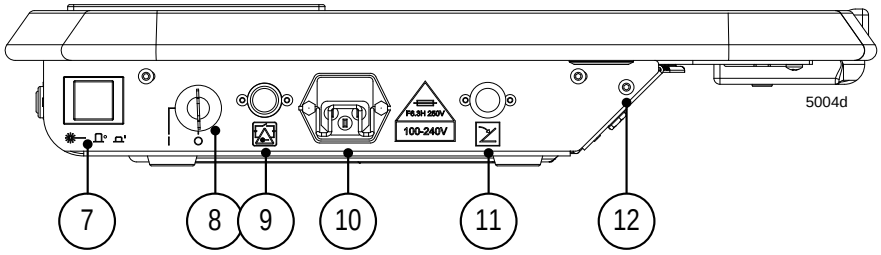


Figure 2-10 Console — Right

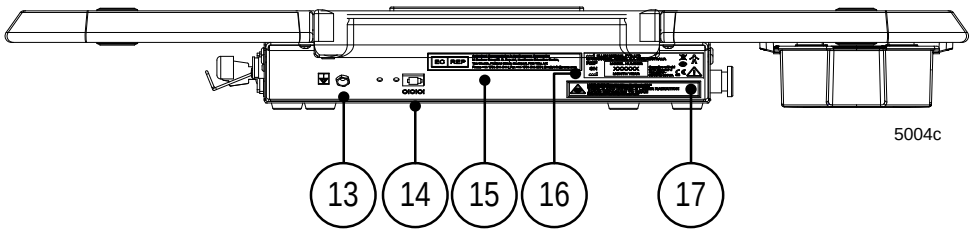
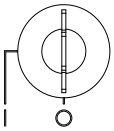
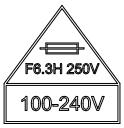


Figure 2-11 Console — Rear

Table 2–8 Parts of the console

1		Patient handles (screwed to the tabletop – may instead be fitted to chinrest mount) (only shown above in the front view).
2		Emergency Stop switch label (switch is on the side)
3		Unique device identification (UDI). For more information refer to 2.4.9 Unique device identification (UDI) on page 32.
4		Mains power indicator Illuminated (green) when the key is turned to On.
5		Rear panel access screw
6		Emergency Stop switch Press to activate (cuts power to the device). Rotate clockwise to release the switch.
7		Laser (illuminated [amber] push button) = On (button depressed) = Off (button released)
8		Key switch The main power switch for the device. Key cannot be removed unless in the Off position. Device cannot be turned on if the Emergency Stop switch has been activated. | = On O = Off
9		Safety interlock
10		Mains power inlet (with mains supply voltage, fuse type and rating label)
11		Foot switch
12		Rear panel screw
13		(Service use) Earth point for antistatic wrist strap
14		Remote control

15	EC REP	European authorised representative label Authorised Representative in the European Community: EC Rep Ltd, 5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland Phone + 353 1 2 544 944 | Email: info@ecrep.ie
16		Compliance label (refer to 2.4.8 Compliance label on page 31).
17		Laser safety label (refer to 2.4.10 Laser safety label on page 32). Indicates laser radiation hazard and class of treatment and aiming beam lasers.

Console with rear cover lowered

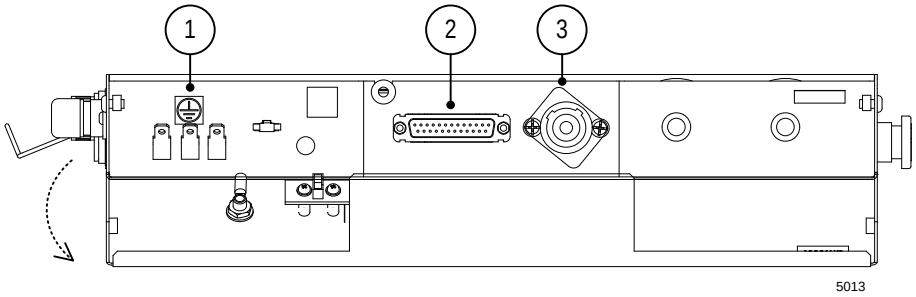


Figure 2-12 Console with the rear cover lowered

Table 2–9 Parts behind the rear cover

1	Device earth point
2	Electrical connector
3	High voltage connector

2.4.4 Remote control

Layout

The console beeps each time you press a key on the remote control.

The display indicates the purpose of the three context sensitive buttons.

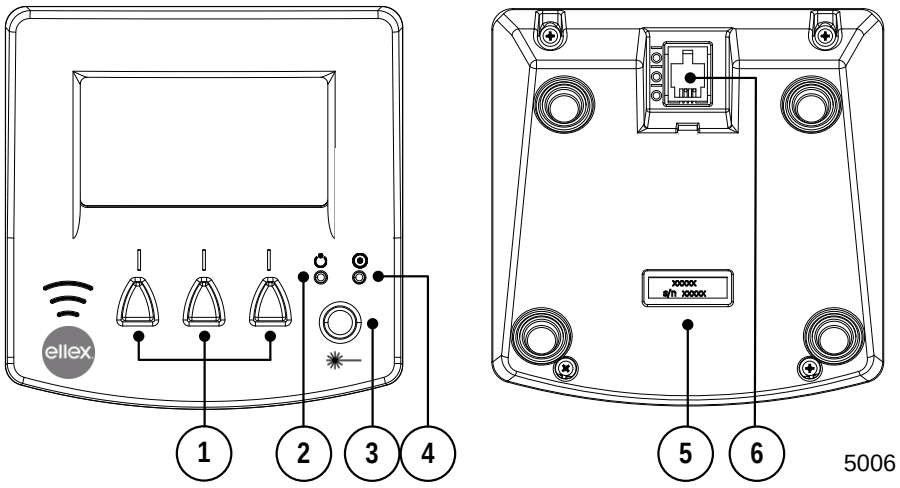


Figure 2-13 Remote control unit

Table 2–10 Parts of the remote control

1		Context sensitive buttons Function depends on what displayed on the screen immediately above the button.
2		STANDBY indicator (yellow light)
3		State button Switches between STANDBY and READY
4		READY indicator (red light)
5		Serial number
6		Cable connector

Main display

Extreme cases of electrostatic discharge may cause segments of the display to go blank. If this occurs, turn the device off then restart it.

WARNING! Do not use the device if segments of the remote control display are absent or unclear. Contact your Authorised Ellex Distributor.

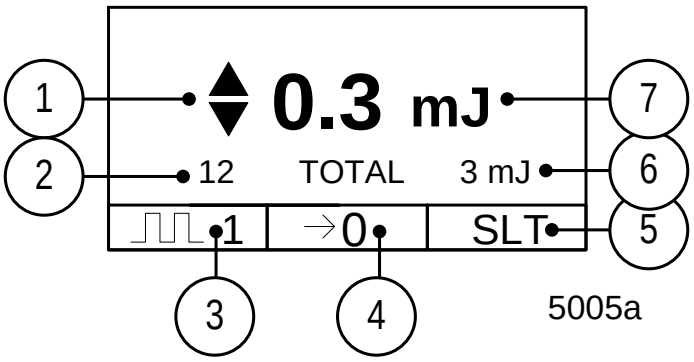


Figure 2-14 Main display

Table 2–11 Parts of the Main display

1	Deviation and excess energy warning A flashing arrow only appears when a deviation of ±18% or more is detected. A persistent up arrow is displayed if more than double the set energy is detected. For more information refer to 9 Alarms on page 89.	
	▲ Flashing	Energy delivered to the treatment site is ⩾ 118% of the set energy
	▲ Persistent	Energy delivered ⩾ 200% of the set energy. Cleared on commencement of the next laser fire.
	▼ Flashing	Energy delivered to the treatment site is ⩽ 82% of the set energy.
2	Total pulses Number of pulses fired since last reset. Increments by one for each pulse fired. (Tango [YAG], UltraQ and UltraQ Reflex) Increments by two for double pulse mode and three for triple pulse mode.	
3	(Tango [YAG], UltraQ and UltraQ Reflex) Pulse mode Select from single (1), double (2) or triple (3) pulse mode. Single (1) pulse only displays (without the symbol) in SLT mode.	
4	Reset Resets total pulses and total energy.	
5	(Tango) Treatment mode Select either SLT or YAG.	
6	Total energy The cumulative total energy used during a procedure (rounded to the nearest mJ). This updates only when treatment shots are fired.	

7	Energy The energy value set by the operator. (Tango) On start-up the energy value is the set energy of the last treatment fire or the minimum value if the treatment mode has changed. When the laser is fired in READY state the energy of each laser burst is monitored. Any deviation larger than 18% from the test shot energy is indicated by a flashing arrow (see energy deviation warning below). A persistent up arrow is displayed if more than double the set energy is detected. (Tango [YAG], UltraQ and UltraQ Reflex) If you use double or triple pulse mode, the displayed energy is the cumulative total of all pulses within the burst.

Operator menu

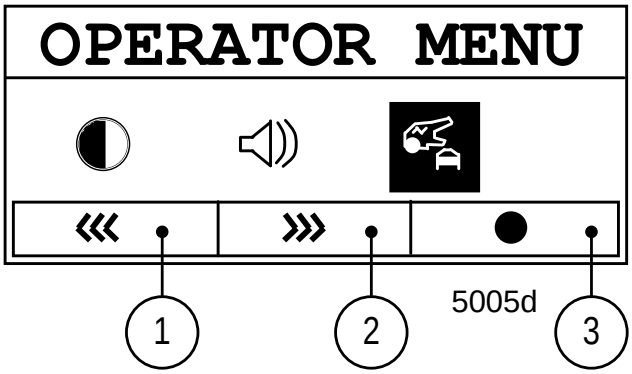


Figure 2-15 Operator menu

Table 2–12 Parts of the Operator menu

1	Moves the highlight to the left or decreases a setting
2	Moves the highlight to the right or increases a setting
3	Selects the highlighted option or saves the selection

2.4.5 Audible indicators

The console emits warnings sounds and other audible indicators to confirm actions, such as pressing buttons on the remote control and to indicate laser emissions.

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.

2.4.6 Foot switch

The foot switch is an optional accessory.

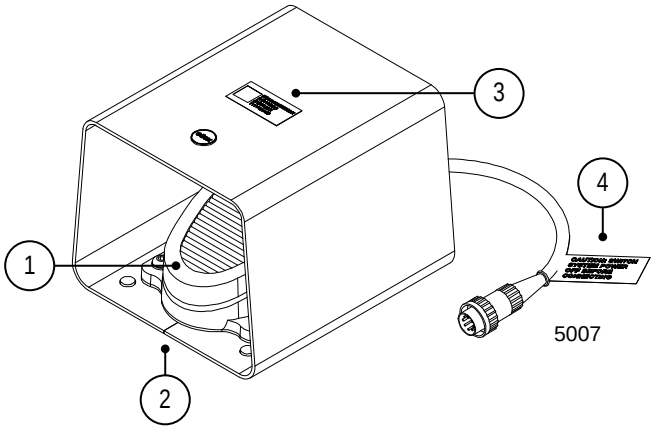


Figure 2-16 Foot switch

Table 2–13 Parts of the foot switch

1		Pedal (triggers laser emission)
2	**S/N XXXX** IP68-1.1m	Serial number and foot switch labels (underneath) IPX68-1.1m indicates that the foot switch is dust tight and protected against the ingress of water during continuous immersion to a maximum depth of 1.1 metres.
3		Unique device identification (UDI). For more information refer to 2.4.9 Unique device identification (UDI) on page 32.
4	**CAUTION: SWITCH SYSTEM POWER OFF BEFORE CONNECTING**	Connection instructions

2.4.7 Laser aperture

The location of the laser aperture is shown below.

The laser aperture label is located immediately below the aperture.

Tango

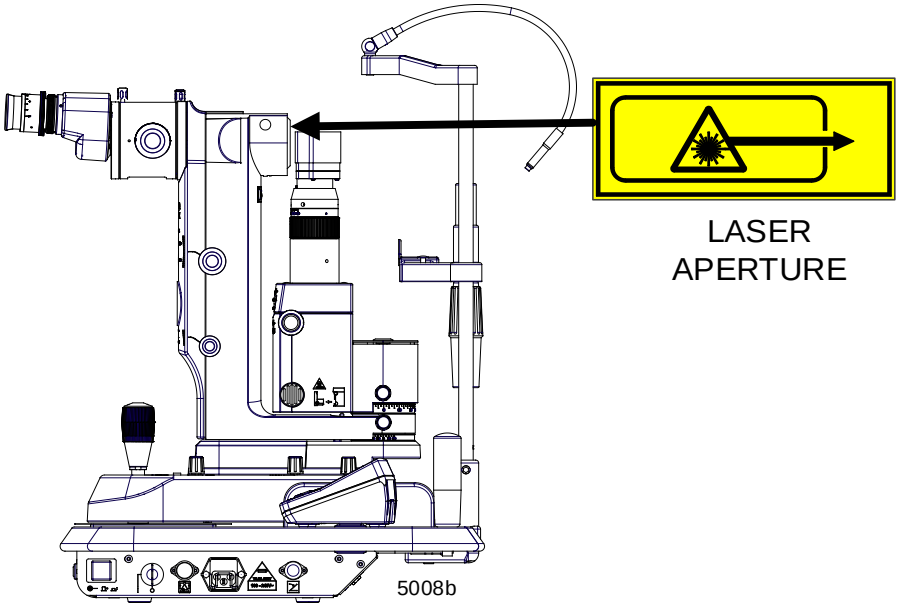


Figure 2-17 Laser aperture — Tango

Solo

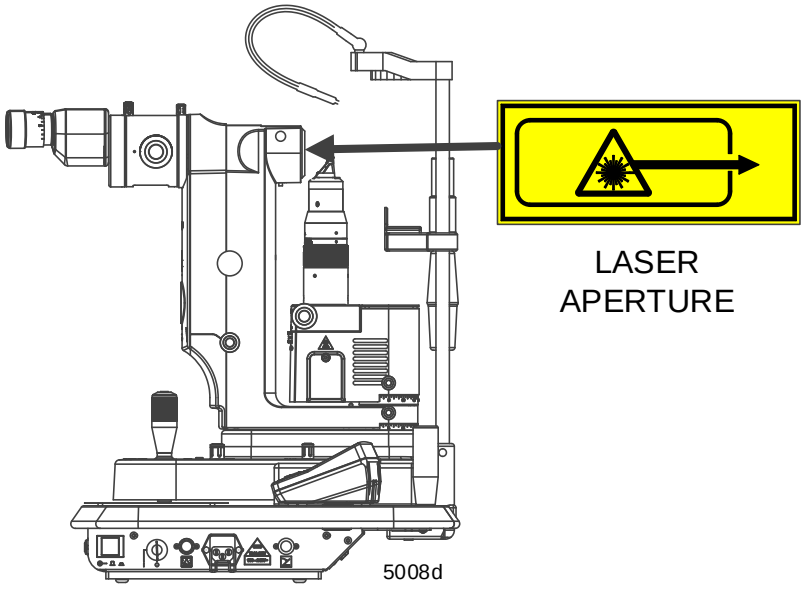


Figure 2-18 Laser aperture — Solo

UltraQ

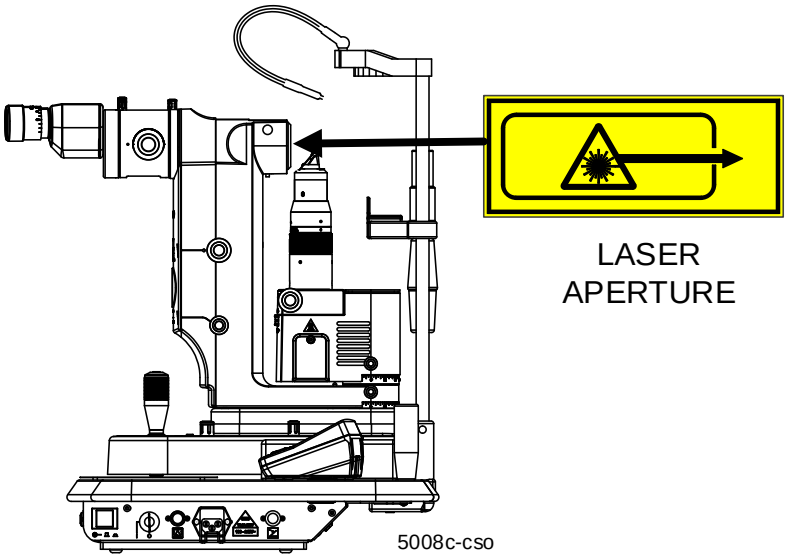


Figure 2-19 Laser aperture — UltraQ (CSO)

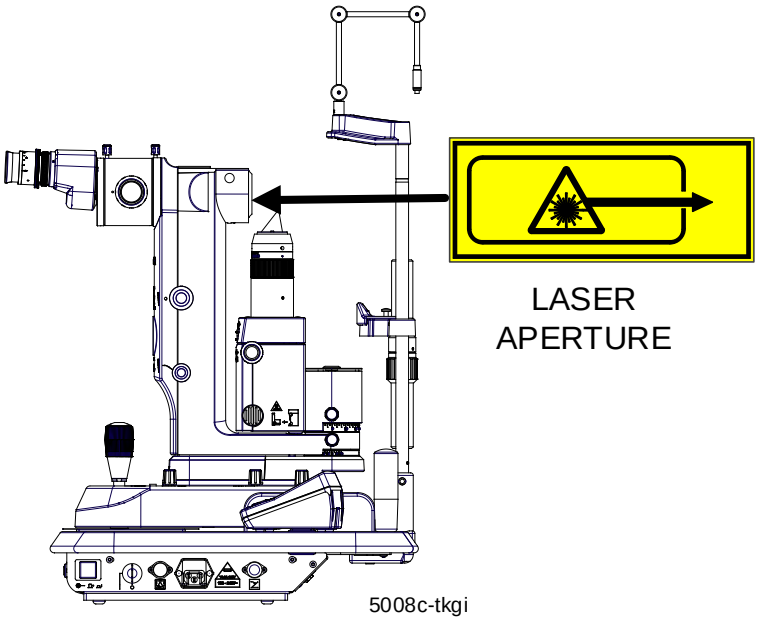


Figure 2-20 Laser aperture — UltraQ (Takagi)

UltraQ Reflex

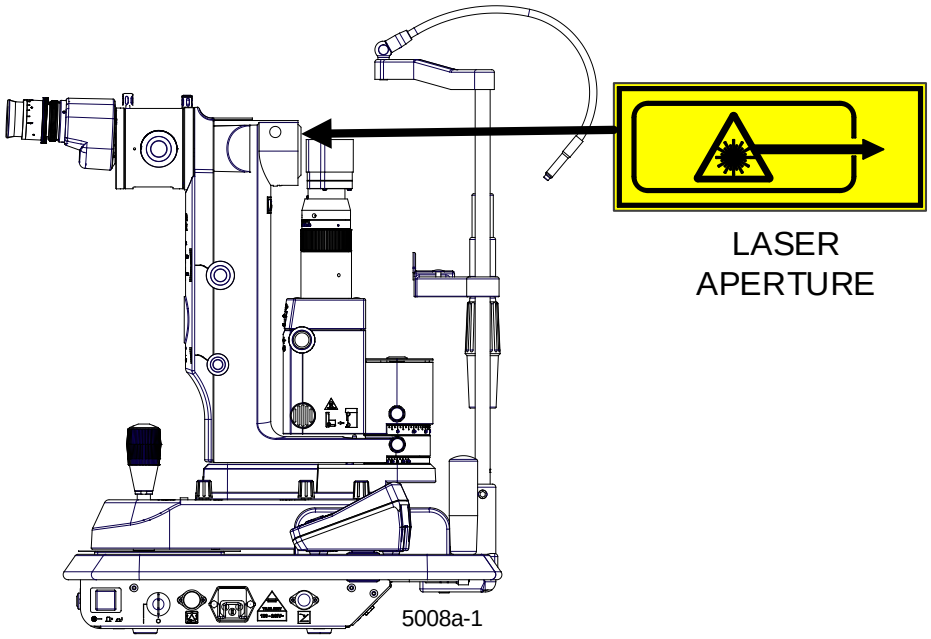


Figure 2-21 Laser aperture — UltraQ Reflex

2.4.8 Compliance label

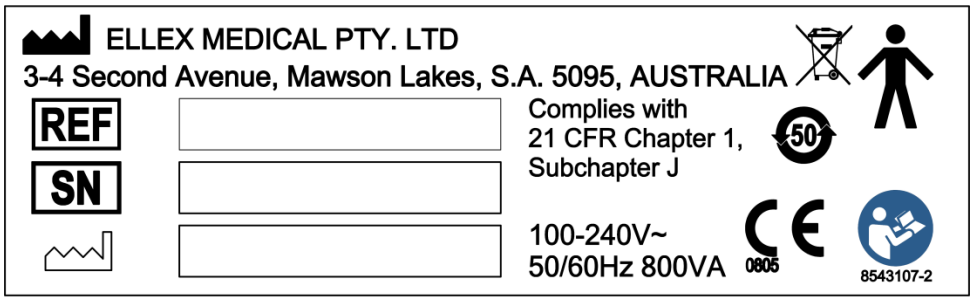


Figure 2-22 Compliance label

Table 2–14 Explanation of the compliance label

	Manufacturer	
REF	Device model designation	
	Solo	LT5106-S
	Tango	LT5106-T
	UltraQ	LQP3106-U
	UltraQ Reflex	LQP3106-U
SN	Serial number in text and barcode formats	
	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.	
	Pollution control label in compliance with People's Republic of China (PRC) standards.	
0805	CE mark in compliance with the EU Medical Device Directive (MDD).	
	The user must read and comprehend the operator manual before use.	

2.4.9 Unique device identification (UDI)

Figure 2–23 Unique device identification (UDI) label

Table 2–15 Explanation of the unique device identification (UDI) label

(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

2.4.10 Laser safety label

Solo

Figure 2-24 Laser safety label — Solo

Tango

Figure 2-25 Laser safey label — Tango

UltraQ

5011a

Figure 2-26 Laser safety label — UltraQ

UltraQ Reflex

Red aiming beam

5011a

Figure 2-27 Laser safety label — UltraQ Reflex (with red aiming beam)

Green aiming beam

5011b

Figure 2-28 Laser safety label — UltraQ Reflex (with green aiming beam)

3 Assembly

Your Authorised Ellex Distributor should assemble and check the device. The Distributor will complete a Product Acceptance and Fault (PAF) report that formally documents this process.

Packing cartons opened by unauthorised personnel may void the warranty.

Retain all packing cartons in case you need to transport the device.

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.

WARNING! During assembly place the slit lamp upright and support it from underneath to avoid crushing the electrical cable.

3.1 Assembling the device

Assemble the device in this order:

1 Total Solution table

2 console

3 delivery head and slit lamp

4 chinrest

5 remote control

6 foot switch (optional)

7 final assembly.

You must check optical alignment after assembly and before using the device.

3.1.1 Total Solution table

Refer to the Total Solution documentation for assembly instructions. Ensure that the Total Solution table is correctly assembled and placed on a level surface before assembling the device. Note that the top plate is packed with the device.

Attaching the top plate to the column

1 Remove the top plate from the base of the console.

2 Using the supplied screws, attach the top plate to the top of the column.

Use the rear set of top plate holes (A) to secure the top plate to the column if you have a Mobile table.

Use the front set of holes (B) if you have a Wheelchair Accessible or Wheelchair Accessible, Mobile table.

Use the four captive screws to secure the top plate to the console.

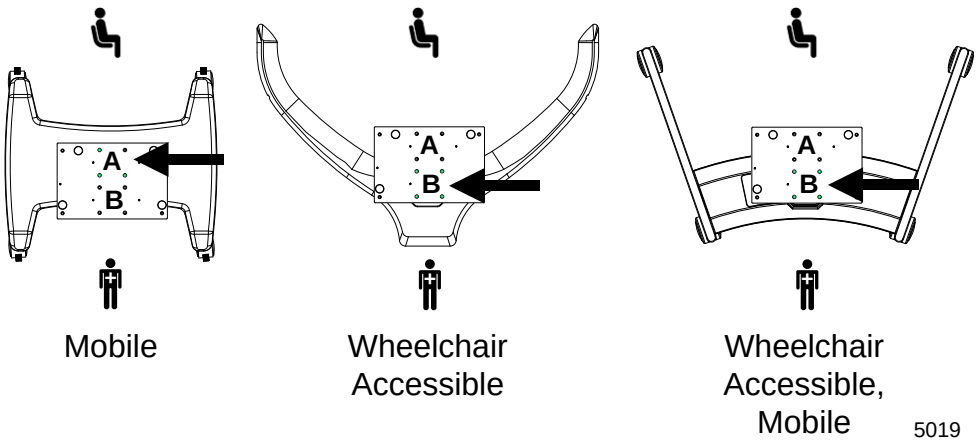


Figure 3-1 Top plate assembly options

The standing figure indicates the physician and the seated figure represents the patient.

3.1.2 Console

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

1. Ensure that the Total Solution table is on a level surface and lock the castors (if present).
2. Place the console on the Total Solution table.

   The front of the console must be on the same side the column switch.
3. Ensure that the rubber feet of the console fit into the recesses on the top plate.
4. Screw the four top plate captive screws from below into top plate and then into the base of the console.
5. Remove the protective plastic from the top of the console.

3.1.3 Delivery head and slit lamp

1. Remove a gearwheel from the shaft.
2. Insert the shaft into the slit lamp/delivery head and reattach the gearwheel.
3. Ensure that the delivery head and slit lamp are locked in place.
4. Lift the delivery head and slit lamp onto the console. Ensure that the electrical cable exits from the rear of the slit lamp and is placed in the access hole in the middle of the tabletop.
5. Position the gearwheels on the tracks. Ensure that the gearwheel shaft is parallel with the console.
6. Unlock the cross slide shaft and move the delivery head/slit lamp to the front of the console.
7. Remove the two rear panel screws (one located on either side of the console) and lower the rear console flap.
8. Connect the electrical connector to the electrical socket.

   Tighten the two electrical connector thumbscrews.
9. Connect the high voltage connector to the high voltage socket, and rotate it clockwise until it clicks into position.
10. Lay the cables to the right and push them into the hole.
11. Shut the rear flap and secure the screws.
12. Fit the gearwheel covers.
13. Move the slit lamp over the full extent of travel from left to right, and forward and back. Ensure that the cables do not become strained or tightly bent, and the slit lamp moves freely over the full extent of travel.

    Reposition cables if necessary to avoid straining them or rubbing the outer sleeves.

14 (UltraQ Reflex) Carefully remove the protective cap from Reflex Coaxial Illumination (RCI) mirror. Retain this cap and place it on the RCI to protect it when the device is not in use.

15 (UltraQ Reflex) Carefully remove the tape that holds the RCI mirror down during transport.

16 Verify that the safety filter is not damaged and then fit the binocular to the delivery head.

3.1.4 Chinrest

1 Ensure that the chinrest power connector is clean. Wipe it with a cloth if necessary.

2 Stand in the patient's position and lower the chinrest all the way into the chinrest mounts. Ensure that the power connector is on your left.

3 Secure the chinrest to the mounts by screwing the patient handles into the mounts or, where bolts are present in the mounts, use the supplied Allen key to tighten the bolts.

4 If you used bolts to secure the chinrest, screw the patient handles to the tabletop.

5 Fit the chinrest paper.

3.1.5 Remote control

1 Connect the coiled cable to the remote control.

2 Place the remote control in the mounting hole provided.

3 Connect the remote control cable to the console.

Match the red mark on the cable connector to the red mark on the console connector.

3.1.6 Foot switch (Optional)

1 Place the foot switch on the floor in a convenient position.

2 Connect the foot switch to the console.

3 Ensure the foot switch cable is routed to avoid it being damaged or becoming a tripping hazard.

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

3.1.7 Final assembly

1. Install any remaining accessories (including the drawer).
2. Remove all remaining protective plastic from the device.
3. Fit the safety interlock emulation plug.
4. Connect the power cable from the console to the power socket at the top of the column.
5. Connect the power cable from the column base to the mains power, and turn mains power on. The power indicator on the column will illuminate.

   The power cable has an EU style plug; replace it with a locally approved type if necessary.

   Power cables may be held in place with a metal strain relief to ensure the cable is not accidentally dislodged from the connector. To remove the power cable, lift the strain relief.

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.

6. Turn the Emergency Stop switch clockwise to release it.
7. Insert the key and turn it to Slit Lamp. Verify that the device starts up.
8. Push in the Laser button (On) and verify that the remote control is operational.

3.2 Checking optical alignment

Verify the optical alignment of the device after assembly or reassembly. Refer to 8.2.4 Checking focus and optical alignment on page 76.

3.3 Disassembling the device

Follow the reverse of the assembly instructions to disassemble the device.

Removing the high voltage connector

1 Pull the slider forward.

2 Turn the connector anticlockwise as far as possible.

3 Pull the plug out of the socket.

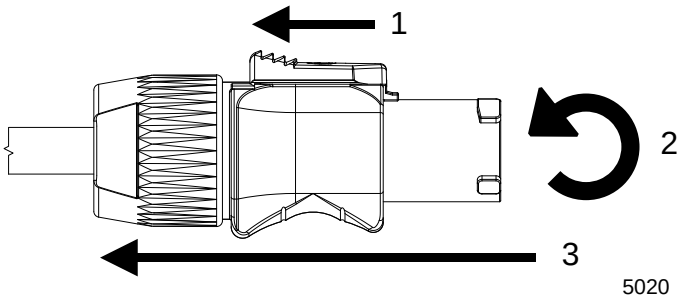


Figure 3-2 Disconnecting the high voltage connector

3.4 Safety interlock

A safety interlock connection is provided to connect to the theatre or clinic door. If the door is opened, the treatment laser turns off immediately and the device enters STANDBY. The interlock wiring is rated at 3.3 V DC.

A suggested circuit diagram is shown below (pins 1 and 3 of the DIN plug are wired). All cables and switches are user supplied. Ellex recommends that the cable is wired to the connector and switch by an electrician. A Microswitch Omron VX56-1A3 or similar should be used, with 2-core shielded 18–22 AWG cable.

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

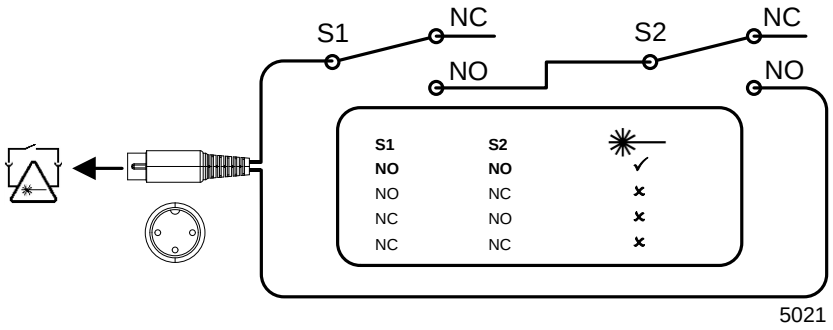


Figure 3-3 Safety interlock circuit diagram

4 Clinical Use

WARNING! This information is provided as a guide only and is not intended to present complete or thorough instructions. It is not meant to replace the judgment of a trained 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.

WARNING! If the user finds the plasma burst doesn't occur where expected, the clinical treatment should be immediately terminated until the device is serviced by the Ellex Service technician.

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).

4.1 General purpose

4.1.1 Solo and Tango (SLT mode)

This device is intended to be used for selective laser trabeculoplasty (SLT) operations (laser trabeculoplasty for primary open angle glaucoma).

4.1.2 UltraQ, UltraQ Reflex and Tango (YAG mode)

This device is intended to be used to perform procedures requiring the rupture of tissue in the eye.

4.2 Operating principle

4.2.1 Clinical concept

Solo and Tango (SLT mode)

The operating principle is based on a low energy, short pulse of laser light which produces a non-thermal effect in pigmented cells in the trabecular meshwork of the eye.

UltraQ, UltraQ Reflex and Tango (YAG mode)

The operating principle is based on a non-thermal cutting or disrupting effect capable of damaging any tissue or structure on which the beam is focussed.

4.2.2 Device operation

When you turn the device on 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 a 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:

- (Tango only) treatment mode (SLT or YAG)
- energy
- offset (YAG only)
- number of pulses (YAG only).

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 or 515 nm green laser located in the delivery head. This light is directed to an angled mirror 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 or depress the joystick fire button to fire the treatment laser, the device passes current to the laser engine and regulates laser output to the set energy level. Treatment settings selected by the operator are controlled by electronics and software.

The optical output from the YAG aiming beam and treatment laser engine is directed to the delivery device.

4.3 Indications

4.3.1 SLT mode (Solo and Tango)

Selective Laser Trabeculoplasty (SLT).

4.3.2 YAG mode (UltraQ, Tango and UltraQ Reflex)

Iridotomy and iridectomy (insertion of a hole in the iris)

- Posterior capsulotomy
- Posterior membranectomy
- (UltraQ Reflex only) Vitreolysis; which is defined as "photodisruption and vaporization of visually significant fibrous strands and/or opacities in the vitreous body, commonly known as floaters, with the YAG laser".

4.4 Contraindications

4.4.1 Solo and Tango (SLT mode)

The following indications contraindicate the use of this device:

- neovascular glaucoma
- angle closure glaucoma where the trabecular meshwork is inaccessible
- blood vessels in the Schlemm's canal.

Objective assessment of candidate patients for these procedures must be done in the light of the risks and contraindications with consideration to the possible adverse effects.

The laser is designed to damage tissues. Make sure it is focused only on tissues that are to be operated on. Do not use the device for retinal treatments.

The beam should never enter the eye at an angle greater than 30 degrees from the visual axis.

4.4.2 UltraQ, UltraQ Reflex and Tango (YAG mode)

The following indications contraindicate the use of this device:

The following pre-existing ocular pathologies may represent contraindications for Nd:YAG ophthalmic laser surgery:

- Corneal edema that interferes with visualisation.
- Diffuse haze of the aqueous humour.
- Extensive corneal dystrophy.
- Chronically elevated intraocular pressure, especially when uncontrollable under medication.
- Eyes with no potential visual function.
- Subjects with glass posterior chamber IOLs, except in those subjects whose medical condition precludes invasive surgery.

Do not focus it on or near iris blood vessels because the shock wave may produce bleeding and induce astigmatism.

The YAG treatment laser has a cutting or disrupting effect capable of damaging any tissue or structure on which the beam is focused.

Like all Nd:YAG ophthalmic laser surgery, there are risks involved and use of the laser may be contraindicated for patients with certain pre-existing ocular pathologies. Objective assessment of candidate patients for this procedure must be performed in light of the risks.

Vitreolysis (only for UltraQ Reflex)

In addition to the contraindications mentioned above, Vitreolysis is contraindicated when below conditions are present:

- Asteroid hyalosis
- Vitreous opacities/floaters associated with untreated, symptomatic retinal tears or untreated retinal detachment.
- Floaters peripheral to the central visual axis to the point that they are untreatable.
- Excessive lenticular astigmatism. This can prevent a precise focus of the laser treatment beam
- Glaucoma, or Chronically elevated intraocular pressure, especially when uncontrollable under medication.
- Active retinal pathology or inflammation
- Peripheral flashes of light, suggestive of an incomplete posterior vitreous detachment, or untreated tear and hence pose a risk of further retinal tear or detachment.
- Opacities located within 3-4 mm of the retina or lens
- High myopia, as there may be higher risk of retinal tear or detachment.
- Diffuse, cloud-like syneresis type of opacities, which are more difficult to treat effectively.

4.5 Potential Risks/Complications

4.5.1 Capsulotomy/Posterior Membranectomy

- Elevated IOP – Elevation of IOP may be related to the number of laser pulses and total energy delivered. IOP should be checked following the procedure. This IOP rise is usually transient. If IOP remains elevated, treatment can be initiated by the physician.
- Pitting of IOL – Pitting of the IOL can occur if the laser pulse occurs too close to the lens optic. Use of posterior offset, posterior defocus at start of treatment, and a capsulotomy contact lens will decrease the likelihood of damage to the IOL
- Intraocular inflammation
- Cystoid macular edema
- Retinal detachment
- Iris injury – If the laser discharge hits the iris, bleeding may occur.
- Pupillary block (in aphakia)

4.5.2 Vitreolysis

- Retina injury, contusion or haemorrhage - If this occurs in the retinal periphery, there may be no long-term consequences. If this occurs in the macula, vision loss may occur.
- Traumatic cataract – Phakic patients may experience a rapid onset of symptoms if there is a breach of the posterior capsule.
- Pitting of IOL – Pseudophakic patients may have damage to their intraocular lens (IOL).
- Increased intraocular pressure – This is more likely to occur in older patients with compromised trabecular meshwork drainage combined with treatment of dense, vitreous strands/opacities in the anterior vitreous.
- Retinal detachment – The risk of retinal detachment may be higher following laser vitreolysis
- Increased symptomatic vitreous opacities/floaters

WARNING! It is important to maintain an adequate distance of more than 3-4mm from the lens and more than 3-4 mm from the retina at all times. This is referred to as the “safe zone”.

WARNING! The vitreous opacity/floater may move or become mobile during vitreolysis due to the shock wave produced with each laser pulse. When aiming the laser at a mobile opacity, always wait for it to settle before continuing with treatment. This avoids unnecessary energy delivery into the eye.

4.5.3 Iridotomy/Iridectomy

- Elevated IOP – Elevation of IOP may be related to the number of laser pulses and total energy delivered. IOP should be checked following the procedure. If IOP is elevated, treatment can be initiated or continued by the physician. If the iridotomy is being performed to treat acute angle closure or pupillary block glaucoma, continued elevation of IOP may signify failure of the laser to create a full thickness opening in the iris.
- Hyphema
- Corneal edema – Areas of focal corneal edema may occur in front of the iridotomy site, especially if the anterior chamber angle is shallow at the time of laser procedure. Use of an iridotomy contact lens will decrease the likelihood of damage to cornea.
- Lens/zonule injury – Injury to the phakic lens and/or zonules can occur if laser pulses are delivered through and behind a patent iridotomy. Use of zero or anterior offset and an iridotomy contact lens will decrease the likelihood of damage to the lens or zonules.
- Intraocular inflammation

4.5.4 SLT

- Blurred vision may occur for several hours transiently following laser procedure.
- Elevated IOP – Elevation in IOP may be related to the number of laser pulses, total energy delivered, level of trabecular meshwork pigmentation and degrees (0-360) of trabecular meshwork treated. The incidence of pressure elevation may be reduced by the use of IOP lowering medications. IOP should be checked following the procedure. If IOP remains elevated, treatment can be initiated by the physician.
- Intraocular inflammation
- Corneal edema
- Retinal injury – Laser misdirected through the pupil can cause damage to the retina. If the laser system has dual YAG/SLT modalities, the correct mode must be used for the intended procedure
- Pain – Slight pain and/ or discomfort may occur transiently following the laser procedure.

4.6 (UltraQ Reflex only) Vitreolysis

This section is applicable to only UltraQ Reflex.

Note: Vitreolysis treatment usually requires multiple sessions to achieve the desired result. Also, each treatment session may vary in duration due to density, location, size and number of opacities.

4.6.1 Recommendations

The following sections of this topic provide a range of recommendations/best practices to aid in performing the vitreolysis.

Lens

Choose a lens based on the opacity to be treated or the position of the vitreous strand. Do not use the Goldmann (3 mirror) lens for treating vitreous strands or opacities.

Patients

Patient population/selection for Vitreolysis:

- Patient has clinically significant vitreous opacities/floaters.
- Patient has significant symptoms from the vitreous opacities/floaters such as difficulty in driving, reading, using a computer, significant annoyance, or altered concentration.
- Patient symptoms should be stable for at least three months. For new onset of symptoms defer any considerations of treatment a minimum of 3 months.
- Older patients (>45) with sudden-onset symptoms will most likely have experienced a posterior vitreous detachment (PVD). Many of these patients present with a Weiss-ring type opacity. Because they are fibrous, they absorb the laser energy well and can be vaporized efficiently.
- Patients should not undergo multiple simultaneous laser procedures e.g., capsulotomy and vitreolysis.
- Initially, treat only pseudophakic patients to avoid risk of causing traumatic cataract. Treat phakic patients only after gaining experience on the technique and visualization system i.e., on-axis and off-axis illumination for spatial context.

Note: Performing on pseudophakic patients post YAG Capsulotomy: Avoid using too many shots on pseudophakic patients who have anterior opacities located close to the posterior capsule and have undergone YAG capsulotomy.

Pre-treatment

Examination of the eye is needed to observe the eye and rule out retinal pathology.

Administer tropicamide and phenylephrine drops on the eye(s). Dilute the pupil aggressively to achieve a 6 mm size or more. Note that every mm of pupil dilation is beneficial.

Post dilation, observe the eye particularly the retina and periphery regions.

Instil topical anaesthetic 2-3 times on the operative eye. Wait for a few minutes between each instillation. Consider instilling an anaesthetic drop on the non-operative eye as well, as it helps to decrease the blink reflex.

Treatment

Consider the following recommendations while treating the patient:

Utilizing On-Axis (Coaxial) and Off-Axis Illumination

Start the procedure by using On-axis illumination to view the retina and then move anterior by using Off-axis illumination i.e., slit lamp in the oblique position. This helps in analysing the anterior vitreous and posterior lens capsule and provides the necessary spatial context for:

- identifying the vitreous opacity(s) and surrounding structures
- determining if it is safe to proceed with treatment

Vitreous opacity(s) located in the middle and posterior vitreous:

Do not fire the laser if both retina and opacity are in focus OR close to being in focus at the same time.

Fire the laser if vitreous opacity is in focus but the retina is not in focus as this provides sufficient space to fire the laser.

Vitreous opacity located in the anterior vitreous

Use the Off-axis illumination as it helps in following ways:

- helps visualize the posterior lens capsule to determine if there is sufficient distance between the opacity and the lens
- provides additional contrast of the opacity by removing the red glow and thus causing it to appear white in front of a black background

Toggling between off-axis and on-axis modes

Toggle between Off-axis and On-axis modes to achieve the optimal visualization of the vitreous strand or opacity, and surrounding structures throughout the procedure. Also, titrate the intensity of red reflex by settling the illumination tower in between “on-“ and “off-” axis.

Reviewing the position of the vitreous strand or opacity

To ensure constant feedback i.e., spatial context, review the position of the vitreous strand or opacity in relation to the retina and lens. Perform this task throughout the procedure.

Energy, Number of Pulses and Shots

Always start with a lower level of energy and titrate upwards until there is adequate optical breakdown and vaporization of the vitreous collagen.

Determine the number of shots required based on the type of vitreous opacity.

If new to the technique, then try to limit the number of shots per treatment session to a maximum of 300-400 shots, single pulse. Note that after significant number of shots are fired, gas bubbles can build up, making visualization difficult.

Direction of Treatment

Determine the opacities and their location before commencing laser firing. Some opacities can be present in challenging locations. Consider the following steps to work around these opacities:

- Start treating the opacities in the anterior section of the eye, moving from top to down. Target the easily visible ones and then proceed to higher vitreous opacities. The advantages of this approach are:
    1. Removal of opacities that may impede vision of the posterior structures.
    2. Reduce the risk of gas bubbles impeding higher vitreous opacities

  Move to posterior section after completing the anterior part of the eye.
- Move the eye up-down or left-right directions to move the opacities into easily treatable locations. Note that if the opacities are too far in the periphery of the contact lens, the laser energy will not achieve the necessary therapeutic effect.
- Do not fire the laser if the opacity is over the macula and the retina is also in focus. If unsure of the distance between the vitreous opacity and retina, move the eye up and down to try and manoeuvre the vitreous opacity to a different position.

Note: Take extreme care when treating close to the retina, especially when working at higher energies.

Post Treatment

After the treatment, patients may see small, dark specks in their lower field of vision in the initial few hours following the procedure. These are small micro-gas bubbles at the roof of the globe. They dissolve quickly and disappear within a day or so.

In very rare cases, inflammation of the anterior segment can occur. In the unlikely event that this does occur, treat with non-steroidal anti-inflammatories (ketorolac), or a steroid (prednisolone acetate) for a few days.

Follow-up treatments

Follow-up treatments can be scheduled on consecutive days. However, consider allowing a few days for the eye's condition to stabilize. Patient symptomatic improvement can vary depending on the type of clinically significant vitreous opacities. It may take up to a month to truly assess if another session is necessary based on their symptoms.

4.7 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.

YAG Laser Vitreolysis vs Sham YAG Vitreolysis for Symptomatic Vitreous Floaters: A Randomized Clinical Trial. Shah CP, Heier JS.JAMA Ophthalmol. 2017 Sep 1;135(9):918-923

Long-Term Follow-Up of Efficacy and Safety of YAG Vitreolysis for Symptomatic Weiss Ring Floaters. Shah CP, Heier JS. Ophthalmic Surg Lasers Imaging Retina. 2020 Feb 1;51(2):85-88.

Novel OCT Application and Optimized YAG Laser Enable Visualization and Treatment of Mid- to Posterior Vitreous Floaters. Singh IP. Ophthalmic Surg Lasers Imaging Retina. 2018 Oct 1;49(10):806-811

Nd:YAG Laser Vitreolysis for Symptomatic Vitreous Floaters: Application of Infrared Fundus Photography in Assessing the Treatment Efficacy. Sun X, Tian J, Wang J, Zhang J, Wang Y, Yuan G.J Ophthalmol. 2019 Jan 27;2019:8956952.

Nd:YAG vitreolysis and pars plana vitrectomy: surgical treatment for vitreous floaters. Delaney YM, Oyinloye A, Benjamin L.Eye (Lond). 2002 Jan;16(1):21-6

Efficacy and safety of yttrium-aluminium garnet (YAG) laser vitreolysis for vitreous floaters. Luo J, An X, Kuang Y.J Int Med Res. 2018 Nov;46(11):4465-4471.

Acute retinal detachment after Nd:YAG treatment for vitreous floaters and postertior capsule opacification: a case report. Liu X, Wang Q, Zhao J.BMC Ophthalmol. 2020 Apr 19;20(1):157

Objective assessment of YAG laser vitreolysis in patients with symptomatic vitreous floaters. Souza CE, Lima LH, Nascimento H, Zett C, Belfort R Jr.Int J Retina Vitreous. 2020 Jan 21

To Treat or Not to Treat: Management Options for Symptomatic Vitreous Floaters. Broadhead GK, Hong T, Chang AA.Asia Pac J Ophthalmol (Phila). 2020 Mar-Apr;9(2):96-103.

Treatment of vitreous floaters with neodymium YAG laser. Tsai WF, Chen YC, Su CY.Br J Ophthalmol. 1993 Aug;77(8):485-8.

5 Safety

Only fully trained and qualified 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.

5.1 Before first use

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

Ensure that the equipment is correctly installed and that 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.

5.2 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.
- Carefully handle optical fibres and delivery systems, and regularly inspect them for damage.
- Ensure that delivery devices and optical fibres are correctly connected before using the device.
- Regularly inspect the safety filter.

5.3 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.

5.3.1 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.

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

5.3.2 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 physician.

WARNING! Do not use liquids with this device.

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 that 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 toAiming Laser

Table 10–4 Aiming laser specifications Aiming Laser Specifications on page 94.

5.3.3 Treatment laser

WARNING! Do not look into the treatment beam unless under the control of a qualified 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 10.5

Treatment Laser on page 95 .

5.3.4 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 required optical density (OD) value shown in Table 5–1, are required for the treatment wavelengths.

Table 5–1 Minimum specifications for safety glasess

Mode	Minimum required optical density (OD)	EN 207 resistance to laser radiation minimum scale number
YAG	5 @ 1064 nm	DR LB3
SLT	5.5 @ 532 nm	DR LB4

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 directly look into the path of a laser beam. Correctly selected safety glasses offer protection against accidental exposure to a direct laser beam for a minimum exposure of 50 pulses.

Ellex recommends safety glasses with a minimum optical density (OD) value shown in Table 5–2 for the treatment wavelength. The table also summarises the energy density H_R incident on the glasses and minimum required resistance to laser radiation scale numbers for the delivery device beam divergence Φ and maximum output energy E at a distance of 1 m from the laser aperture.

Table 5–2 Ellex recommended specifications for safety glasess

Mode	λ (nm)	E (J)	Φ (degrees)	H_R (J/m^2)	Scale Number	Min OD
YAG	1064	0.055	16	1.07	DR LB3	5
SLT	532	0.015	< 3	17.9	DR LB4	5.5

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%.

Ellex supplies with this device NoIR Laser Company LaserShields Model DBY (OD 7+ @ 532 nm, OD 6+ @ 1064 nm) safety glasses with 35% luminous transmittance.

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.

5.3.5 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.

5.3.6 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.

5.3.7 Electromagnetic compatibility

Radio frequency sources (for example, mobile phones) may affect the device. Make sure that 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.

5.3.8 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.

5.3.9 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.

5.3.10 As Low As Reasonably Achievable

Any laser procedure should be performed following the principle of ALARA (As Low As Reasonably Achievable). The licensed practitioner should limit the time of patient exposure to laser radiation using the principle of ALARA.

5.4 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.

5.5 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.

6 Operation

6.1 Slit Lamp

Turn the key to On (with the Laser button released (Off)) to put the device in Slit Lamp mode. Only the slit lamp and fixation lamp are available.

6.2 Laser On

In Slit Lamp mode, push the Laser button in (On) to turn the laser on. In Laser On mode, the device has two states: STANDBY and READY.

6.2.1 STANDBY

When the key is turned to On, and the Laser button is depressed (On), the device automatically enters STANDBY. In STANDBY, you can select treatment settings, target and focus the aiming beam knowing that the treatment laser cannot be accidentally fired. The device automatically returns to STANDBY if an interlock or other error occurs.

(Tango) The device automatically switches to STANDBY when the treatment mode is selected or changed.

6.2.2 READY

Press the State button to put the device in READY.

The device automatically reverts to STANDBY if it is left inactive in READY for five minutes.

6.3 Treatment workflow

Before starting the device

1 Ensure that the safety interlock (or emulation plug) is connected.

2 (UltraQ Reflex) Carefully remove the black protective cap from the RCI.

3 Ensure that all observers are wearing appropriate eye safety glasses, and are aware of the device's safety requirements.

Preparing the patient

1 Ensure that all patient contact surfaces have been cleaned.

2 Seat the patient.

3 Adjust the patient's and physician'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 treatment.

6 Position the fixation lamp and ask the patient to focus on it.

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 Ensure that the Laser button is released (Off).

4 Turn the key to Slit Lamp.

The device can now be used as a slit lamp. Note that the Laser button is illuminated.

Using the slit lamp

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

1 Ensure that the device is in STANDBY.

2 Check focus and optical alignment (refer to 8.2.4 Checking focus and optical alignment on page 76).

3 Adjust slit width.

4 Adjust illumination intensity (use the lowest useful setting).

5 Select a filter.

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

7 Finely position the slit lamp using the joystick.

8 Rotate the joystick to raise or lower the slit lamp.

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

Firing the SLT laser (Solo and Tango)

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

1 Push in the Laser button (On).

(Solo) The device performs a laser self-test and presents the average energy of the last test fires. All totals are reset to zero. The device is placed in STANDBY.

2 Check focus and optical alignment (refer to 8.2.4 Checking focus and optical alignment on page 76).

3 (Tango) Select a treatment mode.

On the remote control, press the button below SLT and press ●. The mode is displayed on the remote control. The device is placed in STANDBY. All totals are reset to zero. The device performs a laser self-test and presents the lowest usable predicted energy.

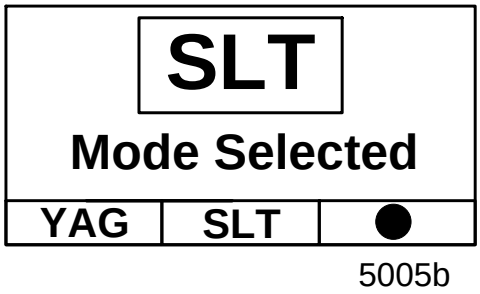


Figure 6-1 Selecting a treatment mode — SLT mode selected

4 Press reset if you are treating a new patient. This resets the cumulative energy and pulses to zero.

5 Position and adjust slit lamp illumination.

For better depth perception place the illumination slightly off-axis to the aiming beam. While any illumination angle may be used for SLT treatment the centre position is recommended.

6 Set the energy.

(Solo) The device fires three test shots with the safety shutter closed. The average energy of the test fires appears on the remote control.

(Tango) The laser will fire between 3 and 10 test shots with the safety shutter closed to configure the device for the selected energy.

7 If you are using a contact lens, place it in position.

8 Press the State button to place the device in READY.

WARNING! (Tango) Always check that you have selected the correct treatment mode. Eye damage may result if the wrong mode is selected.

9 Press the fire button (or press the foot switch pedal).

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

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.

A single pulse is delivered. This is indicated by an audible tone from the console, and the remote control indicators flashing from READY to STANDBY and back to READY as the laser recharges. The total energy delivered and pulse count increments.

Any deviation greater than ±20 per cent from the predicted energy is indicated by flashing up/down arrows on the LCD (mJ field). If this occurs repeatedly try resetting the energy.

If more than double the set energy is detected, a persistent up arrow is displayed as the system corrects. The arrow will disappear when the next laser shot is fired.

The device will automatically return to STANDBY and emit a warning sound if you press the fire button for more than two seconds.

10 When treatment is complete, press the State button to place the device in STANDBY.

Firing the YAG laser (Tango, UltraQ and UltraQ Reflex)

To achieve the precise spatial context necessary for safe anterior and posterior YAG procedures, both off-axis (slit lamp in the oblique position) and on-axis (slit lamp in the coaxial position) illumination is required. Examples are shown below using the UltraQ Reflex (images courtesy of Paul I Singh, MD).

5022a

Figure 6-2 Off-axis position

5022b

Figure 6-3 On-axis position

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

1 Push in the Laser button (On).

The device performs a laser self-test and presents the predicted energy of the last used treatment fire. All totals are reset to zero. The device is placed in STANDBY.

2 Check focus and optical alignment (refer to 8.2.4 Checking focus and optical alignment on page 76).

3 (Tango) Select a treatment mode.

On the remote control, press the button below YAG and press ●. The mode is shown on remote control display. All totals are reset to zero. The device performs a self-test and presents the predicted energy.

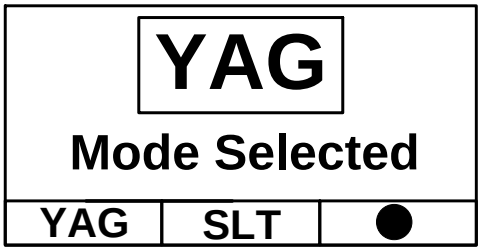


Figure 6-4 Selecting a treatment mode — YAG mode selected

4 Press reset if you are treating a new patient. This resets the total energy and pulses to zero.

5 Set the energy.

The laser fires between 3 and 10 test shots with the safety shutter closed to configure the device for the selected energy value.

A Nd:YAG contact lens is recommended for some treatments to minimise risk to non-target sites such as the cornea and particularly the lens, and to stabilise the patient's eye. Since contact lenses alter the energy density at the treatment site, the energy setting should be readjusted.

6 If you are using a contact lens, place it in position.

7 Set the number of pulses.

Choose between 1, 2 and 3. Wait for the test fire to complete before selecting the next parameter. Each time you change the pulse, the device fires 3 to 10 test shots and a new energy value appears. The energy is the cumulative total for all pulses within the burst.

8 (UltraQ) Set the posterior offset.

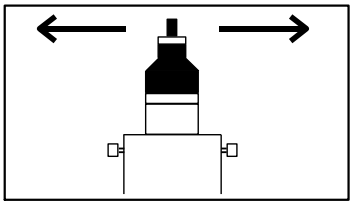
The focal point of the invisible Nd:YAG treatment beam is posterior to that of the aiming beams. The amount of offset is set by the Posterior Offset control.

Move the slit lamp illumination tower to one side. Better depth perception occurs if the illumination is slightly off-axis to the aiming beam.

9 (Tango [YAG], UltraQ Reflex) Set the offset for the treatment beam.

The focal point of the invisible Nd:YAG treatment beams may be set coincident to the aiming beams, or anterior (A) or posterior (P) to the focal point of the aiming beams. The amount of offset is determined by the position of the Offset controls on the delivery head. For more information refer to 6.6 Offset (Tango and UltraQ Reflex) on page 67.

(Tango [YAG]) Tower interlock safety feature. You cannot fire the treatment laser if the slit lamp illumination tower is in line with (blocking) the objective lens. The aiming beams will flash and a warning (shown below) will appear on the remote control if the illumination tower is not out of the way. To resolve this problem, move the slit lamp further out of the way.



5005e

Figure 6-5 Tower interlock error graphic

10 Adjust illumination intensity.

Multiple reflections of light from the aiming beams and slit lamp can make accurate focusing difficult. To solve this problem, use a contact lens, reorient the aiming beams, position the slit lamp slightly off-axis, or reposition the patient.

11 Press the State button to place the device in READY.

WARNING! Never leave the device unattended in READY.

WARNING! (Tango) Always check that you have selected the correct treatment mode. Eye damage may result if the wrong mode is selected.

WARNING! (UltraQ Reflex) Do not impede movement of the RCI illumination mirror.

12 Press the fire button (or press the foot switch pedal).

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.

(UltraQ Reflex) If the slit lamp illumination tower is in front of the objective lens, the RCI illumination mirror will automatically move (flip down) out of the treatment beam path. If the mirror is not in the path of the treatment beam it remains stationary.

The selected number of pulses are delivered to the treatment site each time the laser is fired. Firing is indicated by an audible tone from the console, and the remote control indicators flashing from READY to STANDBY and back to READY

as the laser recharges. The total energy delivered and pulse count are both incremented.

Any deviation greater than ±20 per cent from the predicted energy is indicated by flashing arrows on the LCD (mJ field). If this occurs repeatedly try resetting the energy. If more than double the set energy is detected, a persistent up arrow is displayed as the system corrects. The arrow will disappear when the next laser shot is fired.

The device will automatically return to STANDBY and emit a warning sound if you depress the fire button for too long.

13 When treatment is complete press the State button to return the device to STANDBY.

Turning the device off normally

WARNING! Wait at least 10 seconds after turning off before turning the device on again, to allow the device to restart properly.

1 Select STANDBY.

2 Press the Laser button to release it (Off).

3 Turn the key to Off, remove the key from the console and store it in a safe place to prevent unauthorised use.

4 (UltraQ Reflex) Place the black protective cap over the RCI.

5 Cover the device with the dust cover.

After heavy use leave the device powered but in STANDBY to allow the device to properly cool down before turning the device off (especially if you expect to restart the device immediately). If you ignore this advice, you may encounter errors when you try to use the device.

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.

6.4 Operator menu

Use the Operator menu to change these options:

- LCD contrast
- volume
- firing mechanism.

Accessing the Operator menu

- Press the State button for five seconds.

  Options are displayed as icons. A selected icon is highlighted in black.

Exiting the Operator menu

- Press the State button.

6.4.1 Configuring options

All Operator menu options are selected and adjusted in the same way.

Selecting an option

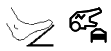
1 Use the arrow buttons to highlight the icon.

2 Press the black circle ● to select the icon.

3 Use the arrow buttons to select a new value.

4 Press the black circle ● to return to the Operator menu.

Table 6–1 Explanation of Operator menu options

	Contrast
	Volume Volume of the console speaker for laser emission and input tones. The greater the number of bars the higher the volume. The volume of alarm tones is controlled independently by the device. For more information refer to Audio Table 10–3 Audio specifications on page 94.
	Firing mechanism. Select between foot switch and joystick. Always restart the device after you change the firing mechanism.

6.5 Posterior Offset (UltraQ)

WARNING! This posterior offset information only applies to the UltraQ device. It does not apply to the Solo, Tango and UltraQ Reflex devices.

The Posterior Offset control allows you to change the focus of the Nd:YAG energy relative to the aiming beams.

As the risk of pitting the IOL increases when using MIN offset, 1.5 mJ is the maximum recommended energy setting when using MIN. If using a larger energy setting, set a larger offset. A typical posterior YAG offset setting of +150 at about 1.2–1.5 mJ will minimise risk of pitting an IOL. The user should start the treatment away from the centre of the optical axis of the IOL.

Posterior offset is illustrated below. Distances shown reflect measurements in air and F indicates the focal plane. The red dashed line indicates the aiming beam.

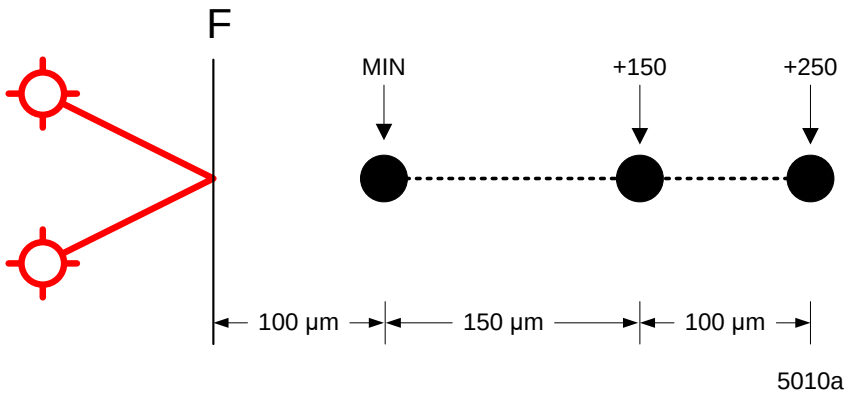


Figure 6-6 Explanation of posterior offset (UltraQ)

6.6 Offset (Tango and UltraQ Reflex)

WARNING! This offset information only applies to the Tango and UltraQ Reflex devices. It does not apply to the Solo and UltraQ devices.

WARNING! The Offset control is a wide ranging anterior and posterior treatment beam offset. Take extreme care to accurately target the treatment laser, particularly in the posterior region approaching the retina. Always confirm the offset direction (anterior (A) or posterior (P)) and offset measurement before you fire the treatment laser.

WARNING! To minimise the risk of pitting an IOL during posterior capsulotomies, set the posterior (P) offset to at least 100 µm with a minimum energy setting. If using a higher energy setting, choose a greater posterior (P) offset. The user should start the treatment away from the centre of the optical axis of the IOL.

WARNING! Membranectomies close to the retina or the posterior surface of the natural lens should not be attempted.

Peripheral iridotomy (PI) is typically performed at a slightly posterior offset.

The Offset control changes the focus of the Nd:YAG treatment laser relative to the aiming beams.

Offset is illustrated below where distances shown are measurements in air, F indicates the focal plane and the dashed red lines represent the aiming beams.

Anterior (A) offset positions are recommended for treatments close to the retina.

Posterior (P) offset positions are recommended for posterior capsulotomies.

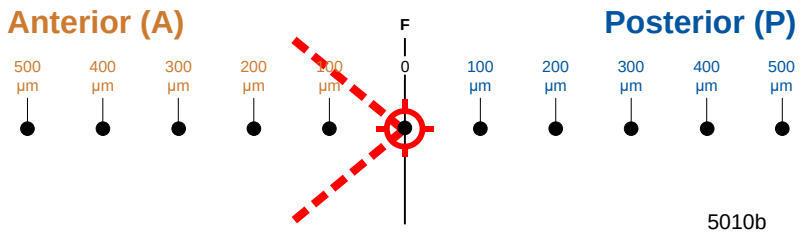


Figure 6-7 Explanation of anterior and posterior offset (Tango/UltraQ Reflex)

Offset operation is further illustrated below with the aiming beams indicated by the red target and the offset treatment beam positions as grey lines terminating with a star (note that the image, including the offset positions, are not to scale). The letter A and the colour orange on the Offset control indicate Anterior positions. The letter P and the colour blue on the Offset controls indicate Posterior positions.

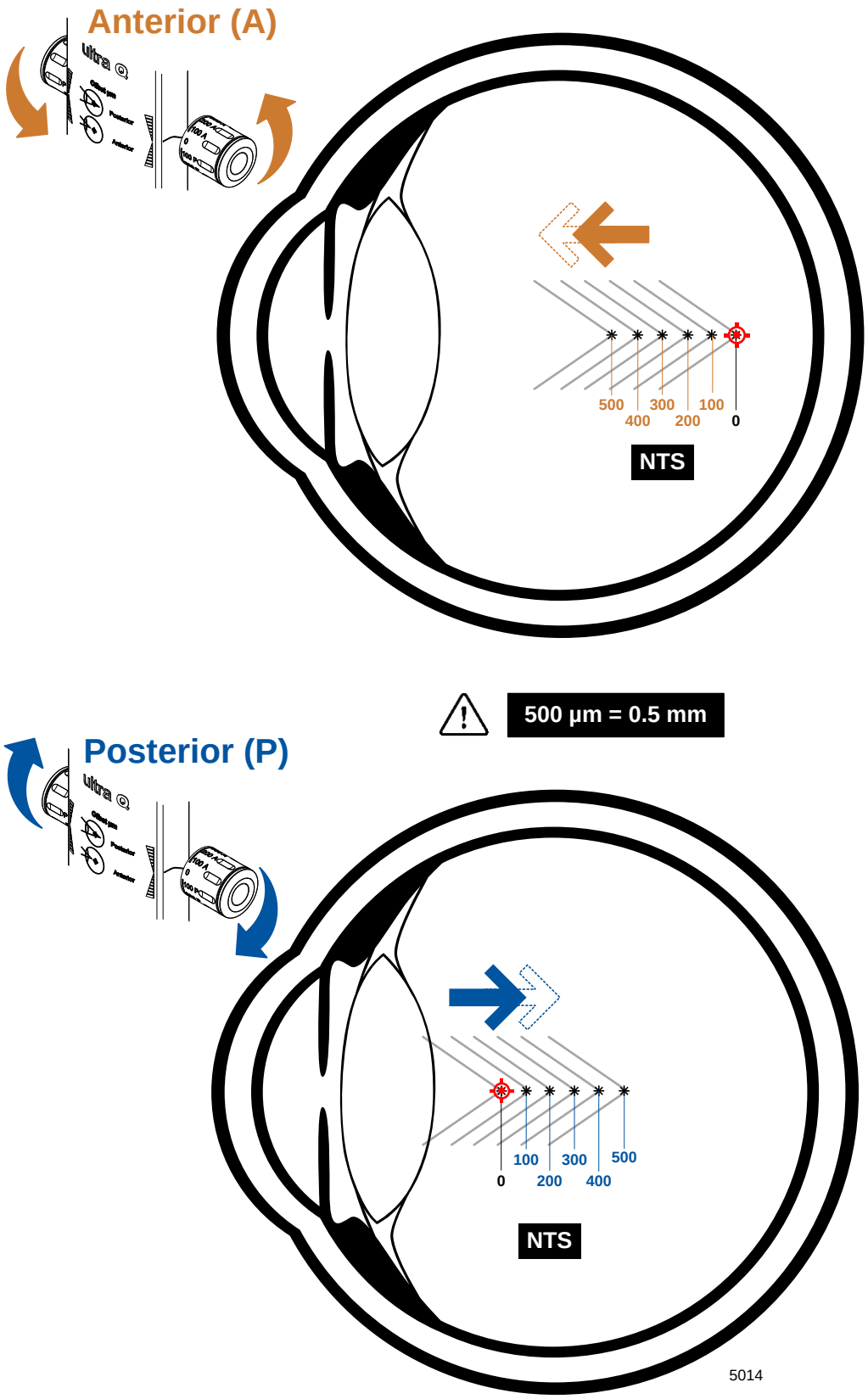


Figure 6-8 Anterior and posterior offset shown in the eye (Tango/UltraQ Reflex)

NTS = image not to scale

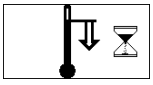
7 Troubleshooting

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

Table 7–1 Suggestions for troubleshooting

Problem	Probable cause	Resolution
Device does not start	Power cable is not connected	Check that the power cable is connected to the local supply and to the stand, and from the stand to the device
	No mains power	Check that 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

Problem	Probable cause	Resolution
	Slit lamp globe incorrectly seated	Reseat globe
	Slit lamp illumination timed out after 5 minutes of inactivity. This is a time-out feature.	Illumination available on the next slit lamp usage
	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
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
Remote control display not working	Remote cable not connected	Connect remote control cable to the console. Check the cable connection at the remote.
	Laser button set to Off	Press laser button to turn it on
No treatment beam and no aiming beam	Internal laser failure	Contact your Authorised Ellex Distributor
	(UltraQ Reflex) The RCI is jammed, or the return spring is broken. Device indicates a shutter error.	Contact your Authorised Ellex Distributor
No treatment beam, aiming beam is present	READY not selected	Select READY

Problem	Probable cause	Resolution
	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, remote control is illuminated, a continuous audible tone may be heard	Safety interlock has been activated	Correct safety interlock condition (close door or fit emulation plug)
Treatment and aiming beams not aligned	Internal misalignment	Contact your Authorised Ellex Distributor
Treatment beam ineffective	Dirty objective lens	Clean objective lens
	(SLT) Low pigmentation of treated tissue	Refer to the Clinical Use chapter on page 41.
	(YAG) Offset incorrectly set	Adjust offset
Flashing up or down arrows in mJ field on the remote, a beep is heard every time a shot is fired	Energy has deviated from the set value by more than 20%	Reset energy but observe the delivered energy. If beeping continues, contact your Authorised Ellex Distributor.
Cannot select READY, or cannot fire treatment beam, device beeping, aiming beams flashing, message on remote (icon of illumination tower)	(Tango) Slit lamp illumination tower obstructing treatment beam	Swing the illumination tower off-axis by at least 15°
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.
Cool down symbol appears on remote control and device reverts to STANDBY. After 20 seconds the warning is removed. 	(Tango [YAG], UltraQ, UltraQ Reflex) YAG laser cavity temperature is too high.	Wait 20 seconds until the warning clears automatically or press any button on the remote control to clear the error.

7.1 Error messages

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

Resolving a fault

1 Press the State button once.

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

If the error code remains, 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 device. If the error code appears again contact your Authorised Ellex Distributor.

7.2 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.

8 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.

8.1 Cleaning and disinfection

WARNING! Device intended to be in contact with intact skin.

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.

8.1.1 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.

8.1.2 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.

8.2 Routine maintenance

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

- cleaning the device
- cleaning the external optics
- checking the safety filters
- checking optical alignment (only for devices that include a slit lamp).

Cleaning frequency should follow clinic protocol.

8.2.1 Cleaning the device

Cleaning the device

1. Turn the device off and disconnect mains power.
2. Wipe external surfaces (except the optics) using a damp (not wet) cloth and either a neutral enzymatic cleaner or a mild 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.

8.2.2 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.

Cleaning the external optics

1 Turn the device off and disconnect from 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.

8.2.3 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 that there are no surface imperfections or deterioration of the coating.

Checking a delivery head safety filter

1 Place the device in STANDBY.

2 (Tango) Select YAG treatment mode.

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.

5 (Tango) Select SLT treatment mode.

6 (Tango) Remove the binocular and external magnification changer.

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

8 (Tango) Replace the binocular and magnification changer.

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

8.2.4 Checking focus and 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 focus and optical alignment:

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

Checking focus

1 Look into the right ocular with your left eye.

2 Adjust the ocular until the reticle is in focus.

3 Adjust the left ocular to the right ocular setting.

4 Look into the right ocular with your right eye.

5 Adjust the ocular until the reticle is in focus.

Checking optical alignment

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

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

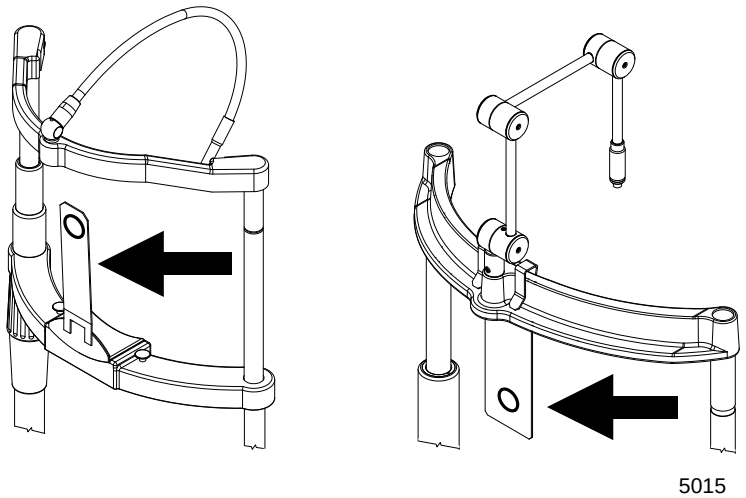


Figure 8-1 Attaching a target to the chinrest

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

4 Fire the laser at the target.

WARNING! Ensure that there are no reflective surfaces behind the target when checking optical alignment.

WARNING! If the user finds the plasma doesn't occur where expected, terminate the clinical treatment immediately and contact Ellex service or distributor.

5 Compare what you see through the binocular to the illustrations below. Consider contacting your Authorised Ellex Distributor if you observe B. Contact your Authorised Ellex Distributor immediately if you observe C or D.

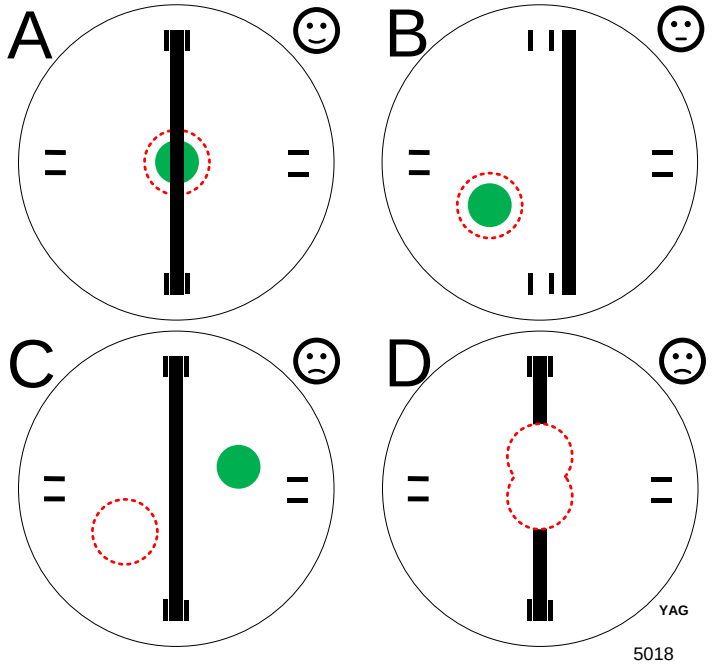


Figure 8-2 Laser burn comparison chart

Table 8–1 Laser burn analysis

	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	No centred to aiming beam	**WARNING!** Do not use the device. Contact your Authorised Ellex Distributor immediately.

D YAG only	Aligned	Twin aiming beams do not converge	N/A	**WARNING!** Do not use the device. Contact your Authorised Ellex Distributor immediately.

WARNING! Do not use the device if you cannot make the aiming spots converge, or 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.

8.3 Additional maintenance

8.3.1 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.

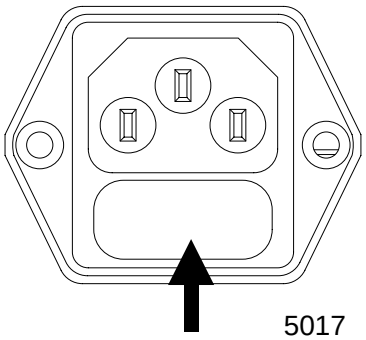


Figure 8-3 Fuse location

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.

8.3.2 Replacing the slit lamp illumination source

For equipment type A and B, ensure that a 12 V pre-centred spare globe is 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 may be located on the side (A) or the front (B) of the slit lamp (see the illustration below).

The illumination source for type C can only be replaced at an Ellex authorised service centre.

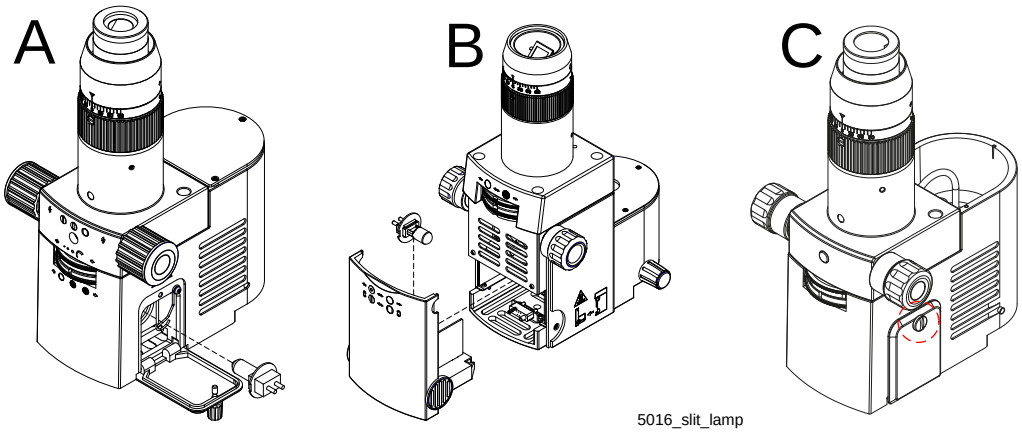


Figure 8-4 Replacing the slit lamp globe

(A) Side mounted globe holder

Replacing the globe

1 Turn the device off.

2 Unscrew and open the globe cover.

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

3 Pull the restraining clip to one side and pull out the globe holder.

4 Replace the globe. Ensure that the globe notch is on the left.

5 Ensure that the globe is correctly seated and push the holder back.

6 Slide the restraining clip back and secure the cover.

7 Turn the device on and check slit lamp illumination.

(B) Front mounted globe holder

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 slit lamp 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.

(C) Service-replaceable

Contact your Authorised Ellex Distributor to replace the illumination source for Type C device.

8.4 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 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 Lower the slit lamp.

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

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

9 (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 the device may overbalance when it is being moved.

10 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.

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

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

8.4.1 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 that 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.

8.5 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 term 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 may include:

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

8.6 Verifying laser calibration

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. Follow the instructions immediately below if you wish to informally verify the calibration of this device outside the regular service cycle. Note the following points:

- 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 and be within its specified recalibration interval.

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 to 10.5 Treatment Laser on page 95.

8.6.1 SLT laser calibration

Verifying calibration (Solo/Tango)

1. Ensure that observers are wearing appropriate eye protection. For more information refer to 5.3.4 Eye safety on page 53.
2. (Tango) Select SLT mode.
3. Place the laser energy meter detector in front of the objective lens so that the aiming beam covers 60% of the detector.
4. Follow the laser energy meter instructions to measure the output from this device for the 532 nm wavelength.
5. Follow the firing protocol below, allowing one second between firing and 10 seconds between changing energy settings.

Table 8–2 SLT laser output calibration protocol

Energy (device) (mJ)	Number of shots to fire
0.6	10
1.5	10
2.0	10
2.6	10

6. Laser output is verified if the average energy recorded by the meter for each energy setting is within ±15% of the energy shown on the device.

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.

8.6.2 YAG laser calibration

Verifying calibration (Tango/UltraQ/UltraQ Reflex)

1. Ensure that observers are wearing appropriate eye protection. For more information refer to 5.3.4 Eye safety on page 53.
2. (Tango) Select YAG mode.
3. Select single pulse.
4. Place the laser energy meter detector in front of the objective lens so that the aiming beams cover 60% of the detector.
5. Follow the laser energy meter instructions to measure the output from this device for the 1064 nm wavelength.
6. Follow the firing protocol below, allowing one second between firing and 10 seconds between changing energy settings.

Table 8–3 YAG laser output calibration protocol

Energy (device) (mJ)	Number of shots to fire
1	10
2	10
4	10
10	10

7. Laser output is verified if the average energy recorded by the meter for each energy setting is within ±15% of the energy shown on the device.

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.

8.7 Product lifetime

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

8.8 Product disposal

This device contains natural resources and may contain hazardous substances that could have a harmful effect on the environment and human health if disposed of improperly. Do not dispose of this device as unsorted municipal waste: use appropriate recycling systems to reuse or recycle its component materials. Contact local or regional waste administration for more information about the collection, reuse or recycle systems available in your area.

8.9 Restriction of hazardous substances (China RoHS)

Table 8–4 Names and contents of the hazardous substances (China RoHS)

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。

O：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。

X：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。

8.10 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.

Table 8–5

Category	Accessories
Total Solution Table	Total Solution Mobile Base (h-base)
	Total Solution Wheelchair Accessible Base (u-base)
	Total Solution Wheelchair Accessible, Mobile Base (v-base)
	Low Voltage (110-120V) Column
	High Voltage (220-240V) Column
Vitreolysis Lens	Wide Field Vitreous Peyman (18mm)

Category	Accessories
	Wide Field Vitreous Peyman (25 mm)
	Wide Field Vitreous Peyman (12.5 mm)
	Ocular Vitreous Karickhoff (21 mm)
	Off-Axis Vitreous Karickhoff (25mm)
	Off-Axis Vitreous Karickhoff (30mm)
	Mid Vitreous Singh
	CGVL Vitrectomy Contact
	CGPL Capsulotomy Contact
	Vitreous Lens Kit includes all 3 Vitreous lenses (Peyman 18mm, Karickhoff 21mm and 25mm)
Slit Lamp accessories	Co-observation Tube (Includes Eyepiece) - Silver colour Requires Beam Splitter part #6334990
	Beam Splitter (2 Ports) - Silver Colour
	35 mm Camera Adapter - Silver Colour Requires Beam Splitter part #6334990
	5m Position Magnification Changer (6x, 10x, 16x, 28x, 45x) - Silver Colour
	5m Position Magnification Changer (6x, 10x, 16x, 25x, 40x) - Silver Colour
	Acc. Mag changer, 3 Pos, Housing, Silver
Photodisruptor Laser Lenses	Volk Iridectomy Lens
	Volk Capsulotomy Lens
	Abraham Iridectomy Lens
	Abraham Capsulotomy Lens
	Lens, Laser Blumenthal Iridotomy
	Lens, Laser Iridectomy/ Iridotomy
	Lens, Laser MagPlus Iridectomy
	Lens, Laser Capsulotomy
	Lens, Laser, Single Use, Capsulotomy
	Lens, Laser Single Use, Iridotomy
SLT Laser lens	Volk Rapid SLT lens
	Ocular Latina SLT Lens
	Latina SLT Gonio Lens
	Lens, Laser Three-Mirror - NF - Gonio
	Lens, Laser One Mirror SLT Gonio

Category	Accessories
	Lens, Laser Three-Mirror Glass Gonio Fundus, Flange AR Coating
	Lens, Laser Four-Mirror Glass Gonio Flange Fluid AR Coating
	Lens, Laser Four-Mirror High Mag Gonio Flange
	Lens, Surgical Gonio
	Lens, TVG
	Lens, Laser Single Use 3-Mirror Gonio
	Lens, Laser Single Use 4-Mirror Gonio
	Lens, Laser Single Use SLT
	G 4 Mirror Large Ring, NF
MidVitreous Laser Lens	Lens, Idrees MidVitreous
	Lens, Singh MidVitreous
Safety glasses	Dual Wavelength OD $\geqslant$ 5.5 at 532nm OD $\geqslant$ 5 at 1064nm
Foot Switch	Standard non-foldable, IP68

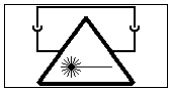
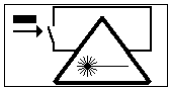
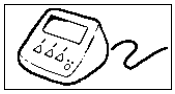
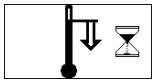
Contact your Authorised Ellex Distributor for more details on the consumables and accessories available for this device.

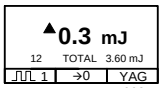
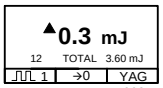
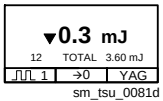
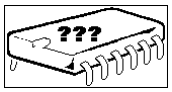
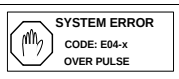
9 Alarms

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

For information about how to respond to alarms, refer to the Troubleshooting chapter on page 69.

Table 9–1 Explanation of device alarms

Error code	Symbol	Description
		External interlock was triggered.
		Accessories interlock was triggered.
		Communication to the console is lost
		YAG laser cavity temperature is too high – cool down symbol (present for 20 seconds, overridden by pressing any key on the RCU)

Error code	Symbol	Description
	 sm_tsu_0081e 	Energy high deviation warning: Flashing up arrow indicates the current delivered laser pulse is greater than 118% of the set energy. Audible alert indicating the average delivered energy is greater than 118% of the set energy.
	 sm_tsu_0081e  Persistent up arrow and audible alert	Excess energy. Energy greater than 200% of the set energy.
	 sm_tsu_0081d 	Energy low deviation warning: Flashing down arrow indicates the current delivered laser pulse is less than 82% of the set energy. Audible alert indicating the average delivered energy is less than 82% of the set energy.
0000		CRC checksum failure of EEPROM memory on start-up
0400		YAG PSU controller error. Unable to establish communications with the YAG PSU controller on start-up.
8107		Unable to find half-wave plate minimum
8108		Voltage window determination error. Single pulse voltage exceeded 600 V.
8109		Voltage window determination error. Single pulse voltage exceeded 899 V.
8205		A calibration task was attempted while the device was in Service mode (use Engineering mode instead).
E04-Y or S		Over-pulse error. Energy calibration is out of tolerance. Error can be cleared by pressing any key on RCU.
E05-Y or S		Closed shutter detector error. The closed sensor indicates the shutter is not fully closed.
E06-Y or S		Open shutter detector error. The open sensor indicates that the shutter is not fully open.
E07-Y or S		Aiming laser malfunction

Error code	Symbol	Description
E10-Y or S		Pulse detector failure. Energy was detected without pulses.
E11-Y or S		Energy monitor failure. Pulses where detected without energy.
E12-Y or S		Excess energy monitor. It indicates that multiple excess energy corrections were unable to bring the delivered energy back to the set value. Error can be cleared by pressing any key on RCU.
E13		Laser timeout error. The internal CPLD or FPGA timed out waiting for the shutter to move.
E20		Unexpected pulse detected. Pulses were detected outside of the laser fire authorisation window.
E30-F or E30-J		Laser fire controller error (F = foot switch, J = joystick)
E40-H or E40-P		Communication error. Unable to establish communication with delivery head (H) or YAG PSU controller (P).
E50-Y or S		Laser overload error. Software has not cleared the internal flag within the laser fire window.
E51- Y or S		Laser no trigger error. The CPLD or FPGA has gone through the laser fire sequence, but the software did not see a trigger pulse check on U1 pin 20.
E52- Y or S or S		Laser no request error. The microprocessor received a trigger pulse check signal on U1 pin 20 but did not ask the CPLD or FPGA to fire.
E53- Y or S		Laser timeout error. Microprocessor asked the CPLD or FPGA to fire the laser, but laser did not fire within 150 ms.
E60- Y or S		Shutter did not open. No shutter signal on U1 pin 27 during a CPLD or FPGA fire sequence.
E61- Y or S		Shutter no request error. The microprocessor did not ask the shutter to be opened when it was opened.
E62- Y or S		Shutter timeout error. The shutter did not move before the timeout.
E70- Y or S		DAM not operating error. DAM comparator output into the CPLD or FPGA is not on.
E80- Y or S		Unable to reach the set output energy. System could not perform three consecutive test fires within 16% of the set energy within 10 test fires.

Error code	Symbol	Description	
E90- Y or S		YAG attenuator EEPROM CRC error	
E91- Y or S		YAG HWP (half wave plate) over energy position error	
E92		Motorised eye safety filter error	
x800		Under-pulse detection error on start-up. The x prefix indicates one of the following tests.	
	YAG (Tango, UltraQ, UltraQ Reflex)		
		0	Memory
		1	YAG shutter
		2	SLT shutter
		3	YAG double pulse
		4	YAG triple pulse
		5	YAG single pulse
		6	YAG single pulse
		7	YAG single pulse
		8	YAG single pulse
		9	SLT single pulse
		A	SLT single pulse
		B	SLT single pulse
		C	SLT single pulse
	SLT (Tango/Solo)		
		0	SLT shutter
		1	SLT single pulse
		2	SLT single pulse
		3	SLT single pulse
		4	SLT single pulse
		5	SLT single pulse
x900		Over-pulse detection error on start-up. The x prefix is as for the x800 code (see above).	

10 Specifications

10.1 General

Table 10–1 General specifications

Weight (kg) [2]	≤ 32
Dimensions (mm) Height Width Depth	 575 757 452
Operating conditions	+10 °C to +40 °C 10% to 85% relative humidity non-condensing
Storage and transport conditions	−10 °C to +55 °C 10% to 85% relative humidity non-condensing

[2] Approximate weight of laser system with standard accessories (not base or column).

10.2 Power Supply

Table 10–2 Power supply specifications

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

10.3 Audio

Table 10–3 Audio specifications

Tone	**Frequency (Hz)**	**Volume (dB)**
Emission Normal Energy deviation warning	 784 698	45–52
Input Accepted Rejected	 1319 523	
Alarm	325	The alarm volume is at least 2 dB louder over the range of selectable volume levels for all tones.
	The alarm volume is not independently 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.	

10.4 Aiming Laser

Table 10–4 Aiming laser specifications

	Tango, Solo, UltraQ & UltraQ Reflex		
Type	Visible laser diode		
Wavelength (nm)	Mode	Wavelength nm	Devices
	YAG	635	UltraQ, Tango, UltraQ Reflex (Red aiming Laser variant)
		515	UltraQ Reflex (Green aiming Laser variant)
	SLT	635	Tango, Solo
Class	2		

Operation	Continuous wave
Power	< 1 mW continuously variable

10.5 Treatment Laser

Table 10–5 Treatment laser specifications

	SLT **Tango, Solo**	**YAG** **UltraQ, Tango,** **UltraQ Reflex**
Type	Q-switched frequency doubled Nd:YAG	Q-switched Nd:YAG
Wavelength (nm)	532 (green)	1064 (infra-red)
Class	3B	3B
Operation	Pulsed	Pulsed
Spot size (µm)	400	8 (Full Width Half Maximum)
Energy (mJ)	0.3–2.6 single pulse continuously variable	0.3 to 10.0 single pulse 0.6 to 20.0 double pulse 0.9 to 30.0 triple pulse All energy settings are adjustable in increments ranging from 0.1 to 1.5 mJ In Service mode, the device is capable of delivering up to 55 mJ.
Maximum allowable firing rate (Hz)	3.0	**Tango, UltraQ and UltraQ Reflex (Japan only)**: 3.0 single pulse 1.8 double pulse 1.6 triple pulse
		UltraQ Reflex (other regions): >3.0 single pulse. Typical limit:4 Hz single pulse 1.8 double pulse 1.6 triple pulse
Pulse width/duration (ns) (typical)	3	4
Pulse setting	1 pulse per shot	1, 2 or 3 pulses per shot
Safety filters	OD ≥ 5.5 @ 532 nm	OD ≥ 5 @ 1064 nm

Nominal ocular hazard distance (NOHD) (m)	Normal:71.6 Service: 171.8	Normal:7.1 Service: 9.5
Beam divergence	< 3° (84% included energy)	16° full cone angle
Offset (µm)	Not applicable	**UltraQ:** Posterior only, continuously variable with detents at 100, 250 and 350 **Tango, UltraQ Reflex:** Anterior (A) & posterior (P), continuously variable with detents at 0, 100, 200, 300, 400 and 500

10.6 Slit Lamp

Table 10–6 Slit lamp specifications

Type	Galilean stereoscopic microscope with converging optics	
Objective lens	1.25×	
Eyepiece lens	12.5× dioptre adjustable in range of ±5 D. One lens includes a cross hair reticle.	
Magnification changer (removable)	Standard	10×, 16×, 28×* OR 25x*
	Accessory	6×,10×, 16×, 28×, 45×
		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, 5.0, 8.0 & 12.0* OR 0.5, 3.0, 8.0 & 12.0*	
Slit rotation	±90°	
Illuminating angle	180° at horizontal plane (90° for right/left)	
Filters	Blue-green, violet-blue, red and none* OR Blue-green, violet-blue, heat absorbing (28% attenuation) and none*	
Fixation lamp	Yellow OR green LED*	

***** *based on regional configurations*

11 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 11.1.3 Recommended separation distance on page 103.

The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals. 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.

11.1 Guidance and manufacturer's declarations

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.

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.

11.1.1 Electromagnetic emissions

Table 11–1 Electromagnetic emissions specifications

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, provided the following warning is heeded.
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 by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as reorienting or relocating this device or shielding its location.

11.1.2 Electromagnetic immunity

Table 11–2

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 100 kHz for power supply lines; ±1 kV 100 kHz 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.
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.

Test condition	IEC 60601 test level	Compliance	Electromagnetic environment guidance
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. Recommended separation distance $d = \frac{6}{E}\sqrt{P}$ 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.

11.1.3 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 11–3

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
0.1	0.07	0.07	0.21	0.07	0.07	0.07	0.21
1	0.22	0.22	0.67	0.22	0.22	0.22	0.67
10	0.7	0.7	2.12	0.7	0.7	0.7	2.12
100	2.2	2.2	6.7	2.2	2.2	2.2	6.7

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.