Operator Manual

8448026EN 10

eyecubed

Eye Cubed Diagnostic Ultrasound Image System

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This manual describes the operation of the Eye Cubed Diagnostic Ultrasound Image System (the Eye Cubed system), which may also be referred to as I^3 System – ABDU Diagnostic Ultrasound, V4, Original or New Generation. This device is manufactured in Australia by Ellex Medical Pty Ltd.

These instructions comprise part of the product and must be kept for the life of the product. If the product is sold, these instructions must be provided to the new owner. Ensure that any amendment is incorporated into the instructions.

Some Eye Cubed features require a software licence or are hardware dependent. This document may describe features that are not licensed on your device or are otherwise unavailable. Be aware that new features may not always be backwards compatible.

Names and data used in the examples are fictitious.

This document describes features available in software release 2.4.0 or higher.

US federal law restricts this device to sale by, or on the order of, a physician.

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CE 0805

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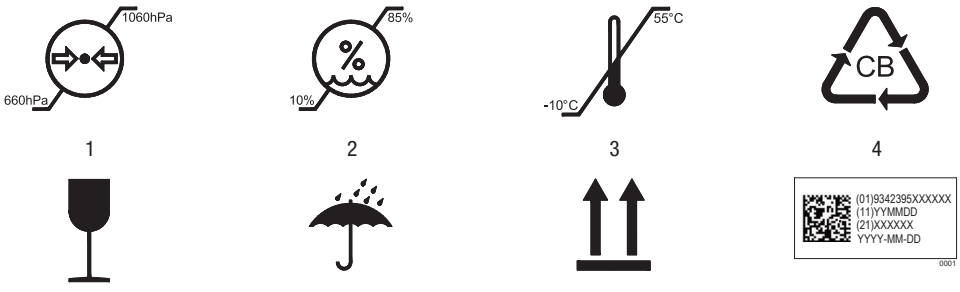
Document revision history

Version	ECR	Date	Description
1.0	3987	November 2012	Initial release of this document.
2.0	4061	January 2013	Revised for software release 2.0 (DICOM functionality).
3.0	4090	March 2013	Revised for software release 2.1.2.
4.0	4121	July 2013	Revised for software release 2.2.2.
5.0	4115	July 2013	Revised for software release 2.3.0 and the introduction of the New Generation console.
6.0	4191	December 2013	Minor revisions to support regulatory requirements and software release 2.4.0.
7.0	4161	February 2014	Revised operation conditions and corrected ECR number for version 6.0.
8.0	4277	June 2014	Revised for software release 2.4.8. Disinfection instructions revised.
8.1	4315	October 2014	Revised for Windows 7 compatibility with Eye Cubed New Generation introduced with this release, additional disinfection instruction revisions, and minor functional updates. EC representative added. Electromagnetic compatibility description added.
9.0	XXXX	XXXX	Not released.
10	6579	June 2019	Updated compliance label and address, Windows 10 information, recycling labels. Update to probe care instructions.

Before You Begin

Carton labelling



1	2	3	4
5	6	7	8

1	Atmospheric pressure limitation
2	Humidity limitation
3	Temperature limitation
4	Corrugated board (packaging may be recycled)
5	Fragile. Handle with care.
6	Keep dry
7	This way up
8	Unique device identification (UDI). For more information about this label refer to Unique device identification (UDI) on page 16.

Assembling and configuring Eye Cubed

Refer to the separate assembly instructions.

Eye Cubed is ready for use as soon as it is assembled and turned on. However, you may wish to configure your system before introducing it into your practice. The list below presents some items to consider before implementing Eye Cubed.

Most of these functions are under the **Utilities** tab and can only be configured using an administrator account.

- Create additional user accounts for security (**Utilities** > **General**).
- Consider implementing data entry guidelines to maintain data consistency within your Eye Cubed database.
- Define your examiners (**Utilities** > **User Information**).
- Define your physicians and their lenses (**Utilities** > **Users**). These must be defined before IOL calculations can be performed.
- Refine the list of diagnoses (add to, or remove, entries from the existing list) (**Utilities** > **General**).
- Determine if you want to automatically generate patient IDs (**Utilities** > **General**).
- Determine automatic log off settings (**Utilities** > **General**).
- Determine patient privacy settings (**Utilities** > **Reports**).
- Determine report preferences (**Utilities** > **Reports**).
- Define scan protocols (**Utilities** > **Scans**).
- Determine a backup (archive or export) protocol.
- Decide if you want to use averages in your IOL calculations (**Utilities** > **Reports**).
- Configure and use custom corneal and retinal caliper settings if you are not using a Prager Shell (**Utilities** > **Scans** > **Caliper positions**).
- Determine the default **Interpolation Mode** (**Utilities** > **Scans** > **B-Scan Default Settings** > **Interpolation Mode**).

Training

Eye Cubed training and consultancy services may be available in your area. For more information contact your Authorised Ellex Distributor.

Warnings

Read and understand all warnings before using this device.

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.

Probes are delicate instruments. Do not drop the probe or allow the tip to be damaged. Do not pinch or allow the probe cable to be damaged. Do not allow the connector (or anything else) to come into contact with the probe tip during storage. Damage to the probe or cable may require the entire probe to be replaced. Damage due to misuse, abuse, or accidents is not covered by the warranty.

This information is provided as a guide only and is not intended to present complete or thorough instruction. It is not meant to replace the judgement of a trained ophthalmic physician.

Turning the device off using the hardware power buttons while the Eye Cubed software is running may result in data corruption.

Do not turn the power off to the Eye Cubed system when it is in Windows Stand By.

Visually confirm that the calipers are placed on the correct echoes. Failure to confirm this may lead to axial length errors of 3.0 mm or greater.

This liquid should not have a high mineral content (saline or hard water) to avoid sedimentation of minerals onto the probe membrane, which could cause the membrane to harden and crack, causing oil to leak from the probe.

The ClearScan Ultrasound Probe Cover is a single-use item. Do not reuse.

Do not allow liquid to spill onto the Eye Cubed console or peripheral equipment, including the footswitch.

The liquid should not have a high mineral content (saline or hard water) to avoid sedimentation of minerals onto the probe membrane, which could cause the membrane to harden and crack causing oil to leak from the probe.

Do not over, or under pressurise the probe cover. If there is too much pressure the cover will not conform to the shape of the cornea and will press against it. If there is not enough pressure, the transducer will be too close to the cornea, increasing the risk of abrasion.

If fluid is leaking from the membrane after the probe has been inserted, the membrane has been punctured. Discard and replace with a new probe cover.

If fluid is leaking from the flexible collar after the probe has been inserted, the probe may have been inserted into the wrong side of the probe cover.

Do not move the shell once it has been placed on the eye, as you risk abrading the cornea.

Do not allow the probe tip closer than 5.0 mm to the cornea. The tip must not contact the cornea. Contact may result in corneal abrasion.

Applanation is invasive. Minimise probe movement on the cornea.

Using this device requires substantial knowledge of the clinical significance of ultrasound images. Ellex cannot, and makes no attempt to, instruct the customer in the interpretation of ultrasound images and echograms. The responsibility lies with the customer to study professional literature and obtain medical training. Procedures should be performed prudently using the principle of ALARA (As Low as Reasonably Achievable).

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 an isolation transformer.

The isolation transformer must be connected 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 the isolation transformer must incorporate an earth terminal and earth conductor.

Installing a printer changes the electrical safety profile of the system. Commercial printers are not generally qualified for use in medical systems where direct patient contact is involved, and may present a higher risk of electrical shock to the patient. Although such risk may generally be alleviated through the use of an isolation transformer, the connection of any electrical device to the Eye Cubed system that is not approved by Ellex must be evaluated for safety by the installing party. Ellex is not, and cannot be responsible for modifications affecting electrical safety that customers may make to the system after it has been delivered.

Always handle probes carefully. Damaged probes account for the majority of Eye Cubed service calls and introduces the potential risk of patient cross contamination.

Clean and disinfect probes before first use and between patient uses.

Using other types of solutions may result in probe damage.

Probes must not be heat (autoclave) or gas sterilised. Only clean the probe tip. Do not completely submerge the probe in cleaning or rinsing solutions.

Clean and disinfect immersion shells before first use and between patient uses.

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

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

Do not disconnect the probe by pulling on the cord.

Overview

About this document

This manual explains how to operate and maintain the Eye Cubed Diagnostic Ultrasound Image System. This is instrument is designed for use by sonographers in clinics or outpatient facilities in a hospital or surgery.

All instructions in this manual can be performed by a limited user unless noted otherwise. For more information about the types of users in Eye Cubed refer to Logging on and off on page 30.

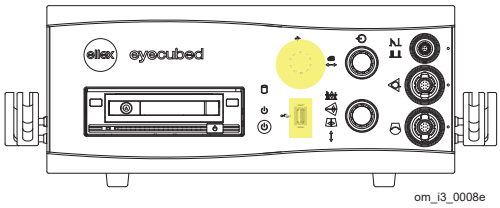
Suggested examination workflows are presented describing the use of each probe, modify these to suit your needs or create new ones as required.

Refer to the separate assembly instructions for information about assembling the Eye Cubed system including the cart.

Information in this manual is applicable to all Eye Cubed devices (unless otherwise stated) starting from console serial number V409-00110 unless otherwise specified.

Applicability

Features that are console dependent are indicated in the text by the prefixes, briefly described below.



Transmit Gain control (grey cap)

Single USB connector

No CD/DVD drive

No multi-card adapter

Compatible with the Anterior B-Scan probe (green shroud)

Who should read this manual

Operators and owners of this device should read this manual.

To operate this device you must be familiar with ophthalmic ultrasound technology and understand the structures of the eye.

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.

Third party software notice

Third party software (for example antivirus or EMR software) other than factory pre-installed software should not be installed on an Eye Cubed system. If you install third party software, Eye Cubed functionality may be affected and the warranty may become void.

Licensing

Eye Cubed features are controlled by a software licence. This means that this document may describe features that you have not purchased.

Documentation updates

Updates or corrections to this manual may be supplied as separate documents.

If you upgrade your Eye Cubed software always check to see if a supplement or a new manual is provided with the upgrade.

Device description

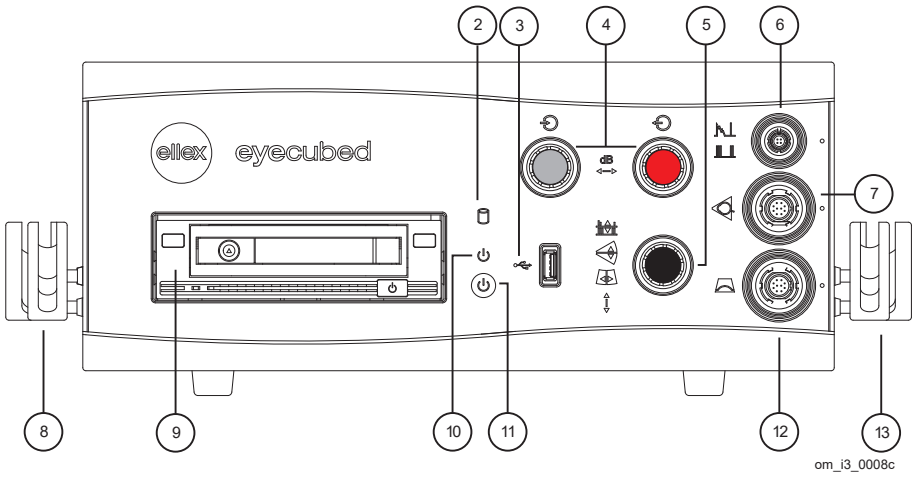
Hardware

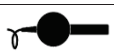
Individual Eye Cubed components may change over time due to product or manufacturing improvements, or because a part has become obsolete.

Console

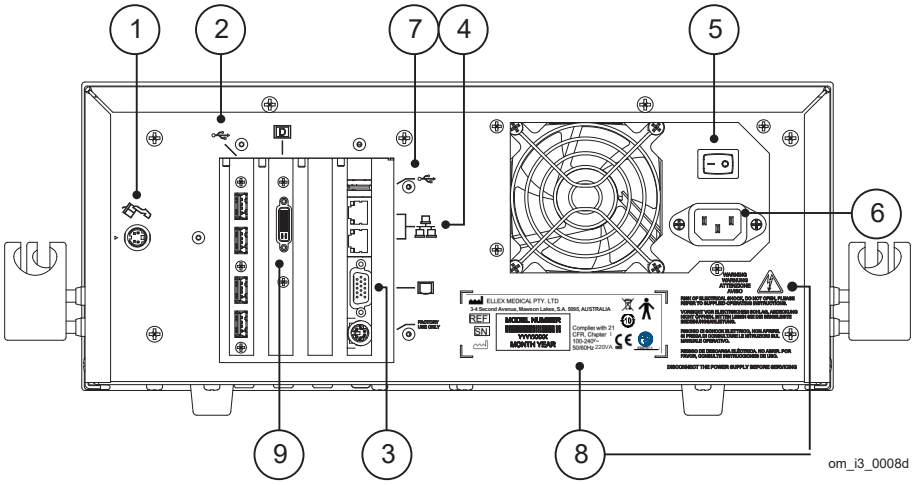
The console has an Ingress Protection rating (IP) of 00 which means that it offers no special protection to the ingress of particulate matter or water.

Front (New Generation)



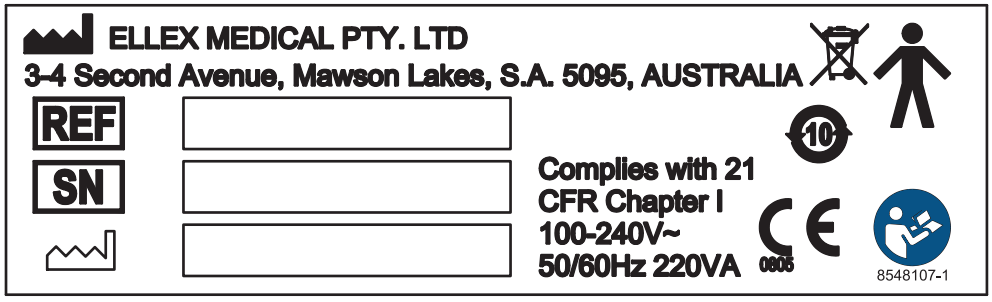
1		CD/DVD rewriteable drive
2		Internal hard drive activity light
3		(Original) Multi format card reader (New Generation) Front USB port
4	dB	**Gain** Controls image brightness.
		(New Generation) **Transmit Gain** (grey cap) Only available when you are actively scanning.
		**Receive Gain** (red cap) (Note that only the Original console displays the dB symbol)
		Move caliper horizontally (red cap knob only)
5 Black cap		Biometry and threshold line adjustment
		Posterior B-Scan cross-vector adjustment. You can also move the cross-vector by clicking the right mouse button on the scan.
		Anterior B-Scan cross-vector adjustment. You can also move the cross-vector by clicking the right mouse button on the scan.
		Move caliper, biometry/threshold line, ruler, or percent threshold vertically.
6		Diagnostic (8 MHz) probe connector
		Biometric (10 MHz) probe connector
7		Posterior (10 MHz) B-Scan probe connector (black)
8 & 13		Probe holders (total of four: two on either side that accommodate all probe sizes).
9		Removable hard drive
10		Standby indicator Indicator flashes when the Eye Cubed software is shut down and the console rear power switch is left in the on position.
11		**Power** button Illuminated when the console has been turned on.
12		Anterior (40 MHz) B-Scan probe connector The coloured ring around the connector matches the coloured cable shroud on compatible anterior probes. For more information refer to Probes on page 16.

Rear (New Generation)



1		Footswitch connector
2 & 7		USB connectors
3		Monitor connector
4		Ethernet connector (10/100/1000 Mbps)
5		Power switch 0 = Off I = On
6	100-240 V~ 50-60 Hz 220 VA	Mains electrical supply voltage and connector
8		Compliance information (refer to Compliance information on page 15).
9		Digital video in (DVI)

Compliance information



	Manufacturer
REF	Model number
SN	Serial number as text and barcode
	Date of manufacture
CE 0805	CE mark in compliance with the EU Medical Device Directive (MDD).
	Pollution control label in compliance with PRC standards.
	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.
	Applied Part 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.
	The user must read and comprehend the operator manual before use.
	Risk of electric shock. Do not open. Warning is repeated in German, Italian and Spanish.

Unique device identification (UDI)

(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

Isolation transformer

Refer to the manufacturer's instructions supplied with the transformer. The isolation transformer must exceed the power requirements of the connected devices by 25%.

Probes

General information

You may attach and detach probes from the console at any time, even while the system is running. If you detach a probe while scanning is in progress, scanning will stop but the examination session will remain open. Reconnect the probe and press F11 or press SCAN/FREEZE to restart scanning.

For all immersion methods, ensure that air bubbles do not exist between the probe tip and the eye as ultrasound waves cannot travel through air.

Always ensure that the probe is perpendicular to the structures of the eye being examined.

B-Scan probes include a marker to help you orient the transducer.

For information about cleaning and sterilising probes refer to Probes on page 92.

(New Generation) If an incorrect licence message appears it means that the probe that you just connected, or which was already connected when you started the system, is not licenced to be used on this device. Contact your Authorised Ellex Distributor to resolve these problems.

Ellex recommends that you place the probe cable around your neck when scanning. This avoids placing unnecessary stress at the point that the cable enters the probe and extends the life of your probe.

Each probe connector includes a label with the symbol described below.

	Applied Part 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.

Probe serial numbers

Each probe has a serial number that is located as described in the table below. The probe number is also included on the probe packaging.

Probe	Location of serial number
Diagnostic A	External –printed into the body of the probe.
Biometry A	Internal – etched into the plastic underneath the silver collar (to view the number carefully unscrew the rear of the probe a short distance [do not remove] and move the collar down).
Anterior B	External – printed on a label that is attached to the barrel of the connector.
Posterior B	External – printed on a label that is attached to the barrel of the connector.

Diagnostic (8 MHz) A-Scan

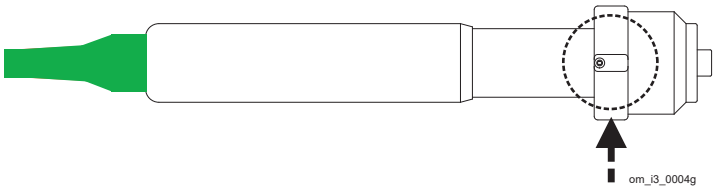
Connect the probe to the upper console connector (the same used for the biometry probe).

Biometry (10 MHz) A-Scan

Connect the probe to the upper console connector (the same used for the diagnostic probe).

Anterior (40 MHz) B-Scan[1]

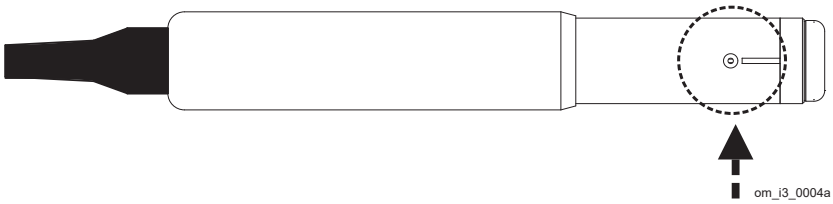
[1] This probe is also called the Anterior (40 MHz) Wide Field Anterior Segment Probe, or UBM probe.



Connect this probe to the lower console connector.

The probe marker is highlighted by an arrow in the illustration above.

Posterior (10 MHz) B-Scan



Connect this probe to the middle console connector. This probe has a black connector shroud and the connector at the console has a black ring. The probe marker is highlighted by an arrow in the illustration above.

Connecting a probe to the console

1. Align the red dot on the probe connector with the small cut out marked in red in the right side of console connector.
2. Push the probe straight into the socket until it clicks into place.

Disconnecting a probe from the console

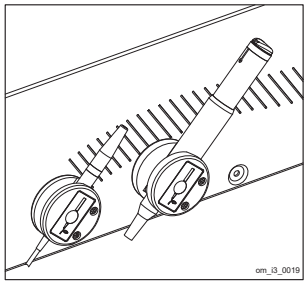
- Pull the connector out from the console by the connector barrel (the knurled band).

WARNING! Do not disconnect the probe by pulling on the cord.

(B-Scan probes) If the wrong probe for the scan mode is connected to the console you will see a warning message instructing you that the incorrect probe has been connected.

Safely storing a probe between sessions

- Thread the probe cable through the holder first, before carefully placing the probe in the holder with the tip facing upwards.



- Attach the probe tip protective cover if supplied.

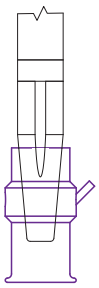
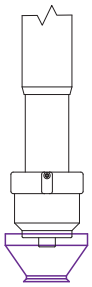
Storing a probe for longer or when transporting the system

1 Disconnect the probe from the console.

2 Place the probe in its original packaging. Ensure that the probe tip (with protective cover were supplied) is placed apart from the coiled cable and avoids contact with the connector.

WARNING! Probes are delicate instruments. Do not drop the probe or allow the tip to be damaged. Do not pinch or allow the probe cable to be damaged. Do not allow the connector (or anything else) to come into contact with the probe tip during storage. Damage to the probe or cable may require the entire probe to be replaced. Damage due to misuse, abuse, or accidents is not covered by the warranty.

Shells[2]

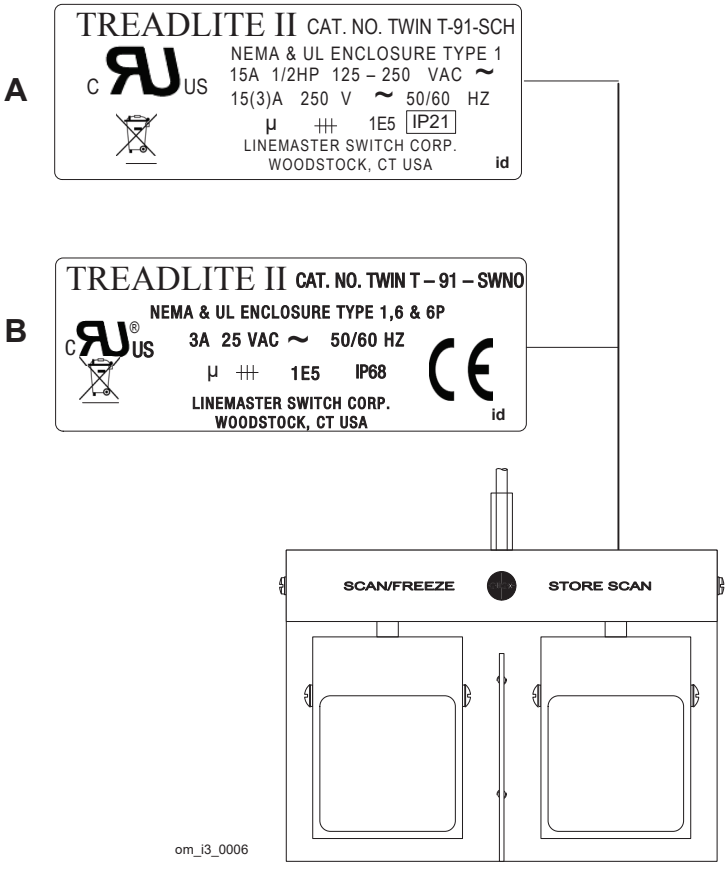
Prager Shell	Scleral Shell
The Prager Shell includes a tubing connector. Child and adult sizes are available. Prager Shells are used for biometry A scans.	Two sizes of scleral shell are available: 18 mm and 20 mm. Scleral shells are used for anterior B scans.
 om_i3_0015a	 om_i3_0015b

Footswitch

The footswitch has two pedals labelled:

- SCAN/FREEZE
- STORE SCAN.

The footswitch also includes a compliance label.



[2] Probe drawings are not to scale.

Cart

Refer to the separate assembly instructions.

Keyboard

A decal on the keyboard indicates function key assignments. Function keys provide short cuts; repeatedly pressing a function key cycles through the options for that key.

Arrow keys move selected threshold lines, calipers and the ruler.

In **Scan** the **Print Screen**[3] key acts like the Easy Print function and prints the current scan directly to the printer.

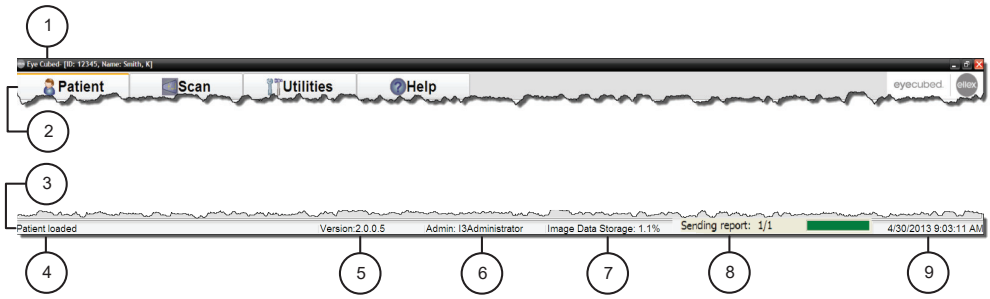
Mouse

Double-clicking the left mouse button selects and loads a record from a list. Right mouse click in the image tray to display an options menu.

Software

Interface

Common interface elements, which are located at the top and bottom of the screen, are described below.



om_i3_0002

1	Title bar Includes patient details and the Windows screen controls **Minimise**, **Maximise** and **Close**.
2	Application tabs: **Patient**, **Scan**, **Utilities** and **Help**.
3	Status bar
4	System message area
5	Software version
6	The user account type (Admin or User) and user name.
7	Storage indicator Displays the disk that has the least amount of space remaining (database and image drives only).
8	DICOM message area (messages only appear if you have licensed DICOM functionality).
9	Date and time

A red text box indicates invalid or missing information.

A blue text box indicates new data (for example when you create or edit a record).

An asterisk indicates mandatory information (for example **Patient ID***).

Many columns in the application may be sorted by clicking on the column header.

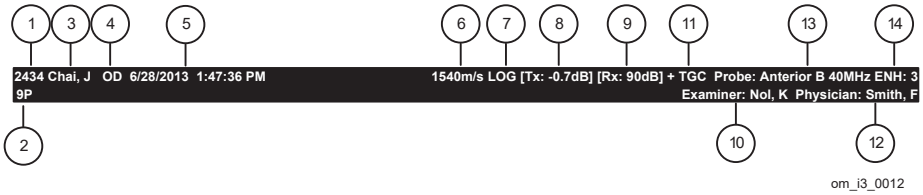
[3] This key may be abbreviated to **Print Scrn** or **Prt Sc** or similar depending on the keyboard supplied.

Do not ask again

Some functions include a Do not ask again option which allows you to temporarily turn off that prompt. If you select this option the prompt is disabled for as long as you are logged on.

Image banner

Every image and movie includes a banner that identifies the patient and scan details.



1	2434	Patient ID
2	9P	Position label or comment (if recorded)
3	Chai, J	Last Name, First Name
4	OD	Eye (OD or OS)
5	6/28/2013 1:47:36 PM	Date and time that the scan was taken
6	1540m/s	Media Velocity
7	LOG	Contrast
8	[Tx: -0.7dB]	(New Generation) Transmit Gain
9	[Rx: 90dB]	Receive Gain
10	Examiner: Nol, K	Examiner name
11	+ TGC	Indicates that Time Gain Compensation has been used
12	Physician: Smith F	Physician name
13	Probe: Anterior B 40MHz	Probe
14	ENH:3	Enhance setting

Selecting records

Using the keyboard

You can select multiple records where a list of records is displayed.

Selecting all records

- Click once in the list of records then press Ctrl+A to select all records are selected.

Selecting individual records

- Press Ctrl and select each record that you need.

Selecting consecutive records

1. Click the first record to select it.
2. Press Shift and click on the last record in range. All records in that range are selected.

Using the mouse

You can use the mouse to select gallery images and movies.

Selecting all or consecutive items

- Click and drag a box around the images.

Selecting individual records

- Press Ctrl and click each image that you want to select.

Shortcuts

You control Eye Cubed using the keyboard, mouse and footswitch. In addition, the red and black knobs on the front of the console control some scanning functions (gain, caliper and biometry/threshold line position).

[Tab] Function	Keyboard	Mouse	Footswitch
[Scan] Posterior (10 MHz) B-Scan mode	**F1** repeatedly		Not applicable
[Scan] Anterior (40 MHz) B-Scan mode (or 20 MHz B-Scan mode)	**F2** repeatedly		Not applicable
[Scan] Diagnostic (8 MHz) A-Scan mode	**F3**		Not applicable
[Scan] Biometry (10 MHz) A-Scan mode	**F4**		Not applicable
[Scan or Patient] Create a new patient	**F5**	Not applicable	Not applicable
[Scan] Select the operative eye	**F6** (from **OD** to **OS**)	Not applicable	Not applicable
[Patient] Switch between **Search** and **Session History**	**F7**	Not applicable	Not applicable
[Patient] Switches to **Search**	**F8**	Not applicable	Not applicable
[Scan] Print report	**F9**	Not applicable	Not applicable
[Scan] Select caliper (cycle through calipers)	**F10** repeatedly	Not applicable	Not applicable
[Scan] Start or stop scanning	**F11**	Not applicable	**SCAN/FREEZE** pedal

[Tab] Function	Keyboard	Mouse	Footswitch
[Scan] Save the image	**F12**		**STORE SCAN** pedal
[All] Displays **Help**	**Shift**+**F1**	Click **Help**	Not applicable
[Utilities] Change the B-Scan contrast	**Shift**+**F2**	Click **Contrast (Live)**	Not applicable
[Scan] Reset (images restored to its original condition)	**Shift**+**F3**	Not applicable	Not applicable
[Scan] Eye type	**Shift**+**F4**	Select **Eye Type**	Not applicable
[Scan] Contact calipers (biometry A-Scan only)	**Shift**+**F5**	Select **Exam Technique**	Not applicable
[Scan] Exam Technique (biometry A and B -Scans only) – changes the calipers	**Shift**+**F6**	Select **Exam Technique**	Not applicable
[Scan] Physicians	**Shift**+**F7**	Click **Utilities** > **User Information** > **Physician**	Not applicable
[Patient] Archive	**Shift**+**F8**	Not applicable	Not applicable
[Patient and Scan] Export	**Shift**+**F9**	Not applicable	Not applicable
[Scan] Display/hide calipers[4]	**Shift**+**F10**	Not applicable	Not applicable
[Scan] Save movie	**Shift**+**F11**		**Shift**+**SCAN/FREEZE** pedal
[Patient and Scan] **Utilities**	**Shift**+**F12**, toggles through the tabs	Click **Utilities**	
[Scan] Easy Print	**Print Screen**		Not applicable
[Scan] Enhance	**Ctrl**+**E**		Not applicable

[4] In **Scan** this key combination hides or reveals image data (exam technique, eye type, measurements) and annotations.

Clinical Use

WARNING! This information is provided as a guide only and is not intended to present complete or thorough instruction. It is not meant to replace the judgement 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.

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

The information provided under the General purpose, Regulatory indications and Regulatory contraindications headings in this chapter has been cleared by the US Food and Drug Administration (FDA). This information is generally valid for other countries.

General purpose

Eye Cubed is a diagnostic ophthalmic ultrasound instrument specifically designed to be used by ophthalmologists, sonographers or trained echographers, in clinics or outpatient facilities in a hospital or surgery, for imaging and diagnosis of ocular structures and pathologies.

It is assumed that the examiner is trained in the operation of the instrument and on the medical interpretation of ultrasonic images.

The patient is unable to influence the operation of the device.

Indications

The Eye Cubed system is used for ophthalmic imaging when the following conditions are present or suspected:

- cataracts
- retinal detachments (a separation of the retina from the middle coat of the eyeball)
- orbital lesions
- tumours
- foreign bodies
- inflammation
- vascular irregularities.

Scan	Application	Operator
Biometry A- or B-Scan	Axial length measurement to determine IOL power	Cataract and refractive surgeon Paediatric ophthalmologist General ophthalmologist
Diagnostic A-Scan	Tissue characterisation to identify and differentiate tumours	Retinal specialist Ultrasonographer Oncologist Neuro-Ophthalmologist
Anterior B-Scan	Evaluation of the anterior segment Intraocular lens positioning Diagnosing tumours of the anterior segment Accommodative behaviour of IOLs Angle analysis	Glaucoma specialist Cataract and refractive surgeon Oncologist Ultrasonographer
Posterior B-Scan	Retinal detachment evaluation Evaluation of vitreous haemorrhage Determine the presence of foreign bodies Determine the condition of the globe and orbit after trauma Diagnosing tumours Evaluate optic nerve, extra-ocular muscles and orbit	Retinal specialist Ultrasonographer General ophthalmologist Paediatric ophthalmologist Oncologist Neuro-Ophthalmologist

Contraindications

Contraindications in the use of the Eye Cubed system include the presence of air in the eye (ultrasound technology does not present images from a gas filled eye).

There are no health related precautions or contraindications to ophthalmic ultrasound.

Operational indications and contraindications

Refer to the Warnings and Operation chapters for operational indications and contraindications.

Further reading

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

Background and safe use

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Common Tasks

The tasks listed in this chapter cover those that you perform frequently or that are common to all types of examinations.

General

Turning the device on and off

Turning the device on

1 Ensure that all cables are connected (to both the console and the isolation transformer).

2 Ensure that mains power to the transformer is turned on.

3 Turn on the transformer.

4 Turn on the monitor.

5 Turn on the rear power switch of the Eye Cubed console.

The Standby icon on the front of the console will now slowly pulse.

6 Press the **Power** button at the front of the console.

The hard disk activity icon, as well as the **Power** button, is illuminated and the Windows **Welcome** screen displays.

Turning the device off

1 Click the **Close** button in the Eye Cubed application.

2 Click **Log Off**.

3 (Windows 10) Click to reveal the logon screen, click the **Power** button at the lower right of the screen and select **Shut down**.

WARNING! Turning the device off using the hardware power buttons while the Eye Cubed software is running may result in data corruption.

Logging on and off

The Eye Cubed software is delivered with two accounts: `I3Administrator` and `i3system`. Ellex recommends that you create additional accounts for day to day and administration use.

Account name	Password (case sensitive)	Type
I3Administrator	`Eye3Admin`	Administrator Full access to all licensed Eye Cubed functions and parameters.
i3system	`i3system`	Limited user Can perform examinations but has limited access to parameters.

Logging on

1 Click the account name on the Welcome screen.

2 Type the password and click **Enter**.

Logging off

1 Click the **Close** button.

2 Click **Log Off**.

You may be automatically logged off if there is no activity on Eye Cubed for a specified duration. There may be a slight delay when logging off to ensure that and data transfers currently in progress are successfully completed.

Windows Stand By

To save power, you can place Eye Cubed in Windows Stand By or sleep mode. This is a suspended state which can be reactivated almost immediately.

WARNING! Do not turn the power off to the Eye Cubed system when it is in Windows Stand By.

Placing the device in Windows Stand By

1 Log off.

2 (Windows 10) Click the **Power** button on the lower right and click **Sleep**.

Waking the device

- Press the front **Power** button or press any key.

Auto recovery

If the system crashes while you are examining a patient, Eye Cubed recovers all saved images, movies and reports when you restart the system. Should this occur you will have the option of saving or deleting these items but note that scan comments are not saved.

Working with patient records

Adding a patient record

1 Click the **Patient** tab.

2 Click **New**.

3 Enter the patient details and click **Save**.

Patient ID is the only mandatory field.

IOL parameters are only used for biometry scans. Valid K values are shown below.

Keratometer Index Value	Minimum (mm)	Maximum (mm)
1.3360	5.61	10.18
1.3375	5.63	10.22
1.3380	5.64	10.24
1.3390	5.65	10.27

Editing a patient record

1 Click the **Patient** tab.

2 Search for the patient.

3 Highlight the patient record in the search results and click **Load Selected Patient** (or double-click the patient record).

4 Click **Edit**.

5 Modify the patient record and click **Save**.

Click **Cancel** if you want to discard your changes.

Editing a patient record when you know the patient ID

1 Click the **Patient** tab.

2 Type the ID into the **Patient ID*** box and press **Enter**.

Patient IDs are case insensitive. You must enter the full ID including any leading zeros if they exist.

Deleting a patient record

To delete a patient record you must be either an administrator user, or the system must be configured to allow limited users the ability to delete patient records (see **Utilities** > **General** > **Patient Settings** > **Allow Patient Deletion**).

1 Click the **Patient** tab.

2 Click **Search**.

3 Clear the **Session Search** check box.

4 Search for the patients that you want to delete.

5 Select the patients to delete.

6 Click **Delete**. The patient and their session data are deleted.

7 Click **OK**.

You can also delete a patient by loading the patient record and clicking **Delete**.

Deleting patient records automatically after archiving

- When selecting your archive options select **Delete Patient Data After Completion**. Data that has been archived will be deleted from Eye Cubed, including the patient record.

Searching for a patient

1 Click the **Patient** tab.

2 Click **Search**.

3 Enter your search criteria.

4 Select the **Session Search** check box if you want to list all sessions for each patient.

5 Select **Filter** if you wish to restrict your results to only those patient records that were last modified by the current Eye Cubed user.

6 Click **Search**.

Searches on text based fields (including the patient ID) will find the search term anywhere within that field.

Sessions

A session contains the images, movies and reports created during the patient examination. When you click **Begin Session** a session is created on Eye Cubed. This session is only retained if you save at least one capture before clicking **End Session**.

Select the **Session Search** check box (on the **Search** tab) to list all examination sessions for each patient. Clear the **Session Search** check box and patients only appear once in the list (session details are hidden).

Starting a new session

1 Click the **Patient** tab.

2 Load the patient record.

You can locate and then load a patient record by searching for it in Eye Cubed. Loading a patient record forces **New Session** tab to display.

3 Select an **Examiner** and **Physician**, or use the defaults.

4 (Optional) Enter **Suspected Diagnosis** and **Session Notes**.

A prompt will appear at the end of each session that lets edit or add to your session notes.

5 (Optional, DICOM) If required enter an **Accession Number** if the Modality Worklist Service Class Provider (SCP) doesn't supply a value.

6 Click **Begin Session**.

The **Scan** tab displays and you can begin scanning.

Ending a session

1 Click **End Session** to end the current examination session.

2 Click Yes to confirm that you wish to end the session.

Other prompts may appear confirming additional actions or requesting confirmation (for example to export data). The appearance and sequence of these prompts depends upon how Eye Cubed has been configured, what licences you have, and the archive/export choices made during the exam.

Description	Notes
Confirmation that you wish to end the session	Click **Do not ask again** to bypass this prompt (this applies until you log off). Click **No** to continue the examination session.
Enter **Session Notes**	Click **Do not ask again** to bypass this prompt (this applies until you log off). Only appears if you have saved an image or movie.
Send via DICOM	Send using the default destinations or manually select the storage entities (Station AEs). This feature is only available if you have an Eye Cubed DICOM licence. You may close this screen even while items are being sent: the transfer status appears at the bottom of the screen in the DICOM message area (adjacent the date and time) (refer to Interface on page 21). If you see a DICOM error message you can manually resend the item (refer to Resending via DICOM on page 47).
Prompt to export items	Only appears if you have placed something in the **Export** tab.
Prompt to remove unreported items	Only appears if there are items in the **Report** image tray tab which were not used.
Prompt to delete un-archived items in the **Recycle Bin**	Only appears if there are items in the Eye Cubed **Recycle Bin**.
Session data is then saved to the database	Shown as a progress bar.
Auto-archive session items progress dialog	Shown as a progress bar. **Utilities** > **Archive/Export** > **Automatically Archive Session at End of Session**
Export dialog	This option only appears if there is something in the **Export** bin and you clicked **Yes** to step 3 above. Confirm the action or click **Cancel** to continue. **Utilities** > **Archive/Export** > **Export Default Settings**.
Session is closed	The **Patient** tab displays.

Viewing details of previous sessions

1 Click the Patient tab.

2 Select the Session Search check box.

3 Click Search.

4 Search for the patient.

5 Click the session once to select it.

6 Click View Session Details to see a summary of that session.

You can also:

- click Transfer using DICOM to resend this information (select multiple patient sessions to transfer them using DICOM in a batch)
- right-click the session itself to display the session information
- right-click (or click View Session Details) the session in Session History.

Opening previous sessions

1 Click the **Patient** tab.

2 Click **Search**.

3 Search for a patient.

4 Double-click the patient.

5 Click **Session History**.

6 Double-click the session.

You can now review the material captured during that session. While you cannot save anything in previous sessions, you can export data.

If you see an **Invalid Scan** message it may mean that the scan is incompatible with your system because the scan came from a newer version of the software that contains un-supported features.

Deleting a previous session

You must be either an administrator user, or the system must be configured to allow limited users the ability to delete (see **Utilities** > **General** > **Patient Settings** > **Allow Patient Deletion**).

1 Click the **Patient** tab.

2 Select the **Session Search** check box.

3 Search for the sessions.

4 Select the sessions that you want to delete.

5 Click **Delete**.

6 Click **OK**.

The selected sessions are deleted.

Measuring scans

Measurements may taken to identify the size of lesions and track their growth. All caliper and measurement settings can be reset by pressing **Shift**+**F3**.

For B-Scan images the probe marker corresponds to the:

- top of the screen for posterior B-Scans
- left of the screen for anterior B-Scans.

For Biometry A and B scans refer to Measuring biometry scans on page 38.

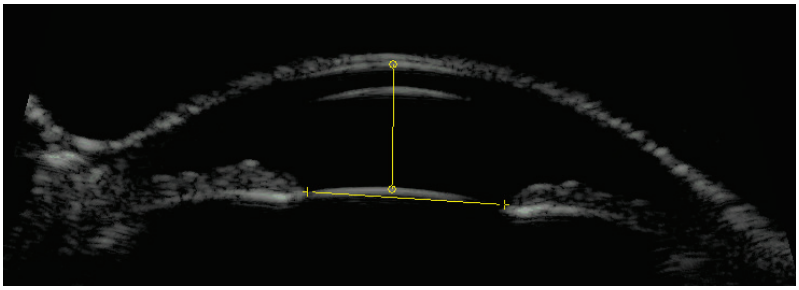
Measurements appear at the top left of the image.

Measuring distances

Use the calipers to measure straight lines. The illustration below show two calipers placed on an anterior B-Scan.

1 Click **Calipers**.

2 Click once in the image to define the beginning of the caliper, move the pointer and click again to define the end of the caliper. The measurement appears at the top left of the image.



om_i3_0017

Measuring angles

Use the angle annotation to measure angles.

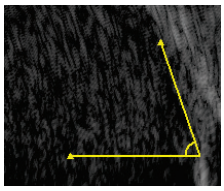
1 Click **Angle**.

2 Click once in the image to define the beginning of the angle.

3 Move the pointer and click again to define the vertex.

4 Move the pointer and click a third time to define the end of the angle.

The measurement appears at the top left of the image.



om_i3_0032

Ruler

Use the ruler on Diagnostic A-Scan, Anterior B –Scan and Posterior B-Scan images where the vector A-Scan displays.

Use the ruler to measure the size of an elevated lesion. You do this by placing two lines — each with its own caliper — on an image, and then moving the calipers so they detect the edges of rising or falling echoes. Measurement is in millimetres to two decimal positions.

Using the ruler to measure the height of a lesion

1 If measuring the A-Scan image generated from the cross-vector on a B-Scan image (B+Cross Vector):

- Press **F2** to switch to Cross Vector A mode.
- A vertical moveable red line displays and an A-Scan, representing the segment of the scan that the red line pass through, appears at the bottom of the image.
- Centre the lesion on the monitor.
- Position the cross-vector line through the highest point of the lesion using the front knob with the black cap, or by clicking the right mouse button.

- Press **F2** to select Cross-Vector A.

2 Click **Ruler** (while scanning or on a frozen scan).

The legend `Valid Edges: - -` appears at the top left of the image, and two superimposed yellow ruler lines appear in the centre of the image. The legend to `Distance:` and a value when each caliper detects an edge.

3 Press Tab or F10 to select the first ruler line.

The Tab key toggles between the two yellow lines, and Shift+Tab removes the focus from the rulers.

4 Move the selected ruler line by:

- rotating the black knob on the front of the console, or
- pressing the up and down arrow keys on the keyboard, or
- dragging the threshold line using the pointer.

5 Move the calipers by:

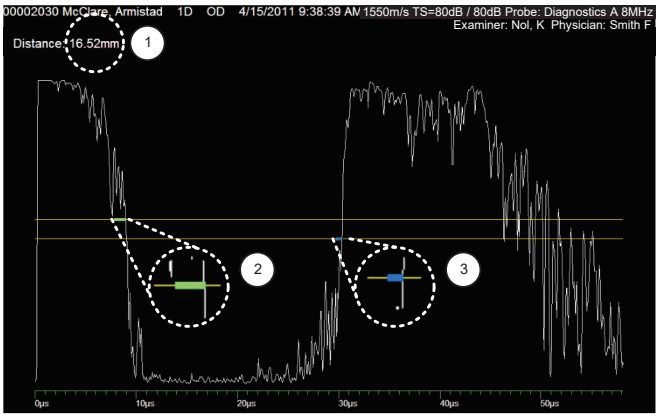
- rotating the red knob on the front of the console, or
- pressing the left and right arrow keys on the keyboard, or
- dragging the caliper with the pointer.

Measurements are taken from the right edge of the caliper. Colour indicates caliper status:

- White: not selected, no edge is detected.
- Blue: selected (edge may or may not be detected).
- Green: not selected, an edge is detected.

Distance is calculated when both calipers detect an edge.

6 Click Ruler to turn this function off.



om_i3_0007

1	Legend showing the distance.
2	(Magnified) Caliper is green (edge detected).
3	(Magnified) Caliper is blue (selected) however, it has detected an edge and a distance has been calculated.

Percent threshold

Use percent threshold to measure the internal reflectivity of an elevated lesion.

Raise or lower the threshold line to measure the height of the internal echoes within a tumour. The heights of the echoes that are between the front and back of an elevated lesion (the internal reflectivity) indicate the following tissue characteristics:

- Low internal reflectivity generally indicates a malignant lesion.
- Medium to high internal reflectivity generally indicates a metastatic lesion.
- High internal reflectivity generally indicates a benign lesion.

The percent threshold line may also be useful in characterisation of retinal detachment versus vitreous detachment.

Using percent threshold to measure the reflectivity of a lesion

1 Click **Percent Threshold** (while scanning or on a frozen scan).

The legend `Threshold: 50%` displays at the top left of the image and the yellow percent threshold line is presented in the centre of the scan.

2 Press **Tab** to select the threshold line.

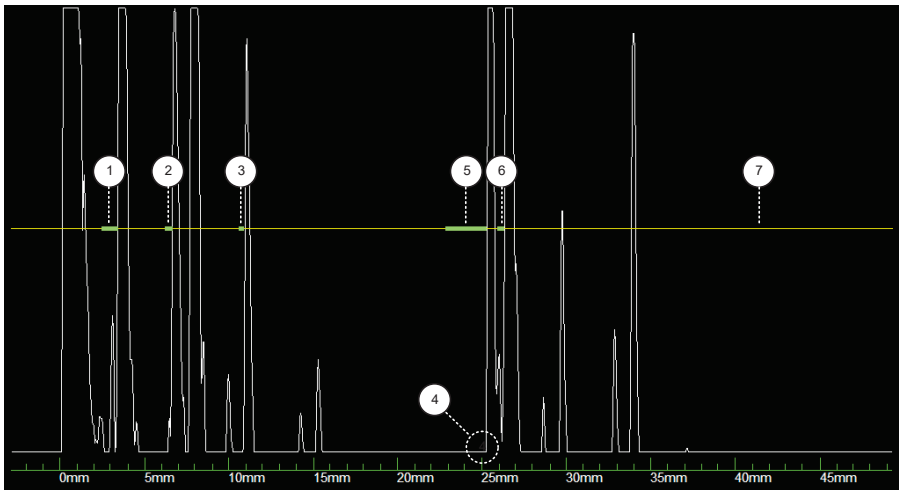
3 Move the threshold line up or down to measure the reflectivity of the echoes from the lesion. To move the threshold line:

- rotate the black knob on the front of the console
- press the up and down arrow keys on the keyboard
- drag the threshold line using the pointer.

4 Click **Percent Threshold** to turn this function off.

om_i3_0014

Measuring biometry scans



om_i3_0013

1	Corneal caliper (C)
2	Anterior lens caliper (A)
3	Posterior lens caliper (P)
4	Well shaped retinal echo (+)
5	Retinal caliper (R)
6	Scleral caliper (S)
6	Threshold line

Measurements display automatically in the top left of the biometry image.

A yellow threshold line with cornea and retina calipers (white or green blocks on the line) appears on the scan. Other calipers (anterior and posterior lens and sclera) may display depending on selected eye type).

Examiners may prefer to measure the patient's right eye (OD) and then the left (OS), or to measure the non-operative eye first to obtain a reference measurement for comparison with the operative eye. The difference between axial lengths between eyes should not be more than 0.3 mm. If there is a greater discrepancy measure both eyes again, and review the patient's visual history. If necessary have another examiner verify measurements. A B-Scan is recommended to check for pathologies (such as staphyloma in long eyes, detached retina, macular edema, and tumour) that might produce a false reading.

Calculations are not provided for movies.

Ellex recommends that several scans per eye be performed to verify measurements. The difference between measurements on the same eye should be between 0.05 and 0.10 mm. A difference of 0.1 mm amounts to an IOL power difference of 0.25 dioptres. Usually a group of valid scan patterns are reproducible to within a few hundredths of a millimetre.

Measurements are taken from the right edge of each caliper (these are automatically positioned by the software on a rising edge of the echo pattern). The combination of a fixed left edge and an automatically positioned right edge means that the calipers vary in width. Calipers change from white to green when an edge is detected. Blue indicates a selected caliper.

WARNING! Visually confirm that the calipers are placed on the correct echoes. Failure to confirm this may lead to axial length errors of 3.0 mm or greater.

Moving calipers

In most cases the calipers do not need to be adjusted however, it may be necessary to move the calipers to measure eyes:

- that are shorter than 20.0 mm or longer than 35.0 mm
- if the posterior lens caliper attaches to an echo in the vitreous.

In these situations only the caliper furthest to the right needs to be repositioned.

Moving a caliper

1 Press **F10** or **Tab** repeatedly to select the caliper. You can also select a tab with the pointer.

2 Move the caliper or threshold line.

To move a caliper left or right use the:

- left and right keys
- front knob with the red cap
- pointer.

To move the threshold line use the:

- up and down keys
- front knob with the black cap
- pointer.

If you manually adjust the calipers the term `(Adjusted)` appears in the legend on the scan.

Creating reports

You can only create a report during an examination session, with images taken from the **Current Session** or historical session tabs.

Common report tasks

Making an unsaved report anonymous

1 Click **Utilities** > **Reports**.

2 Under **Privacy Settings**, clear the **Enable Use of Patient's ID in Report** check box.

Reports saved from this point will be anonymous.

Changing the report header

1 Click **Utilities** > **Reports**.

2 Under **Report Default Settings**, modify the **Report Title** and **Report Subtitle**.

Reports saved from this point will include the new header.

Adding a logo to all reports

Only GIF, JPG, JPEG or PNG files can be used and the image will be scaled to fit the report.

1 Rename your logo file to `reportlogo` (for example `reportlogo.gif`). Do not change the file extension.

2 Copy the logo file to `E:\EyeCubedApplicationData\`.

3 Reports created from this point will include the logo.

Removing a logo

1 Delete the `reportlogo` file located in `E:\EyeCubedApplicationData\`.

2 Reports created from this point will not include the logo.

Deleting a report

1 If this is a report that you just created but have not saved:

- (Standard Report) Click **Clear All** or **New**.
- (IOL Report) Click **Start Over**.

2 Click **Current Session**.

3 Select the report from the **Session Reports** gallery.

4 Click **Delete**.

Reports cannot be deleted once you have ended the session unless you are deleting the session itself or the patient record.

Creating a standard report

A standard report can contain up to 10 pages of images and comments.

Pages cannot be reordered and new pages are always appended to the end of the report.

Any blank pages at the end of a report are automatically deleted when the report is saved.

Creating a standard report

1 Select images from the **OD (Right)** and **OS (Left)** galleries and click **Add to Report**.

You can also add images from older sessions.

2 Click **Reports** (top of screen) or **Report** in the image tray.

3 Click **Standard Report**.

4 Select one of the seven report templates.

You can change the template at any time when creating a report however, you will lose all images and comments that you have added. The template cannot be changed once you have saved a report. A template applies to all report pages.

5 Add images by:

- dragging a single image to a blank image box or over the top of an existing image, or
- selecting one or more images from the same eye and clicking **Build Report**, or
- clicking **Build Report** without selecting any images to add all images for both eyes to the report.

If multiple images are being added to the report at the same time, they are sorted by date and time with the earliest scans first.

Build Report automatically adds up to 10 pages to the report using the default template (see **Utilities** > **Reports** > **Default Template**). A message will display if you do not have enough room in the report for all your images.

You cannot reposition images within the report: you must always take them from the image tray.

You can add a movie to a report but only the last frame will be printed.

6 To save the report click **Save**.

The report is then saved under the **Current Session** image tray tab in the **Session Reports** gallery.

Once a report is saved it cannot be changed.

7 To print the report click **Print** or press **F9**.

When printing a PDF report that includes images or other graphics always ensure that you select the highest quality image output.

Removing an image from the report

1 Click the image in the report.

2 Click **Clear** button (located under **Scan Image**).

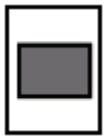
Adding or editing comments

1 Click the image.

2 Type your comments into **Comments for Image** and click the **Save** button below this field.

Eye Cubed automatically saves a new comment if you forget to click **Save**. Eye Cubed also prompts you to save a comment if you edit and it and forget to click **Save**.

Comments are limited to the number of characters that can be printed. A character count shows you how many characters you have left.

Template	Description (Number of images + number of comment boxes per page)
	1+1
	2+2
 	3+3 and 4+4
	4+1
 	5+5 and 6+6

Deleting a comment

1 Click the comment in the **Report Preview**.

2 Click in the comments area under **Comments for Image** and press the space bar.

3 Click **Clear** and then click **Save**.

Creating an IOL report

IOL reports are only created for biometry scans.

Use the **Previous** and **Next** buttons to navigate the IOL Report screens. Click **Start Over** to discard your choices and start a new IOL report.

IOL calculations are only performed on measurements taken from biometry scans of the same eye type. Biometry scans are only added to an IOL report if they match the eye type already in use in the report, or if it is a new report and a group of scans is selected, only scans that match the eye type of the first selected scan are added (a message will display advising the examiner that some scans were not added).

Biometry scans (manually or automatically acquired) that meet the valid edge criteria are copied to the **IOL Report** image tray tab automatically.

Creating an IOL Report

1 Click **Reports** > **IOL Report**.

You can also click the **IOL Report** tab in the image tray.

2 Complete **Step 1- Select Eye Data**.

(Optional) Select the **Operative Eye**.

3 Click **Single Page Report** if you only want to create a one page report.

If you choose this type of report you can select no more than two lenses and only one formula.

4 Select **Calculation Inputs** for one or both eyes.

Use **Single Scan**[5] to base the calculations one scan selected from the list.

Use **Multiple Scan Average** to base calculations on an average of the listed scans.

Use **Manual Entry** to manually enter the distances for the structures of the eye (valid ranges are shown below).

ACD (mm)	0.00 to 7.00
Lens (mm)	00.00 to 30.00
Vit (mm)	00.00 to 50.00
Offset	(Pseudophakic eyes only) The pseudophakic offset value.
AXL (mm)	10.00 to 60.00 Calculations using the Haigis formula will only be performed using this value if an Aphakic eye type is selected.

Use **AXL Only** to manually enter the axial length.

5 (**Manual Entry**, **AXL Only**, **Single Scan**) Select the **Eye Type**.

6 (**Single Scan**) Select which scan to use for the calculations (**Show In Report**).

You may remove scans from the report, or select one image as a single scan and discard the rest. (There is no undo function for **Select as Single Scan**. To reload these measurements you will need to select the biometry image/s and add click **Add to Report**.)

Closest Match indicates the scan closest to the **Average**. If multiple scans match the **Average**, then the **Closest Match** will be determined by **ACD**, then **LENS** and finally **VIT**.

[5] **Utilities** > **Reports** > **Calculation Settings** > **Default IOL Input Style** determines if **Single Scan** or **Multiple Scan Average** can be selected.

Adding new scans automatically refreshes the list.

Double-click a list entry for a full screen image of that scan.

7 Click **Next**.

8 **Step 2 – Select Lenses.** Select the physician and lenses.

If you are creating a single page report you will only be able to select up to two lenses.

9 **Step 3 – Select Formulae**.

Select the **Rounding** and **Formulae** to use. The Haigis formula will only appear if it is licensed on this system. If you are creating a single page report you will only be able to select one formula.

10 **Step 4 – Patient K Values and Target Rx**.

Enter the IOL parameters (K1, K2 if they do not exist on the patient record, and **Target Rx**).

Target Rx represents the target refraction, from −20 to 21 dioptres.

11 Click **Next**.

A report is generated which you can save, print, preview or discard.

Always check the report for errors and warnings. Warnings may include messages for unusually short or long eyes, eyes with unusual K-readings, and where both eyes are measured, for unusually large variations between the two eyes. If any warnings appear, review the images to be certain that calipers are correctly positioned. Ensure that the K readings are valid for unusually long or short eyes.

The following Haigis formula specific warnings exist.

Valid ONLY for lens exchange with identical model implanted lens	Always present when the Haigis formula is used.
Error : Invalid attempt to use Haigis pseudophakic formula with multiple lenses	The Haigis formula is for “IOL Exchange” so calculations for more than one lens model are invalid. The only valid calculation result is for the lens that is already implanted in the patient and being ‘exchanged’ (removed and replaced with the correct one).

Click **Start Over** if you wish to return to Step 1 but note that any **Manual Entry** data will be deleted and scan images that were removed earlier will not be restored.

Archiving or exporting data

Archiving refers to saving patient and image data to files for data exchange between Eye Cubed devices or for backup purposes. These files are in an Ellex proprietary format and can only be accessed by Eye Cubed devices starting from console serial number V409-00110. In addition, items exported from earlier versions of the software (for example the very first release that was version 1.0, which was installed on consoles starting from serial number V409-00110) will be successfully imported on more recent Eye Cubed software versions (this is forward compatibility). However, because of continuous product improvements, in some cases items created on more recent software versions will not import, display correctly or display at all in earlier software releases. In such cases Ellex recommends that you upgrade the older software.

Exporting means saving data from Eye Cubed into formats that can be used by other software applications. Images can be saved as BMP, JPEG, TIFF or PNG; movies can be saved as AVI or WMV, and reports are saved as both a single JPEG and a PDF file.

Manually archiving or exporting data

1 Click the **Patient** tab.

You can also archive and export data from the **Session History** tab.

2 Select the patients or sessions to archive or export.

Note that the **Session Search** check box determines whether patients or sessions are listed in the **Search Results**.

3 Click the **Archive/Export** button at the bottom of the screen.

4 Click **OK** to proceed.

5 Select your archive or export options.

6 Click **OK**.

(Administrator only) If you are copying data to CD or DVD (where such a drive exists) you may be prompted to insert additional disks if the data spans more than one disk.

7 Click **Close** when the process is finished.

Manually exporting or archiving records during an examination

1 Select the items that you wish export and click **Add to Export**.

2 Click **End Session**.

The session ends as normal however, as items have been added to the **Export** image tray tab you are prompted to export them.

3 Click **Yes.**

4 Select your export options.

5 Click **OK**.

Only administrators may copy data to CD or DVD (where such a drive exists). Note that you may be prompted to insert additional disks if your data spans more than one disk.

You do not need to end the session to export these records: click **Export** and then click **Export All**.

Automatically archiving session data at the end of an examination

1 Logon as an administrator user.

2 Click **Utilities** > **Archive/Export**.

3 Under **General Archive Settings** select the **Automatically Archive Session at End of Session** check box.

4 Specify an **Automatic Session Archive Location**.

When this feature is turned on, a directory containing the session archive files is created at the end of each session. The directory name format is `YYYYMMDD-XXX` where `XXX` is a running three digit number starting from `001`; the rest of the file name records the session year, month and day.

Automatically exporting session data at the end of an examination

1 Logon as an administrator user.

2 Click **Utilities** > **Archive/Export**.

3 Under **Export Default Settings** select the **Automatically Export Session at End of Session** check box.

4 Specify an **Automatic Export Session Location**.

5 Specify the **Name Format**, **Image File Format**, **Image Resolution**, **Movie File Format** and **Movie Resolution** as required.

DICOM

Eye Cubed support for DICOM (Digital Imaging and Communications in Medicine) is a licensed feature that you must configure before use (refer to Configuring DICOM on page 81).

If you have a licence for DICOM and have configured Eye Cubed you may still create patient records and perform examinations locally (not using the worklist) and, when ending the examination session, you will have the option of sending (copying) the data to DICOM storage entities.

Note that the imaging and reports created using Eye Cubed remain stored on Eye Cubed: data is only copied using DICOM to storage devices and the data is not deleted from Eye Cubed unless you explicitly delete at a later time through the Eye Cubed application.

Overview

As an example, a typical Eye Cubed workflow using DICOM may follow this sequence:

1. The Patient will present to the Eye Cubed Operator.
2. The Operator will search/refresh today's worklist items (today's schedule) for a worklist item for this Patient. If they don't find one they may create a Patient record in Eye Cubed (or use an existing record if it exists).
3. The Operator will load that worklist item (or Patient record) for that Patient into Eye Cubed and begin a new Eye Cubed examination session.
4. When ending the examination session the Operator will be automatically prompted to send information via DICOM to default or manually defined destinations.
5. The Operator may then examine the next Patient.

Using the worklist

Worklist items are retrieved from your electronic medical records (EMR) system by Eye Cubed. You may restrict this list using search criteria including a range of dates, or by scheduled station name (for example you can show the worklist for another Eye Cubed station if you have two or more Eye Cubed devices operating simultaneously in your DICOM environment).

Refreshing the worklist

You may refresh the worklist at any time.

1. Click **Patient** > **Worklist**.
2. Click the **Search/Refresh** button to retrieve items for today's schedule.

Loading a worklist item

1. Click **Patient** > **Worklist**.
2. Double-click a work item to load it, or click to select a work item and then click **Load Selected Work Item**.

   The Eye Cubed patient record will be loaded if all the incoming worklist patient data matches the data in an existing Eye Cubed patient record.

   A new patient record will be created and loaded if the incoming patient worklist data do not exist in Eye Cubed or if there is a mismatch between the worklist data and the Eye Cubed patient record on one (or more) of these fields: **Patient ID**, **First Name** or **Last Name**.

A message will appear if the incoming worklist patient data matches the Eye Cubed patient record on patient ID, first and last name, but do not match on one or more of the following fields: **Middle Name**, **Date of Birth**, **Gender** or **Comments**. In this case click **OK** to update the Eye Cubed database with the incoming worklist data and load the record, or click **Cancel** to load the record without updating it with the worklist data.

3 Complete the fields on the **New Session** tab and click **Begin Session**.

If you discover prior to clicking **Begin Session** that you mistakenly loaded the wrong worklist item, click **Worklist** and then select and load the correct worklist item.

Searching the worklist

1 Click **Patient** > **Worklist**.

2 Click the **Search** option button.

This button is located immediately below **Today's Schedule**.

3 Enter the search criteria for one or more fields.

If searching by **Scheduled Station** the name must match the unique station Application Entity title of that device.

4 Click the **Search/Refresh** button.

Viewing work item details

1 Click **Patient** > **Worklist**.

2 Select a worklist item.

3 Click **View Details** (or right click the worklist item).

The full details for the worklist item are displayed. Note that you may also load the work item from this screen by clicking **Load Work Item**.

Sending via DICOM

Each time you end an Eye Cubed session you are prompted to manually select the destination station AEs or use the defaults.

To use the defaults click **Send all session items to default destination Station AE** and click **Send**.

To manually select the application entities click **Manually select destination Station AEs** and then tick the **Send To** box next to the required entities and click **Send**.

Click **Close** to if you do not wish to send data via DICOM or if you clicked **Send** and want to close the dialog and begin the next examination (the transfer will continue in the background and any DICOM messages will display in the DICOM message area at the bottom of the screen next to the date and time).

Select **Do not show again** to hide this dialog and automatically send the items to the default station AE.

Resending via DICOM

If items are not successfully transferred via DICOM and you have the **Send via DICOM** screen open, you can click **Send** to resend the transfer.

If you closed the **Send via DICOM** screen and later notice an error message in the DICOM message area (at the bottom of the screen next to the date and time) you can also resend the item.

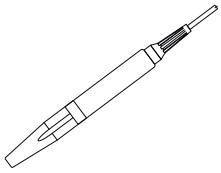
Resending via DICOM

1. Find and load the patient record.
2. Select the session from the list and click **View Session Details**.
3. Click **Transfer using DICOM**.
4. At the **Send via DICOM** dialog select the destinations and click **Send**.

Troubleshooting

Refer to Troubleshooting DICOM on page 83 if you encounter problems using DICOM.

Biometry (10 MHz) A-Scans



Biometry (10 MHz) A-Scans measure length of the eye along the visual axis. This measurement is used with data about the curvature of the cornea (the Keratometry readings: K1 and K2) to calculate intraocular lens power. The biometry A-Scan probe has an internal fixation light which can be turned on or off (refer to Utilities > Scans > Fixation Light).

The immersion method is recommended because it is less intrusive to the patient, fast, accurate and repeatable.

The contact method is less reliable because it is possible to produce either a falsely short measurement by compressing the cornea, or a falsely long measurement by allowing a fluid bridge to occur between the cornea and probe tip. False measurements can result in the wrong IOL being prescribed.

Both the immersion and contact methods are described in this chapter.

To avoid accidental spillage Ellex recommends the use of low volume squeeze dispensers to store liquids in the Eye Cubed operating environment.

Examination workflow (immersion method)

Preparing the probe and device (immersion method)

1 Disinfect the probe (refer to Cleaning and disinfecting probes on page 92).

2 Disinfect the Prager Shell and tubing.

3 Insert the probe tip into the straight (not flanged) end of the shell and slightly twist the probe to secure it to the shell.

4 Attach a bottle or syringe of saline solution to the tubing. If you need to replace the tubing:

- Cut the plastic tubing with a blade along the metal port and remove the old tubing.
- Cut the needle off a butterfly infusion set (scalp vein infusion set).
- Using a haemostat or forceps, stretch the hole in the newly cut end of the tubing and place onto the metal port.

5 Load the patient record

You may add the K1 and K2 values by editing the patient record now, or add them in Step 4 of the IOL report (at which time they will be saved to the patient record).

6 Select an **Examiner** and **Physician** or use the defaults.

7 (Optional) Select a **Suspected Diagnosis** and create **Session Notes**.

8 Click **Begin Session**.

9 Press **F6** to select the eye to be scanned.

10 Press **F4** repeatedly to select Biometry A Manual or Auto mode.

Manual mode is recommended for the immersion method. In Auto mode (**Auto-Acquisition Mode**), Eye Cubed automatically saves up to five images that match the indicated valid edges.

11 Select **Exam Technique**, **Tolerance** and **Eye Type**. **Shift**+**F6** toggles through the available immersion techniques.

Preparing the patient

1 Place the patient in the supine position or for patients in wheelchairs, tilt their head back 45 degrees.

2 Anesthetise the cornea with topical eye drops.

3 Place the bottle of saline solution that is connected to the Prager Shell on the patient's chest or shoulder.

4 Place the shell (with probe already inserted) on the sclera. There are two placement methods:

- With the patient fixating in primary gaze, straddle the cornea and gently place the shell on the sclera.
- With the patient looking up, place the shell edge in the inferior fornix, holding the eyelid against the orbital bone with the shell and holding the upper edge of the shell at such an angle that the cornea is not abraded when the patient looks down. Then hold the upper eyelid and have the patient look down, inserting the upper edge of the shell against the superior sclera beneath the upper eyelid.

5 With the patient fixating in primary gaze, align the probe with the visual axis of the eye.

Observe the alignment of the fellow eye as this can help determine the visual axis.

6 Place a tissue at the lateral canthus to capture spilt solution. Do not allow hearing aids to become wet.

Scanning the eye

1 Press F11 or the SCAN/FREEZE pedal to start scanning.

2 Ask the patient to fixate on the red light or to a target in primary gaze.

3 Gently squeeze the bottle of saline until you see an echo pattern on the monitor.

4 Press F11 or the SCAN/FREEZE pedal to stop scanning. F11 also interrupts the auto-acquisition scanning sequence.

5 (Optional) Use the image adjustments tools to enhance the gain.

6 Review scan measurements (refer to Measuring biometry scans on page 38).

7 (Optional, Manual mode) Press F12 or the STORE SCAN pedal to save the image.

Any auto or manually saved image that meets the valid edges criteria is automatically placed in the IOL Report image tray tab.

Press Shift+F11 or Shift+SCAN/FREEZE pedal to save the movie.

Press Print Screen on the keyboard or click the Easy Print icon to print the scan.

8 Press F11 or the SCAN/FREEZE pedal to resume scanning.

Ellex recommends that multiple scans are performed to verify results. Ideally, the difference between measurements on the same eye should be ≤ 0.10 mm.

Once the appropriate scans are obtained, hold position for a few seconds to populate a movie then save the movie. This means that you have many good scans from which to choose the best ones.

9 To scan the fellow eye, press F6 to change eyes and then press F11 or the SCAN/FREEZE pedal to start scanning.

Ellex recommends always measuring both eyes for maximum accuracy.

Completing the examination

1 Remove the shell and probe from the patient's eye and blot away any excess solution from the patient's eye with a tissue.

2 Delete any unnecessary scans from the Current Session image tray tab.

3 Clean the probe tip with a tissue, thoroughly wipe the tip with an alcohol swab and wipe dry.

4 Place the probe in the probe holder.

5 Create a report.

6 Click End Session to close the session.

7 (Optional) Complete your session notes when prompted.

Examination workflow (contact method)

Preparing the probe

The probe is handheld with the patient in supine position. Alternatively, the probe may be mounted in a spring loaded transducer holder or Goldmann type tonometer holder.

Preparing the device and patient

1 Load the patient record.

2 Select the **Examiner** and **Physician** or use the defaults.

You may add the K1 and K2 values by editing the patient record now, or add them in Step 4 of the IOL report (and they will be saved to the patient record).

3 (Optional) Select a **Suspected Diagnosis** and create **Session Notes**.

4 Click **Begin Session**.

5 Press **F6** to select the eye to be scanned.

6 Press **F4** repeatedly to select Biometry A Manual or Auto mode.

Auto-acquisition is recommended for the contact method. In Auto mode (**Auto-Acquisition Mode**), Eye Cubed automatically saves up to five images that match the valid edges.

7 Select **Exam Technique, Tolerance** and **Eye Type**.

8 Anesthetise the cornea with topical eye drops.

9 Position the patient as follows:

- If using the transducer holder, position the patient with their forehead and chin firmly supported in the chinrest. Ensure that they are comfortably seated.
- If using the handheld method, recline the patient in an examination chair.

Scanning the eye

1 Press **F11** or the **SCAN/FREEZE** pedal to start scanning.

2 Slowly and carefully move the probe to within a short distance of the cornea, just outside of eyelash range. This enables the patient to blink freely while the probe is aligned.

3 Align the probe so that it is perpendicular to the X, Y and Z planes.

4 Ask the patient to blink and then slowly move the joystick forward toward the open eye while the patient looks into the probe's fixation light or a target at distance.

5 When contact is made with the cornea, review the scan. Use the smallest possible movements to further adjust the probe to obtain a good echo pattern.

Since you selected **Auto-Acquisition Mode**, the device will automatically save the first five scans that match the valid edges criteria.

6 Press **F11** or the **SCAN/FREEZE** pedal to stop scanning.

F11 also interrupts auto-acquisition scanning sequence.

7 Use the image adjustments tools to enhance the image.

8 Review scan measurements (refer to Measuring biometry scans on page 38).

9 (Optional, Manual mode) Press **F12** or the **STORE SCAN** pedal to save the image.

Any auto or manually saved image that meets the valid edges criteria is automatically placed in the **IOL Report** image tray tab.

Press **SHIFT**+**F11** or **Shift**+**SCAN/FREEZE** pedal to save the movie.

Press **Print Screen** on the keyboard or click the **Easy Print** icon to print the scan.

10 Press **F11** or the **SCAN/FREEZE** pedal to resume scanning.

Ellex recommends that multiple scans are performed to verify results. Ideally, the difference between measurements on the same eye should be ≤ 0.10 mm.

11 To scan the fellow eye, press **F6** to change eyes and then press **F11** or the **SCAN/FREEZE** pedal to start scanning.

Ellex recommends always measuring both eyes for maximum accuracy.

Completing the examination

1 Delete any unnecessary scans from **Current Session** image tray tab.

2 Clean the probe tip with a tissue, thoroughly wipe the tip with an alcohol swab and wipe dry.

3 Place the probe in the probe holder.

4 Create a report.

5 Click **End Session** to close the session.

6 (Optional) Complete your session notes when prompted.

Diagnostic (8 MHz) A-Scans

Use diagnostic (8 MHz) A-Scans to help characterise ocular lesions. Use the ruler or percent threshold tool to measure these types of scans.

Examination workflow

Preparing the probe and device

1. Disinfect the probe (refer to Cleaning and disinfecting probes on page 92).
2. Load the patient record.
3. Select an **Examiner** and **Physician**, or use the default values.
4. (Optional) Select a **Suspected Diagnosis** and create **Session Notes**.
5. Click **Begin Session**.

6. Press **F6** to select the eye to be scanned.
7. Press **F3** to toggle between Diagnostic A scan modes (Eye 45mm or Orbit 70mm).

Preparing the patient

1 Place the patient in a prone or semi-prone position.

2 Anaesthetise the cornea of the operative eye.

Scanning the eye

1 Press F11 or the SCAN/FREEZE pedal to begin scanning.

2 Align the probe and gently place it on the open eye.

WARNING! Applanation is invasive. Minimise probe movement on the cornea.

3 Use the image adjustments tools to enhance the image.

4 Press F11 or the SCAN/FREEZE pedal to stop scanning.

At this point you can:

- Measure the scan (refer to Ruler on page 35, or refer to Percent threshold on page 37).
- Press F12 or the STORE SCAN pedal to save the image.
- Press Shift+F11 or Shift+SCAN/FREEZE pedal to save the movie.
- Press Print Screen on the keyboard or click the Easy Print icon to print the scan.

When saving an image or movie you can optionally record the probe position or a comment.

5 Press F11 or the SCAN/FREEZE pedal to resume scanning.

6 To scan the fellow eye, apply gel to the probe, press F6 to change eyes and then press F11 or the SCAN/FREEZE pedal to start scanning.

Completing the examination

1 Clean the probe with a tissue, thoroughly wipe the tip with an alcohol swab and wipe dry.

2 Place the probe in the probe holder.

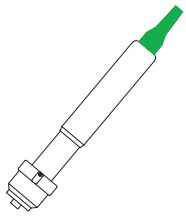
3 Further annotate the images and then add them to your report.

4 Create a report.

5 Click End Session to close the session.

6 (Optional) Complete your session notes when prompted.

Anterior (40 MHz) B-Scans



The 40 MHz Wide Field Anterior Segment Probe provides sulcus to sulcus visibility within the eye, and may be used with either a ClearScan Ultrasound Probe Cover or a scleral shell.

Refer to the documentation supplied with the ClearScan Ultrasound Probe Cover.

A small screw acts as the probe marker and remains visible even when the probe cover is attached.

Anterior segment scans are used to identify pathologies within the anterior segment of the eye (including iris and ciliary body melanomas), and in the evaluation of the angle for glaucoma.

Use calipers to measure these types of scans.

To avoid accidental spillage Ellex recommends the use of low volume squeeze dispensers to store liquids in the Eye Cubed operating environment.

Examination workflow

Preparing the device

1 Load the patient record.

2 Select an **Examiner** and **Physician** or use the defaults.

3 (Optional) Select a **Suspected Diagnosis** and add **Session Notes**.

4 Click **Begin Session**.

5 Press **F6** to select the eye to be scanned.

6 Press **F2** repeatedly to select the desired Anterior B mode (B-Scan, B+Cross Vector, Cross Vector A).

7 (Optional) Select an **Exam Protocol**.

(Scleral shell) Preparing the probe and patient

1 Disinfect the probe (refer to Cleaning and disinfecting probes on page 92).

2 Disinfect the scleral shell (refer to **Error! Reference source not found.** on page **Error! Bookmark not defined.**).

3 Place the patient in the supine position.

For patients in wheelchairs tilt their head back 45 degrees.

4 Anaesthetise the cornea.

5 Place the scleral shell on the sclera. There are two placement methods:

- With the patient fixating in primary gaze, straddle the cornea and gently place the flanged end of the shell on the sclera.
- With the patient looking up, place the flanged shell edge in the inferior fornix, holding the eyelid against the orbital bone with the shell, and holding the upper edge of the shell at such an angle that the cornea is not abraded when the patient looks down. Hold the upper eyelid and have the patient look down, inserting the upper edge of the shell against the superior sclera beneath the upper eyelid.

6 Fill the shell with artificial tears.

WARNING! This liquid should not have a high mineral content (saline or hard water) to avoid sedimentation of minerals onto the probe membrane, which could cause the membrane to harden and crack, causing oil to leak from the probe.

7 Place a tissue at the lateral canthus to catch any solution that spills.

Do not allow hearing aids to become wet.

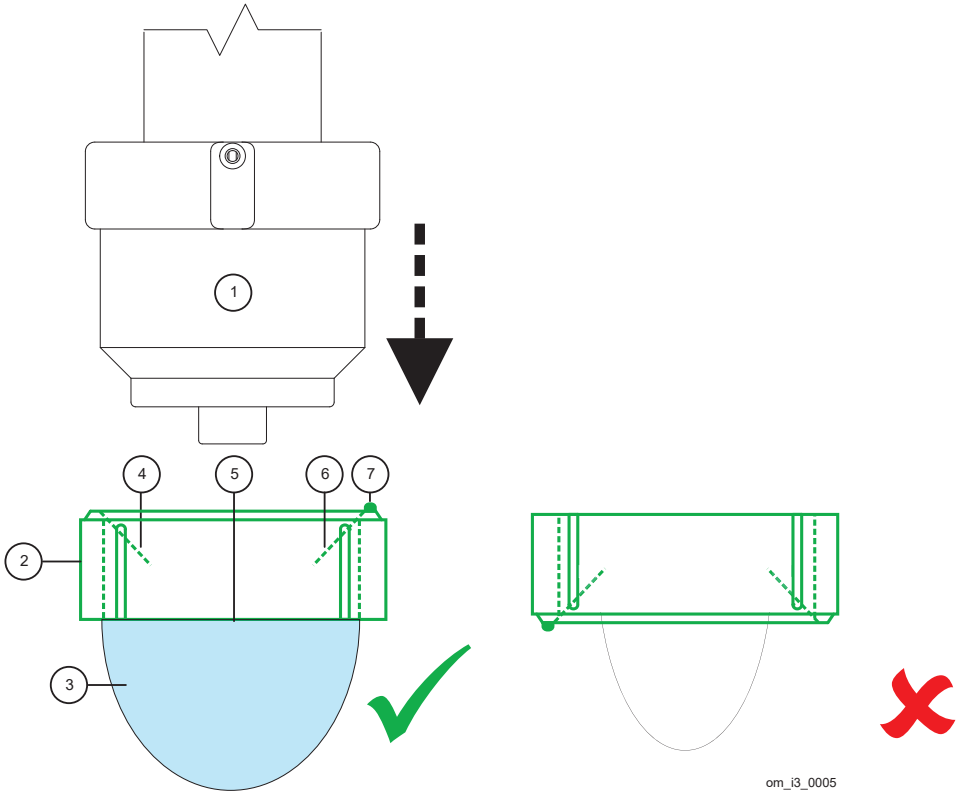
(ClearScan Ultrasound Probe Cover) Preparing the probe and patient

WARNING! The ClearScan Ultrasound Probe Cover is a single-use item. Do not reuse.

The probe does not require disinfection as patient contact only occurs on the single-use probe cover.

1 Place the patient upright in a seat or in the supine position.

2 Hold the ClearScan Ultrasound Probe Cover with the probe marker (raised post) on top.



1	40 MHz probe tip
2	Flexible collar
3	Clear membrane
4 & 6	Sealing ring
5	Liquid level
7	Probe marker (raised post)

3 Fill the probe cover with distilled water up to the flexible collar. Minimise the formation of air bubbles. To avoid spillage do not overfill.

WARNING! Do not allow liquid to spill onto the Eye Cubed console or peripheral equipment, including the footswitch.

WARNING! The liquid should not have a high mineral content (saline or hard water) to avoid sedimentation of minerals onto the probe membrane, which could cause the membrane to harden and crack causing oil to leak from the probe.

4 Slide the cover onto the probe as far as it will go while at the same flexing the collar of the probe cover to control pressure and avoid over-pressure.

The cover must easily confirm to the shape of the cornea (the pressure in the probe cover must be equal to the pressure within the eyeball).

WARNING! Do not over, or under pressurise the probe cover. If there is too much pressure the cover will not conform to the shape of the cornea and will press against it. If there is not enough pressure, the transducer will be too close to the cornea, increasing the risk of abrasion.

WARNING! If fluid is leaking from the membrane after the probe has been inserted, the membrane has been punctured. Discard and replace with a new probe cover.

WARNING! If fluid is leaking from the flexible collar after the probe has been inserted, the probe may have been inserted into the wrong side of the probe cover.

5 Align the cover probe marker (raised post) with the marker on the probe itself.

6 Anaesthetise the cornea with topical eye drops.

Scanning the eye

1 Press **F11** or the **SCAN/FREEZE** pedal to start scanning.

2 (Scleral shell) Align the probe with the visual axis while the patient is fixating in primary gaze, and insert the probe into the shell. Move the probe to the desired position.

If the probe is temporarily removed from the shell, a bubble could form in the concave transducer surface on the tip. If this occurs, images will not be seen until the bubble is removed. To remove air bubbles, gently shake the probe, irrigate the bubble away or force the bubble into the tip cavity.

WARNING! Do not move the shell once it has been placed on the eye, as you risk abrading the cornea.

3 (ClearScan Ultrasound Probe Cover) Use your thumb to push the upper eyelid upward to the brow. While holding the probe in the other hand, curl your fingers and pull downward on the cheek to maximally retract the lower lid. Using minimal downward pressure, gently touch the eye with the probe cover until the structures of the eye appear. Move the probe to the desired position.

Best focus occurs 12.5 mm from the tip of the transducer. Image may be moved into the focal zone by pressing harder or pulling back on the probe.

WARNING! Do not allow the probe tip closer than 5.0 mm to the cornea. The tip must not contact the cornea. Contact may result in corneal abrasion.

4 Use the image adjustments tools to enhance the image.

5 Press **F11** or the **SCAN/FREEZE** pedal to stop scanning.

At this point you can:

- Measure the scan using calipers or the ruler.
- Press **F12** or the **STORE SCAN** pedal to save the image[6].
- Press **Shift**+**F11** or **Shift**+**SCAN/FREEZE** pedal to save the movie.
- Press **Print Screen** on the keyboard or click the **Easy Print** icon to print the scan.

[6] Follows the standard clock hour labelling approach: click within the clock face for T (transverse) or outside the clock face for L (longitudinal) clock hours.

When saving an image or movie you can optionally record the probe position or a comment.

Alternatively, you may wish to capture all the required scans first then, after the patient has gone, perform the edits and measurements.

6 Press F11 or the SCAN/FREEZE pedal to resume scanning.

7 To scan the fellow eye, press F6 to change eyes and then press F11 or the SCAN/FREEZE pedal to start scanning.

Completing the examination

1 Remove the probe (and shell).

2 Blot away excess solution from the eye.

3 Clean the probe with a tissue.

There is no patient contact with the probe so it does not require disinfection.

4 Discard the ClearScan Ultrasound Probe Cover and gently shake water from the probe tip.

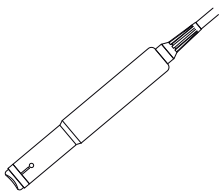
5 Place the probe in the probe holder.

6 Create a report.

7 Click End Session to close the session.

8 (Optional) Complete your session notes when prompted.

Posterior (10 MHz) B-Scans



Posterior (10 MHz) B-Scans scan at 25 frames per second and present a 52° sector image.

Use posterior (10 MHz) B-Scans to identify structures and pathologies within the globe and orbit, including detached retinas, tumours and vitreous haemorrhage.

The B-Scan image can be displayed as is or with a cross-vector A-Scan.

Posterior B-Scans can be performed against open (recommended) or closed eyes. Be aware that scanning a closed eye diminishes image resolution because the eyelid attenuates the ultrasound signal.

Examination workflow

Preparing the probe and device

1. Disinfect the probe (refer to Cleaning and disinfecting probes on page 92).
2. Load the patient record.
3. Select an **Examiner** and **Physician**, or use the default values.
4. (Optional) Enter a **Suspected Diagnosis** and **Session Notes**.
5. Click **Begin Session**.
6. Press **F6** to select the operative eye.

7 Press **F1** repeatedly to select a posterior B-Scan Scan Mode.

8 Apply gel to the probe tip.

Preparing the patient

1 (Optional) Place the patient in the supine position.

For patients in wheelchairs, tilt their head back 45 degrees.

2 If scanning an open eye (recommended) anesthetise the cornea with topical eye drops.

Scanning the eye

1 Press **F11** or the **SCAN/FREEZE** pedal to start scanning.

2 Gently place the probe tip on the eye.

WARNING! Applanation is invasive. Minimise probe movement on the cornea.

3 Use the image adjustments tools to enhance the image.

4 Press **F11** or the **SCAN/FREEZE** pedal to stop scanning.

At this point you can:

- Measure the scan using the ruler or the calipers.
- Press **F12** or the **STORE SCAN** pedal to save the image.
- Press **SHIFT**+**F11** or **Shift**+**SCAN/FREEZE** pedal to save the movie.
- Press **Print Screen** on the keyboard or click the **Easy Print** icon to print the scan.

If you are following a protocol, the system will advance to the next probe position.

5 Press **F11** or the **SCAN/FREEZE** pedal to resume scanning.

6 To scan the fellow eye, apply gel to the probe, press F6 to change eyes and then press **F11** or the **SCAN/FREEZE** pedal to start scanning.

Completing the examination

1 Blot away excess gel from the patient's eye.

2 Clean the probe with a tissue, thoroughly wipe the tip with an alcohol swab and wipe dry.

3 Place the probe in the probe holder.

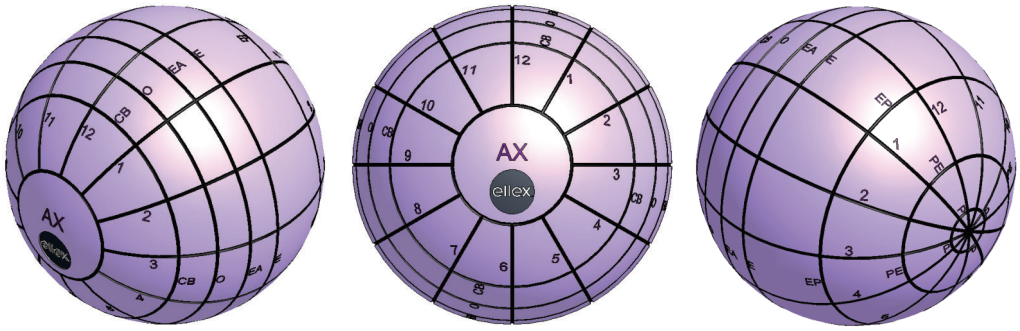
4 Create a report by adding images and comments, and then save it.

5 Click **End Session** to close the session.

6 (Optional) Complete your session notes when prompted.

Labelling posterior B-Scans

Label probe positions using a clock face analogy (hours and half hours) and anatomical locations within the eye.



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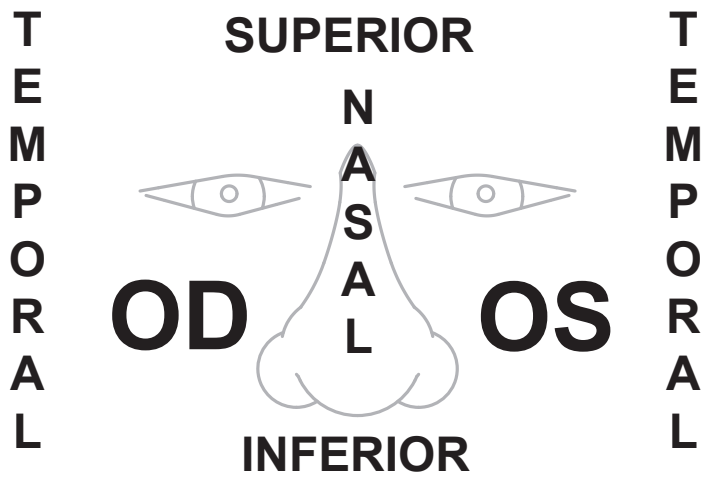
Abbreviation	Description
AX	Axial (probe on the cornea)
CB	Ciliary body
O	Ora serrata
EA	Equator towards anterior
E	Equator
EP	Equator towards posterior
PE	Posterior towards equator
P	Posterior pole

Facial positions are illustrated below for reference.



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Safety

WARNING! Using this device requires substantial knowledge of the clinical significance of ultrasound images. Ellex cannot, and makes no attempt to, instruct the customer in the interpretation of ultrasound images and echograms. The responsibility lies with the customer to study professional literature and obtain medical training. Procedures should be performed prudently using the principle of ALARA (As Low as Reasonably Achievable).

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.

Only connect Ellex supplied or approved (to IEC 60950 for example) computer peripherals to the Eye Cubed ultrasound system.

Electrical

WARNING! To ensure adequate electrical safety you must connect this device to an isolation transformer.

WARNING! The isolation transformer must be connected 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 the isolation transformer must incorporate an earth terminal and earth conductor.

To isolate the equipment from the mains supply, turn the device off as normal.

Commercial computer peripherals are not generally qualified for use in medical systems where direct patient contact is involved, and may present a higher risk of electrical shock to the patient.

To alleviate this risk and for compliance to international standard IEC 60601-1-1, computer peripherals shall not be connected directly to the mains wall outlet but connected to mains through an isolation transformer (available from Ellex).

The connection of any electrical device to the Eye Cubed ultrasound system that is not approved by Ellex must be evaluated for safety by the installing party. Ellex is not, and cannot be responsible for modifications affecting electrical safety made to the system after delivery.

Electromagnetic

This device may be affected by external radio frequency (RF) sources (for example mobile phones) in the vicinity during operation. As a precaution, ensure that all mobile phones in the treatment room are turned off and remain off while the system 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.

HIPAA compliance (US only)

The Health Insurance Portability and Accountability Act (HIPAA) final rule for security standards (CMS-0049-F) is applicable to all health plans, including small health plans as of April 20th 2006. HIPAA regulations include elements that focus on securing electronic medical records in order to ensure patient privacy. Ellex has implemented the technical measures listed below that allow our customers to maintain HIPAA compliance.

Regulation	Requirement	Implementation
164.308(a)	Log-in Monitoring	The Windows event log is capable of monitoring all user log in activity. Log in activity is also monitored by the system log file.
164.312(a)	Restrict access to authorised users only	The system log in is configured such that an authorised user name is required to access any data on the system.
164.312(a)(2)(i)	Requires a unique User name for each authorised user	New Users may be added by any administrative user, using the Windows Control Panel. User accounts are configured automatically.
164.312(a)(2)(iii)	Requires that a timed log off be used	Timed logouts are implemented.
164.312(b)	Requires auditing of information systems access	Windows Event Log service may be configured to audit account log in and other activity. The Eye Cubed software logs and timestamps all patient record and image file activity.
164.312(a)(Data)	Requires a mechanism for encryption of data	Image data is stored separately from identifying information. Fields linking the image data to the patient data are encrypted. Individual image filenames are encrypted.
164.312(c)(Data)	Requires a mechanism for authentication of data	A checksum is used to verify that image data has not been damaged or improperly modified.
164.312(e)	Requires encryption whenever appropriate for network data transmission	Depends on configuration of entire network. Security may be increased as desired through standard Windows 10 networking policies.
164.308	Must implement protection from Malicious software	Windows Firewall is enabled. Windows Defender is enabled in Windows 10. Third party antivirus programs are available.

164.308(a)(5)	Requires implementation of periodic security updates	System is up to date with latest software when shipped from the factory. Standard operating system security updates are available from Ellex.
164.308(a)(7)	Requires users to have a backup plan for creating and maintaining retrievable exact copies of EPHK (Required)	Individual patient records and/or images may be archived to external disks. The entire image database may be backed up across the network or by using the DVD writer (where such a device exists).
164.312(c)	Requires mechanisms to corroborate that EPHI has not been altered or destroyed in an unauthorised manner	All image saving operations are logged. All image frames are time stamped with an unalterable date/time value. A checksum is used to verify image file integrity.
164.514(d)	Limits access of information to the 'minimum necessary disclosure'	System is designed such that data is not readily readable without access to the system program, which is not transferable to different computers. Administrators may be denied access to the data and/or the system program to limit access if desired.
164.312(a)(ii)	Requires creation of a contingency plan that allows emergency access to information	A dedicated user account with a well-known name and password is used for this purpose.

System Administration

This chapter includes material explaining various system administrator tasks. Ellex assumes that most health care organisations will have reasonably sophisticated computer networking capabilities and resources, and in most cases will be familiar with Windows networking and administration in particular.

Administering Windows computers and networks is a complex task and is beyond the scope of this manual.

Ellex also assumes that a qualified Windows Administrator is available to connect the Eye Cubed system to a network and to administer user (domain) accounts if required.

External hard disks

You may want to add an external hard disk to Eye Cubed. Ellex recommends using external hard disks that are powered through the USB cable. Should an external hard disk be used that has a separate power supply, it must be powered through the isolation transformer.

Backups

You should follow a backup protocol and regularly backup your Eye Cubed system.

You can do this by creating a software configuration archive (see Utilities > Archive/Export > System Configuration Archive).

Backing up your Eye Cubed data

1 Click **Utilities** > **Archive/Export**.

2 Under **System Configuration Archive** click **Create**.

3 Select the output (**Optical Media (CD/DVD)** or **Filesystem Location**).

Burning a CD or DVD is only possible if such a drive is available. Depending on the file size the archive file may be split over multiple disks if optical media is used.

4 Select the type or types of data that you want to backup.

5 Select the patient data that you wish to backup.

6 Click **Start**.

You can import the archive using the **Archive Import** found under **Utilities** > **Archive/Export**.

Recovery media

Recovery media to reinstall the system is included with your system (please contact your Ellex Authorised Distributor if you cannot locate it). Contact your Authorised Ellex Distributor if you wish to reinstall your system.

Changing the time

Changing the system time

1 Logon as an administrator user.

2 Minimise Eye Cubed.

3 Windows 10 devices:

- Right-click the time display in the Windows Taskbar.
- Select Adjust date/time.
- Adjust the date or zone as required.

4 Maximise Eye Cubed.

Changing the language (locale)

Changing the language for a specific user

1 Log in as that user.

2 Minimise Eye Cubed.

3 For Windows 10, in the search box on the taskbar, type control panel, and then select **Control Panel**.

4 Click **Region** in Windows 10.

5 Select the locale under **Formats** in Windows 10.

The Eye Cubed interface supports these languages:

English	German	Chinese (Simplified and Traditional)
French	Spanish	
Polish	Japanese	

6 Click **Apply**.

7 Click **OK**.

8 Close the **Control Panel**.

9 Maximise Eye Cubed.

10 Log off and log in as that user.

Windows 7/10 and Chinese Simplified

For Windows 7 and 10 users intending to use Eye Cubed in Chinese Simplified language, please follow these instructions while logged on with an Administrator user account. Note: The following instructions apply for Chinese (Simplified, PRC) and (Chinese Simplified, Singapore) only.

1 Click **Control Panel > Region and Language.** For Windows 10, in the search box on the taskbar, type control panel, and then select **Control Panel > Region**.

2 Under **Formats** select **Chinese (Simplified, PRC)**.

3 Under **Administrative** and under **Language for non-Unicode programs** click **Change system locale** and select **Chinese (Simplified, PRC)**.

4 Click **Apply** and restart the device.

Log files

You may be asked to provide log files for troubleshooting purposes. The following log files, recording system and application events, are available:

- Windows event logs are available under **Start** > **Control Panel** > **Administrative Tools** > **Event Viewer**.
- The Eye Cubed application logs system activity to the following files located in `e:\EyeCubedApplicationData\` directory:
    - `ellexeventlog.txt`
    - `eyecubedaudit.log or COMPUTERNAME_eyecubedaudit_YYYYMMDD.log`
    - `reportdaemonlog.txt`.

DICOM log files are also accessible if required (for more information refer to Troubleshooting DICOM on page 83).

Strong passwords

You may need to use strong passwords to meet security protocols established by your organisation.

Setting strong password criteria (for local system accounts only)

1 Log on to Eye Cubed as an administrator user.

2 Minimise Eye Cubed.

3 Click **Start** > **Control Panel**.

4 Click **Administrative Tools**.

5 Double-click **Local Security Policy**.

6 Expand **Account Policies** to display the password options. Configure these as required.

Contact your network administrator if domain accounts are being used, or if you need more information or assistance.

Printers

Refer to the Eye Cubed section of the Ellex website for a list of printers qualified for use with Eye Cubed or, alternatively, contact your Authorised Ellex Distributor.

Installing a local printer (including Easy Print)

Follow the printer manufacturer's installation instructions and then follow the instructions below.

WARNING! Installing a printer changes the electrical safety profile of the system. Commercial printers are not generally qualified for use in medical systems where direct patient contact is involved, and may present a higher risk of electrical shock to the patient. Although such risk may generally be alleviated through the use of an isolation transformer, the connection of any electrical device to the Eye Cubed system that is not approved by Ellex must be evaluated for safety by the installing party. Ellex is not, and cannot be responsible for modifications affecting electrical safety that customers may make to the system after it has been delivered.

1 Log into Eye Cubed as an administrator.

2 Click **Utilities** > **Connectivity** and select the printer as the **Reports Printer** or **Easy Print Printer**.

Easy Print prints the currently displayed scan direct to the printer. A small thermal printer is often used for this purpose (printers are not supplied by Ellex).

3 Test printing from Eye Cubed to the printer.

4 Log in to all other Eye Cubed accounts to confirm that the printers are available for those accounts.

Installing a network printer

Contact your network administrator to install a network printer.

To avoid printing delays, if an account name and password is required to access a network printer, ensure that the password for the account name does not expire.

Printer installation problems

Cannot print from limited user accounts

This may occur because there is more than one printer installed, and the default printer is not set correctly for the limited user. To correct this, only one local printer should be installed, and that printer must be selected as the default.

Correctly setting the default printer for limited user accounts

1 Log on with the limited user account.

2 Minimise Eye Cubed.

3 Click **Start** > **Printers And Faxes** (or **Devices and Printers**).

4 Locate the printer you are trying to use in the list of installed printers. If it does not appear, follow the instructions in installation instructions above.

5 If the printer is not currently set as the default, right-click on the printer name, then select **Set As Default**.

6 Delete all other local printers (do not delete network printers). If this is not done, the default printer is likely to be wrong when logging in as a limited user, and there is no simple way to change the default printer for limited users.

Licensing

Eye Cubed functionality is determined by a software licence. Contact your Authorised Ellex Distributor if you wish to purchase additional functionality.

If your licence file is missing (or becomes corrupt), a licence error will appear when you log on to Eye Cubed. While Eye Cubed will still run, scanning is not possible. Contact your Authorised Ellex Distributor if this situation occurs.

Software upgrades

Eye Cubed software upgrades may be available as software downloads (accessed through the internet) or via USB drives supplied by your Authorised Ellex Distributor. Follow the instructions that accompany the software to apply the upgrade to your system.

Sharing a directory

You can share a directory on the Eye Cubed system across a network.

Avoid sharing Eye Cubed program or operating system directories.

Sharing a directory

1 Log on to Eye Cubed as an administrator.

2 Create a new directory to share. Ellex recommends that such a directory is created on the C or E drives and not the D drive (which is the data drive). Another option is to share a directory on an external hard disk.

3 Right click the new directory and configure sharing using the operating system.

By default, other users will only have read access to this directory.

Accessing a shared network drive

A network share can be configured in Eye Cubed to access other resources. Contact your network administrator for advice.

System customisation

The operating system has been configured specifically for Eye Cubed. These variations are described below and must not be changed.

- Screen resolution is set to 1920 × 1200.
- Eye Cubed software starts automatically via an All Users Startup Menu shortcut.

Windows 10 Embedded

- Windows Defender is enabled.
- Taskbar will not auto-hide. If you wish to enable this option:

1 Right click the Windows taskbar.

2 Select **Taskbar Properties**.

3 Select **Automatically hide the taskbar in desktop mode** option.

4 Close the window.

Managing disk space

Follow these suggestions if you are running out of disk space on the Eye Cubed device.

Purging data

1 Log on as an administrator level user.

2 Click Utilities > Connectivity.

3 Click Purge Deleted Data.

If there is data to remove you will be prompted to delete it.

4 Click Yes if data exists and can be purged, otherwise click OK to exit.

Deleting temporary image files

1 Restart the device.

2 Log on using the most commonly used user name.

3 Minimise Eye Cubed.

4 Delete all image files in the following directory (the value for *User name* is the name of user that you logged on with):

`C:\Documents and Settings\User name\Local Settings\Temp`

5 To delete more temporary files log on as another user and delete the files from their local settings directory.

6 Empty the Windows Recycle Bin.

Image noise

High power devices, such as lasers or construction equipment, can add noise to the image. This noise is often described as 'sparks' in a B-Scan image. Such noise is often intermittent. In many cases you can actually see the noise appear and disappear as the noise source is turned on and off.

By far the most common cause in an ophthalmic setting is that an active laser is nearby. It should be easy to prove this by turning on the ultrasound system when you know the laser is active. (A pair of cell phones can be used to orchestrate an exact test). The other common cause of noise is a damaged cable.

Damaged probe cable

Checking a cable for damage

1 Start scanning.

2 Gently flex the probe cable in a circular motion so that it is bent in various directions.

3 Repeat the flexing at the connector end of the cable.

If noise can be eliminated or increased by this test, return the probe to the factory for repair or replacement.

Basic B-Scan troubleshooting

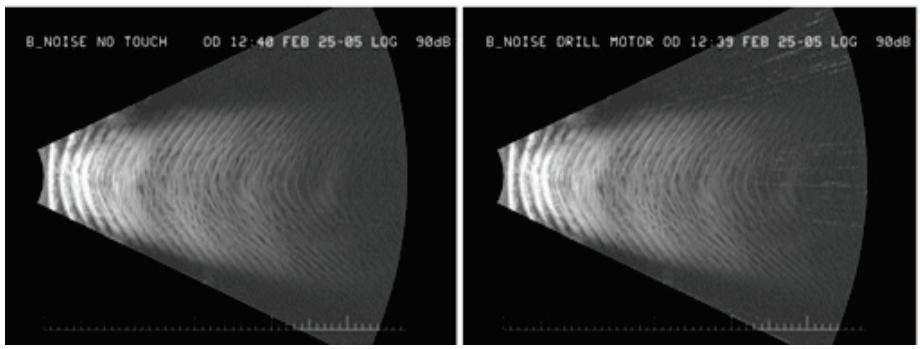
Performing basic B-Scan noise troubleshooting

1 Activate the laser or wait for the noise to reoccur.

2 Start scanning and adjust the **Receive Gain**.

3 Hold the probe by the cable about 15 cm away from the probe.

4 Wet the fingertip of your other hand and grasp the probe body. If the problem is noise from an external source then the noise will increase when your hand touches the probe body.



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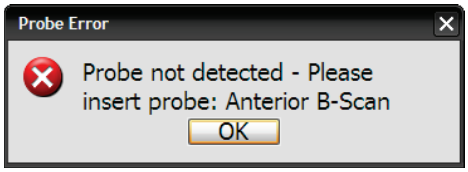
The left image shows the system with an external noise source (a drill motor) active, but with the probe being held by the cable (no physical contact with the probe itself). The right image shows the 'sparks' or 'streaks' in the image that appear when the probe is grasped firmly by the body. When an operator is touching the probe their body acts as an antenna and couples noise to the image.

Probe not detected message

Scanning is not possible if the relevant probe is not connected, or if the probe is connected to the wrong connection (B-Scan probes only).

If this occurs, the system will display a **Probe not detected** message when scanning is attempted, and the status bar will show a message that the probe is not connected.

This message also appears if the probe is broken (unusable).



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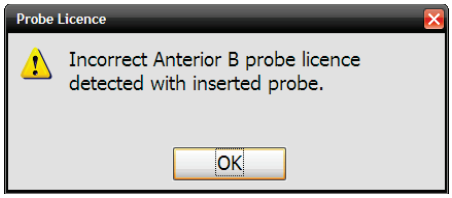
Probe licence error

(New Generation consoles only) If you see an incorrect licence message it means that the probe you just connected is not licenced to be used on this device. You will also see this message when you log on if an unlicensed probe is connected when the console is started. Contact your Authorised Ellex Distributor to resolve these types of problems.



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Cannot enter the logon password

Under some conditions, the password cannot be entered at the Windows **Welcome** screen after a user has logged off. The password field displays but does not accept keyboard input.

This problem can be resolved by restarting the system, or by pressing the **Ctrl**+**Alt**+**Del** keys simultaneously (note that you will then need to type both the **User Name** and **Password** and click **OK** to log on).

Placing Eye Cubed on a network

The system can be placed on a Windows TCP/IP network to access network printers and drives.

Successful network installation requires configuration of both the server and the ultrasound system (client). The technician performing this installation must have administrative access to the server as well as network experience and familiarity with the existing network in order to perform this installation. The information presented here is as a general guide only.

To place the system on a Windows network both the client and server must be configured.

Prerequisites

The following prerequisites are required:

- A qualified network technician shall be present at the installation.
- The technician shall review this section prior to the installation date, and perform all necessary server-side configurations prior to the installation.
- A working, tested network port in the room in which the instrument is to be installed, along with a standard (not crossover) RJ-45 network cable to connect the instrument to the network port.

The total time required to perform the network installation is approximately one hour of the technician's time. Of this time, approximately 30 minutes is required to read the network pre-installation document and perform the necessary server-side configurations; another 30 minutes is required to complete the on-site portion of the network installation.

The Server is a Windows computer running TCP/IP used to provide a location to store images, and optionally manage user accounts for the ultrasound system.

The Client is an Eye Cubed ultrasound system running Windows Embedded. The primary purpose of the client is to generate ultrasound images.

Configuring the server

Configuring the server

1 Create user accounts and/or a user group for the people who will use the ultrasound system.

2 Create a shared folder to store images, and allow the appropriate users and/or user groups read/write access to that folder.

3 For static IP addressing, assign an address and subnet mask for the ultrasound system.

Configuring the client

Accessing the desktop

1 Log on to Eye Cubed as an administrative user.

2 Minimise the Eye Cubed application.

The following steps are required to allow the instrument to see and exchange data with other computers on the network. Most networks will not require you to set up a static IP address, however all networks require the use of workgroup and computer names. Most networks will require a username and password in order to actually view any data that is stored on the network.

Configuring a static IP address

Most Windows networks use the automatically configured DHCP (Dynamic Host Configuration Protocol) addressing and do not require this step.

Windows 10

1 In the search box on the taskbar, type control panel, and then select **Control Panel**.

2 Click **Network and Internet** > **Network and Sharing Center** > **Change adapter settings**.

3 Right-click the connected local area connection then select **Properties**.

4 On the **Networking** tab, select **Internet Protocol Version 4 (TCP/IPv4)** from the list of items and click **Properties**.

5 Click **Use the following IP address** and enter the IP address and subnet mask.

6 Click **OK** until all of the configuration windows have been closed. It is not necessary to restart the computer until after the workgroup and computer name have been set.

Creating the workgroup and computer names

Windows 10

1 Right-click **My Computer** on the desktop and select **Properties**.

2 Click **Advanced system settings**.

3 Select the **Computer Name** tab, and then click **Change**.

4 Enter a new computer name if desired. Ellex recommends that the default name, which is the same as the instrument serial number, is not changed.

5 Click **Workgroup** and enter the name of the workgroup.

6 Click **OK** until all of the configuration windows have been closed. The computer will automatically restart, after which, the network connection will be working.

Creating user accounts (non-domain use only)

Log in with an administrator account and create a new user (**Utilities** > **Manage User Accounts**).

Troubleshooting network connections

Computer networking can be a very complicated subject and providing complete network troubleshooting is beyond the scope of this manual. However, the following tools and methods are will help in troubleshooting any network connection problems.

Windows 10

Troubleshooting network connections

1. Click **Control Panel** > **Network and Sharing Center**.
2. Select **Troubleshoot problems**.

Repairing or enabling a network connection

1. Click **Start** > **Control Panel** > **Network and Internet** > **Network and Sharing Center** > **Change adapter settings**.
2. Right-click on the connected Local Area Connection then select **Diagnose**.

Mapping network drives

1. Connect the Eye Cubed to the network via Ethernet.
2. Allocate Eye Cubed an IP address (the interface is configured to get an IP address through DHCP by default).
3. Map a network drive to the Eye Cubed system (usually M drive is the first available drive letter).
4. Create a folder on that drive called `autoarchive`.

   This is the location for material that is automatically archived at the end of a session.
5. Create another folder on that drive called `autoexport`.

   This is the location for material that is automatically exported at the end of a session.
6. Create a `defaultexport` folder.

   This will be used when you manually export items.
7. Log in to Eye Cubed as an administrator.
8. Click **Utilities** > **Archive/Export** and select **Automatically Archive Session At End of Session.**
9. Set the **Automatic Session Archive Location** to the `autoarchive` directory created earlier.
10. Select **Automatically Export Session At End of Session**.
11. Set the **Automatic Session Export Location** to the `autoexport` directory created earlier.
12. Set the **Export Location** to the `defaultexport` directory created earlier.
13. Map the network drive to the same drive letter for each Eye Cubed user account.

Configuring DICOM

The following instructions are written based on the assumption that you:

- have an understanding of DICOM
- have purchased a DICOM licence for Eye Cubed (you will not see DICOM functionality in Eye Cubed unless you have licensed it)
- are familiar with your DICOM environment.

You may need to liaise with other staff in your organisation to successfully configure Eye Cubed in a DICOM environment.

Overview

DICOM is a communications standard designed to allow independent medical devices to share information. In a DICOM environment Eye Cubed is an ultrasound Modality (US) that receives worklist data from an electronic medical records (EMR) system and sends ophthalmic data to a picture archiving and communications system (PACS).

Using DICOM terminology the Eye Cubed Application Entity (AE), as a Modality Worklist Service Class User (SCU), queries the EMR Application Entity (the Modality Worklist Service Class Provider or SCP) for worklist data. This SCU/SCP relationship is called the Modality Worklist Service Object Pair (SOP).

After the Operator performs the eye exam and ends the session Eye Cubed sends ophthalmic data, as a Storage Service Class User (SCU), to the PACS Application Entity, which acts as the Storage Service Class Provider (SCP). The type of SCU/SCP relationship varies depending on the nature of the ophthalmic data being sent (for example Encapsulated PDF Storage SOP).

DICOM Conformance Statement

Refer to the Eye Cubed *DICOM Conformance Statement* to understand the level of conformance supported by Eye Cubed. Check that the software version mentioned in the conformance statement matches the version of Eye Cubed device (Utilities > Support > Software Version).

Configuring DICOM

For Eye Cubed to operate successfully in a DICOM environment you must configure the:

- Eye Cubed device with the details of the station AEs
- station AEs with the details of the Eye Cubed station AE.

Eye Cubed also lets you test the communications between the defined DICOM station AEs and includes a log file to help you troubleshoot problems.

Configuring DICOM

1. Ensure that the Eye Cubed device is physically connected to your network.
2. Ensure that there are no virtual barriers (for example firewalls) to network traffic between the Eye Cubed device and the remote application entities.
3. Collect details of the relevant Service Class Providers (SCPs) such as station AE title, host IP and port number.
4. Log on to Eye Cubed (as an administrator or limited user).
5. Define the Eye Cubed local Application Entity Station AE Title (Utilities > DICOM > Local Application Entity) and the Modality. Remember to click Apply to save these values.

6 Define the station AEs in Eye Cubed (**Utilities** > **DICOM** > **Station AEs**).

These are the Service Class Providers (SCPs).

7 Under **Default Roles Configuration** choose which station AEs provide the required services. Remember to click **Apply** to save these selections.

8 Record the Eye Cubed Application Entity details (**Station AE Title**).

9 If you are using modality worklist set the **Modality Worklist Tolerance** to **Loose** if the MWL AE does not fully comply with the DICOM standard.

10 Define Eye Cubed as a station AE (SCU) in the relevant DICOM Service Class Providers (SCPs) on your network.

Refer to the DICOM conformance statements of the other Service Class Providers (SCPs) to configure these entities to recognise Eye Cubed.

11 Verify DICOM connectivity using the Eye Cubed verify functions (**Utilities** > **DICOM** > **Station AEs** > **Verify AE Connectivity**). A green tick indicates that an Application Entity was successfully verified; a red cross indicates a failure and should be investigated.

12 When connectivity has been established check that DICOM works using test patients and exams.

At this point you should also consider training your Eye Cubed operators including any procedures that should be followed in case of network outages or similar events.

13 Begin live operations with Eye Cubed and DICOM.

Creating or editing the local Application Entity

1 Enter the **Station AE Title**.

2 Click **Apply**.

3 Ensure that any Service Class Provider (SCP) that refers to Eye Cubed also refers to this value otherwise DICOM transfers will fail.

If you make a mistake click **Revert** to return to the last applied settings.

Adding or editing station AEs

1 Click **Utilities** > **DICOM**.

2 Under **Station AEs** click **New**.

3 Enter the details (fields marked with an asterisk must be completed).

Once you have defined the **Station AE Title**, **Host** and **Port** values, tabbing to the **Description** field, or clicking in another field automatically populates the **Capabilities**. If no capabilities are listed you should check that you have entered the correct values for title, host and port.

4 Click **Check** to verify these details. If no capabilities are listed it may be because you have not yet configured the remote Application Entity. Otherwise double-check the details that you have just entered. Note that the results of the checking function are always cleared once you exit the record.

5 Click **OK** to exit.

Deleting a station AE

1 Review **Utilities** > **DICOM** > **Default Roles Configuration** to ensure that the station AE that you are about to delete is not being used (you cannot delete a default station AE).

2 Select the station AE record and click **Delete**.

3 Click **OK**.

Verifying station AEs

- Click **Verify AE Connectivity**.

  The availability for each station AE will be updated (a tick for success or a cross for failure). If communication to the entity fails view the log file to help determine the cause of the failure.

Setting or changing default roles

1 Click **Utilities** > **DICOM**.

2 Under **Default Roles Configuration** select the default **Modality Worklist SCP** from the list and then select the default **Encapsulated PDF Storage SCP** from that list.

3 Click **Apply**. If you make a mistake click **Revert** to return to the last applied settings.

Troubleshooting DICOM

The following symptoms indicate that Eye Cubed can no longer access station AEs:

- you do not see new records in the worklist (it does not refresh)
- you see a worklist message indicating that results could not be retrieved
- at the end of a session you cannot send records via DICOM.

In these situations you should check the following:

- Determine if the problem exists only with Eye Cubed or with all applications that are using DICOM (the problem may not be with Eye Cubed).
- Check the physical connections of Eye Cubed to the network (cable and connector).
- Ensure that no software barriers (e.g. firewalls) have isolated the station AEs.
- Confirm that the network is working correctly.
- Review the Eye Cubed log file to see if you can identify the problem (**Utilities** > **DICOM** > **View Log**). The log file, which is recreated every time someone logs onto Eye Cubed and is kept for 20 generations, can be found in `E:\EyeCubedApplicationData\DicomGatewayServer\Dicom-Gateway-Server-Service.log.txt`.
- Review the log files of the devices to which Eye Cubed connects.
- Confirm that the remote Service Class Providers (SCPs) are functioning correctly.
- Verify that the configuration of the station AEs has not changed (the station AE name, IP address and port number: these values must be exactly as displayed on the station AEs). This information is defined under **Utilities** > **DICOM** > **Station AEs**.
- Double-check that you have correctly assigned the station AEs to the correct roles (**Utilities** > **DICOM** > **Defaults Roles Configuration**).
- Verify using **Utilities** > **DICOM** that Eye Cubed can connect to the station AEs.

Problem: Modality worklist results are not retrieved

Solution 1: Configure and confirm Station AE settings

1 Click **Utilities > DICOM**.

2 Click **Verify AE Connectivity**.

3 Confirm that you can see green ticks next to the station application entities. If you red crosses check the AE definition.

Solution 2: Check compulsory DICOM fields

All Modality Worklist appointments stored on the Modality Worklist AE (third party software) should conform to the specifications in the table below. Critically, the fields marked Mandatory must exist under their exact parent tags to conform to DICOM and be retrieved by Eye Cubed.

Some users may configure the mandatory fields of the Modality Worklist AE appointments (third party software) to be present but in a different structure to what is shown below (for example Scheduled Station AE Title placed in a different section). If that is non-negotiable then as a compromise a duplicate field must be created in its correct location to satisfy DICOM and Eye Cubed (for example Scheduled Station AE Title should exist under two different parent tags).

An alternative is to set Utilities > DICOM > Modality Worklist Tolerance to Loose.

Description / Module	Tag	Return Key Type	Field Requirement
Scheduled Procedure Step			
Scheduled Procedure Step Sequence	(0040, 0100)	1	MANDATORY
>Scheduled Station AE Title	(0040, 0001)	1	MANDATORY
>Scheduled Procedure Step Start Date	(0040, 0002)	1	MANDATORY
>Scheduled Procedure Step Start Time	(0040, 0003)	1	MANDATORY
>Modality	(0008, 0060)	1	MANDATORY
>Scheduled Performing Physician's Name	(0040, 0006)	2	EMPTY FIELD PERMITTED
>Scheduled Procedure Step Description	(0040, 0007)	1C	ONLY REQUIRED IF TAG IS PRESENT
>Scheduled Station Name	(0040, 0010)	2	EMPTY FIELD PERMITTED
>Scheduled Procedure Step Location	(0040, 0011)	2	EMPTY FIELD PERMITTED
>Scheduled Protocol Code Sequence	(0040, 0008)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Coding Scheme Version	(0040, 0103)	3	OPTIONAL
>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Code Meaning	(0040, 0104)	3	OPTIONAL
>>Protocol Context Sequence	(0040, 0440)	3	OPTIONAL
>>>Value Type	(0040, A040)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>Concept Name Code Sequence	(0040, A043)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Coding Scheme Version	(0040, 0103)	3	OPTIONAL
>>>>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT

>>>DateTime	(0040, A120)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>>Person Name	(0040, A123)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>>Text Value	(0040, A160)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>>Concept Code Sequence	(0040, A168)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Coding Scheme Version	(0040, 0103)	3	OPTIONAL
>>>>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>Numeric Value	(0040, A30A)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>>Measurement Units Code Sequence	(0040, 08EA)	1C	ONLY REQUIRED IF TAG IS PRESENT
>>>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>>Coding Scheme Version	(0040, 0103)	3	OPTIONAL
>>>>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>>All other attributes from Protocol Context Sequence		3	OPTIONAL
>Pre-Medication	(0040, 0012)	2C	EMPTY FIELD PERMITTED
>Scheduled Procedure Step ID	(0040, 0009)	1	MANDATORY
>Requested Contrast Agent	(0032, 1070)	2C	EMPTY FIELD PERMITTED
>Scheduled Procedure Step Status	(0040, 0020)	3	OPTIONAL
>All other Attributes from the Scheduled Procedure Step Sequence		3	OPTIONAL
Scheduled Specimen Sequence	(0040, 0500)	3	OPTIONAL
>Container Identifier	(0040, 0512)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Container Type Code Sequence	(0040, 0518)	2	EMPTY FIELD PERMITTED
>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Coding Scheme Version	(0040, 0103)	3	OPTIONAL

>>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Specimen Description Sequence	(0040, 0560)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Specimen Identifier	(0040, 0551)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Specimen UID	(0040, 0554)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>All other Attributes from the Specimen Description Sequence		3	OPTIONAL
>All other Attributes from the Scheduled Specimen Sequence		3	OPTIONAL
Requested Procedure			
Requested Procedure ID	(0040, 1001)	1	MANDATORY
Requested Procedure Description	(0032, 1060)	1C	ONLY REQUIRED IF TAG IS PRESENT
Requested Procedure Code Sequence	(0032, 1064)	1C	ONLY REQUIRED IF TAG IS PRESENT
>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Coding Scheme Version	(0040, 0103)	3	OPTIONAL
>Code Meaning	(0040, 0104)	3	OPTIONAL
Study Instance UID	(0020, 000D)	1	MANDATORY
Study Date	(0008, 0020)	3	OPTIONAL
Study Time	(0008, 0030)	3	OPTIONAL
Referenced Study Sequence	(0008, 1110)	2	EMPTY FIELD PERMITTED
>Referenced SOP Class UID	(0008, 1150)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Referenced SOP Instance UID	(0008, 1155)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
Requested Procedure Priority	(0040, 1003)	2	EMPTY FIELD PERMITTED
Patient Transport Arrangements	(0040, 1004)	2	EMPTY FIELD PERMITTED
All other Attributes from the Requested Procedure Module		3	OPTIONAL
Imaging Service Request			
Accession Number	(0008, 0050)	2	EMPTY FIELD PERMITTED
Requesting Physician	(0032, 1032)	2	EMPTY FIELD PERMITTED
Referring Physician's Name	(0008, 0090)	2	EMPTY FIELD PERMITTED
All other Attributes from the Imaging Service Request Module		3	OPTIONAL
Visit Identification			
Admission ID	(0038, 0010)	2	EMPTY FIELD PERMITTED

All other Attributes from the Visit Identification Module		3	OPTIONAL
Visit Status			
Current Patient Location	(0038, 0300)	2	EMPTY FIELD PERMITTED
All other Attributes from the Visit Status Module		3	OPTIONAL
Visit Relationship			
Referenced Patient Sequence	(0008, 1120)	2	EMPTY FIELD PERMITTED
>Referenced SOP Class UID	(0008, 1150)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Referenced SOP Instance UID	(0008, 1155)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
All other Attributes from the Visit Relationship Module except those explicitly included in this table (see Note 3)		3	OPTIONAL
Visit Admission			
All Attributes from the Visit Admission Module		3	OPTIONAL
Patient Relationship			
All Attributes from the Patient Relationship Module except those explicitly included in this table		3	OPTIONAL
Patient Identification			
Patient's Name	(0010, 0010)	1	MANDATORY
Patient ID	(0010, 0020)	1	MANDATORY
All other Attributes from the Patient Identification Module		3	OPTIONAL
Patient Demographic			
Patients Birth Date	(0010, 0030)	2	EMPTY FIELD PERMITTED
Patient's Sex	(0010, 0040)	2	EMPTY FIELD PERMITTED
Patient’s Primary Language Code Sequence	(0010, 0101)	3	OPTIONAL
>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Patient’s Primary Language Modifier Code Sequence	(0010, 0102)	3	OPTIONAL
>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
Patient's Weight	(0010, 1030)	2	EMPTY FIELD PERMITTED

Confidentiality constraint on patient data	(0040, 3001)	2	EMPTY FIELD PERMITTED
All other Attributes from the Patient Demographic Module		3	OPTIONAL
Patient Medical			
Patient State	(0038, 0500)	2	EMPTY FIELD PERMITTED
Pregnancy Status	(0010, 21C0)	2	EMPTY FIELD PERMITTED
Medical Alerts	(0010, 2000)	2	EMPTY FIELD PERMITTED
Allergies	(0010, 2110)	2	EMPTY FIELD PERMITTED
Special Needs	(0038, 0050)	2	EMPTY FIELD PERMITTED
Pertinent Documents Sequence	(0038, 0100)	3	OPTIONAL
>Referenced SOP Class UID	(0008, 1150)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Referenced SOP Instance UID	(0008, 1155)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Purpose of Reference Code Sequence	(0040, A170)	2	EMPTY FIELD PERMITTED
>>Code Value	(0040, 0100)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Coding Scheme Designator	(0040, 0102)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>>Code Meaning	(0040, 0104)	1	ONLY REQUIRED IF PARENT TAG IS PRESENT
>Document Title	(0042, 0010)	2	EMPTY FIELD PERMITTED
All other Attributes from the Patient Medical Module		3	OPTIONAL

Solution 3: Ensure that the modality fields match

The **Modality type** field may be defined differently on the Eye Cubed and Modality Worklist AE. By default, Eye Cubed only accepts modality worklist items with their modality field set to `US` (ultrasound). If the Modality Worklist AE does not use `US` Eye Cubed may fail to retrieve the appointments.

There are two ways to resolve this problem.You can configure the Modality Worklist AE (your third-party software providing Modality Worklist support, which supplies the appointments Eye Cubed retrieves). In the third party software configure the following field to be `US`:

`(0008,0060) Modality`

Alternatively, configure Eye Cubed to filter for Modality fields matching the field specified on the third party software.

If using Eye Cubed 2.5.0.1 or higher:

1. Click **Utilities > DICOM**.
2. Set the **Modality type** field to the same modality field as the third party software (for example OP).
3. Click **Apply** to save the settings.

If using Eye Cubed 2.4.6.0 or lower:

1. Close Eye Cubed using **Ctrl + Alt + Shift + X**.
2. Use Windows Explorer to access `E:\EyeCubedApplicationData`.

3 Open `eyecubedprefs.lua` in Notepad.

4 Add the following line to the end of the file (where `xx` is the Modality field you are using on the third party device (for example OP).

```
SystemSet("DicomMwlQueryModality", "xx")
```

5 Save the file.

6 Start Eye Cubed and the system should now retrieve appointments matching the correct Modality field.

Solution 4: Configure the Scheduled Procedure Start/End dates to match

Ensure that the Scheduled Procedure Start/End dates specified in Patient > Worklist matches the same date fields specified on the appointments on the third party software (Modality Worklist AE).

The fields that need to be configured are the following in the appointments are:

`(0040,0002) Scheduled Procedure Step Start Date`

`(0040,0004) Scheduled Procedure Step End Date`

User Maintenance

Service visits

Contact your Authorised Ellex Distributor at least every 12 months to arrange a preventive maintenance visit. Regular servicing by an Authorised Ellex Distributor will improve the reliability and prolong the life of your Eye Cubed system.

Service work must only be performed by fully trained and qualified Ellex Service Technicians and includes, but is not limited to, such activities as:

- Checking probes for damage.
- (Diagnostic A-Scan probe) Ensuring that the **Utilities** > **Scans** > **Tissue Sensitivity** matches the value recorded on the Diagnostic A-Scan tissue sensitivity document.
- General cleaning of the console.
- Ensuring that data is being archived correctly.
- Ensuring that the device has enough free disk space.
- Inspecting the console to ensure that the fans and vents are free of debris.
- Checking the software release (**Utilities** > **Support**) and advising if upgrades are available.

In the case of a defect a service visit will confirm the nature of the problem and seek to repair the device.

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 includes:

- circuit diagrams
- list of components
- descriptions.

Cleaning the console

Clean the external surfaces of the console with a soft cloth dampened with a mild soap solution. Do not allow liquid to enter the device.

Probes

General maintenance

Regularly inspect the cabling and tip of the probe for damage (cracks or leaking oil from the tip; bent or missing pins in the connector; cuts or abrasions on the cable). Remove the probe from use and contact your Authorised Ellex Distributor if damaged is detected.

WARNING! Always handle probes carefully. Damaged probes account for the majority of Eye Cubed service calls and introduces the potential risk of patient cross contamination.

10 MHz B-Scan probe

Check for holes in the membrane. If there is a hole, oil will leak out and air will fill the probe, introducing scanning errors and a risk of cross infection. Contact your Authorised Ellex Distributor if you detect a hole in the probe membrane.

Replacing diagnostic A-Scan (8 MHz) probes

If a diagnostic A-Scan (8 MHz) probe is replaced, the default tissue sensitivity value on the system (Utilities > Scans > Diagnostic A Default Settings) must be updated to match the tissue sensitivity (TS) value documented with the probe.

Cleaning and disinfecting probes

Protocol

If your healthcare facility has an existing protocol for cleaning and disinfection, it can be applied to clean and/or disinfect the probes. For additional information about cleaning and disinfection, refer to the recommendations of the Association for Professionals in Infection Control (APIC), American Academy of Ophthalmology (AAO), the U.S. Food and Drug Administration (FDA), the U.S. Centers for Disease Control (CDC), AAMI TRI12, AAMI TIR30 and ISO 17664. For country specific disinfection regulations, check with your local regulatory infection control authorities.

Advisory description

WARNING: highlights the information related to the safety of the user and the patient.

CAUTION: information to prevent damage to the probes. Adherence ensures product warranty.

Safety

WARNING - Cleaning and disinfecting solutions are recommended for their suitability to use with the probes not limited to biological efficacy.

WARNING - Disinfection level required by the probes depends on the type of tissue in contact during use. Various levels of disinfection requirements are based on the recommendations of the U.S. Centers for Disease Control and Prevention.

WARNING - If using a pre-mixed solution, ensure to observe the solution expiration date.

WARNING - Disinfected probes should be used with sterile gel and a sterile probe cover if there is a risk that it will come into contact with an open wound.

WARNING – Clearscan® bags and sterile probe covers are disposable and must not be reused.

WARNING - Before performing any system maintenance or cleaning, always turn off the system and disconnect the power.

WARNING - It is recommended to follow the directions provided by the manufacturers of cleaning and disinfecting solutions.

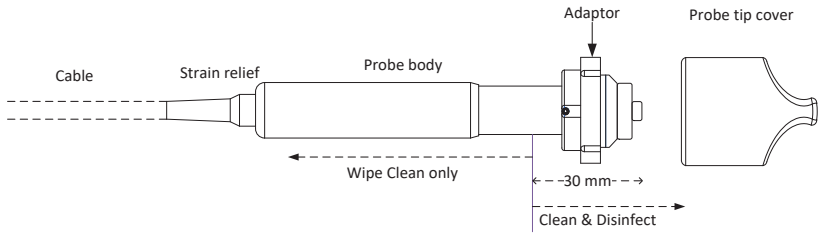
CAUTION - Do not use abrasive cleaners, acetone or other strong solvents on the system and peripherals.

Infection control- Issues related to infection control affect the operator and the patient. Follow the infection control procedures established in your facility for the protection of both the staff and the patient.

Handling contaminated probes– The primary area of concern is the handling of probes that have contacted infected patients. Always wear gloves when you handle used probes that have not been previously disinfected.

Probe care

Probe components are depicted in this figure.



While cleaning or disinfecting, immerse the probe into the appropriate cleaning or disinfectant agent for your probe.

CAUTION - Some cleaning and disinfectant products may result in discoloration if residual disinfectant and gel have not been completely removed between each use. Always remove gel completely before using cleaners and disinfectants.

CAUTION - Ensure that no sharp objects come in contact with the probe or the cables.

CAUTION - When handling a probe, do not bump the probe on hard surfaces.

CAUTION - Do not use a surgeon's brush when cleaning probes. Even the use of soft brushes can damage probes.

CAUTION – It is not recommended to use paper or abrasive cloth to clean the probes. They can harm the probe tip (acoustic window).

CAUTION - During cleaning and disinfection, orient the connector housing and cable higher than the wet parts to prevent the liquid from entering unsealed areas.

Cleaning procedure

Recommended cleaning agent

If your healthcare facility has an existing protocol for cleaning, it can be applied to clean the probes, for additional guidance refer to the Protocol. Alternatively, Ellex recommends Cidezyme enzymatic cleaning agent that is available worldwide and is compatible with all probe types and immersion/scleral shells. It is important rinse the probe tip thoroughly with flowing water before performing the enzymatic cleaning.

Cleaning agent		
Trade name	Cidezyme - Enzymatic Detergent Solution	Prolystica 2X Enzymatic Cleaning Agent
Manufacturer †	Advanced Sterilization Products www.aspjj.com	Steris Healthcare www.steris.com

† Consult manufacturer's directions prior to using the cleaning agent.

WARNING - It is recommended to use protective eyewear and gloves when cleaning or disinfecting the probes.

WARNING - It is recommended to clean the probes after each use. It is essential to clean the probe before disinfecting it.

CAUTION - Follow these instructions to prevent any damage to the probes, cable or connector during cleaning and disinfecting procedures. Using alternative methods may damage the equipment and void product warranty.

CAUTION - When wiping the distal tip of the anterior B-Scan, 40 MHz PROBE, never apply excessive force to the tip because this may damage the probe.

CAUTION - Move the tip of the anterior B-Scan only with the controls; do not forcibly move it with your hand. For this start and stop the probe until the tip rests in the central position.

CAUTION - Ensure to use proper concentration when using an enzymatic cleaner. Refer Table 1-1 for the recommended enzymatic cleaners. Rinse the probes thoroughly before using the enzymatic cleaner.

CAUTION - Do not immerse the probes in the cleaning and disinfectant solutions for longer than recommended periods of time. Limit the time according to the minimum time durations recommended by the manufacturer.

Steps to clean

For Anterior B-Scan probe, start and stop the probe until the tip rests in the central position. This allows easy access to the tip.

1 Disconnect the probe from the system and remove any accessory attached or sterile cover.

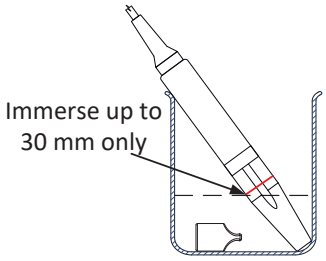
2 The soiled devices must be properly contained before reprocessing/cleaning. The ultrasound gel shall be removed from the probe tip by using a soft cloth after each patient use.

3 Remove any residual gel from the probe tip by using flowing water and a soft sponge or gloved hand. If flowing water is not available, use a pre-moistened soft cloth. Use a gentle wiping or blotting motion to remove gel from the probe tip.

4 Before proceeding to the next step, clean and rinse the probe tip thoroughly with flowing water.

5 Wipe the entire probe body and cable with a non-abrasive cloth moistened with an enzymatic cleaning agent.

6 Clean the probe by immersing the tip of the probe up to 30 mm from the distal end in the cleaning agent. Immerse the probe tip cover as well. For contact time refer to the manufacturer's instructions for the cleaning agent.



7 Immediately after immersion rinse the probe tip and the probe tip cover with adequate amount of flowing water (for at least one minute) to remove residual solution. Follow the cleaning solution manufacturer's directions for minimum duration to rinse.

8 Dry using lint-free non-abrasive cloth.

9 Inspect the probe tip under adequate lighting, to ensure that it is visibly clean, dry and undamaged. Repeat these cleaning steps if the tip remains dirty. Discard the probe if the tip cannot be cleaned or if it is damaged.

Disinfection procedure

Recommended disinfectant

If your healthcare facility has an existing protocol for disinfection, it can be applied to disinfect the probes, for additional guidance refer to the Protocol. Ellex recommends a number of disinfectants. Using other types of disinfectant solutions may result in probe damage. Ellex has also validated the cleaning and disinfection with 1 % Sodium Hypochlorite solution which has been shown to be effective for this purpose. However, a concentration range of 0.5% to 1% Sodium Hypochlorite can be used to disinfect the probe for clinical use. Cidex OPA and Cidex Glutaraldehyde are internationally recognised high-level disinfectants and have been evaluated for material compatibility with the probes.

Disinfectants			
Trade name		Cidex OPA	Cidex
Chemical base	0.5% Sodium Hypochlorite*	Ortho-phthaldehyde (OPA)	Glutaraldehyde 2.4%
Manufacturer		Advanced Sterilization Products aspjj.com	Advanced Sterilization Products aspjj.com

*0.5% sodium hypochlorite solution (NaClO) is equivalent to 5000 ppm of available chlorine. Household bleach (that includes 5.25% or 6.00%–6.15% sodium hypochlorite depending on manufacturer) is usually diluted in water at 1:10. Approximate dilutions are 1.5 cups of bleach in a gallon of water for a 1:10 dilution (~6,000 ppm). Sodium hypochlorite products that make pesticidal claims, such as sanitization or disinfection, must be registered by EPA and be labeled with an EPA Registration Number. If 0.5% sodium hypochlorite is used, the probes /shells shall be immersed for duration of 10 minutes.

WARNING - Always use protective eyewear and gloves when disinfecting any equipment.

WARNING – It is recommended to clean the probes after each use. It is essential to clean the probes before disinfecting them.

WARNING – Prevent any residual solution on the probes by carefully following the manufacturer's instructions.

WARNING - Clean and disinfect probes and immersion shells before first use on a patient and between patient uses.

WARNING - Do not use immersion shells if there are any signs of damage (degradation, discoloration or cracks).

CAUTION – Do not sterilize the probes with gamma-radiation, gas, steam, autoclave, or heat sterilization. Probe damage due to any of these methods is not covered by the warranty.

CAUTION - Avoid immersing the probes in cleaning and disinfecting solutions for longer periods of time than prescribed.

CAUTION - When wiping the probe-tip of the anterior B-Scan, 40MHZ probe, never apply excessive force to the tip because this may damage the probe.

CAUTION - Move the tip of the anterior B-Scan only with the controls; do not forcibly move it with your hand. For this start and stop the probe until the tip rests in the central position.

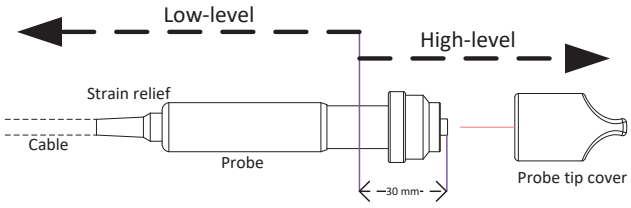
CAUTION - Do not wipe or scrub aggressively as it may damage the distal tip (acoustic window) of the probe.

CAUTION – Long term exposure to the bleach solution can cause discolouration and rust. It is recommended to rinse the probes with sterile demineralised water after immersion in the bleach solution.

CAUTION - Follow these instructions to prevent any damage to the probes, cable or connector during cleaning and disinfecting procedures.

Steps to disinfect

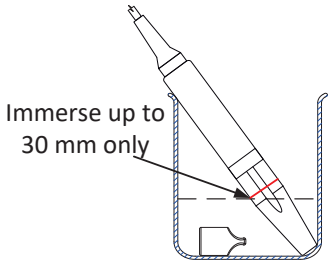
The probe handle, cable and connector do not come in contact with the patient and do not require the same level of disinfection as the probe tip. Therefore, use separate procedures to disinfect the patient contacting and non-patient contacting parts. It is critical to adhere to these procedures to ensure long term reliability of the probes.



The probe tip requires high-level disinfection. Liquid chemical disinfectants can be effective:

1 Prepare the disinfectant according to the disinfectant manufacturer's directions. Ensure that you have followed all precautions for storage, use and disposal.

2 Place the cleaned and dried probe surface in contact with the disinfectant solution for the time specified by the disinfectant manufacturer. High-level disinfection can be accomplished by soaking according to the contact time recommended by the disinfectant manufacturer Immerse the probe in the disinfectant to up to 30 mm from the distal end. Immerse the probe tip cover as well.



3 Rinse the probe to the point of immersion and probe tip cover with adequate amount of flowing water (preferably sterile water) for at least one minute, to remove residual disinfectant solution. Follow the disinfectant manufacturer's directions for rinsing and duration.

4 Dry them with a lint-free sterile non-abrasive cloth.

5 Under adequate lighting, inspect the probe for cleanliness and damage or degeneration to the housing, strain relief, lens and seal. Do not use a damaged or defective probe.

6 Ensure the probe tip and probe tip cover are dry before covering the probe to prevent recontamination.

NOTE - Ellex recommends the same level of cleaning and disinfection before first use and between uses, regardless of whether the next use is on the same patient or a different patient.

Probe storage and transport

If a carrying case is provided with your probe, always use the carrying case to transport the probe from one site to another and for long-term storage. Follow these guidelines to properly store probes for transport or long term storage:

1 Make sure that the probe is clean and disinfected before placing it in the case to avoid contaminating the foam that lines the carrying case.

2 Place the probe in the case carefully to prevent kinking of the cable.

3 Before closing the lid, make sure no part of the probe is protruding from the case.

Daily storage

Follow these guidelines to store your probe securely during daily use:

- Always store probes in the probe holders on the console of your system
- Between each patient use, wipe the probe holders with a soft cloth moistened with the enzymatic cleaning agent or mild soap

Ensure the probe holders are dry before storing probes

It is recommended to use a carrying case to transport the probe from one site to another and for long-term storage. Follow these guidelines to store the probes for long term or to transport them properly:

1. Ensure that the probes are clean and disinfected before placing them in the case to avoid contaminating the foam-lining of the carrying case.
2. Place the probes in the case while preventing any bends in the cable.
3. Fit the probe parts in the case and ensure that no part of the probe is protruding out, before closing the lid.

Immersion and scleral shells

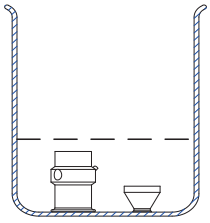
If your healthcare facility has an existing protocol for cleaning and disinfection, it can be applied to disinfect the shells. For additional guidance, refer to the Protocol. Alternatively, use the following steps to clean and disinfect the immersion and scleral shells.

Steps to clean

1. For immersion shell, remove and discard tube before cleaning and disinfection. The tube is a single-use item.
2. Rinse the shells with flowing water.
3. Wipe the shells with a non-abrasive cloth moistened with an enzymatic cleaning agent.
4. Clean the shells by immersing them in the cleaning agent. For the contact time refer to the cleaning solution manufacturer’s instructions for the cleaning agent use.
5. Immediately after immersion rinse the shells with adequate amount of flowing water (for at least one minute) to remove residual solution. Follow the cleaning solution manufacturer's directions for minimum duration to rinse.
6. Dry using lint-free non-abrasive cloth.
7. Inspect the immersion shells to ensure that they are visibly clean, dry and undamaged. Repeat these cleaning steps if they remain dirty.

Steps to disinfect

1. Prepare the disinfectant according to the disinfectant manufacturer’s directions.
2. Soak the shell in the disinfectant for the contact time per manufacturer’s instructions.



3 Immediately after immersion rinse the shells with adequate amount of flowing water (preferably sterile water) for at least one minute to remove residual solution. Follow the disinfectant manufacturer's directions for minimum duration to rinse.

4 Dry the shells using a sterile lint-free non-abrasive cloth.

5 Inspect the shells to ensure they are visibly clean, dry and undamaged.

6 Store immersion and scleral shells in a manner that will protect them from damage or contamination before the next patient use.

Testing

Test probes every six months to verify their operation. If a probe is mishandled or dropped, or if it begins to operate erratically or generates spurious readings, test it immediately. Contact your Authorised Ellex Distributor if problems continue.

The following instructions are provided for each probe:

- Basic operational tests (test procedure to verify normal operation including comparative graphics of normal output on a human eye, a probe in air [no target] and a probe against a target).
- Measurement verification instructions (A-Scan probes only).

B-Scan measurements are determined by fixed geometry and hard-coded into the instrument and therefore do not require verification.

The following instructions assume that you have logged on to the system (using type of user), loaded or created a test patient record, connected the probe, and have started a new session.

Create a patient record for each type of probe used (use the probe serial number as part of the patient name or ID in case multiple probes of the same type are used). Save sample scans and use these for comparison over the life of the probe.

Test fixtures

To obtain usable images an ultrasound probe you must submerge the probe in a water bath with a suitable target, or place the wet probe tip on your closed eyelid. Several simple test fixtures are described below.

Test block

All biometry systems include a test block (a small clear plastic cube). The aphakic mode measurement at 72 ºF/ 22 ºC is printed on the side of the block.

Measurement accuracy with the test block depends on temperature and probe alignment to the block itself. Any significant deviation in temperature from the value recorded on the test block will result in a different measurement than shown on the block. Only temperatures within a few degrees of the value listed on the block are guaranteed to meet specifications. It is possible to make the measurement change by up to ± 0.2 mm by varying the receive gain and the angle of the probe tip.

om_i3_0024a

Sponge bath

A test fixture for A and B-Scan probes can be made by submerging a sponge in a shallow plastic dish of water. Embed a coin or other object in the sponge to make an additional target and weigh the sponge down. Ensure that all of the air is expelled from the sponge to prevent air pockets.

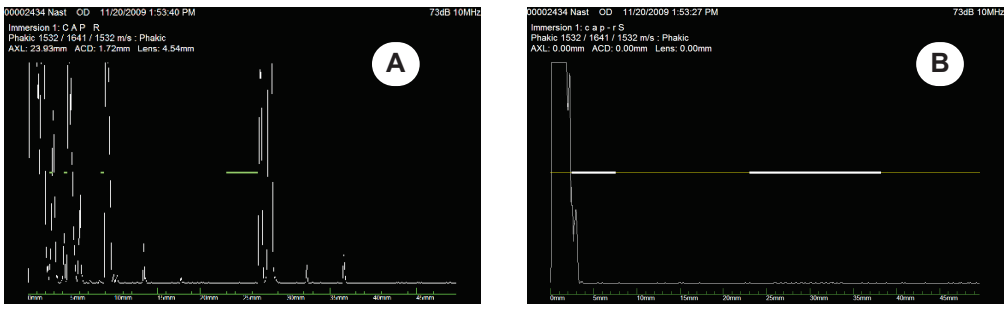
om_i3_0024b

Biometry 10 MHz A-Scan probe

Operational test

1. Press **F4** to select biometry A-Scan mode.
2. Press **F11** or the **SCAN/FREEZE** pedal to begin scanning.
3. Adjust the receive gain so that the probe tip echo grows taller and wider.
4. Check the imaging. Comparative test images are shown below.

Scan A	A scan of a normal human eye and is similar to what you would see when scanning through the eyelid. Note that this exact image is only obtained when the probe is aligned with the visual axis.
Scan B	A scan when the probe tip exposed to the open air.



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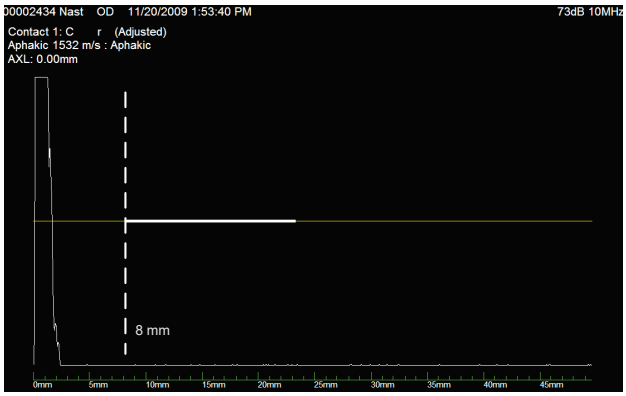
Measurement test

1. Press **F4** to select the Biometry A (Manual) mode.
2. Change **Exam Technique** to Contact 1.

3 Change **Tolerance** to Expert.

4 Change **Eye Type** to Aphakic.

5 Align the caliper to the 8 mm mark as shown below.



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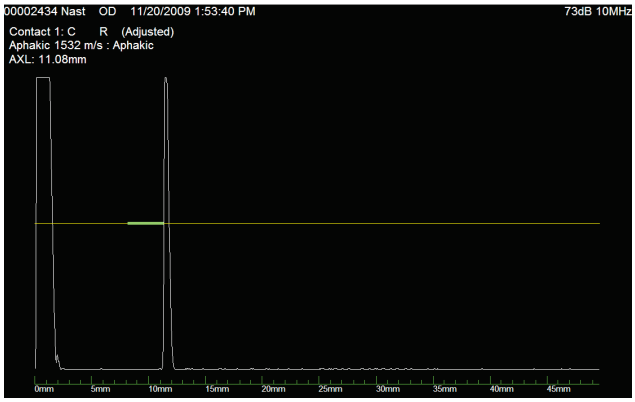
6 Place a drop of water on the probe tip and apply the tip firmly to the top of the test block, so that the tip is perpendicular to the black dot.

7 Press **F11** or the **SCAN/FREEZE** pedal to begin scanning.

8 Make adjustments as necessary to maximize the height of the ultrasound echo.

9 Press **F11** or use the footswitch to freeze an image similar to that below.



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10 Repeat this process to verify that the AXL length displayed on the screen is within ±0.10 mm of the value printed on the test block (at a room temperature of 22 °C or 72 °F).

Diagnostic 8 MHz A-Scan probe

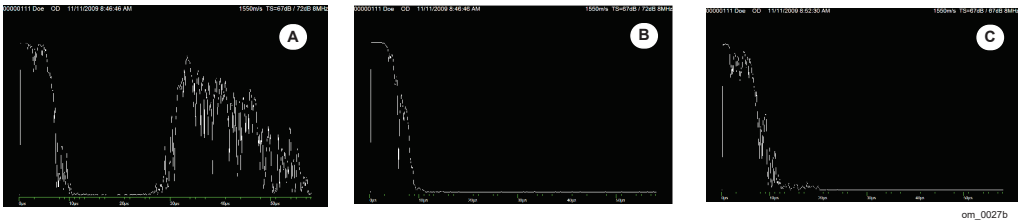
Operational test

1 Press **F3** to select diagnostic A-Scan mode.

2 Press **F11** or the **SCAN/FREEZE** pedal to begin scanning.

3 Adjust the receive gain and check the imaging. Comparative test images are shown below.

Scan A	A scan of a normal human eye, and is similar to what would be seen if the wet probe tip is placed over a closed eyelid while scanning.
Scan B	A scan when the probe tip is exposed to the open air.
Scan C	A scan of with a wet fingertip placed over the probe tip.



om_0027b

Measurement test

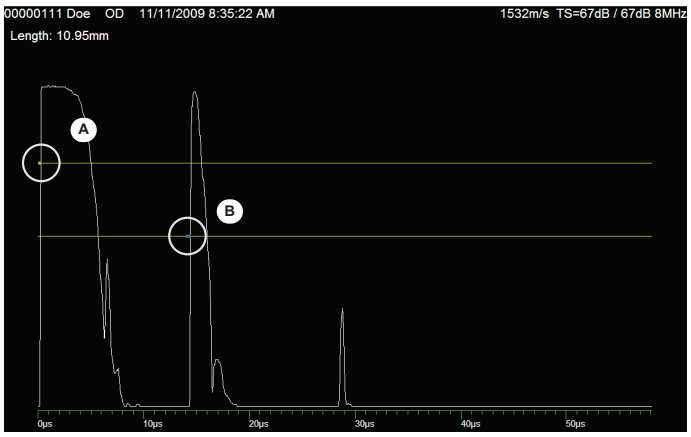
1 Press **F3** to select diagnostic A-Scan mode.

2 Place the test block close to the instrument.

3 Place a drop of water on the probe tip and apply the tip to the top surface of the test block. Press **F11** or the **SCAN/FREEZE** pedal to begin scanning.

4 Align the probe so that it is perpendicular to the cube. Make adjustments as necessary to maximize the height of the spike.

5 Press **F11** or the **SCAN/FREEZE** pedal again to freeze an image similar to that shown below.



om_i3_0026

A	Leading edge, leftmost spike.
B	Leftmost edge, right spike.

6 Change **Media Velocity** to 1532 ms (you may need to create a new media type) and click **OK**.

7 Display the ruler.

8 Move the calipers so that the first (top) caliper is positioned on the leading edge of the leftmost spike, and the second caliper is on the leftmost edge of the right hand spike. The measurement will display at the top left of the image.

9 Verify that the number shown on the screen is within ± 0.10 mm of the value printed on the test block (at a room temperature of 22 °C or 72 °F). Repeat the process if necessary.

Posterior 10 MHz B-Scan probe

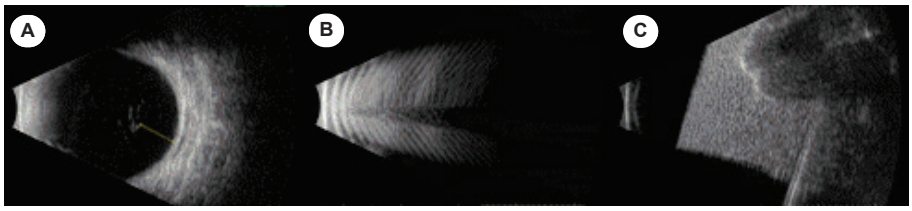
1 Press **F1** to select Posterior B mode.

2 Press **F11** or the **SCAN/FREEZE** pedal to begin scanning.

3 Adjust the **Receive Gain**.

4 Check the imaging. Comparative test images are shown below.

Scan A	A scan of a normal human eye, and is similar to what would be seen if the wet probe tip is placed over a closed eyelid while scanning.
Scan B	A scan when the probe tip exposed to the open air.
Scan C	A scan of a sponge test target. A rock embedded in the sponge is visible at the top centre of the image.



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Anterior 20 MHz or 40 MHz probe

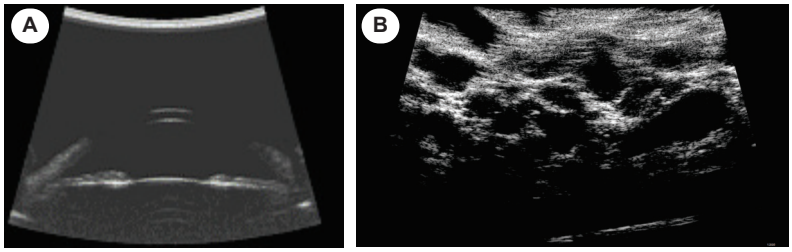
1 Press **F2** to select Anterior B mode.

2 Press **F11** or the **SCAN/FREEZE** pedal to begin scanning.

3 Adjust the receive gain.

4 Check the probe's imaging. Comparative test images are shown below.

Scan A	A scan of a normal human eye. This image was obtained using a water filled stand-off.
Scan B	A scan of a sponge test target. A rock embedded in the sponge is visible.



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Transporting the device

Moving the system a short distance

1 Turn the device off.

2 Remove the mains power connection to the system.

3 Place the footswitch on the cart.

4 Ensure that all cables are clear of the cart wheels.

5 Move the cart to the new location.

6 Reposition the footswitch.

7 Reconnect the system to mains power.

8 Turn the system on.

Transporting the device a long distance

The Eye Cubed is a durable system but it may become damaged if the unit is mishandled or subjected to excessive shock or vibration. Ensure that the requirements for storage temperature are maintained during storage and transportation (refer to System on page 111).

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

To relocate the device, pack the instrument and all accessories in the original packaging to protect against damage from shock during transportation.

Factory return

If you believe the system needs to be returned to the factory, contact your Authorised Ellex Distributor who will organise for its repair, replacement, or factory return.

Product lifetime

The Eye Cubed console has a design life of at least seven years from the date of manufacture (recorded on the compliance label at the rear of the console).

Product disposal

This device contains natural resources, and may also contain hazardous substances which 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 when the device reaches the end of its working life. Recycling systems reuse or recycle many of the materials in the equipment. This avoids these substances entering the environment and promotes natural resource conservation. Contact local or regional waste administration for more information about the collection, reuse or recycle systems available in your area.

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)
主机外壳和机械固定装置	X	0	0	X	X	X
主机连线及电器元件	X	0	0	X	X	X
主机前端组件（模块）	X	0	0	X	X	X
主机前面板控制及指示器	X	0	0	X	X	X
主机印刷电路板	X	0	0	X	X	X
数据存储外设	X	X	X	X	X	X
主机电源	X	X	X	X	X	X
传感器探头	X	0	0	0	X	X

Prager 沉浸外壳	0	0	0	0	X	X
电力线	X	0	0	0	X	X

0: 表示该部件中有害物质成分低于 SJ/T 11363-2006 标准中规定的极限.

X: 表示该部件中至少有一种有害物质成分高于 SJ/T 11363-2006 标准中规定的极限.

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.

Acoustic Property Tables

This information is provided to meet the US Food and Drug Administration (FDA) ultrasound guidelines.

The tables in this chapter include data for the outputs listed below.

$I_{SPPA.3}$	The derated spatial-peak pulse-average intensity measured in Wcm^2.
$I_{SPTA.3}$	The derated spatial-peak temporal-average intensity measured in mW/cm^2.
MI	Mechanical index. The value of MI at the position of $I_{SPPA.3}$, (MI @ $I_{SPPA.3}$) may be reported instead of MI (global maximum value) if $I_{SPPA.3} \leq 190$ W/cm^2.

Diagnostic A-Scan (8 MHz)

Transducer model	diagnostic A-Scan
Operating mode	non-auto scanning mode
Applications	ophthalmic

Acoustic output			**MI**	**$I_{SPTA.3}$ (mW/cm²)**	**$I_{SPPA.3}$ (W/cm²)**
Global maximum value			0.23	1.0	-
Associated acoustic parameter	$P_{r.3}$ (MPa)				
	W_0 (mW)				
	f_c (MHz)				
	Z_{sp} (cm)				
	Beam dimensions	X_6 (cm)			
		Y_6 (cm)			
	PD (µ sec)				
	PRF (Hz)				
	EBD	Az (cm)			
		Ele (cm)			
	EDS (Circular)	D_{eq} (cm)			
	Control 1				
	Control 2				
	Control 3				

Biometric A-Scan (10 MHz)

Transducer model	biometric A-Scan
Operating mode	non-auto scanning mode
Applications	ophthalmic

Acoustic output			**MI**	**$I_{SPTA.3}$ (mW/cm²)**	**$I_{SPPA.3}$ (W/cm²)**
Global maximum value			0.23	1.0	-
Associated acoustic parameter	$P_{r.3}$ (MPa)				
	W_0 (mW)				
	f_c (MHz)				
	Z_{sp} (cm)				
	Beam dimensions	X_6 (cm)			
		Y_6 (cm)			
	PD (µ sec)				
	PRF (Hz)				
	EBD	Az (cm)			
		Ele (cm)			
	EDS (Circular)	D_{eq} (cm)			
	Control 1				
	Control 2				
	Control 3				

Posterior B-Scan (10 MHz)

Transducer model	posterior segment B-Scan
Operating mode	non-auto scanning mode
Applications	ophthalmic

Acoustic output			**MI**	**$I_{SPTA.3}$ (mW/cm²)**	**$I_{SPPA.3}$ (W/cm²)**
Global maximum value			0.23	1.0	-
Associated acoustic parameter	$P_{r.3}$ (MPa)				
	W_0 (mW)				
	f_c (MHz)				
	Z_{sp} (cm)				
	Beam dimensions	X_6 (cm)			
		Y_6 (cm)			
	PD (µ sec)				
	PRF (Hz)				
	EBD	Az (cm)			
		Ele (cm)			
	EDS (Circular)	D_{eq} (cm)			
	Control 1				
	Control 2				
	Control 3				

Anterior B-Scan (40 MHz)

Transducer model	anterior segment B-Scan
Operating mode	non-auto scanning mode
Applications	ophthalmic

Acoustic output			**MI**	**$I_{SPTA.3}$ (mW/cm²)**	**$I_{SPPA.3}$ (W/cm²)**
Global maximum value			0.23	1.0	-
Associated acoustic parameter	$P_{r.3}$ (MPa)				
	W_0 (mW)				
	f_c (MHz)				
	Z_{sp} (cm)				
	Beam dimensions	X_6 (cm)			
		Y_6 (cm)			
	PD (µ sec)				
	PRF (Hz)				
	EBD	Az (cm)			
		Ele (cm)			
	EDS (Circular)	D_{eq} (cm)			
	Control 1				
	Control 2				
	Control 3				

Anterior B-Scan (20 MHz)

Note that this probe has been replaced by the Anterior B-Scan (40 MHz) probe.

Transducer model anterior segment B-Scan

Operating mode non-auto scanning mode

Applications ophthalmic

Acoustic output			**MI**	**I_{SPTA3} (mW/cm²)**	**I_{SPPA3} (W/cm²)**
Global maximum value			0.23	1.0	-
Associated acoustic parameter	$P_{r.3}$ (MPa)				
	W_0 (mW)				
	f_c (MHz)				
	Z_{sp} (cm)				
	Beam dimensions	X_6 (cm)			
		Y_6 (cm)			
	PD (µ sec)				
	PRF (Hz)				
	EBD	Az (cm)			
		Ele (cm)			
	EDS (Circular)	D_{eq} (cm)			
	Control 1				
	Control 2				
	Control 3				

Specifications

Specifications are subject to change without notice.

System

Weight (kg)		<12
Dimensions (mm)		
	Width	390
	Depth	430
	Height	165
Operating conditions		+10 °C to +35 °C 10% to 85% relative humidity (non-condensing)
Storage and transport conditions		−10 °C to +55 °C 10% to 85% relative humidity (non-condensing)

Electrical

Supply voltage (V_{AC})	100-240 auto-ranging
Supply frequency (Hz)	50/60
Input power (VA)	220
Isolation transformer max permitted output load (VA)	1200 (120 V) 1000 (240 V)
Shock protection	Class 1, Type B

Configuration

(New Generation) EYECUBED-CONSOLE	Eye Cubed Console Includes: Wide LCD Monitor, Keyboard & Mouse, Dust Cover, Double Footswitch, Removable Hard Drive for Data storage.
10MHZBSCAN-KIT	10MHz Posterior Segment B-Scan Probe Kit Includes: 10 MHz Posterior Segment B-Scan Probe, Licensing configuration software.
10MHZASCAN-KIT	10MHz Biometric A-Scan Probe Kit Includes: 10 MHz Axial Length Biometric A-Scan Probe, Licensing configuration software, Prager Immersion Shell (adult).
8MHZASCAN-KIT	8MHz Diagnostic A-Scan Probe Kit Includes: 8MHz Diagnostic A-Scan Probe, Licensing configuration software.
(New Generation) UBM40-KIT	Includes: 40MHz Wide Field Anterior Segment B-Scan Probe, Licensing configuration software, Ten ClearScan Ultrasound Probe Cover bags and Two Immersions Scleral Shells.

Network

Network bandwidth estimates	Single frame image files are 3 KB for A-Scans and 513 KB for B-Scans. 256 Frame Movie files are slightly less than 130 MB per movie. Each time a file is stored or retrieved from a network drive the file must traverse the network. During an exam the system might store one file every 30 seconds. The maximum rate is usually about one file every 3-5 seconds.

While the Eye Cubed system may be placed on a network, connection to and operation on a network is the customer's responsibility. Network information is provided for guidance only. Consult your Network Administrator for advice.

Modes/probes

B-Scan	Four sets of electronic distance measurement calipers with variable velocity Two sets of electronic angle measurement calipers with variable velocity Text annotations Movie sequence adjustable up to 10 s Real-time image viewing Movie editing capability	
	Posterior (10 MHz)	Ingress Protection (IP) rating: X7[7] 25 fps image acquisition rate (reduced if noise filtering is active) Sealed probe Gain adjustable from 27-90 dB Adjustable dynamic range via Log, S1, S2, S3 Axial resolution: 50 µm[8] Lateral resolution: 100 µm[9] Scanning angle: 52° Image depth: 45 mm

[7] An IPX7 rating indicates that the probe enclosure is protected against the ingress of a harmful quantity of water to a depth of 1 metre. This IP rating applies to 30 mm from transducer tip for Diagnostic A, Biometry A, Posterior B probes and 23 mm from transducer tip of Anterior B probe (due to length from tip in contact with liquid during normal use with ClearScan Bag).
[8] Electronic sample resolution at the focal point.
[9] As above.

	Anterior (40 MHz) (orange and green cable shroud)	Ingress Protection (IP) rating: X7[7] 12.5 fps image acquisition rate Gain adjustable from 27-90 dB Adjustable dynamic range via Log, S1, S2, S3 Axial resolution: < 25 µm Lateral resolution: < 35 µm Scanning angle: 30° Image depth: 12.5 mm
A-Scan	IOL power calculations and analysis: Holladay-I SRK-T Haigis Hoffer-Q Movie sequence adjustable up to 5 s 50 fps image acquisition rate	
	Diagnostic (8 MHz)	Ingress Protection (IP) rating: X7[7] Two caliper measurements displayed in mm with variable velocities Tissue sensitivity value stored in memory with reset function Probe frequency: 8 MHz parallel beam Measurement accuracy: 50 µm inherent, 100 µm clinical
	Biometry (10 MHz)	Ingress Protection (IP) rating: X7[7] Immersion or contact method Solid focused probe with internal fixation light Probe frequency: 10 MHz Image depth: 40 mm Points on x-axis: 2048 8 bit resolution Measurement accuracy: 50 microns inherent, 100 microns clinical Automatic or manual image capturing Built-in pattern recognition with automatic scleral echo detection Statistics: average and standard deviation

Accessories and consumables

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

Apart from the various probes that may be purchased and connected to the console (refer to Probes on page 16) the following items are available as accessories.

Always refer to and retain any manufacturer's instructions that may be supplied with the accessories provided by Ellex for use with this device.

B-Scan probes

Item	Notes
40 MHz accessory kit	Includes 10 ClearScan bags, two scleral shells.
ClearScan bags	A box of 10 ClearScan bags.

Scleral shells (×2) 18 and 20 mm for the 40 MHz probe	

Biometry A-Scan probe

Item		Notes
Prager Shell	15 mm	Paediatric size
	22 mm	Adult size

IOL Calculation Reference

Lens power calculation formula references

Formula	Reference
Holladay-1	Holladay JT, Prager TC, Chandler TY, Musgrove KH, Lewis JW, Ruiz RS. A three-part system for refining intraocular lens power calculations. *J Cataract Refract Surg* 1998 Jan;14(1):17-24.
SRK/T	Retzlaff JA, Sanders DR, Kraff MC. Lens implant power calculation, a manual for ophthalmologists and biometrists. 3rd edn. Thorofare NJ: SLACK Inc., 1990.
Hoffer Q	Hoffer KJ. The Hoffer Q formula: a comparison of theoretic and regression formulas. *J Cataract Refract Surg* 1993 Nov;19(6):700-12. Errata *J Cataract Refract Surg* 1994 20:677.
Haigis	The Haigis IOL power formula implementation was created based on various documents provided by Dr Haigis including: Haigis, W. 'Formulas for the IOL calculation according to Haigis', (Filename: formdesc Haigis formula description.pdf, dated July 8, 2002 – commercial in confidence) Haigis, W. 'Treatment of aphakic and pseudophakic eyes in the IOL calculation according to Haigis', (Filename: formdescadd Haigis formula pseudophak.pdf, dated March 7, 2003, commercial in confidence) Haigis, W. 2009, The keratometer index problem [Internet], User Group for Laser Interference Biometry (ULIB), University of Wurzburg, Germany. Available from http://www.augenklinik.uni-wuerzburg.de/ulib/czm/texte/kprobl/kprobl.htm [Accessed 18 August, 2009]
Pseudophakic	Holladay MD, Prager TC. Accurate ultrasonic biometry in pseudophakia. *Am J Ophthalmol* 1993 April;115(4):536-537.

ACD-SF conversion table

This table is used to perform conversions between various lens constants used with the different IOL formulas.

A-Constant (SRK I, II, T)	S-Factor (Holladay)	Postop ACD (Binkhorst, Hoffer Q)
114.0	−1.04	2.63
114.1	−0.98	2.69
114.2	−0.93	2.75
114.3	−0.87	2.81
114.4	−0.82	2.86
114.5	−0.76	2.92
114.6	−0.70	2.98
114.7	−0.64	3.04
114.8	−0.59	3.10
114.9	−0.53	3.16
115.0	−0.48	3.21
115.1	−0.42	3.27
115.2	−0.36	3.33
115.3	−0.31	3.39
115.4	−0.25	3.45
115.5	−0.19	3.51
115.6	−0.14	3.56
115.7	−0.08	3.62
115.8	−0.02	3.68
115.9	0.03	3.74
116.0	0.09	3.80
116.1	0.15	3.86
116.2	0.20	3.91
116.3	0.26	3.96
116.4	0.32	4.03
116.5	0.37	4.09
116.6	0.43	4.15
116.7	0.49	4.21
116.8	0.54	4.26
116.9	0.60	4.32

A-Constant (SRK I, II, T)	S-Factor (Holladay)	Postop ACD (Binkhorst, Hoffer Q)
117.0	0.66	4.38
117.1	0.71	4.44
117.2	0.77	4.50
117.3	0.83	4.56
117.4	0.99	4.62
117.5	0.94	4.67
117.6	1.00	4.73
117.7	1.05	4.79
117.8	1.11	4.85
117.9	1.17	4.91
118.0	1.22	4.96
118.1	1.28	5.02
118.2	1.34	5.08
118.3	1.39	5.14
118.4	1.45	5.20
118.5	1.51	5.26
118.6	1.56	5.32
118.7	1.62	5.37
118.8	1.68	5.43
118.9	1.73	5.49
119.0	1.79	5.55
119.1	1.85	5.61
119.2	1.90	5.66
119.3	1.96	5.72
119.4	2.02	5.78
119.5	2.07	5.84
119.6	2.13	5.90
119.7	2.19	5.96
119.8	2.24	6.02
119.9	2.30	6.07
120.0	2.36	6.13

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 Recommended separation distance on page 120.

The emission characteristics of this equipment make it suitable for use in a professional healthcare facility environment and hospital 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. 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.

Accessories

Part No.	Part No. (US)	Description
8MHzASCAN-KIT	3600224	PROBE, DIAGNOSTIC, A-SCAN, EYE CUBED
10MHzASCAN-KIT	3600223	PROBE, BIOMETRY, A-SCAN, EYE CUBED
10MHzBSCAN-KIT	3600221	PROBE, B-SCAN, 10MHz, EYE CUBED
UBM40-KIT	3600259	PROBE, B-SCAN, 40MHz, EYE CUBED

Guidance and manufacturer's declarations[10]

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.

Electromagnetic emissions

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.

Electromagnetic immunity

Test condition	IEC 60601 test level	Compliance	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 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 for power supply lines ±1 kV 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	3 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.

[10] 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.

Voltage dips, short interruptions & voltage variations on power supply input lines IEC 61000-4-11	< 5% UT[11] (> 95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles < 5 % UT (> 95% dip in UT) for 5 s	As for IEC 60601 test level column	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) 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. The formulae for the recommended separation distances are: $d = 1.17 \times \sqrt{P} \ \ for\ 80\ MHz\ to\ 800\ MHz$ $d = 2.33 \times \sqrt{P} \ \ for\ 800\ MHz\ to\ 2.5\ GHz$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the symbol shown in the immediate left margin.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

At 80 MHz and 800 MHz the higher frequency range applies.

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] UT is the AC mains voltage prior to application of the test level.

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.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7.0}{E1}\right]\sqrt{P}$
000.01	00.12	00.12	00.23
000.10	00.37	00.37	00.74
001.00	01.17	01.17	02.33
010.00	03.69	03.69	07.36
100.00	11.70	11.70	23.30

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.

At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

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

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