MEDMONT E300
CORNEAL TOPOGRAPHER

USER MANUAL

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1. Manual Conventions

In discussing the normal interaction between the software and those involved in a particular operation, exam or exam review, this manual uses the term *Clinician* to refer to the person operating the equipment, and *Patient* to refer to the person undergoing the exam.

A small glossary is included for terminology that either originated with Medmont, or is common usage in corneal topography. It also includes some common terms where they apply to Medmont equipment. It is not a definitive glossary of corneal topography.

2. Intended Purpose

The Medmont E300 Corneal Topographer is a computerised Video-keratometer using Placido rings to map the surface of the human cornea. The map is captured in three-dimensions and can be displayed subsequently using a number of representations.

The cornea map can be represented in two-dimensional surface coordinates (Cartesian or Polar) with the third dimension expressed in curvature (mm), optical power (Diopters), elevation (mm), or corneal height (mm). The map is presented as a 2D colour map or a 3D perspective. It can be displayed according to different definitions of curvature or elevation. The options are axial curvature and power, tangential curvature and power, refractive power, elevation, corneal height, shape factor, and best-fit radius.

The clinical applications include providing measured corneal data for contact lens fitting, refractive surgery, orthokeratology and general assessment of the corneal surface.

The E300 shall only be used as described in this manual and only for the intended purpose.

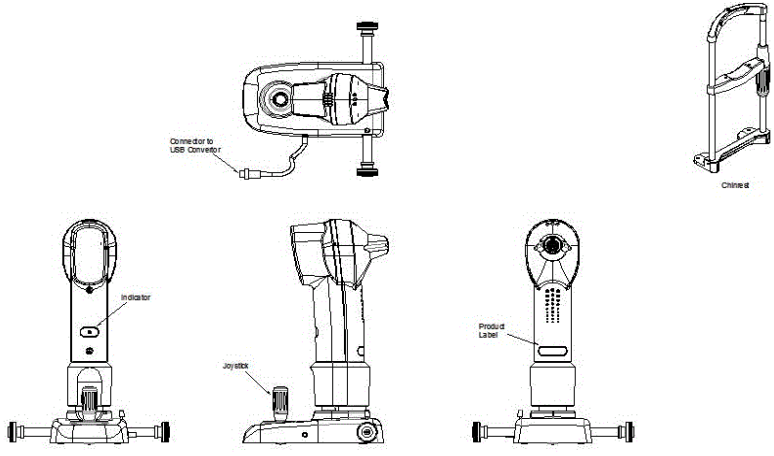


Figure 1. The E300 Instrument.

Power Connection

A typical power connection between the various units is shown in Figure 2.

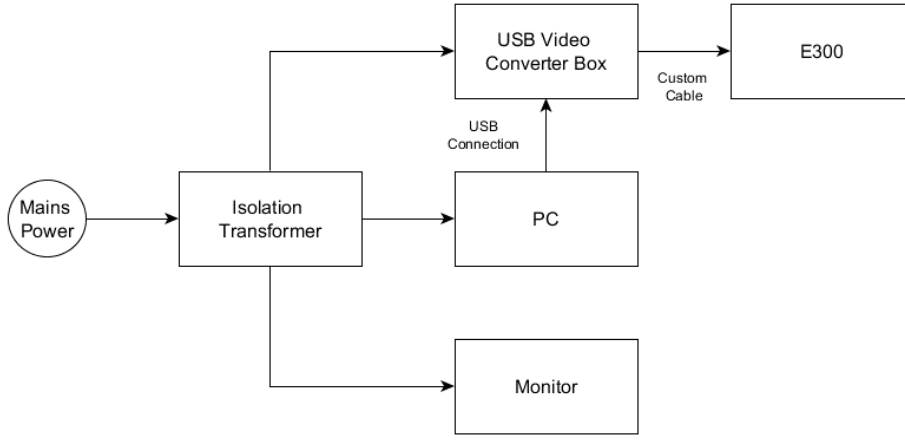


Figure 2. Typical Power Connection.

For information on purchasing an isolation transformer, please contact Medmont for a list of recommended suppliers.

CAUTION

For the diagnosis, treatment or monitoring of a patient under medical supervision there are three area definitions: Patient Environment, Medically used room and Non-medically used room. Each area demands different electrical safety requirements for your system. Please make sure that your system is set up correctly in the right environment.

CAUTION

When used in a Patient Environment, the PC and its Monitor (if separate, refer to Figure 2) must be powered via a protective isolation transformer, compliant to the governing medical standard IEC60601-1 or UL2601/CSA22.2#601-1 for North America only. A hospital grade power cord must be used to achieve reliable grounding. The Isolation Transformer must be certified either cULus or cCSAus for North America, or UL for US market or CSA for Canadian market or meet National Electrical Regulations.

Standard E300 Accessories

- USB Video Converter box
- USB 2.0 cable
- Calibration Object R 8mm with mounting screw
- Standard Table Top
- Chinrest
- Instrument Cover
- Accessory box including: 2 Rail covers, 4 mounting screws for chinrest, 2 chinrest pins, 1 box chinrest paper, Caution label (EN/IEC60950 equipment), Com port insulation plug, spare fuse
- E300 USB Quick install guide
- Medmont Studio Installation Software and calibration file on USB key
- Software license activation number

Optional System Accessories available from Medmont

- DV2000 Diagnostic Video Imaging software module
- Electric Table
- Converter box upgrade kit
- Reverse adaptor cable
- Replacement slide rail replacement kit for E300, E300 W

Spare Parts

- Calibration Ball PN: 0274-370
- Com Port insulation plug PN: 0744
- Main Cable Replacement Kit PN: 2097

Consumables

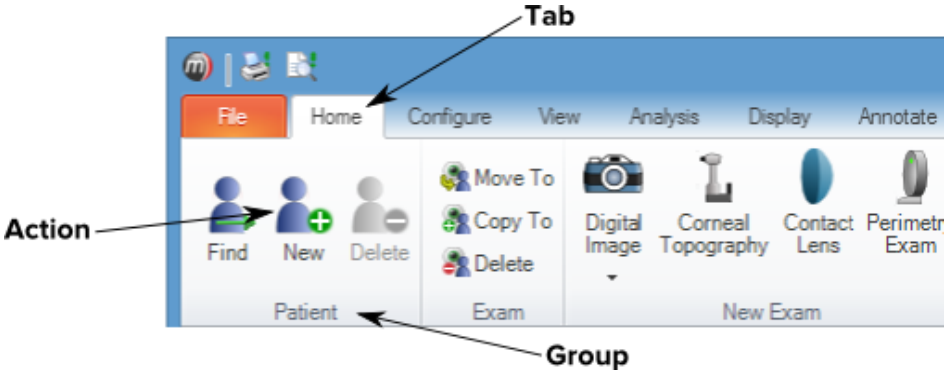
- Chinrest Paper models E300, E300W-pack 300 pc models E300 U, E300 USB - pack 300 pc
- Cotton swabs Tapered double headed on 150mm wooden sticks. Cat No MG 8112-100 bag of 100

The E300 Software

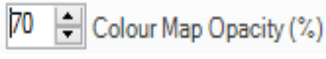
The E300 Software is part of the Medmont Studio integrated software environment. See the Medmont Studio documentation for help on installing and using the Medmont Studio environment.

Software Conventions

When referring to menu selections, the notation **Home > Patient > New** means click on the **Home** ribbon bar tab, then look for the **Patient** group on the ribbon bar and click on the **New** icon. This format conforms to the **Tab > Group > Action** system for identifying menu items in a ribbon bar menu system.



Some keyboard shortcuts can be used when setting spin-box controls like the one shown here. Use the numeric keys for direct entry, up/down arrows for small steps, PgUp/PgDn keys for large steps,



and the Home/End keys to move to max/min of the currently selected number.

3. Warranty

The E300 Corneal Topographer device has been manufactured with all due care and subjected to stringent testing before leaving the factory. The Topographer is guaranteed for 12 months from the date of purchase as evidenced by the invoice. During this warranty period Medmont or an authorised agent will repair or replace all defective parts free of charge. Such repairs do not extend the warranty period. Replaced parts become the property of Medmont. The warranty does not cover defects due to incorrect handling, installation and setup, unauthorised modifications, non-compliance with the requirements for computer hardware and associated mains powered equipment as specified in the User Manual, loss of the license, loss of income, or service and repair costs for components and associated equipment. Warranty claims are the responsibility of the outlet where the device was purchased.

The warranty and calibration is void, if the QA seal between camera and optics housing is broken.

4. Important Facts

The E300 Corneal Topographer is a highly accurate measuring instrument. It measures and maps the surface of the human cornea and represents the results in various quantities and output forms that can be applied in various medical applications. It combines these results with theoretical surface shapes to form the basis for precise contact lens fitting.

Explanation of Symbols and Labels:

Caution - potentially hazardous situation which if not avoided could result in minor or moderate personal injury.

Warning - In event of user error or equipment fault condition there may be a serious risk to health or life of patients or operator, or product damage or loss may occur.

Note – notice that additional attention should be paid to use or maintenance to prevent misuse or unexpected behaviour.

Attention, consult accompanying documents.

Alternating current.

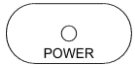
USB – Universal Serial Bus

Compliance with the EC Directive 93/42 EEC and RoHS2 Directive 2011/65/EU

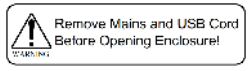
North American compliance mark for US and Canada

The date below this symbol shows the year and month of manufacturing.

Waste Electrical and Electronic Equipment Directive (WEEE Directive) 2012/19/EU on waste electrical and electronic equipment.
No disposal of goods in general waste.



Power Indicator on rear side of unit. The E300 is powered if indicator is illuminated green, unpowered if un-illuminated.



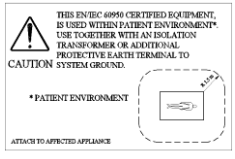
Warning: Remove Mains and USB Cord Before Opening Enclosure!

WARNING: USA and Canada; Grounding reliability can only be achieved to a receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE"

PLEASE REFER TO PRODUCT MANUAL

AVERTISSEMENT: USA et Canada, La fiabilité de la mise à la masse de cet equipment ne peut être réalisé que si celui-ci est connecté à une price marquée "HÔSPITAL SUELMENT" ou "CLASSE HÔSPITAL"

VEUILLEZ VOUZ PRÉFÉRER AU MANUEL DU PRODUIT



The patient environment comprises a 1.5m radius around the area in which patient or some other person can touch parts of the medical system intentionally or unintentionally. This label is to be attached in a visible position on any EN/IEC 60950 compliant equipment used within the electro-medical system of the E300.

This label is found on the PC port insulation plugs. These plugs are for RS232 and Network ports, and these ports are to be covered if the PC is used within the patient environment.

E300 Device Label (here shown for the USB variant) - positioned at bottom of base next to cable exit.

Regulatory Information

This instrument complies with all applicable Regulatory requirements and Safety Standards.

Classification

In accordance with IEC 60601-1 the E300 Corneal Topographer is classified:

Protection against electric shock	Class I
Protection against harmful ingress of water	Ordinary (no protection)
Mode of Operation	Continuous Operation

Clinical Results

This manual **does not** provide guidance on interpretation of clinical results. The clinician must ensure that he or she has received appropriate medical training in such interpretation. For this reason Medmont cannot be held responsible for any misdiagnosis of results.

Accuracy and Calibration

The E300 is delivered to the end user quality tested, calibrated and as per specifications. It is not the responsibility of Medmont to guarantee or police the accuracy of this instrument after delivery. The E300 is delivered with a calibrated and certified test object with an accuracy based on the national standard. The customer can verify the accuracy of the instrument with the calibration object provided. Medical Regulations require, that the functional accuracy of equipment used for professional purposes be verified every two years. This can be achieved by re-calibrating the test object. Medmont or their authorised agents can provide this service in return for a fee. The E300 must then be re-calibrated by the customer using the newly calibrated test object.

Radiation

The E300 emits radiation in the visual range for illumination in the distinct wavelength 660nm (red LED cone illumination), 565nm (green LED fixation target) and 430nm (blue LED profile illumination). The levels of intensity of this illumination are less than 50 cd/m^2, below any levels known to be hazardous.

Electromagnetic Interference

Strong electromagnetic interference from unprotected devices or portable and mobile RF communications equipment or mains disturbances (voltage dips, transient surges) or electrostatic discharge may affect the performance or results of the E300 USB Corneal Topographer. Avoid using the device while such high interference is present. The device is compliant with medical standard EN/IEC60601-2.

Guidance and manufacturer's declaration – electromagnetic immunity			
The E300 Corneal Topographer is intended for use in the electromagnetic environment specified below. The customer or the user of the E300 USB Corneal Topographer should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *UT* (>95 % dip in *UT)* for 0,5 cycle 40 % *UT* (60 % dip in *UT)* for 5 cycles 70 % *UT* (30 % dip in *UT)* for 25 cycles <5 % *UT* (>95 % dip in *UT)* for 5 s	<5 % *UT* (>95 % dip in *UT)* for 0,5 cycle 40 % *UT* (60 % dip in *UT)* for 5 cycles 70 % *UT* (30 % dip in *UT)* for 25 cycles <5 % *UT* (>95 % dip in *UT)* for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the E300 SUB Corneal Topographer requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *UT* is the a.c. mains voltage prior to application of the test level.			
The E300 USB Corneal Topographer is intended for use in the electromagnetic environment specified below. The customer or the user of the E300 USB Corneal Topographer should assure that it is used in such an environment.			

Guidance and manufacturer's declaration – electromagnetic immunity			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of E300 USB Corneal Topographer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $\boldsymbol{d = 1.2\sqrt{P}}$
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	$\boldsymbol{d = 1.2\sqrt{P}}$ 80 MHz to 800 MHz
\Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	$\boldsymbol{d = 2.3\sqrt{P}}$ 800 MHz to 2,5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To 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 the E300 USB Corneal Topographer is used exceeds the applicable RF compliance level above, the E300 USB Corneal Topographer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the E300 USB Corneal Topographer. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the E300 USB Corneal Topographer

The E300 USB Corneal Topographer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the E300 USB Corneal Topographer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the E300 USB Corneal Topographer 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Electromagnetic Emissions

This device does not emit harmful or undesired electromagnetic emissions. The device is compliant with medical standard EN/IEC60601-2. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

If the E300 USB Corneal Topographer is used in a domestic establishment or connected to the Mains Public Network following warning shall apply:

The use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the MANUFACTURER as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the E300 USB Corneal Topographer.

The E300 USB Corneal Topographer should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the ME EQUIPMENT or ME SYSTEM should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The E300 Corneal Topographer is intended for use in the electromagnetic environment specified below. The customer or the user of the E300 Corneal Topographer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The E300 Corneal Topographer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The E300 Corneal Topographer is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Compatibility and Emissions

This instrument conforms to the EMC Standard IEC 60601-1-2. The device emits no harmful or undesired electromagnetic emissions.

Interference

Strong electromagnetic interference from other unprotected devices may affect the performance or results of the E300. If the use of such devices with high electromagnetic emissions cannot be avoided, do not use the E300 and the device simultaneously.

Side effects

No undesired side effects to patient or clinician or other persons are known when using this instrument under normal conditions and for the intended purpose.

Electrical safety of medical electrical system

All the equipment connected of the E300 topographer shall be certified to EN/IEC60950. It must be powered by an isolation transformer compliant to the medical standard EN/IEC 60601-1, UL2601 or CSA22.2#601-1 (see *Standard E300 Accessories* on page 4).

Disposal

The expected service life of E300 equipment is 8 years. For disposal at the end of the product life cycle please follow national regulations.

5. Installation

The installation instructions and this user manual provide guidelines on the installation process. Medmont or Authorised Distributors can provide this service for a fee. If a third party installer is commissioned by the customer, only a qualified PC technician should perform the hardware and software installation.

The basic tasks associated with installing the E300 are

- Setting up the Instrument in a suitable environment.
- Installing the Medmont Studio Software.

PC and Associated Equipment Requirements

When acquiring a PC for the Medmont E300, please observe the minimum requirements as given in the Medmont Studio User manual.

Use only a PC and associated equipment that has been certified to the Standard EN/IEC60950 (Information Technology Equipment) and the Standards for Electromagnetic Emissions CISPR22/EN55022.

If used within a patient environment, power the PC and associated equipment with an EN/IEC60601-1 compliant isolation transformer e.g. TR2450 (230/240V).

Cover any open PC communication ports that have accessible conductors with dummy plugs if used in a patient environment.

Instrument Environment

The E300 is highly precise measuring equipment and must be located in a suitable and clean environment.

The environmental requirements for the E300 are:

Room temperature:	*+10°C to +40°C*
Relative humidity:	*10% to 80%*

Keep the instrument away from direct sunlight and avoid unnecessary exposure to heat and light. Avoid overly bright rooms to keep stray light level low.

Set up the instrument so that any unavoidable bright light sources are opposite the cone opening.

Set up the instrument so that all interface and power cables are easy to access. Do not set up the instrument in proximity to devices with high electromagnetic emissions.

CAUTION

Temperatures too low may cause condensation on the optics, while temperatures too high may result in de-calibration of the instrument. After such an event a calibration check is recommended. Strong surrounding electromagnetic fields may affect performance and results of the E300.

Customers using their own table should ensure the linear guides are assembled parallel and positioned as per Figure 3, and that the table is adequately secured.

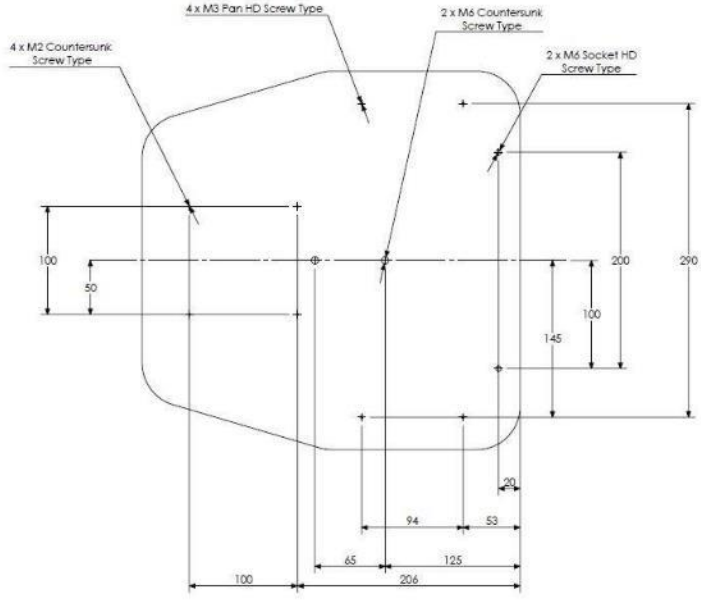


Figure 3. Table setup and dimensions.

Software Installation

It is important that you read the Medmont Studio manual for additional details on installation.

The E300 software is a part of the Medmont Studio software package. A single USB Flash device is supplied with installation software for all Medmont Studio components.

- Insert the Medmont Studio USB software key into your computer. After a few seconds a Windows Explorer window will display. If not, launch Windows Explorer and select the new removable drive now listed in the left pane labelled "MEDMONT".
- Next, expand the removable drive and select folder "Medmont Studio". Double-click on file setup.exe to start installing the software.
- Select the E300 component when asked which components to install.
- Select the correct frame-grabber hardware for your system.
- Restart the computer when the software installation is complete.

Running the Software

Select Medmont Studio from the **Start > Program > Medmont > Medmont Studio 6** menu or double-click the  desktop icon

Connecting the E300 instrument

The following steps should be followed to connect the Medmont E300 Corneal Topographer to the PC for the first time.

> Note the E300 Corneal Topographer requires Microsoft© Windows™ 7 or greater to be installed.

Connecting the USB Video Converter box

1. Firstly, connect the USB Video Converter box to the mains power using the supplied mains power cable. Do not switch the unit on!
2. Connect the USB Video Converter box to the PC using the supplied USB cable.
3. Connect the E300 Corneal Topographer 8-pin DIN plug to the USB Video converter box.
4. Turn on the USB Video Converter box.

Checking the E300 instrument is connected

1. Open Device Manager. Under Microsoft© Windows™ 7 this can be done by selecting the Windows Logo in the bottom left corner of the

main desktop window. Next, right-click while hovering above **Computer** and select **Manage** from the popup menu. When the screen titled *Computer Management* appears, select Device Manager from the *System Tools* menu in the explorer pane (left docked)

2. Expand imaging devices
3. Ensure that the item MEDMONT E300 USB appears in the list of imaging devices as per the screen in Figure 4.

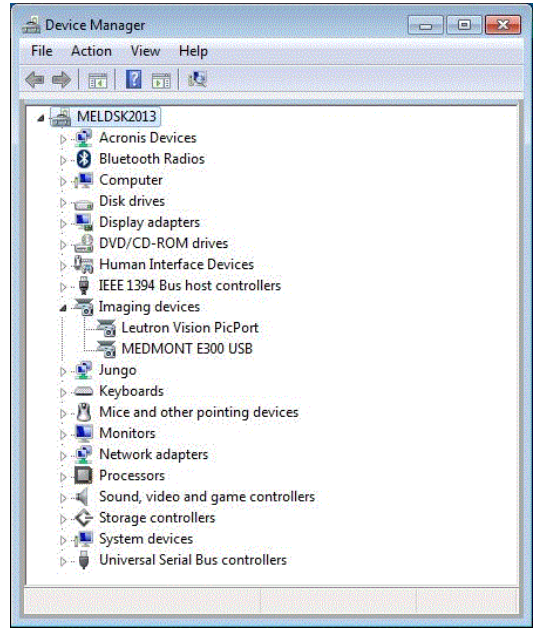


Figure 4. Device Manager showing a successful connection to the Medmont E300 Corneal Topographer

If the E300 Corneal Topographer does not appear as per these instructions refer to the troubleshooting section in this manual for suggested solutions.

Installing the E300

Double-click on the **Medmont Studio** desktop icon or select **Medmont Studio** from the Windows **Start > Programs > Medmont > Medmont Studio 6** menu. A banner with the Medmont Studio logo is displayed while the software loads.

To begin the installation process, click on the **Configure > E300 > Instrument Setup** button  . Click **New** to install the instrument. You will be prompted to enter the serial number of your E300 instrument. Enter the serial number (the format should be E3XXXX) and press OK.

Next, click the **Import Calibration** button to import the instruments calibration file. You will be presented with a standard Windows file selection menu. Insert the Medmont Studio USB Flash Drive medium which contains the calibration file into your PC. Once the USB flash drive is available, browse to your flash drive, ensure the file with the .ECF extension is highlighted and click **Open**.

From the Instrument setup window, you can select edit to add a comment to the instrument and select **Delete** to delete that particular instrument and its configuration. You will need to select the E300 instrument that will be used for E300 exams. This can be done by selecting a particular instrument, then clicking the **Install** button.

It is recommended that ALL instruments are calibrated after their initial setup due to transportation. To calibrate the instrument, select the instrument and click **Calibrate**. For more information about the calibration process, see page 80.

Disconnecting the E300 instrument

The following steps should be followed to disconnect the Medmont E300 Corneal Topographer from the PC and the Mains Power socket if the USB Video Converter box is in use.

Disconnecting the USB Video Converter box:

1. Turn off the USB Video Converter box first.
2. Disconnect the E300 Corneal Topographer 8-pin DIN plug from the USB Video converter box.
3. Disconnect the USB Video Converter box from the PC by removing the supplied USB cable from the PC.

Disconnecting from the Mains Power outlet

1. Disconnect mains power by pulling out the supplied mains power cable connected to the USB Video Converter box.

6. Performing Examinations

The following sections describe the steps to performing an examination with the Medmont E300 instrument.

Patient Selection

The recommended practise is to have a patient selected before starting to capture and analyse an exam. Figure 5 shows the Medmont Studio initial display with a patient selected in the explorer pane.

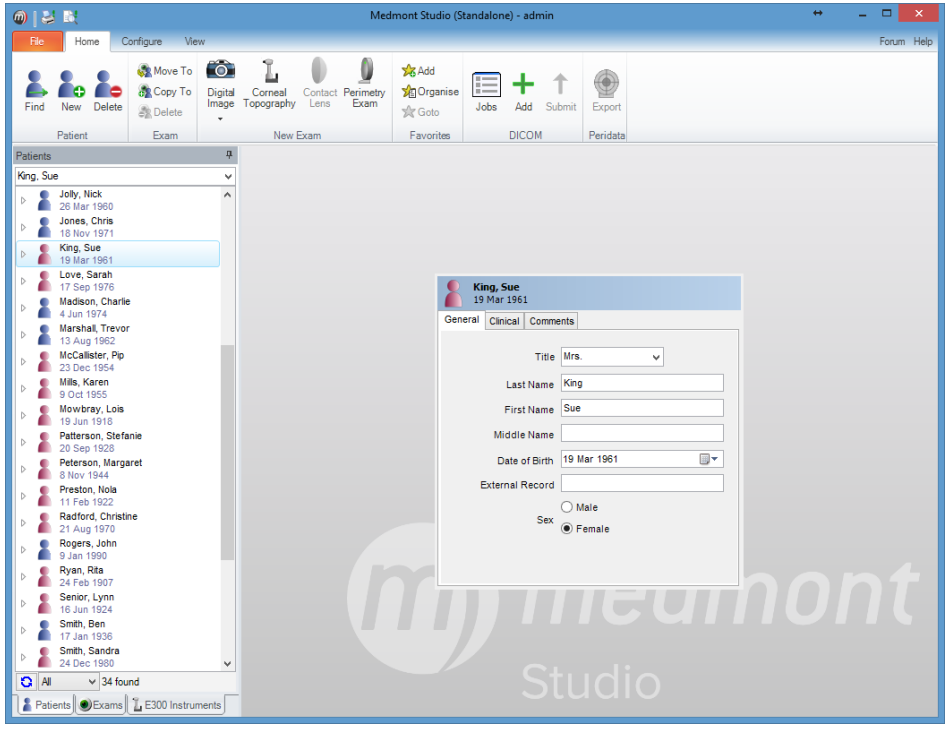


Figure 5. Patient selection.

Positioning the Patient

In order to capture good quality and accurate images some precautions should be followed in positioning the patient correctly. While these are well-known and standard practice for corneal topography examinations, here we reiterate the most important points as they apply to the E300.

The patient should sit comfortably in the chair. Ask the patient to put her chin onto the chinrest and put their forehead firmly against the forehead rest. They should then push their chin forward on the chinrest. If the patient has deep-set

eyes instruct them to move their head back from the headrest. This rotates the eye away from the eyebrow and eyelashes and produces better coverage and fewer interruptions of rings on the upper cornea. Adjust the eye height to the level marks on the chinrest.

Ask the patient to look into the centre of the green fixation target and keep their gaze on the target. The target centre point together with the centre of the ring pattern on the eye defines the Video-Keratoscope axis (VK-axis), the reference axis to which the axial radius/power is calculated (the values for tangential radius/power are less affected by the fixation). If the patient is fixating on the target, the VK-axis is aligned with the line of sight.

When an image is taken with the patient not fixated on the target, the axial power is not referenced to the line of sight, but to an arbitrary axis which may not be reproducible in future exams and may not represent the visual refractive properties of the patient's eye. In most cases examining the position of the centre of the pupil easily identifies this. For images with good fixation the pupil centre is aligned with the centre of the VK-axis (centre of the Polar and Cartesian grids). If unsure, re-capture the image and view the difference between the two images. Axial power maps are identical for fixated eyes. The tangential power for both images should have their centre in the same position relative to the pupil centre.

Ask the patient to open their eyelid as much as possible and close the other eye if necessary.

Selecting the Exam Type

Click on the **Home > New Exam > Corneal Topography** button to display the *Select Exam Type* dialog (see Figure 6).

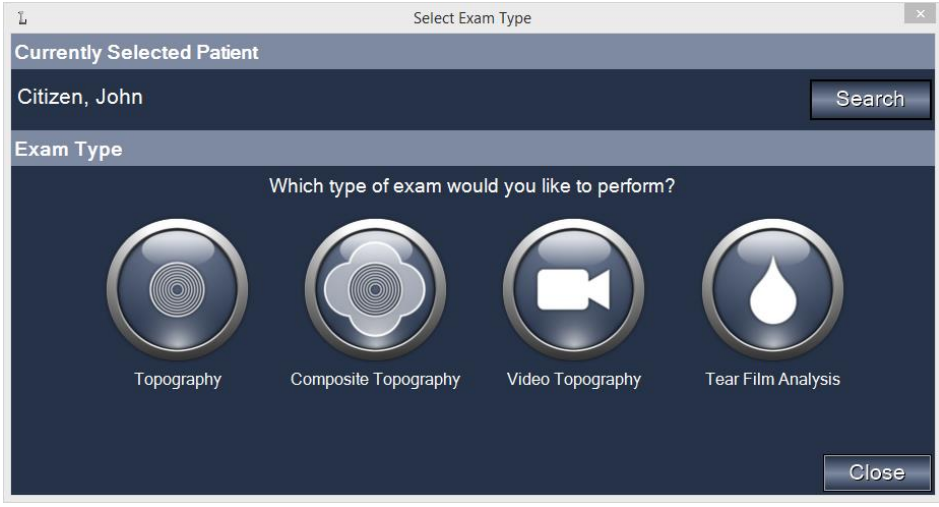


Figure 6. Select Exam Type.

The following exam types are supported and described in more detail below:

- ***Topography*** – standard corneal topography
- ***Composite Topography*** – captures five images covering different portions of the cornea and stitches them together to form a single image with larger coverage
- ***Video Topography*** – captures a sequence of topography images at up to 25 Frames Per Second
- ***Tear Film Analysis*** – automatically captures a sequence of images started by the patient blinking and analyses the changes in tear film surface quality

Topography

Click the **Topography** button (see Figure 6) to start a wizard for capturing standard topographic images (Figure 7). The illumination rings inside the E300 cone should turn on. The wizard provides detailed guidance on the action required at each step inside the **Instructions** box.

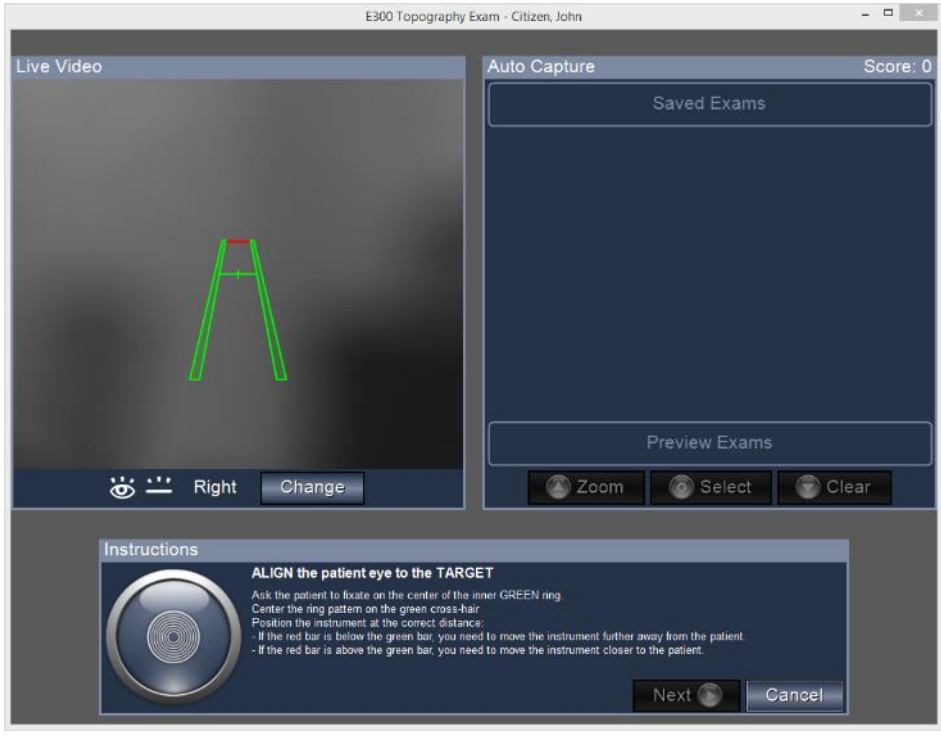


Figure 7. Standard Topography Wizard.

The Live Video window shows video from the instrument. The eye being examined should be auto-selected based on the position of the instrument – however you can manually override this if required by clicking the **Change** button.

The green and red target overlaid on the focussing window provides three-dimensional centring and focussing information. The central green crosshair indicates the keratoscope axis. The red bar moving along the three-dimensional *runway* indicates the distance of the eye from the optimal focussing plane. The "view" is from the camera's perspective, so if the red bar is at the top or narrowest part of the runway then the patient is still too far away.

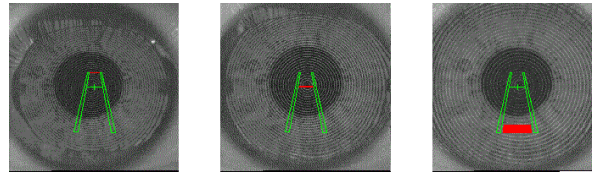


Figure 8. Focus examples showing Too Far, In Focus, and Too Near.

The E300 joystick allows positioning in three dimensions. Move the joystick in the desired direction for movement left and right and for closer to or further away. Rotate the joystick knob for movement up and down, clockwise to raise, anti-clockwise to lower.

Using the joystick, position the E300 relative to the patient's eye so that the reflection of the Placido rings is centred on the green crosshair, and the red bar is over the horizontal green line. Once this is achieved, the software will begin to automatically capturing images and display them in the **Preview Exams** area at the bottom of the **Auto Capture** window (see Figure 9).

It may not be possible to align the red focussing bar over the horizontal cross bar for patients with deep set eyes, because of contact between the bridge of the nose and the instrument. In this case, centre the Placido rings on the green crosshair and bring the red focussing bar as close to the horizontal green line as possible without causing patient discomfort. Provided that the red bar is somewhere within the focussing range (i.e. not at the very end) the software will automatically compensate for the focussing error.

Images are awarded a score out of 100 based on centring, distance (focussing) and eye movement. A good score for a normal eye will be over 75. Calibration balls can achieve scores of up to 100. The preview exam with the highest score is highlighted and displayed enlarged within the **Auto Capture** window. Typically this will be the exam that you should select to save, however in some cases one of the other preview images may be better because of factors not considered by the automatic scoring algorithm. Click on the preview exams to view them in the larger viewing area.

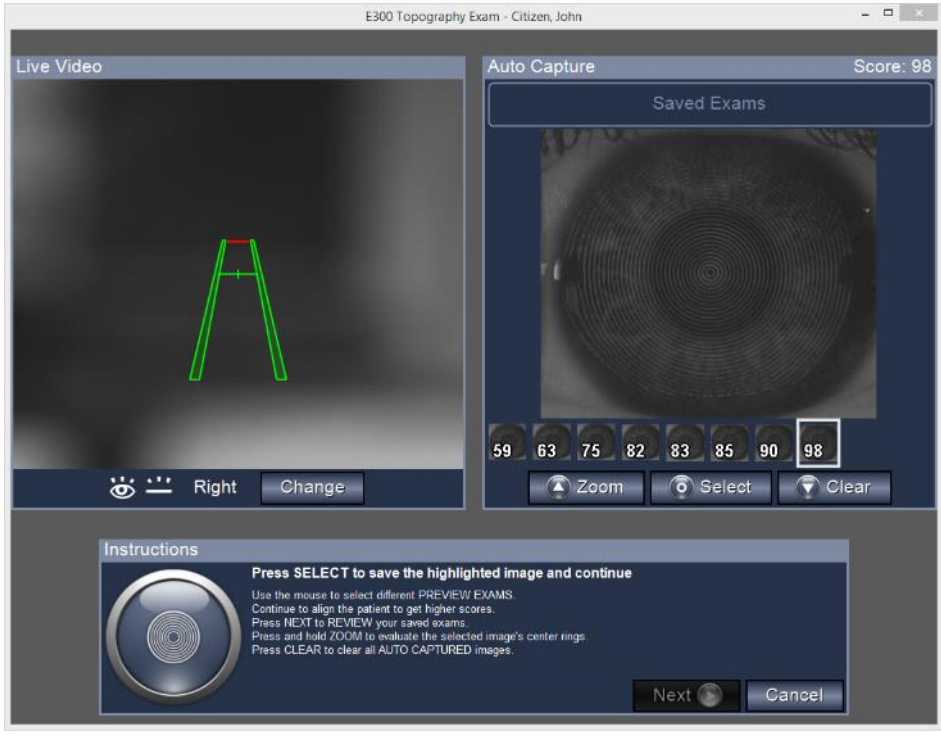


Figure 9. Auto Captured Exams.

You should consider the following factors when assessing images:

- Patient Fixation – choose images where the pupil is centred with respect to the Placido rings.
- Eyelid Position – choose images where the patient's eyelid does not obscure large portions of the cornea or cause large eyelash shadows.
- Central Ring Clarity – choose images where the central Placido ring reflection is clearly visible. For some patients with extreme conditions, this may require shifting their fixation to get the central Placido ring area over an area with less surface irregularity. Click and hold the Zoom button to see an enlarged view of the central zone of the image.

Highlight the preview exam that you wish to keep and click the **Select** button. This saves the selected preview exam in the **Saved Exams** area (see Figure 10) and clears the **Preview Exams** to allow you to capture another exam for the patient (typically of the other eye). The saved exams display an indicator of the eye they were capture for.

In the event that none of the auto captured exams were suitable you can click the **Clear** button to clear the preview exams and start the capture process again.

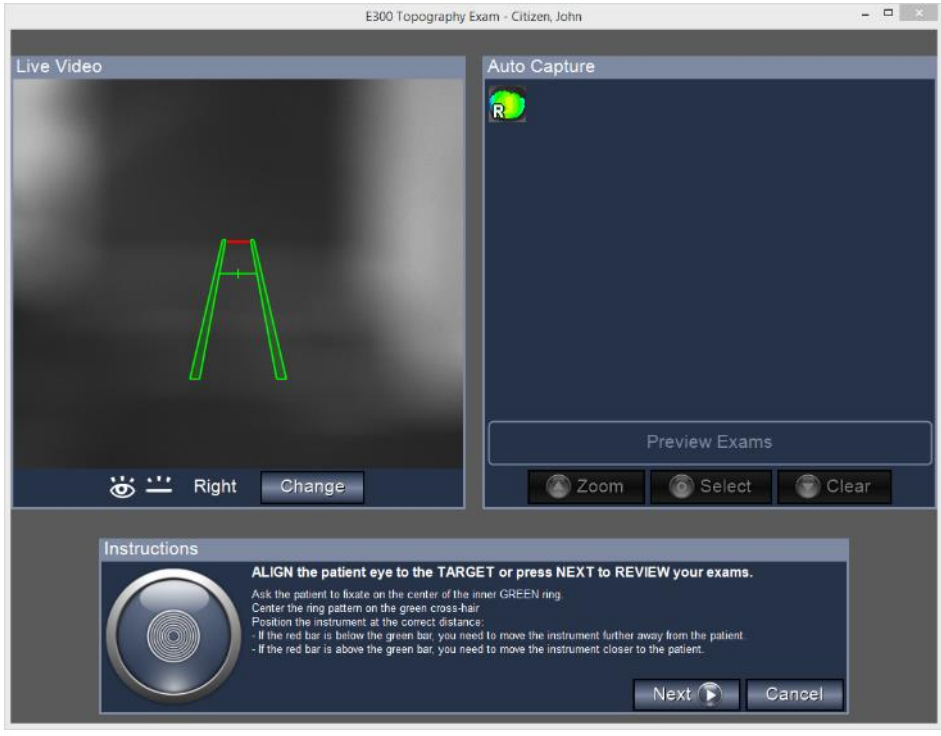


Figure 10. Saved Exam.

You can capture multiple exams for each eye if you wish before clicking the **Next** button to proceed to the review stage. Some contact lens practitioners recommend capturing multiple topography exams in order to assess the level of variability in the exams due to tear film or alignment issues. In this case it is better that the images captured are not sequential frames so that any tear film artefacts are different in each exam. The wizard automatically clears the preview exams when the **Select** button is pressed. This ensures that, where multiple exams are saved, they are not sequential frames.

Click the **Next** button to review the captured exams (Figure 11) before completing the examination.

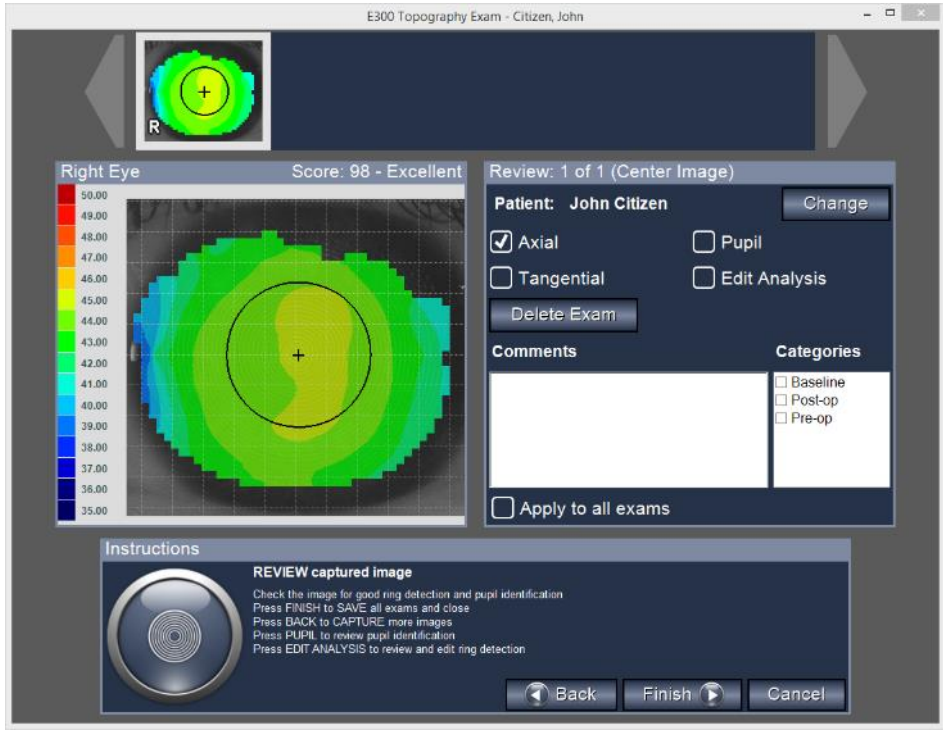


Figure 11. Exam Review.

Clicking the **Next** button selects each of the captured exams in turn for review. Select the **Axial** and **Tangential** options to view the corresponding power map displayed overlaid on the image.

Select the **Pupil** option to display and edit the detected pupil outline. This allows you to confirm that the pupil has been properly detected by the software. If necessary clicking the **Define Pupil** button allows you to manually define the pupil by selecting points on the border and right clicking to complete the selection.

Select the **Edit Analysis** option to show the detected analysis points. This option displays the points that the software has identified as ring reflections and enables you to remove any points that have been misidentified (as described in *Removing Analysis Artefacts* on page 69).

When the last captured exam has been reviewed the **Next** button is replaced by the **Finish** button and clicking this completes the examination. The last exam saved is automatically selected in the Medmont Studio explorer pane.

Composite Topography

A single topography exam typically has analysis data out to a chord of around 10 to 11mm (depending on the patient). The analysis coverage can be extended to the edge of the sclera by capturing a number of images at different patient gaze angles and combining the topography in a composite exam. Click the **Composite Topography** button (see Figure 6) to start a wizard (Figure 12) that guides you through the process of capturing images and combining them into a single extended coverage composite exam.

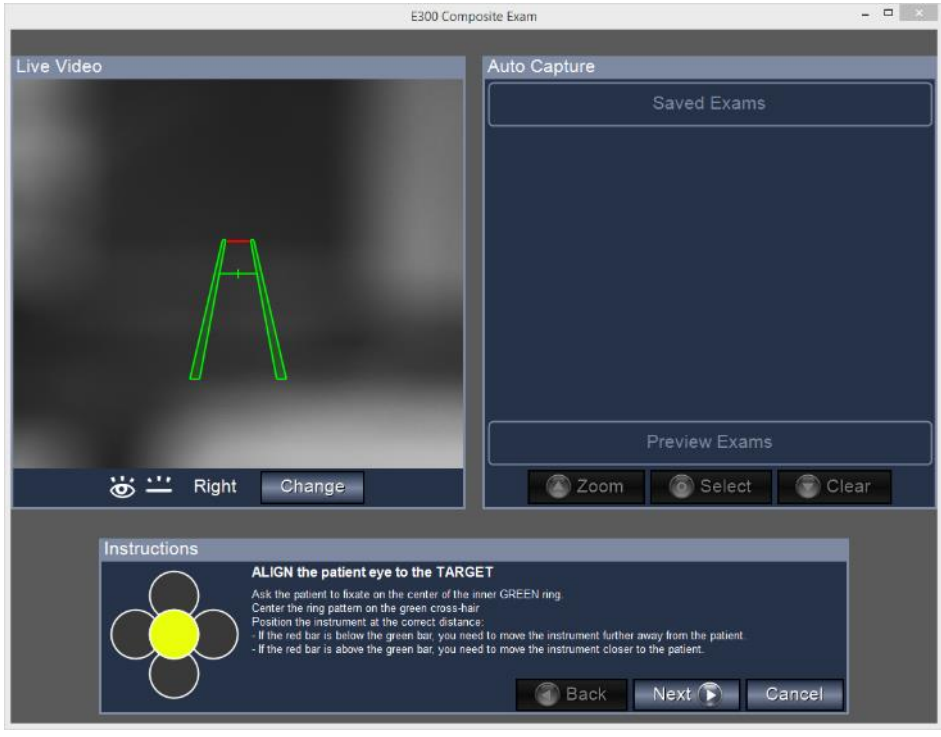


Figure 12. Composite Topography Wizard.

The alignment process is similar to that for standard topography (described above) aligning the central ring reflection over the green cross hair and the red focus bar over the green line. The wizard will guide you through the capture of five images (central, gaze up, gaze down, gaze left and gaze right).

When capturing off axis gaze locations the wizard will not move to the next step and begin auto capturing exams until it detects the pupil in the correct location. The wizard provides instructions on the direction the patient needs to look and provides a visual indicator (as shown in Figure 13) which is displayed until the pupil reaches the required offset from the axis.

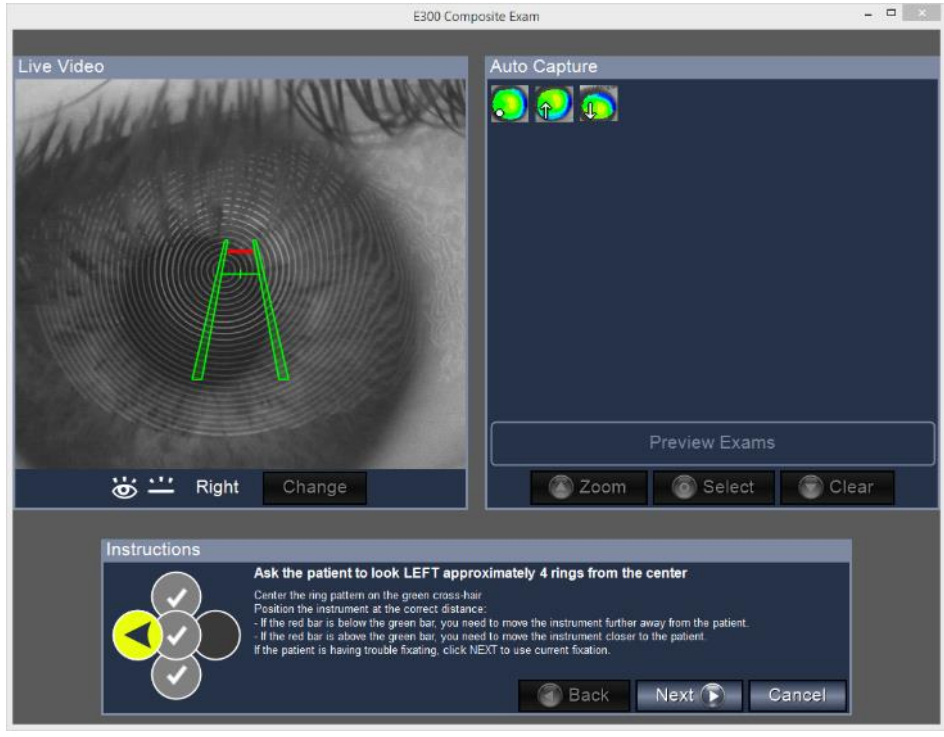


Figure 13. Off Axis Image Capture.

If for some reason the patient's pupil cannot be detected or they are unable to move their gaze sufficiently to trigger auto capture you can manually click the **Next** button to begin auto capturing images using the current fixation location.

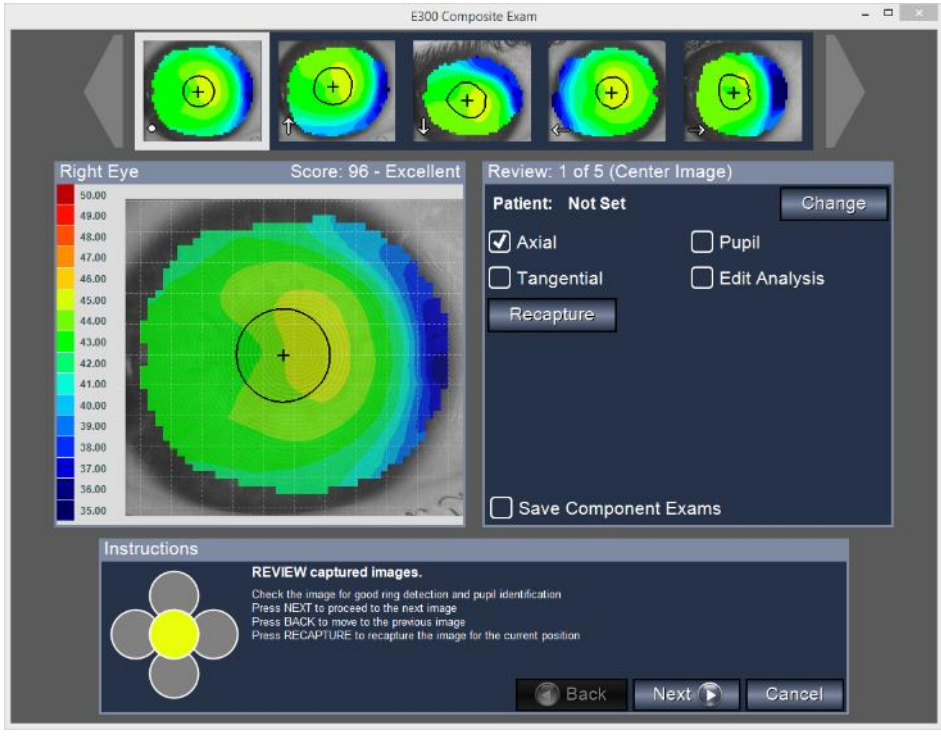


Figure 14. Review Component Images.

At the completion of capturing the five images click the **Next** button to review each of the captured exams. This is similar to the normal topography review screen except that for composite exams it is even more important to ensure accurate identification of the pupil. The composite registration algorithm utilizes the location of the pupil as a starting point and so the pupil must be accurately identified in each image.

The **Save Component Exams** button allows you to select whether the individual exams that make up the composite exam should be saved (in addition to the composite exam). The **Recapture** button allows you to go back to the capture step to recapture the selected image position.

Once each of the component exams has been reviewed, click **Next** to register the captured images and create a composite exam (see Figure 15).

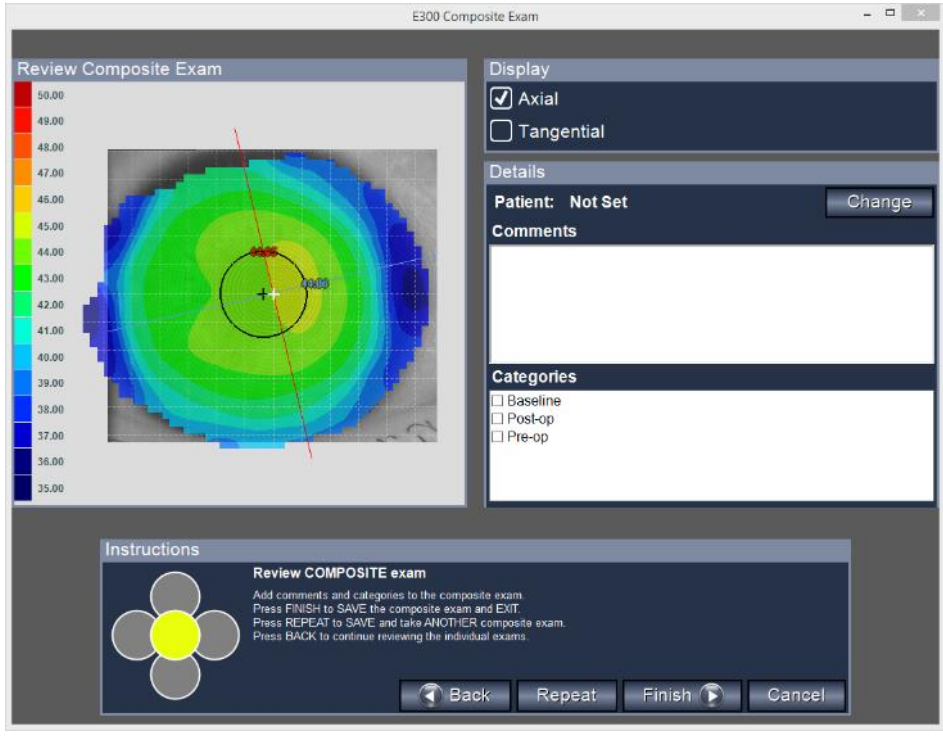


Figure 15. Composite Review.

Click **Finish** to save the exam and complete.

Video Topography

The E300 can capture video at frame rates of up to 25 frames per second. Click the **Video Topography** button (see Figure 6) to start the wizard for capturing video (Figure 16). The red illumination rings inside the E300 cone should turn on. Select the maximum duration that you wish to capture and the frame rate from the numeric spin boxes. The **Compress Video** option greatly reduces the size of the exam storage required (by a factor of about two). It may however cause subtle changes in the analysis if you later reanalyse the images. If the **Auto analyse images** option is selected the video is automatically analysed at the completion of the capture. For long duration video captures this can take considerable time. If you wish to defer the analysis to a later time then deselect this option.

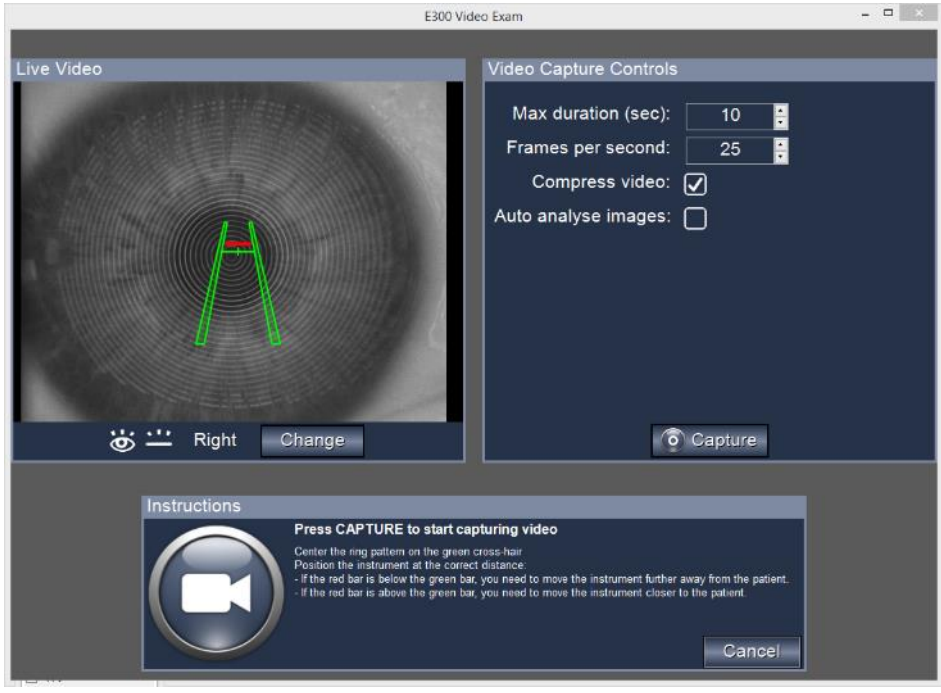


Figure 16. Video Capture.

Align the patient as described in *Topography* on page 24 and then click the **Capture** button (or press the space bar) to begin capturing video. Click the **Stop** button (or press the space bar again) to stop capturing video before the Max duration is reached. Once the video capture stops (because the Max duration has been reached or the **Stop** button was clicked) the wizard will automatically analyse the video (if **Auto analyse** option selected) and move to the Video Review screen (see Figure 17).

The video can be played using video playback controls in the **Video Review** window. The **Review** window provides options to select the displayed colour map overlay. Deselect the **Colour Map** option to display the raw video without an overlay. Click the **Finish** button to save the video and complete the exam.

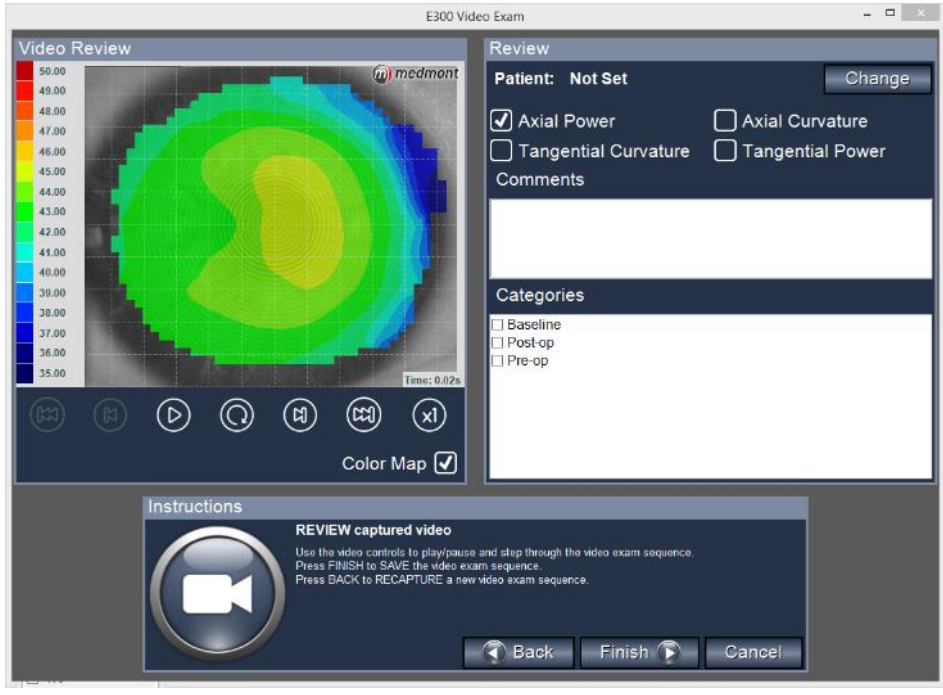


Figure 17. Video Review.

Tear Film Analysis

The software includes the ability to automatically capture a sequence of exams to analyse tear film surface quality and dynamics. Click the **Tear Film Analysis** button (see Figure 6) to start the tear film analysis wizard (Figure 18). The red illumination rings inside the E300 should illuminate.

Align the patient as described in *Topography* on page 24. Once aligned the wizard displays a message to instruct the patient to blink twice quickly in succession. The wizard automatically detects the blinks and starts capturing exams every 0.25 seconds. A live preview of the patient's tear film surface quality is displayed while capturing. The capture is stopped automatically once the specified maximum duration is reached or if the patient blinks again.

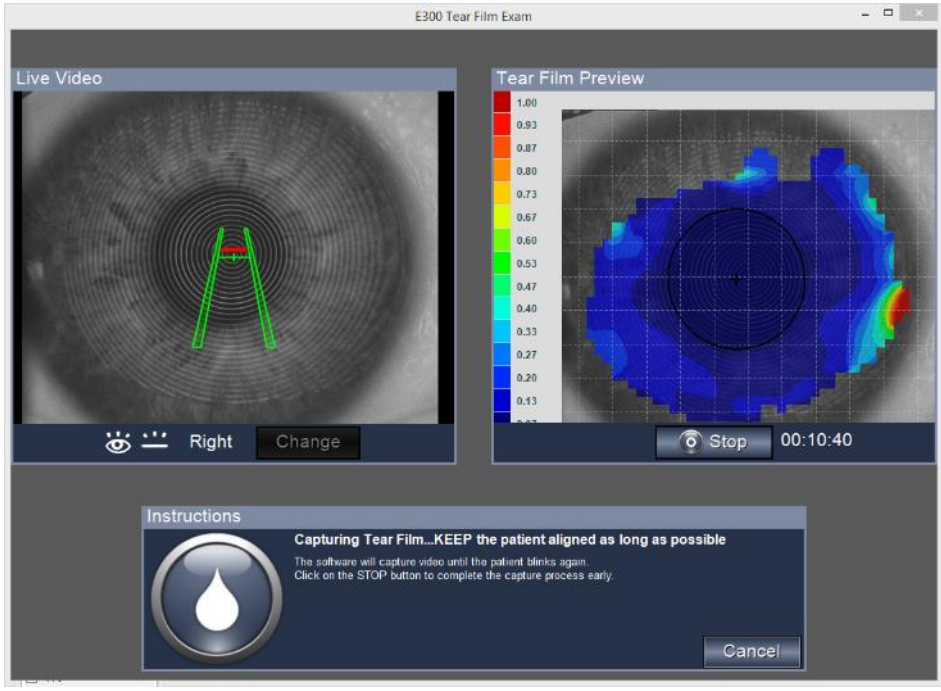


Figure 18. Tear Film Capture.

On completion of the capture the wizard automatically analyses the captured images and displays the Tear Film Review screen (see Figure 19). The **Tear Film Surface Quality** window allows the video to be replayed and paused using the video controls. The **Tear Film Break Up Time** window displays the time (measured from the blink) until the tear film surface quality (TFSQ) in a given region first reaches a predefined threshold level. This is useful for understanding the dynamics of how tear film breakup progresses across regions of the eye.

The **TFSQ Area** graph shows the percentage of the eye within the central 7mm zone that has reached a predefined TFSQ threshold level. The software can also automatically calculate and display a Tear Film Break Up Time (TBUT) by analysing when this TFSQ Area value reaches a predefined threshold. The predefined threshold values can be fully customized through the *Attributes* mechanism described in the Medmont Studio user manual.

The point corresponding to the current video frame in the **Tear Film Surface Quality** window is highlighted in the **TFSQ Area** graph. Clicking on a point in the **TFSQ Area** graph automatically moves the video display to the corresponding frame.

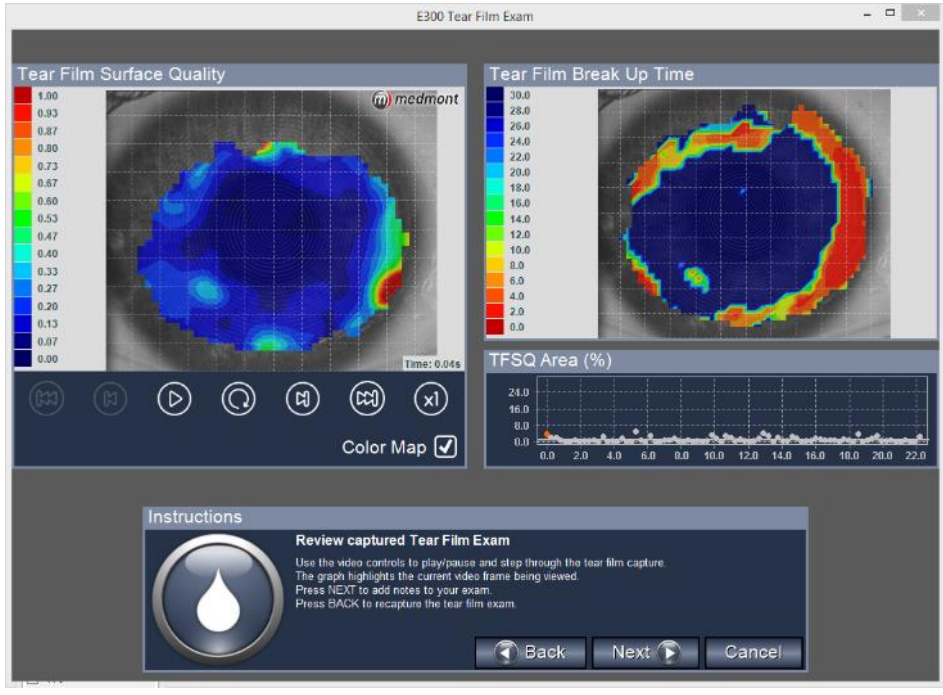


Figure 19. Tear Film Review.

Click the **Next** button to enter comments and add categories to the exam. Then click **Finish** to save and complete the examination.

7. Analysing and Viewing Exam Results

The E300 software provides a variety of ways in which to view exam results. The Exam View mode controls how selected exams are displayed (see *Setting the Exam View Mode* on page 39). For each of these modes you can set the type of data to display (see

Changing the Display Settings on page 45) and the colour mapping (see *Configuring the Colour Scale* on page 61).

Selecting the Exam Results

The first step in viewing Exam Results is selecting the exam(s) to view. To select the exam for a particular patient, click on the exam icon or the date in the Medmont Studio Explorer pane. To select multiple exams hold down the control key while clicking on the icons.

The E300 software supports the following exam types:

Exam – an exam comprising a single captured topography image (see *Topography* on page 24)

Composite Exam – an exam created by combining the topography from multiple captured images (see *Composite Topography* on page 30)

Idealized Eye Exam – an exam created based on the idealized topographic properties of another exam (see *Creating an Idealized Eye* on page 67)

Exam Sequence – a sequence of images with each image analysed to obtain full 3D topography data (see *Video Topography* on page 33)

Tear Film Exam Sequence – a sequence of images with each image analysed for tear film surface quality only (see *Tear Film Analysis* on page 35)

Setting the Exam View

The active View controls how the selected Patient Exams are displayed. You select the active view by going to **View > Active View** from ribbon bar. The available views depend on the exam type.

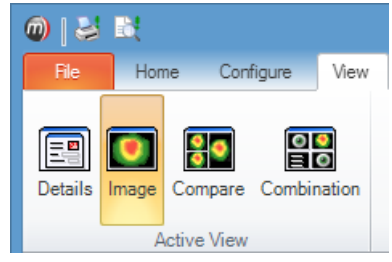


Figure 20 Possible E300 Exam Views.

Details View

 This displays textual information about the selected Exam (see Figure 21). It provides for the clinician to add comments and, where an exam has been attributed to the wrong patient, to change the owning Patient (see *Editing Exam Details* on page 78).

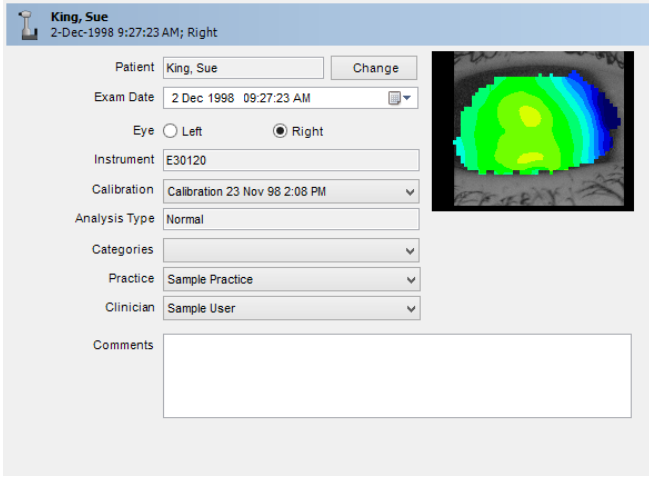


Figure 21. Exam Details View.

Image View

 This displays up to four different selected Exams with the same Map Type (see *Map Types* on page 45) and Colour scale (see *Configuring the Colour* on page 61). Select multiple exams by first holding down the Control key, then left click the mouse on the subject exams. Use this view mode to display full screen colour map images of a single exam or to display images of multiple exams.

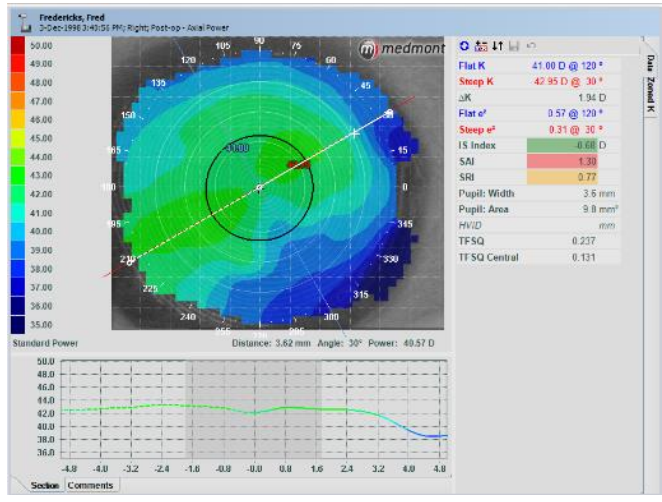


Figure 22. Image View.

Image View (Exam Sequences)

The *Image View* for *Exam Sequences* and *Tear Film Exam Sequences* are similar to the above with some additional features (see Figure 23). These include:

- A customisable graph of attribute values in the bottom pane (see *Graph vs Time Tab* on page 56)
- Video ribbon menu with controls to allow playback control over the sequence
- Separate *Video Data* and *Exam Data* tabs in the right hand pane. The *Exam Data* tab displays the attributes and data for the current image within the exam sequence. The *Video Data* tab displays attributes which are calculated over every exam within the sequence.
- The ability to display and add annotations for either the whole video sequence or individual exams within the sequence (using the ***Display > Options*** ribbon controls)

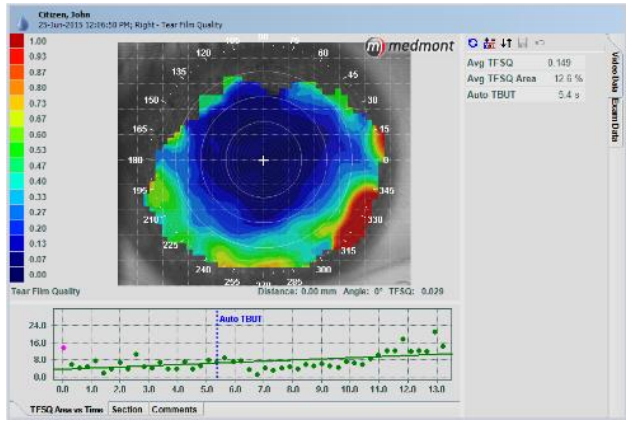


Figure 23. Image View - Tear Film Exam Sequence

Combination View

 This view displays four separate sub-view of the selected Exam (see Figure 24). This view is not applicable for *Exam Sequences*. The Map Type and settings for each sub-view can be configured independently. The ***Display*** and ***Annotate*** ribbons show the options for the currently selected sub-view. Select the sub-view by clicking within the sub-view or on the title. The title bar of the selected sub-view is shown highlighted in a different colour.

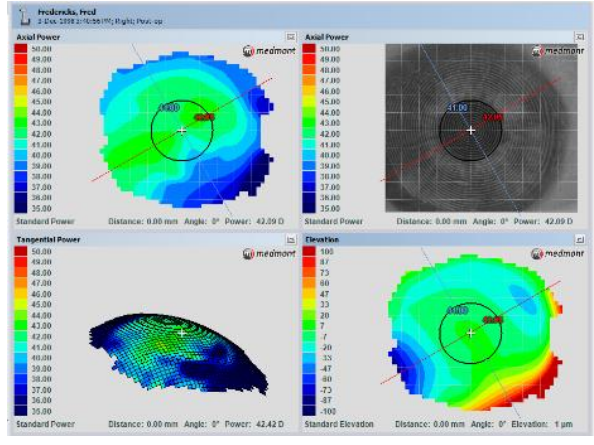


Figure 24. Combination View.

Compare View

 This view displays two selected Exams and the difference between them (see Figure 25). This view is not applicable for *Exam Sequences*. The Map Type and settings for the Difference sub-view (at the right) and for the two Exam sub-views (at the left) can be configured separately. Select the sub-view by clicking within the sub-view or on the title. The title bar of the selected sub-view is shown highlighted in a different colour.

Use this view to observe changes over time and healing patterns.

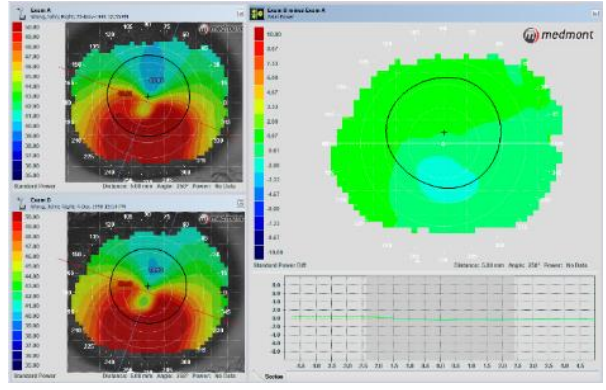


Figure 25. Compare View.

Regression View (Exam Sequences)

 This view displays graphs of attribute values for each exam within an *Exam Sequence* or *Tear Film Exam Sequence* (see Figure 26). The displayed graphs can be fully customized using the *Display* ribbon options. These options are similar to the *Patient Regression View* settings described in detail in the Medmont Studio user manual.

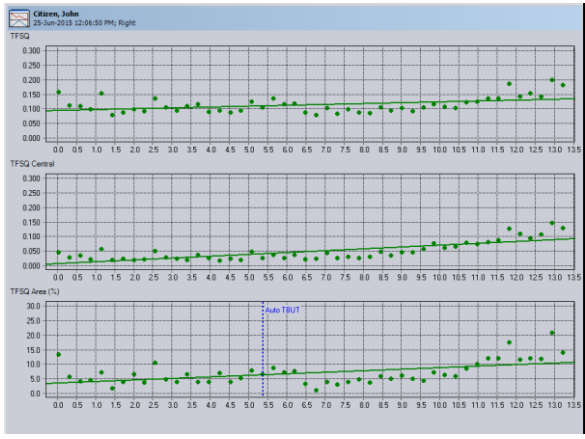


Figure 26. Regression View – Tear Film Exam Sequence.

Thumbnail View (Exam Sequences)

This view displays a thumbnail image of each exam within a sequence for *Exam Sequences* or *Tear Film Exam Sequences* in time order (see Figure 27). The thumbnail images can be expanded to fill the window. This view is useful to get an overview of changes occurring during a video exam sequence.

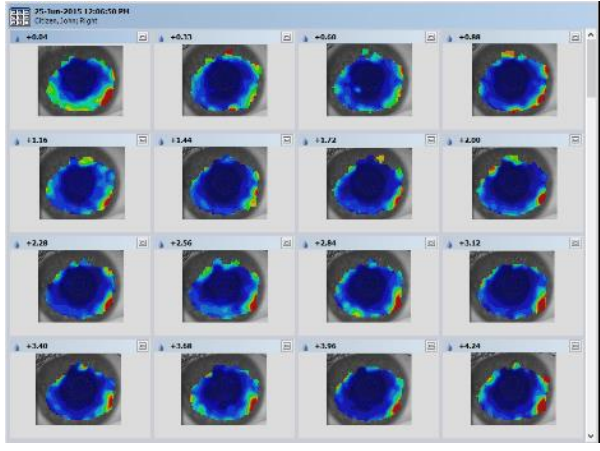


Figure 27. Thumbnail View – Tear Film Exam Sequence.

Changing the Display Settings

You can customise the information displayed for each graphical view (see *Setting the Exam View* on page 39). Once an exam is selected, the **Display** ribbon tab is shown (see Figure 28), allowing you to set the Map Type and other options for the selected view or sub-view.

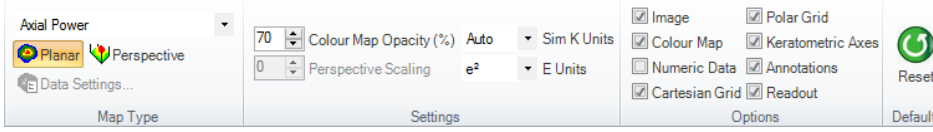
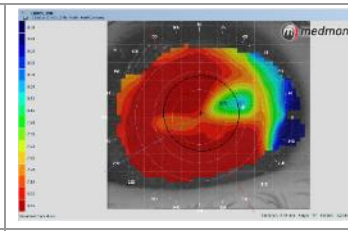
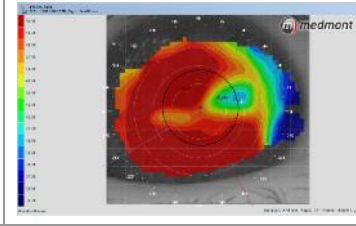
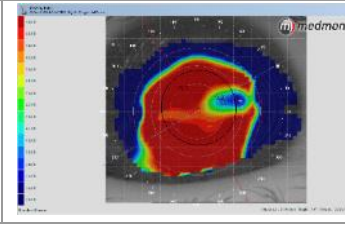


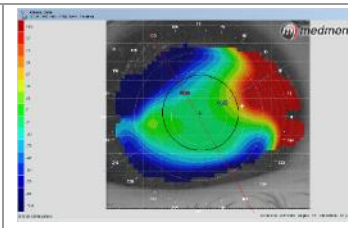
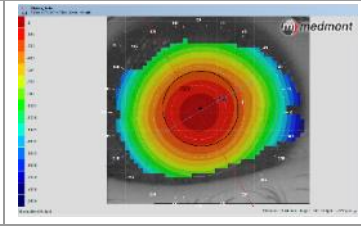
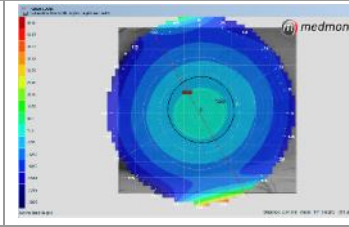
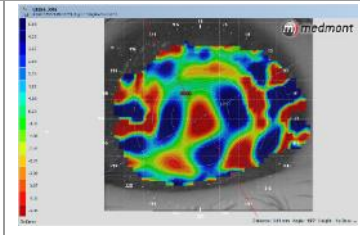
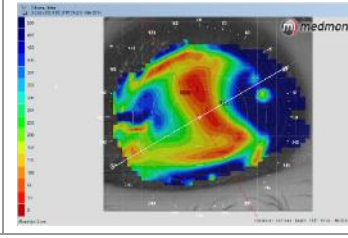
Figure 28. Exam Display Ribbon tab.

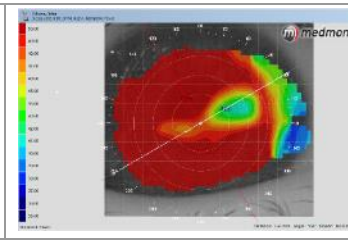
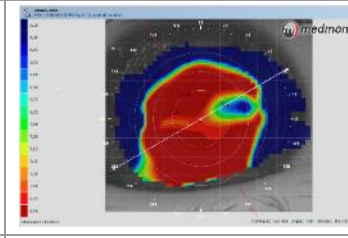
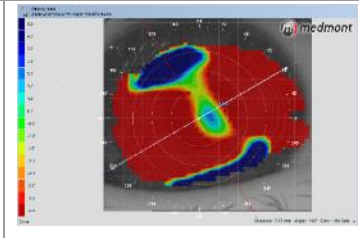
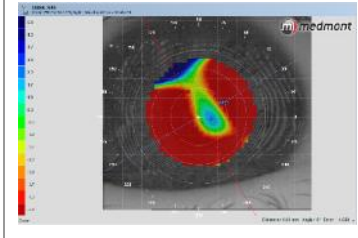
These options are applied to the image as you change them and are immediately visible. The available options depend on the selected exam type. You can click on the **Display > Defaults > Reset** button to restore the software defaults for the current view.

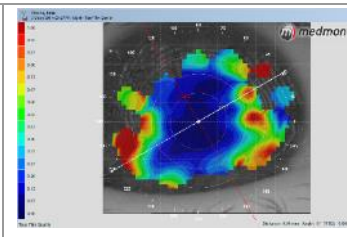
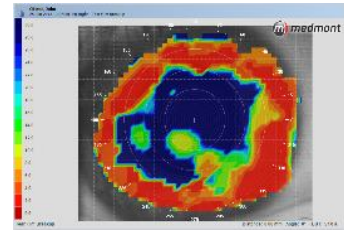
Map Types

The Map Type controls the type of data displayed for an exam. The types displayed in the following list are selected from the drop-down box on the **Display** ribbon bar tab. In each case the images are of the same exam.

Axial Curvature Map Displays the curvature of the surface in mm with respect to the keratoscope axis.	
Axial Power Map Displays the paraxial power of the surface in Diopters with respect to the keratoscope axis.	
Tangential Power Map Displays the local paraxial power of the surface in Diopters.	

Elevation Map Displays the distance from a specified best-fit sphere to the surface in microns. Positive values indicate the surface is above the best-fit sphere.	
Height Map Displays the distance along the axis from the apex of the eye to the surface in microns.	
Height Map - Zernike Fit A decomposition of the height data in terms of the Zernike components. These can be added or removed from the display by selecting the **Data Setting…** button underneath the Map drop-down list.	
Height Map - Zernike Residual A decomposition of the height data in terms of the Zernike components. These can be added or removed from the display by selecting the **Display > Map Type > Data Setting…** button underneath the Map drop-down list. Selecting **Show Residual** will display the Zernike Residual. This measures the error in fitting the height using Zernike functions: *Residual = Zernike Height – Height*	
Ray Error Map The deviation on the image plane between the focal point and a ray from an on-axis distant object refracted through the cornea.	

Refractive Power Map Displays the true refractive power of the surface in Diopters.	
Tangential Curvature Map Displays the local curvature of the surface in mm.	
Wavefront Error Map The difference in optical path length of a ray from an on-axis distant object refracted through the cornea and the principle ray (which passes through the centre of the cornea) to an ideal spherical wavefront inside the eye, divided by 550 nm (the assumed wavelength of the light-ray).	
Wavefront Error Map - Zernike Fit This is a decomposition of the wavefront error data in terms of the Zernike components. Individual Zernike components can be added / removed from the display by selecting the **Display > Map Type > Data Setting…** button underneath the Map drop-down list. Selecting **Show Residual** will display the Zernike Residual. This measures the error in fitting the wavefront error data using Zernike functions: *Residual = Zernike Result – Calculated Wavefront Error*	

Tear Film Quality Displays a measure of the tear film quality over the surface of the eye. Tear film breakup results in a large standard deviation in the local widths of the reflected mires and results in a larger Tear Film Quality value at that point.	
Tear Film Breakup (Exam Sequences) This map type is only available for *Exam Sequences* and *Tear Film Sequences*. The value at each point on the map is calculated from the time taken for the measured TFSQ at that point to reach a pre-defined threshold value corresponding to tear film breakup.	

Data View

The data may be viewed as either a two-dimensional plan as above or as a three-dimensional image. These views are selected by clicking the appropriate button:

Planar – 2-dimensional
Perspective – 3-dimensional

A 3-dimensional exam view is displayed without the eye image. An example for the same image used above is shown in Figure 29.

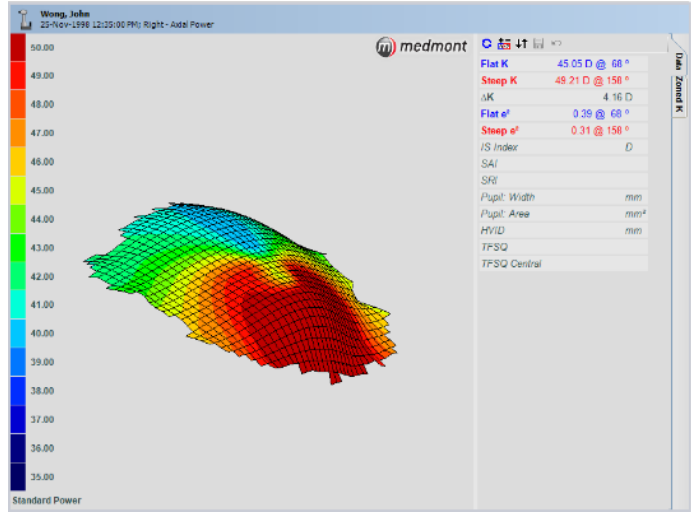
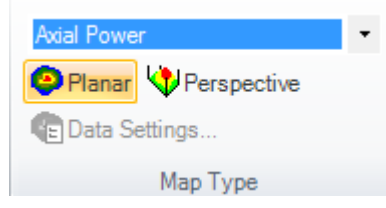


Figure 29. A Perspective or 3-dimensional exam view.

When the Perspective view is selected the **Display > Settings > Perspective Scaling** spin control is enabled and provides for magnifying the vertical perspective scaling (see *Perspective Scaling* on page 50 and *Software Conventions* on page 6).

For the Map View and Compare View modes the **Display > Map Type** ribbon bar group (shown below) provides a quick means of changing the map and display type.



For the Combination View mode (Figure 24) a different map type and data view can be selected for each of the four display areas. Each map can be selected for changing by left clicking on the title bar of the exam view (this contains the name of the Map Type currently being displayed).

Display Settings

The **Display > Settings** ribbon group allows you to control how various data is displayed:

Colour Map Opacity

This spin control allows you to set the level of transparency of the colour map when it is displayed over the raw video image. A value of 0.0 makes the colour map transparent. A value of 1.0 makes the colour map opaque. This option is only available when the exam image is displayed behind the colour map.

Perspective Scaling

This spin control allows you to display 3D Perspective views with enhanced distortion. The deviation of the eye surface from the best-fit sphere is multiplied by the scaling factor and added to the original surface. A value of zero produces a "true" 3D Perspective.

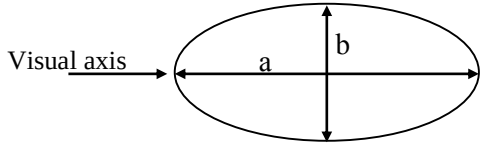
Sim K Units

This allows the user to select the units for the standard Flat K and Steep K (as well as Zoned K) measurements displayed in the Data tab and on the map. Options are: mm (millimetres), D (Diopters), or Auto K, which will automatically select the best unit of measurement based on the chosen map type.

E Units

This allows the user to select the units of measurement for the Flat and Steep E values displayed in the Data tab (at the right of the exam view).

These provide alternative ways of defining the best fit ellipse over the steep and flat meridians. The following definitions are based on the definition of an ellipse as:



e

This is the standard mathematical definition of the eccentricity of an ellipse and is calculated from:

$$e = \sqrt{1 - \frac{\min(a,b)^2}{\max(a,b)^2}}$$

Note that this *e* term for eccentricity cannot distinguish between oblate and prolate eyes.

p

This shape factor attempts to overcome the limitation of the *e* value. It is defined as:

$$p = \frac{b^2}{a^2}$$

Using this shape factor, a circle can be described by p = 1, a prolate ellipse has a p-value less than 1, and an oblate ellipse has a p-value greater than 1.

Q

This shape factor can be used to indicate how far a particular curve departs from sphericity. It is defined as:

$$Q = p - 1$$

Spheres have a Q value of zero. Prolate shapes have negative values and oblate shapes have positive values.

e²

This shape factor is similar to Q except that prolate shapes have positive values and oblate shapes have negative values. It is defined as:

$$e^2 = 1 - \frac{b^2}{a^2}$$

Notes on Shape factors: e, e², p and Q

The shape factors are useful in partially quantifying aspects of the shape of the eye. They are all derived from an ellipse that approximates a specific cross-section of the eye, typically the steep or flat axis. The applicability and usage of these terms is particularly well covered in the article "Corneal Asphericity: The e's, p's and Q's of Corneal Shape" by Swarbrick, H. in Refractive Eyecare for Opthalmogologists, December 2004.

How is the ellipse approximated?

Medmont computes the unique ellipse that gives the same axial curvature at a specified chord and apical curvature as the actual eye. In practice this method gives repeatable and reliable shape factor readings.

An alternative method uses height instead of axial curvature, but it is more sensitive to noise, hence less repeatable and less reliable.

Can you reconstruct height data from the shape-factors?

While the original ellipse can be reconstructed mathematically from these parameters, the height information thus obtained describes a crude approximation, rather than the actual eye.

A better alternative is to use the height data obtained from the Height view directly.

Graph

This button is only applicable to *Exam Sequences* and *Tear Film Exam Sequences*. It allows you to configure the graph displayed in the bottom pane of the Image View. See *Graph vs Time Tab* on page 56 for more detail

Display Options

The **Display > Options** ribbon group allows you to toggle on/off the display of certain features:

Image

Toggles on/off the display of the video image. The colour map is displayed transparently over the image. You can set the level of transparency with the **Display > Options > Colour Map Opacity** spin box (see *Colour Map* on page 52).

Colour Map

Toggles on/off the display of the colour-mapped data. Disabling the colour map allows you to examine the raw image.

> The **Image** and **Colour Map** checkboxes are mutually exclusive options. Once one is disabled you cannot disable the other.

Numeric Data

Toggles on/off the display of numeric data at specific points on each 30 degree spoke. The data displayed at each point will depend on the chosen map type.

Cartesian Grid

Toggles on/off the display of a one millimetre rectangular grid, centred on the keratoscope axes, overlaying on the colour map.

Polar Grid

Toggles on/off the display of a polar reference ring, centred on the keratoscope axis, overlaying the colour map.

Keratometric Axes

Toggles on/off the display of the Keratometric Axes on the map. The steep axis is calculated as the spoke with the highest average axial power whilst the flat axis is always set at 90 degrees from the steep axis.

Annotations

Toggles on/off the display of any annotations added to the exam (including the outline of the pupil). This option is not applicable to *Exam Sequences*. See the *Exam Annotations* and *Video Annotations* options below for controlling annotations for *Exam Sequences*.

Exam Annotations

This option is only applicable to *Exam Sequences* and *Tear Film Exam Sequences*. If selected, annotations associated with individual exams within the sequence are displayed and the *Annotate* ribbon controls allow you to add annotations and attributes to the currently display exam within the sequence. Selecting this option automatically deselects the *Video Annotations* option (described below)

Video Annotations

This option is only applicable to *Exam Sequences* and *Tear Film Exam Sequences*. If selected, annotations associated with the whole sequence are displayed and the *Annotate* ribbon controls allow you to add annotations and attributes to the whole sequence. This is useful if you wish to annotate something that applies to every exam within the sequence. Selecting this option automatically deselects the *Exam Annotations* option (described above).

Readout

Displays a readout marker (a white cross) over the colour map. The location of the readout marker is relative to the keratoscope axis, and the data values at that location, are displayed in the bottom right hand corner of the image. The values presented are in terms of the currently selected Map Type (see *Map Types* on page 45). Clicking and dragging with the left mouse button moves the readout marker and updates the readout in real time.

View Pane Tabs

Tabbed panes are located at the bottom and at the right of the Exam View to display additional information about the exam. These panes can be expanded by clicking and dragging on the separator between them and the main view. The panes can also be completely hidden using the **Display > Panes** ribbon. The content of the tabs is described below:

Data Tab

The data tab displays predefined and custom attributes for the exam in the right hand pane of the view. The following predefined attributes are always displayed:

- **Flat K/Steep K** – displays the simulated Keratometric power and angle along the flat and steep axes of the eye. The display units (Diopters or mm) are controlled by the *Sim K Units* option in the **Display > Settings** ribbon. Clicking on the Steep or Flat attributes sets the Cross-Section indicator (if displayed) to the corresponding angle.
- **Delta K** – displays the difference between the flat and steep K values. The display units (Diopters or mm) are controlled by the *Sim K Units* (see page 50) option in the **Display > Settings** ribbon
- **Flat E/Steep E** – displays the elliptical shape factors for the eye along the flat and steep axes. The display units are controlled by the *E Units* (see page 50) option in the **Display > Settings** ribbon.

The following standard attributes are also displayed by default:

- **IS Index** – this is a measure of the difference between the average inferior and superior power in the eye.
- **Surface Asymmetry Index (SAI)** – a measure of the asymmetry of the eye. It increases with increasing asymmetry in corneal power distribution.
- **Surface Regularity Index (SRI)** – a measure of the surface irregularity. It increases as central corneal irregularity increases.

- **HVID** – this is a measure of the horizontal visible iris diameter. You will need to manually define an iris for this attribute to be defined.
- **TFSQ** – a measure of the tear film surface quality. Tear film breakup results in a large standard deviation in the local widths of the reflected mires and results in a larger Tear Film Quality value at that point. The TFSQ attribute is an average of the local Tear Film Quality value over the entire eye.
- **TFSQ Central** – a measure of the tear film surface quality over the central region (4mm chord) of the eye

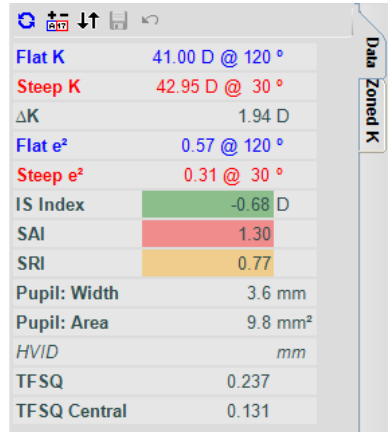


Figure 30. Data Tab

See the Medmont Studio user manual for more information about managing and displaying attributes.

Exam Data Tab

For *Exam Sequences* the *Data Tab* (described above) is named *Exam Data* (to distinguish it from the *Video Data* tab) and displays the attributes for the currently displayed exam within the sequence.

Video Data Tab

For *Exam Sequences* an additional tab is displayed in the right hand pane to display attributes which are calculated over all exams within the sequence (for instance the average value of a given exam attribute value).

Section Tab

The section tab (see Figure 31) displays a graph of a 2D slice through the data in the bottom pane of the view. When the tab is selected a section line is displayed on the main map view to indicate the location of the slice of data

being displayed. You can move this line anywhere over the view to explore a specific cross-section.

The dotted half of the indicator corresponds to the dotted portion of the cross section data. The indicator has three handles. Use the left mouse button to click and drag the handles to a new location. Rotate the cross-section about its centre using the outer handles. Move the cross section through the image using the centre handle. The cross section data updates dynamically as the handles are dragged.

The vertical axis of the Section graph covers the same range as the current colour scale. Note that the image may contain data that is outside the currently selected colour scale, resulting in parts of the section graphic being clipped at the window edge(s). If you need to see the entire graphic, use the ***Normalize*** button in the colour scale Custom Settings dialog (see *Custom Colour Scales Custom Colour* on page 63).

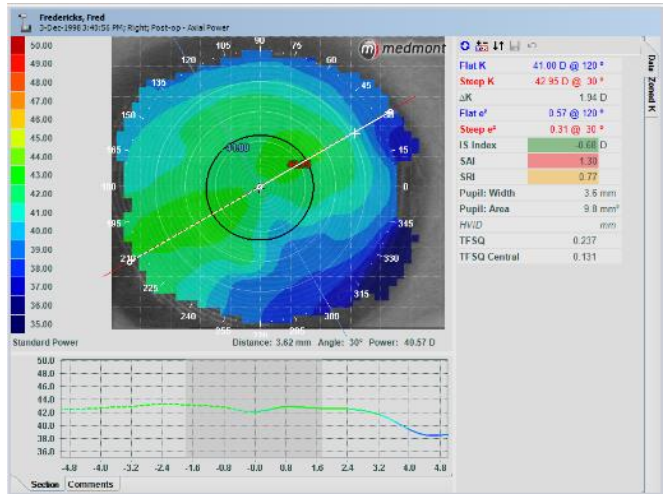


Figure 31. Section Tab

Click on the *Flat K/Steep K* attributes in the *Data Tab* to move the section indicator to the corresponding angle. If Keratometric axes are displayed, then you can also click on the displayed axes to move the section indicator to the selected angle.

Graph vs Time Tab

This tab is only displayed for *Exam Sequences* and *Tear Film Exam Sequences*. The tab (see Figure 32) displays a customisable graph in the bottom pane which can be configured (using the ***Display > Settings > Graph*** ribbon item) to show the change in any exam attribute value over the time

frame of the sequence. The title of the tab is changed to reflect the data being graphed. Selecting a point on the graph changes the main display to the corresponding exam within the sequence.

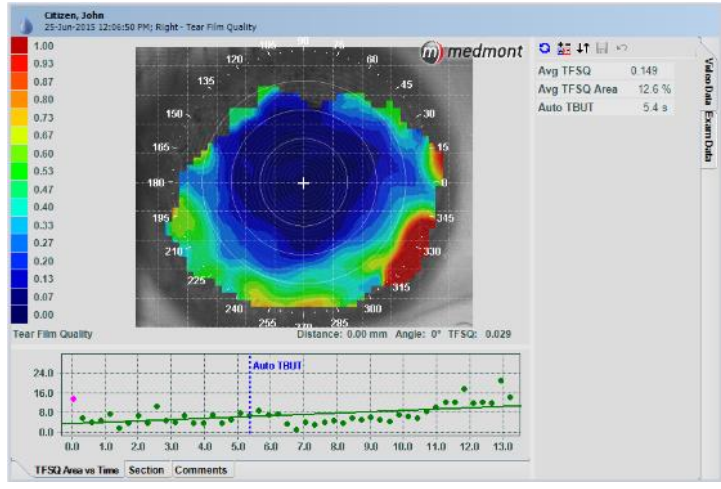


Figure 32. Graph Tab

Zoned K Tab

The Zoned K Tab displays keratometric values over 3 zones; 3mm, 5mm and 7mm in the right hand pane of the view. Each zone is independently analysed to locate the primary (most steep and most flat) and the secondary (second most steep and second most flat area outside of ± 90° of the primary angle for that zone). The primary steep and flat zones are shown on the map display using a thick red or blue line, whilst the secondary steep and flat are shown using a thin red or blue line (respectively).

Unit of measurements are specified by the **Sim K** units drop down box on the **Display** tab.

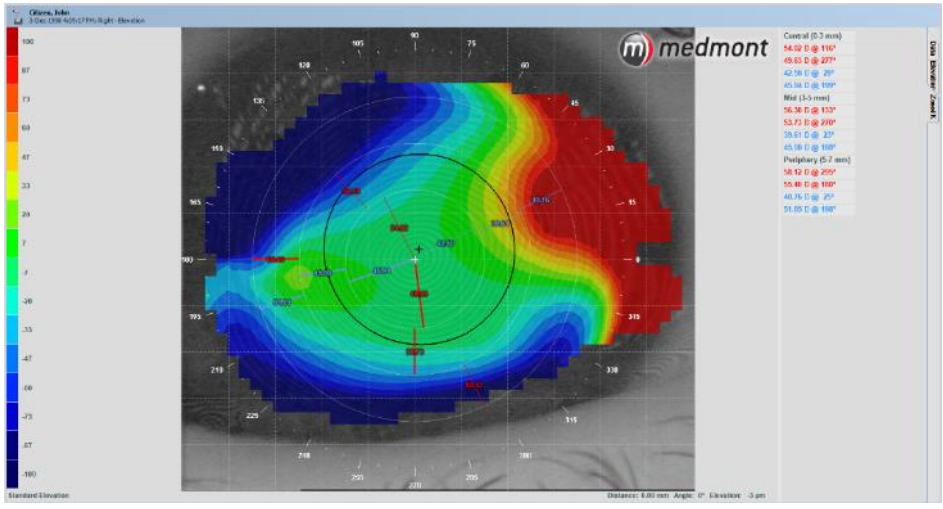


Figure 33. Zoned K Tab

Elevation Tab

The Elevation tab (see Figure 34) is displayed in the right hand pane of the view when the Elevation map type is selected via the **Display > Map Type** ribbon.

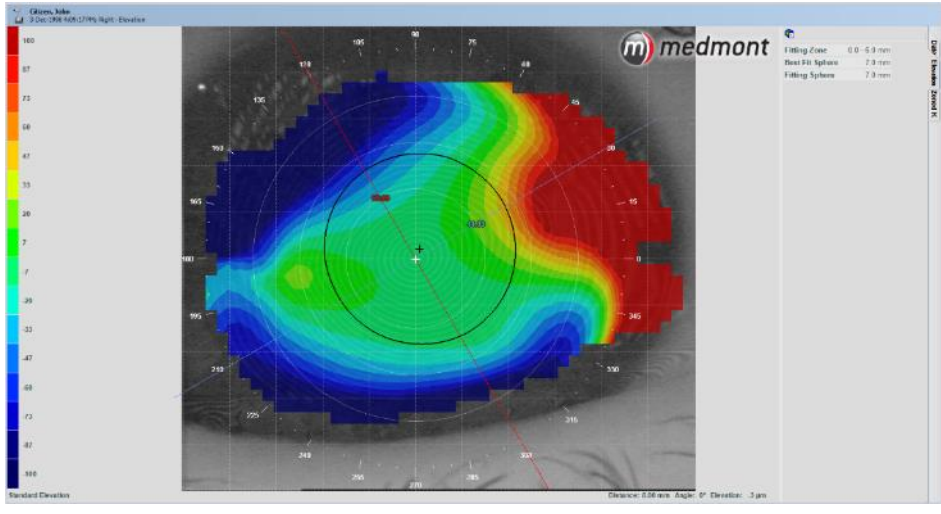


Figure 34. Elevation Tab

The Elevation tab displays the following settings:

- **Fitting Zone** – specifies an annulus of height data to use for fitting.
- **Best Fit Sphere** – the best fit sphere calculated over the fitting zone. The best-fit sphere is the one passing through the eye surface defined by the fitting zone minimising the surface elevations on either side.
- **Fitting Sphere** – the radius of the sphere used to calculate the displayed elevation data. This sphere is fitted to the fitting zone and the elevation (in microns) from the eye to the fitted sphere is displayed.

Clicking on the **Display > Settings > Data** button displays the Elevation Settings dialog shown in Figure 35. This allows you to change the Fitting Zone and Fitting Sphere. By default the software uses the best-fit sphere when calculating elevation data. However you can force it to calculate the elevations from a sphere of a radius you specify by deselecting the **Use Best Fit Sphere** option. Being able to specify a fixed fitting sphere can be useful when displaying elevation differences to ensure that both exams use the same baseline elevation.

Changing the Fitting Zone is useful for viewing changes induced by surgery or Ortho-K to the central zone of the eye. For instance, set the inner radius to 3 mm and the width to 1 mm. The sphere will be fitted to the data in the 3-4 mm radius zone, which will not change significantly before and after surgery, thus providing a stable baseline for comparison.

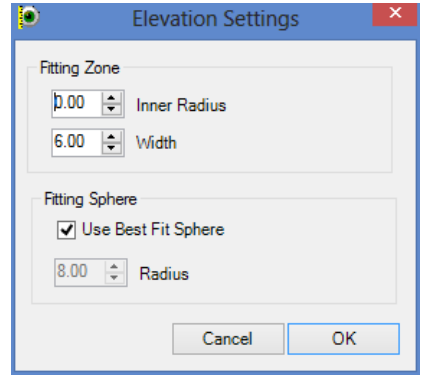


Figure 35. Elevation Settings dialog.

Zernike Tab

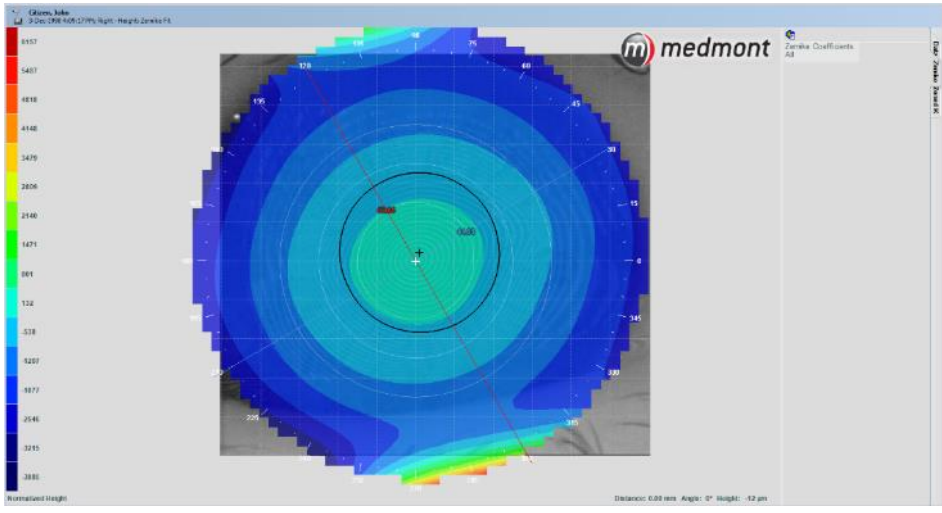


Figure 36. Zernike Tab

The Zernike tab displays the currently displayed Zernike coefficients in the right hand pane of the view. Clicking on the **Display > Settings > Data** button displays the Zernike Settings dialog shown in Figure 37.

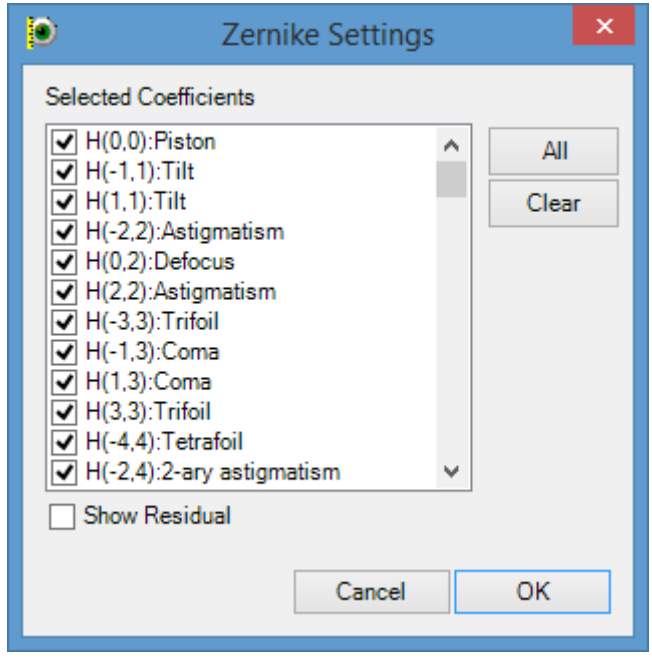


Figure 37. Zernike Settings Dialog

This dialog allows you to select the Zernike components that should be included in the display.

Comments Tab

The Comments tab displays comments in the bottom pane of the view and allows you to add or edit comments for the exam

Configuring the Colour Scale

Colour scales control the mapping of data values to colours. The software allows you to select between predefined colour scales or define and save your own colour scales.

Colour scales for displaying differences between exams are always balanced about zero, i.e. the minimum colour scale value is the negative of the maximum value and zero difference is always the same colour (light green).

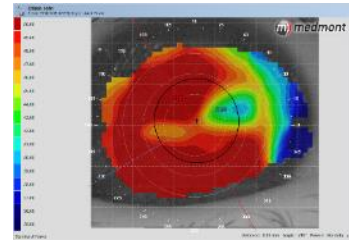
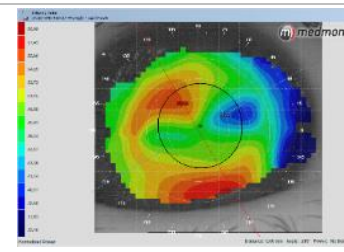
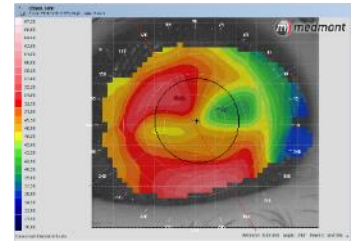
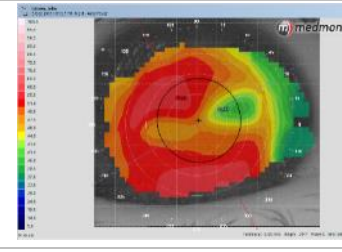
Standard Colour Scales

The E300 provides a number of predefined colour scales for each map type.

Map Type	Predefined Colour Scales
Axial Power	Standard Power, Normalized Power, Universal Standard Scale, K Scale
Tangential Power	Standard Power, Normalized Power, Universal Standard Scale, K Scale
Axial Curvature	Standard Curvature, Normalized Curvature
Tangential Curvature	Standard Curvature, Normalized Curvature
Height	Standard Height, Normalized Height
Refractive Power	Standard Power, Normalized Power, Universal Standard Scale, K Scale
Elevation	Standard Elevation, Normalized Elevation
Ray Error	Absolute Error
Wavefront Error	Error
Tear Film Quality	Tear Film Quality

Colour Scale Descriptions

The more common predefined colour scales are described in more detail below

Standard Power – The standard Medmont E300 colour mapping for refractive power values in Diopters to colour. Similar to the USS scale but with a restricted range.	
Normalized Power – A normalized scale for mapping refractive power values in Diopers to a colour scale using a linear mapping such that it's upper and lower bounds correspond to the limits of the data in the image.	
Universal Standard Scale (USS) – An implementation of the proposed Universal Standard Scale for Corneal Topography by Smolek, Klyce & Hovis. Maps refractive power values in Diopters to colour.	
K Scale – An alternative scale for mapping refractive power values in Diopters to colour.	

Other base colour scales are:

- **Standard Curvature** – Maps the axial and tangential curvature values in mm to colour.
- **Standard Elevation** - Maps the elevation values in microns to colour.
- **Standard Height** – Maps the corneal height values in microns to colour.
- **Fluorescein** – Maps the contact lens fitting clearances in microns to the Fluorescein colour scale.

The current Colour Scale is displayed in a caption at the bottom left of each map display. Alternative Colour Scales can be selected from the drop down menu that appears by clicking on the caption (see Figure 38).

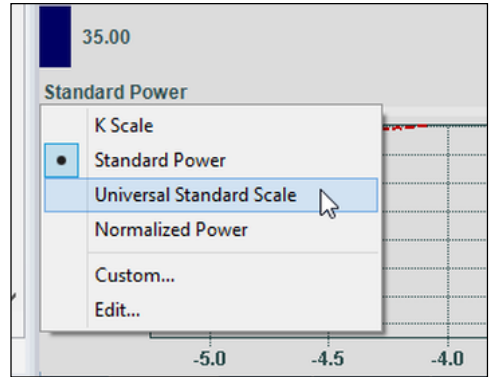


Figure 38. Selecting the current Colour Scale.

Custom Colour Scales

You can customise the colour scale to highlight a particular aspect of an exam. Drop down the Colour Scale selection box (see Figure 38) and click on the **Custom…** entry. This will present the **Custom Settings** dialog shown in Figure 39. The **Base Colour Scale** text box shows the base scale of the currently selected key and the three spin boxes show that scale's parameters (see *Manual Conventions* on page 1).

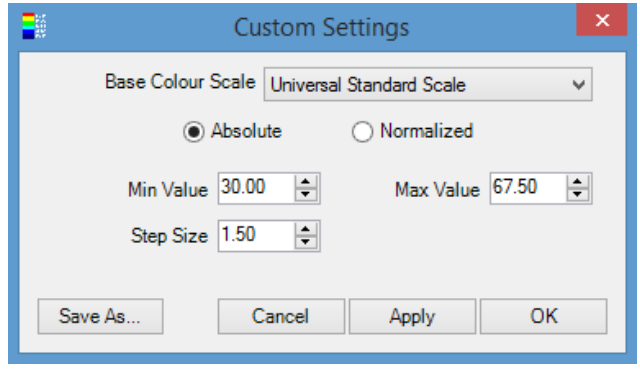


Figure 39. Colour Scale Custom Settings dialog.

The radio buttons provide for switching between **Absolute** and **Normalized** versions of the current Colour Scale. The **Absolute** setting displays the data in the current image mapped into a fixed range of colours that defines the selected Colour Scale. The **Normalized** setting linearly re-scales the current

Colour Scale so that its upper and lower bounds correspond to the limits of the data in the image (see Figure 40)

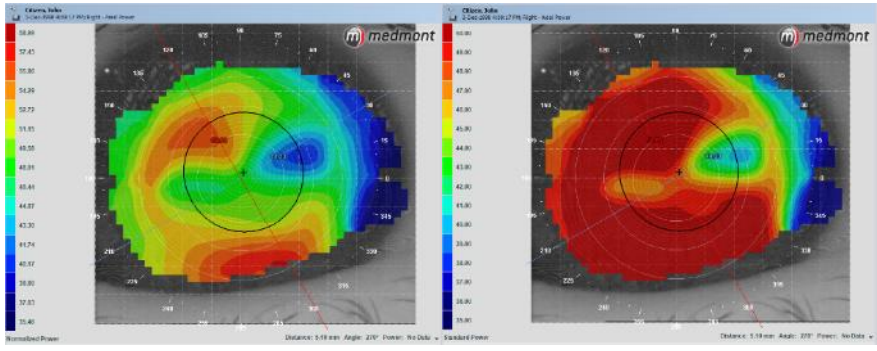


Figure 40. Normalised vs Absolute Colour Scale.

Difference Colour Scales

There are four predefined difference colour scales:

- **Standard Power Difference** – Maps the axial, tangential and refractive power differences in Diopters to colour.
- **Standard Curvature Difference** – Maps the axial and tangential curvature differences in mm to colour.
- **Standard Height Difference** – Maps the elevation differences in microns to colour.
- **Normalized Height Difference –** Maps height differences in micro meters to a linear colour scale using a maximum and minimum corresponding to the data being mapped.

The current Difference Colour Scale type is displayed at the bottom left of a Difference map display, similar to a standard map view (The **Custom Settings** dialog is the same as shown in Figure 39). For difference views the result of normalising the colour scale will usually show a more dramatic change because the differences typically have a smaller range.

Displaying Analysis Details

The Analysis Details dialog provides numerical readouts of various analysis parameters at a specified meridian and chord for the currently selected exam(s). Note that you can select more than one exam to analyse.

Click on the **Analysis > Show > Details** button to display the Analysis Details dialog (see Figure 41). This displays the corneal height, shape factor

and apical curvature at the selected chord and meridian. The ***Steep*** and ***Flat*** buttons set the meridian to the steep and flat axis respectively.

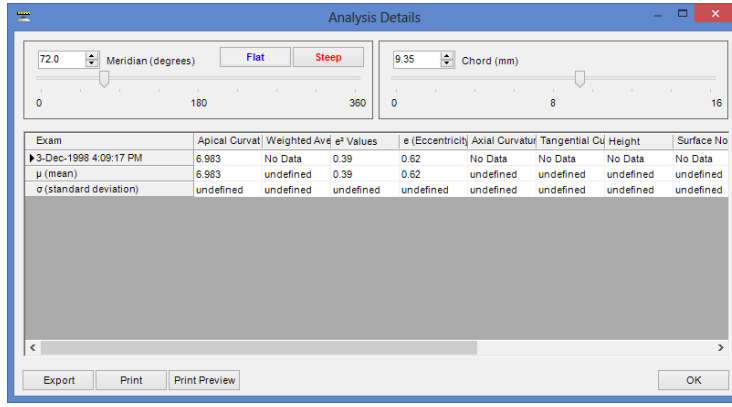


Figure 41. Analysis Details Dialog.

The tabulated data shows the values for the currently selected exam. The statistical measures of mean and standard deviation are also given.

The section and readout indicators of displayed exams are linked to the Meridian and Chord slider to provide visual feedback of the measurement location. This means that if the Section tool is displayed, clicking and dragging the Meridian slider will rotate the Section indicator line on the Map view to a matching angular position, with the attribute display reflecting the data under the white data point cross. Similarly, clicking and dragging the Chord slider will move the cross along the Section indicator line. Alternatively, with this dialog displayed, dragging the Section indicator line around will move the dialog sliders correspondingly. The data point cross will be displayed even if the Section tool is not.

While you can use the lower scroll bar to scroll through the tabulated attributes, the dialog itself can be resized to display more or less of the tabulated data. First move the cursor over an edge of the dialog. When it changes to a double-headed arrow, click and drag the edge as required. You can also click and drag a column divider in the **Exam** row to vary the column's width.

The weighted Average Height column displays the weighted average of the corneal height at either end of the specified chord. The weighting is designed to correct for corneal tilt – this allows the value to be used in 3rd party software that assumes a symmetric eye model.

The ***Export*** buttons produces a comma-separated file (.CSV) readable by most spreadsheet based software.

Exam Filters

Exam filters allow you to restrict which exams are shown in the Explorer pane. Select the exams tab at the bottom of the Explorer pane and the select the **Filter** entry as shown in Figure 42.

Figure 42. E300 exam filter selection.

This displays the dialog shown in Figure 43 and shows the many criteria that may be used for exam filtering. You can also define your own selection criteria in the **Advanced** filter tab.

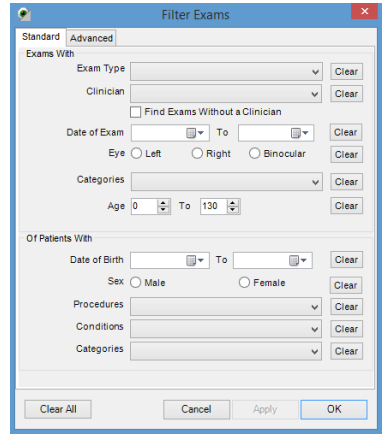
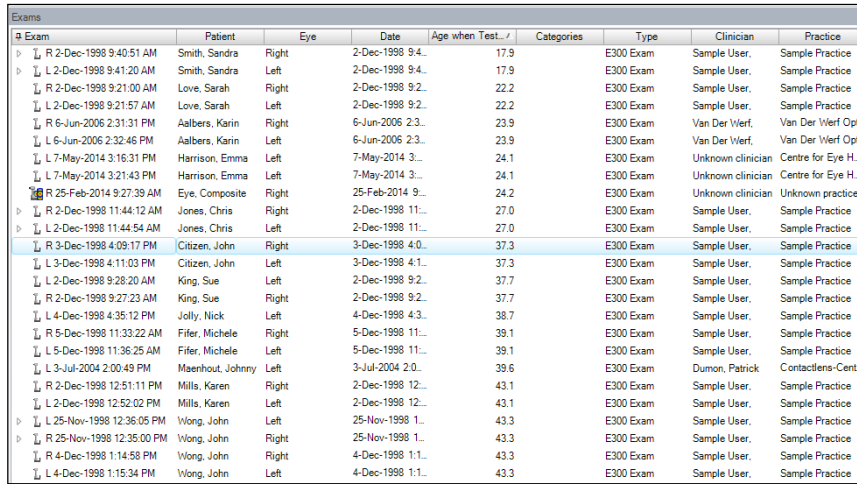


Figure 43. E300 exam filter selection dialog.

Sorting E300 Exams

The E300 exams displayed in the Explorer pane can be sorted by any of the column headings when the exams tab is active. Click on the heading for any column and the display will show exams sorted by entries in that column. Click again to reverse the sort order. Figure 44 shows an example of sorting exams by patient age.



Exams

Exam	Patient	Eye	Date	Age when Test...	Categories	Type	Clinician	Practice
R 2-Dec-1998 9:40:51 AM	Smith, Sandra	Right	2-Dec-1998 9:4...	17.9		E300 Exam	Sample User,	Sample Practice
L 2-Dec-1998 9:41:20 AM	Smith, Sandra	Left	2-Dec-1998 9:4...	17.9		E300 Exam	Sample User,	Sample Practice
R 2-Dec-1998 9:21:00 AM	Love, Sarah	Right	2-Dec-1998 9:2...	22.2		E300 Exam	Sample User,	Sample Practice
L 2-Dec-1998 9:21:57 AM	Love, Sarah	Left	2-Dec-1998 9:2...	22.2		E300 Exam	Sample User,	Sample Practice
R 6-Jun-2006 2:31:31 PM	Aalbers, Karin	Right	6-Jun-2006 2:3...	23.9		E300 Exam	Van Der Werf,	Van Der Werf Opt...
L 6-Jun-2006 2:32:46 PM	Aalbers, Karin	Left	6-Jun-2006 2:3...	23.9		E300 Exam	Van Der Werf,	Van Der Werf Opt...
L 7-May-2014 3:16:31 PM	Harrison, Emma	Left	7-May-2014 3:...	24.1		E300 Exam	Unknown clinician	Centre for Eye H...
L 7-May-2014 3:21:43 PM	Harrison, Emma	Left	7-May-2014 3:...	24.1		E300 Exam	Unknown clinician	Centre for Eye H...
R 25-Feb-2014 9:27:39 AM	Eye, Composite	Right	25-Feb-2014 9:...	24.2		E300 Exam	Unknown clinician	Unknown practice
R 2-Dec-1998 11:44:12 AM	Jones, Chris	Right	2-Dec-1998 11:...	27.0		E300 Exam	Sample User,	Sample Practice
L 2-Dec-1998 11:44:54 AM	Jones, Chris	Left	2-Dec-1998 11:...	27.0		E300 Exam	Sample User,	Sample Practice
R 3-Dec-1998 4:09:17 PM	Citizen, John	Right	3-Dec-1998 4:0...	37.3		E300 Exam	Sample User,	Sample Practice
L 3-Dec-1998 4:11:03 PM	Citizen, John	Left	3-Dec-1998 4:1...	37.3		E300 Exam	Sample User,	Sample Practice
L 2-Dec-1998 9:28:20 AM	King, Sue	Left	2-Dec-1998 9:2...	37.7		E300 Exam	Sample User,	Sample Practice
R 2-Dec-1998 9:27:23 AM	King, Sue	Right	2-Dec-1998 9:2...	37.7		E300 Exam	Sample User,	Sample Practice
L 4-Dec-1998 4:35:12 PM	Jolly, Nick	Left	4-Dec-1998 4:3...	38.7		E300 Exam	Sample User,	Sample Practice
R 5-Dec-1998 11:33:22 AM	Fifer, Michele	Right	5-Dec-1998 11:...	39.1		E300 Exam	Sample User,	Sample Practice
L 5-Dec-1998 11:36:25 AM	Fifer, Michele	Left	5-Dec-1998 11:...	39.1		E300 Exam	Sample User,	Sample Practice
L 3-Jul-2004 2:00:49 PM	Maenhout, Johnny	Left	3-Jul-2004 2:0...	39.6		E300 Exam	Dumon, Patrick	Contactlens-Cent...
R 2-Dec-1998 12:51:11 PM	Mills, Karen	Right	2-Dec-1998 12:...	43.1		E300 Exam	Sample User,	Sample Practice
L 2-Dec-1998 12:52:02 PM	Mills, Karen	Left	2-Dec-1998 12:...	43.1		E300 Exam	Sample User,	Sample Practice
L 25-Nov-1998 12:36:05 PM	Wong, John	Left	25-Nov-1998 1...	43.3		E300 Exam	Sample User,	Sample Practice
R 25-Nov-1998 12:35:00 PM	Wong, John	Right	25-Nov-1998 1...	43.3		E300 Exam	Sample User,	Sample Practice
R 4-Dec-1998 1:14:58 PM	Wong, John	Right	4-Dec-1998 1:1...	43.3		E300 Exam	Sample User,	Sample Practice
L 4-Dec-1998 1:15:34 PM	Wong, John	Left	4-Dec-1998 1:1...	43.3		E300 Exam	Sample User,	Sample Practice

Figure 44. E300 exams sorted by Age.

Creating a Composite Exam

The Create Composite Eye function allows you to combine multiple existing E300 exams for the same patient into a single composite exam. This can be useful for extending the coverage of the E300 by combining several off-axis exams (left/right/up/down) with a central exam to maximize the analysed coverage area. It can also be used to improve the accuracy of the instrument and minimize transient tear film effects by providing an exam which is the average of several exams.

Select the exams that you wish to combine. Ensure that the pupil was correctly detected in each exam. If necessary redefine the pupil using the **Annotate > Add Attribute > Pupil button**. Click on the **Analysis > Create > Composite Eye** button. The software aligns the axes of each of the selected exams with the most central exam (the exam with the pupil closest to the instrument axes) and creates a composite exam by combining the aligned exam data.

Creating an Idealized Eye

The Create Ideal Eye function allows you to create an idealized symmetric, toric ellipsoidal surface based on the average values of the currently selected exam(s). This can be useful when fitting some contact lens designs that are based on a symmetric ellipsoidal model of the eye. It creates a new exam, which also allows you to compare the real surface with the best-fit toric/ellipsoid surface to visualize higher order visual defects.

Select the exams you wish to base the idealized eye on, click on the **Analysis > Create > Ideal Eye** button . The software calculates the average steep and flat angles of the selected exams and creates a toric ellipsoidal surface based on the average height values at a set chord along these axes. The chord used is that set for measuring shape factors in the E300 Options dialog. Note that, unlike the Composite Eye function, the selected exams are not aligned to a common axes before being averaged. The Ideal Eye function should therefore only be used on a single exam or exams where the pupil is aligned.

Adding and Editing Annotations

You can add graphical annotations to the selected exam using the tools in the **Annotate** tab. The Medmont Studio user manual provides detailed guidance on adding and editing annotations.

Pupil and Iris Attribute Annotations

The system will automatically attempt to detect the pupil and create an attribute annotation corresponding to it. This is visible as a black (pink if selected) outline if the **Display > Options > Annotations** checkbox is ticked (see Figure 45). You can re-define the pupil by clicking on the **Annotate > Add Attribute > Pupil** button. You can define the iris by clicking on the **Annotate > Add Attribute > Iris** button.

The pupil annotation created automatically by the system is locked by default to prevent accidental alterations. Refer to the Medmont Studio user manual for more information on the locking mechanism for annotations.

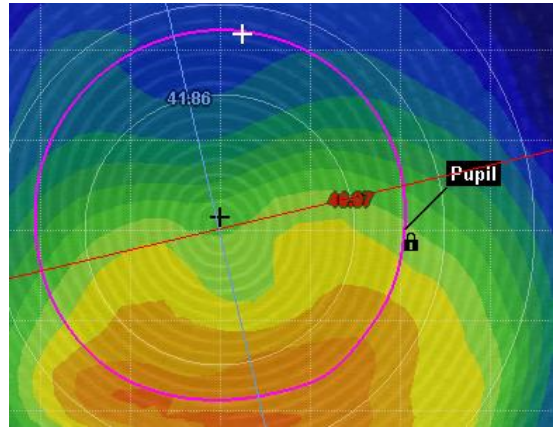


Figure 45 Pupil Annoations showing the lock symbol.

Removing Analysis Artefacts

It is possible to remove analysis artefacts due to eyelash shadows or other misidentified ring features from E300 maps.

Select an E300 exam from the tree view and click on the **Analysis > Data Points > Edit** button . If raw analysis data is not already present, the exam will be re-analysed. This will display all the points that the software has identified as corresponding to ring reflections and enable the eraser tool:

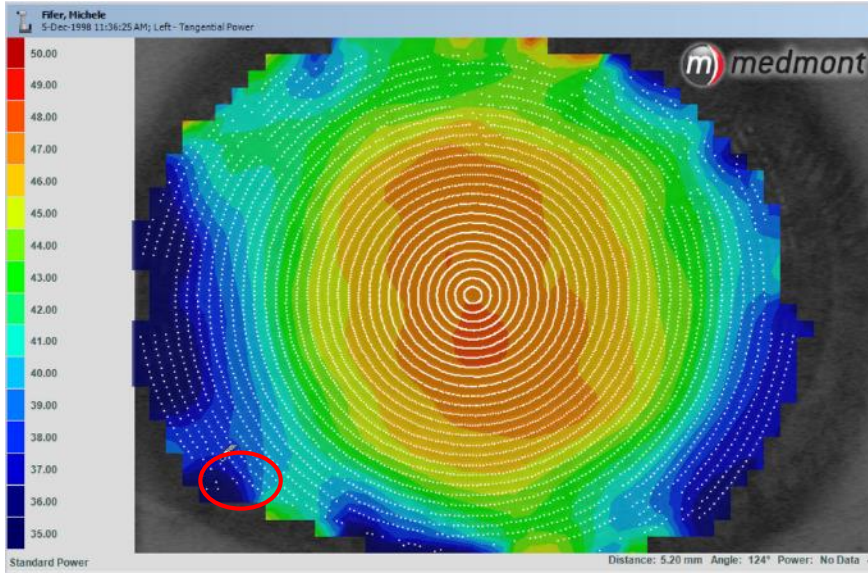


Figure 46. Eraser Tool

With the eraser, click and drag over any points which have been misidentified by the software to select them for removal. Points which have been selected for removal are displayed in black.

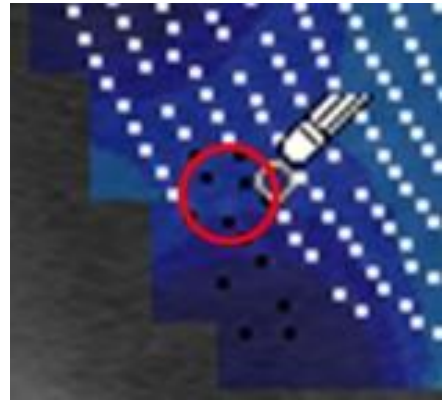


Figure 47. Selected Analysis Points

If you wish to restore a selected point, hold down the **Ctrl** key and click again on that point with the eraser tool.

To remove the selected points from the analysis, click on **Analysis > Data Points > Remove Selected** button. The colour maps and statistics are recalculated with the selected analysis points excluded.

If needed, you can always restore the analysis back to its original form using the **Analysis > Data > Reset Analysis** button.

Printing the Exam Results

Select the patient exam(s) you wish to print then select the View (see *Setting the Exam View* on page 39), and Map Type (see *Map Types* on page 45).

Select the printer and paper size to print by clicking on the **File > Print** menu and then clicking on the **Settings** button**.**

Click on the **File > Quick Print** menu to print the displayed exams immediately or alternatively select the **Print Preview** to adjust titles and margins and view output before printing (see the Medmont Studio documentation for more detail).

Printing to a colour printer provides a concise summary of the exam (see Figure 48).

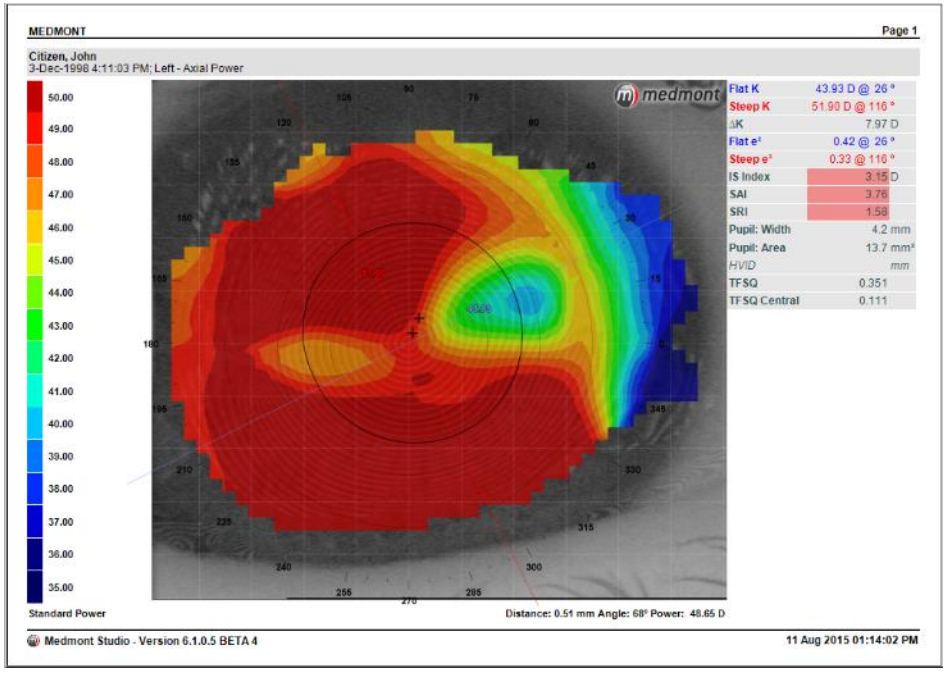


Figure 48. Standard exam printout in Print Preview.

Exporting the Raw Analysis

The E300 software provides the facility to dump raw topography data for the selected exam to a set of text files. This data can then be imported and manipulated by external software and tools.

Note that this exports the raw analysis data (without any resampling or calculation of attributes or other analysis properties). The alternative **File > Export** mechanism can export higher level analysis data in a single XML file and is better suited for most tasks.

First select the exam to export. Then click the **Analysis > Data > Raw Export** button  . Specify the "root" name and location of the files to create. Typically the file name is based on the patient's name, for example "JohnSmyth". The following files are created:

Filename.axl – axial curvature data (in mm)

Filename.tgl – tangential curvature data (in mm)

Filename.hgt – corneal height data (in mm)

Filename.dst – radial distance data (in mm)

Filename.slp – corneal slope data

Each line of the file contains the data for a single spoke (centred at the keratometric axes) with data points for each ring. Missing data is indicated by zero values. There are 300 spokes each with 32 rings.

8. Fitting Contact Lenses

The E300 software provides a simulated fluorescein display for evaluating the fit of RGP contact lenses (see Figure 49). Note the T and N letters denote the Temporal and Nasal orientation of the lens.

NOTE

The fluorescein display is a simulation and should only be used as a guide to the expected fit. Simulated fitting of lenses larger than the captured data area is based on extrapolated data and may therefore be less accurate. A trial lens fitting should always be performed to confirm the simulation results.

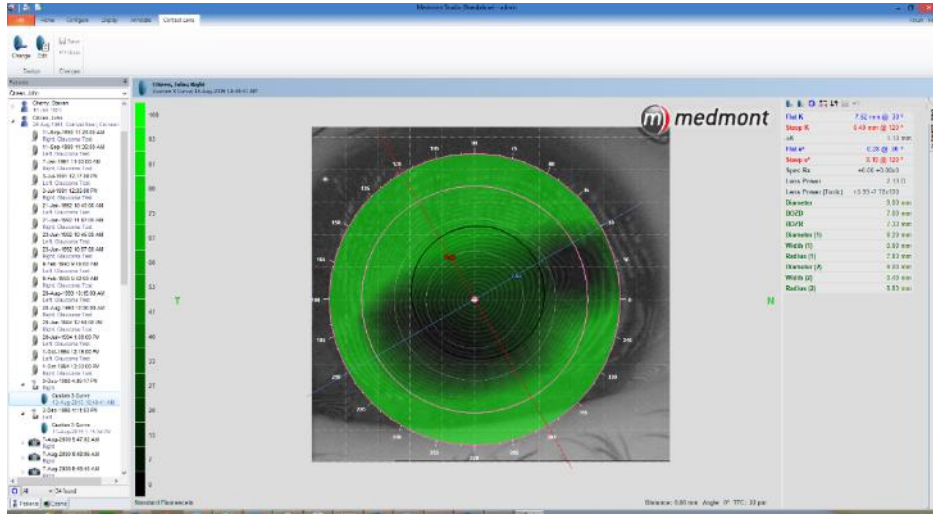


Figure 49. Simulated Fluorescein Display

Creating a new Contact Lens

Before proceeding with contact lens fitting you should have captured exams for both eyes of the patient (see *Performing Examinations* on page 22).

Select the Patient Exam on the Explorer pane and click on the **Home > New Exam > Contact Lens** button. This displays the Contact Lens Design dialog shown in Figure 51.

Restricting the Available Designs

If required you can restrict the set of available lens designs to better suit your practice. Click on **Manufacturers** within the Contact Lens Design dialog to display the lens design selection dialog shown in Figure 50. Check or uncheck the manufacturers as required.

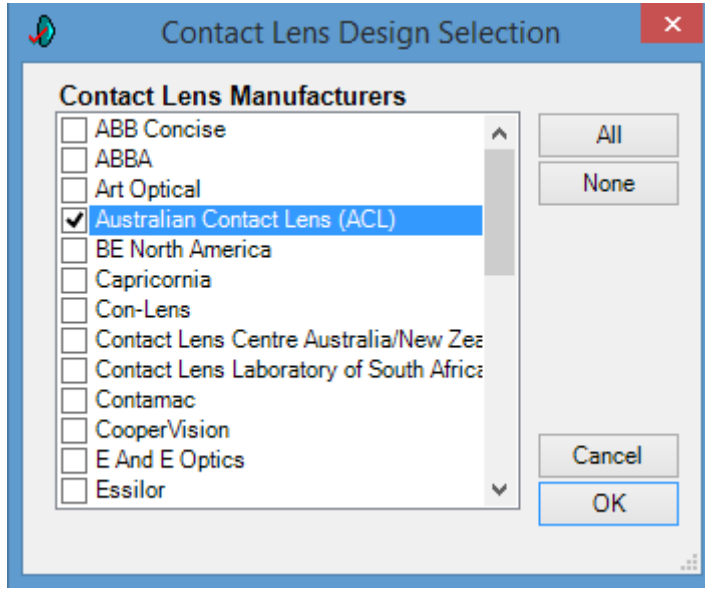


Figure 50. Contact Lens design selection dialog.

Selecting the Lens Design

The Contact Lens Design dialog (see Figure 51) allows you to select the lens design to use. When a new design is selected from the drop-down selection box the recommended parameters for the design are automatically calculated based on the eye geometry. The simulated fluorescein pattern is computed and displayed.

The dialog also allows you to specify the manifest refraction that the software uses to calculate the required contact lens power. For a new lens this will be set by default to the current refraction values for the patient from the Patient Management system.

The dialog is displayed when creating a new contact lens. You can also use it to change the design or refraction for an existing contact lens by clicking on the *Contact Lens* > *Design* > *Change* ribbon button (or the shortcut button in the **Data** tab)

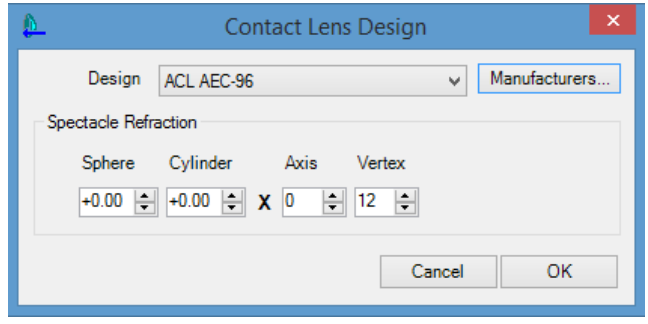


Figure 51. Contact Lens Design dialog

Editing the Lens Design

Clicking on the  *Contact Lens* > *Design* > *Edit* ribbon button (or the shortcut button in the **Data** tab) displays the Contact Lens Designer dialog. This is normally displayed automatically when you create a new contact lens. The parameters that are displayed and can be changed in this dialog depend on the selected lens design. An example for an ACL TriCurve is shown in Figure 52. Typically the controls allow you to change parameters such as the lens diameter, base optic curve radius and peripheral curve parameters.

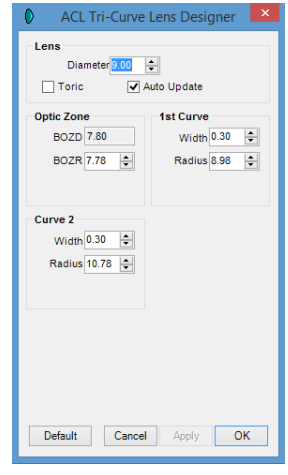


Figure 52. ACL TriCurve contact lens designer dialog.

Enter values in the numeric text boxes by clicking the spin-buttons or using the keyboard (see *Software Conventions* on page 6).

For some lens designs, changing values may cause other values to be recalculated to match. For instance, when the base optic radius is changed the peripheral curve parameters are generally automatically updated. For the lens

design dialogs where this occurs, the automatically generated values can be overridden by changing them manually, and you can uncheck the ***Auto Update*** option if you do not want the peripheral curves to be updated when you change the base curve or diameter of the lens.

Click on the ***Apply*** button to display the simulated fluorescein pattern for the new parameters. The ***Defaults*** button restores the default settings for contact lens designs based on the eye geometry.

Moving the Contact Lens

The contact lens can be moved over the eye to determine how the fit varies as the lens moves. Select the contact lens by clicking on the outside border or central dot. You may need to move the section indicator first. When selected, the lens border and central dot are displayed in pink. Hold the left mouse button down while dragging the lens to move it. When you release the mouse button the lens is left at the current location and a new simulated fluorescein pattern is generated.

Contact Lens Data

The software calculates the required contact lens power by combining the vertex adjustment and manifest refraction with the power required to correct for the tear film lens. If the refraction axes do not align with the corneal keratometric axes then a cross cylinder calculation is used to combine them. The required power is displayed in two forms:

- Lens Power (Toric) – is the full calculated refraction (including cyl) required to correct any residual astigmatism.
- Lens Power – is the spherical equivalent power (in Diopters) and may be used to simplify the lens design when the residual astigmatism is not large.

These values and other lens design parameters are displayed in the **Data** tab.

Printing the Contact Lens Design

First select the contact lens or lenses that you wish to print by selecting them in the Explorer pane. Select the printer to print to and paper size by clicking the **File > Print** menu, then click the **Settings** button. To print immediately, use the **File > Quick Print** menu then click **OK**. Alternatively, use the **File > Print Preview** menu to adjust titles, margins and view output before printing. A typical fluorescein print is shown in Figure 53.

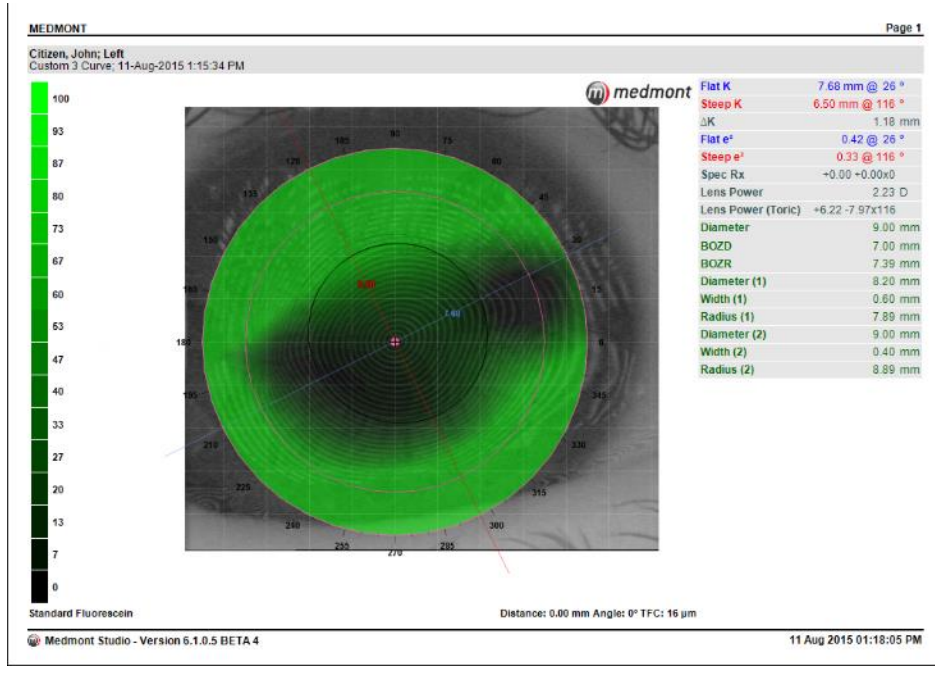


Figure 53. Example fluorescein printout in Print Preview.

9. Managing Exams and Calibrations

This section describes general housekeeping procedures for managing various aspects of the E300 database.

Editing Exam Details

Select the Patient Exam entry in the Explorer pane and select Details Exam View mode (see *Setting the Exam View* on page 39). The software displays the Patient Exam details (see Figure 54).

Enter or change any of the details. Any changes will enable a ***Cancel*** and ***Save*** button. Press ***Save*** to save your changes. The ***Cancel*** button discards any changes.

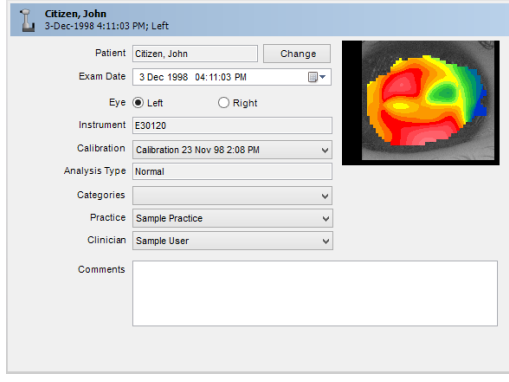


Figure 54. Exam Details dialog.

Moving an Exam to a Different Patient

If you accidentally capture an exam against the wrong patient it is possible to transfer the exam to another patient. Click on the ***Change*** button and enter the details for the correct patient. Click ***OK*** to make the transfer.

Changing the Calibration Used for an Exam

The software sets the calibration used to analyse a Patient Exam when the Exam is captured. It is possible to change this using the Calibration drop-down box. Usually the only reason for doing this would be if you discovered that the instrument has gone out of calibration (see *Calibrating the E300* on page 80). Once you have re-calibrated the instrument select the Patient Exam that you wish re-analyse, and select the new calibration using the Calibration drop-down box. When you next view the Patient Exams in Map, Combination or Difference View Mode they will be analysed using the new calibration.

Categories

Categories are user-defined words or phrases that describe the nature of the examination. You can add, delete and change the available categories (see the Medmont Studio user manual). Categories are displayed in the Details view which can be accessed by selecting **View > Active View > Details** from the ribbon bar menu. They are also displayed under the date of the exam in the patient tree (room permitting).

Deleting Exams, Contact Lenses and Calibrations

You can delete exams, contact lenses and calibrations but keep the following in mind:

- Deleting an Exam also deletes any associated contact lens simulations.
- You cannot delete a calibration that is used by a patient exam.

In general it is not a good idea to delete calibrations.

Select the item(s) to be deleted in the Explorer pane. Then click on **Home > Exam > Delete**.

10. Calibrating the E300

The accuracy and repeatability of exam results is dependent on ensuring that the E300 is correctly calibrated. The instrument is supplied with a calibration object, which is calibrated to the National Standard.

Handle and maintain this object with care! Do not touch, scratch or dent the object surface; it is a delicate optical device.

The calibration object should be verified and re-calibrated every two years as stated on the calibration label, either by Medmont or a Certified Measuring Laboratory. If any surface defects are identified the object must be replaced to ensure the best calibration result. You should check the calibration of the instrument:

- After installation or moving the system to another location.
- On a monthly basis.

To calibrate the installed instrument, navigate to **Configure > E300 > Instrument Setup**. Then from the E300 Instruments window, click on the installed instrument and click **Calibrate** to run the Calibration Wizard, which allows you to check the current calibration and optionally recalibrate the instrument. The following sections describe the Calibration Wizard steps.

Choosing the Video Source

The first step of the calibration wizard is to specify the device used to capture video from the E300 topographer (see Figure 55). The first option is **Leutron PCI Capture Card**, choose this if your topographer connects to a PCI card using a long, flat D shaped connector. The second option is **USB Video Converter Box**, choose this if your topographer connects to a grey box using a round 8-pin connector which then connects to the PC with a USB cable. If you are upgrading from Leutron to USB now is the time to change the Video Source device. Doing so requires a full factory calibration which may take several hours to complete.

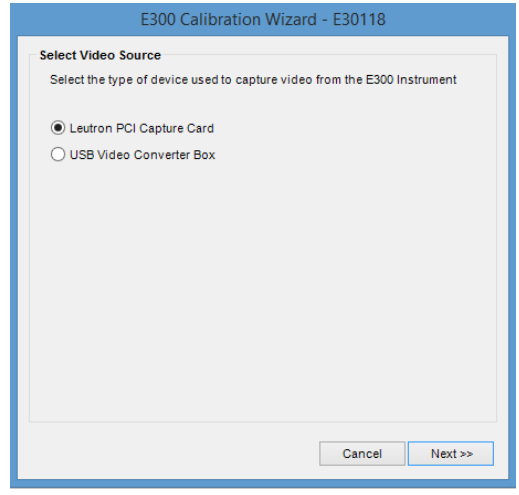


Figure 55. Choosing Video Source

Capturing Calibration Images

The Calibration Wizard captures five separate images of the calibration object at different locations within the instrument's working range (see Figure 56). It analyses these images to measure the error in the current calibration.

To start, mount the calibration object in the E300 chin rest. There is a slot beneath the top rail of the chin rest and a 4mm hole facing the E300. Hold the calibration object with the ball facing the E300, and slide the tab with the threaded hole into this slot from beneath. While holding it in position, insert the retaining screw with the knurled knob into the hole and screw it into the tab. Alignment is not important and only tighten finger-tight.

The E300 joystick allows positioning in three dimensions. Move the joystick in the desired direction for movement left and right and for closer to or further away. Rotate the joystick knob for movement up and down, clockwise to raise, anti-clockwise to lower.

Position the instrument to align the centre of the rings with the central cross hair and the focussing bar over the central horizontal cross hair. When the instrument is properly positioned the wizard will automatically capture the image. Press the ***Next*** button and repeat the process to capture each of the five images.

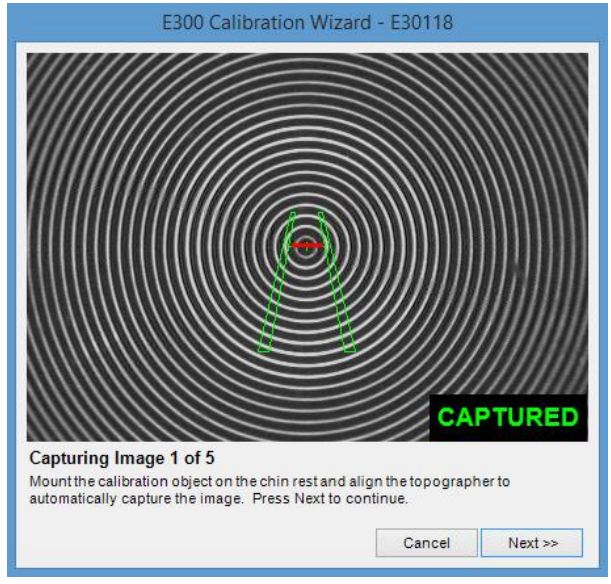


Figure 56. Capturing Calibration Images

Checking the Current Calibration

When the five images have been captured the wizard calculates the error in the current calibration and displays it (see Figure 57). This screen allows you to choose to recalibrate the instrument or continue using the current calibration. The wizard will recommend a course of action depending on the degree of error in the current calibration.

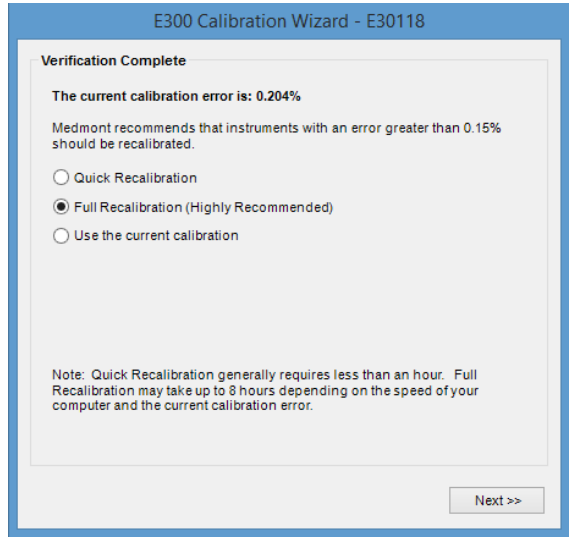


Figure 57. Verifying the Current Calibration

Recalibrating the Instrument

If you elect to recalibrate the instrument the Calibration Wizard will run the calibration process. It displays the current status of the calibration (see Figure 58). If you select the *Quick Recalibration* option then the calibration will stop automatically once the software is unable to reduce the error any further, over a number of consecutive calibration cycles. If you select *Full Recalibration* then the calibration will complete the maximum number of calibration cycles. *Full Recalibration* is generally only required for new instruments (done at the factory) or for instruments where the capture device or other physical hardware has been changed.

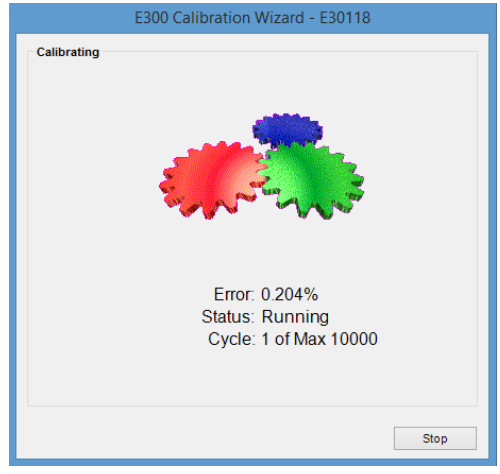


Figure 58. Recalibrating the Instrument

Calibration of the E300 involves analysing and adjusting over 80 software parameters to match the exact physical dimensions of the instrument. Consequently, depending on the speed of the PC, *Full Recalibration* may take several hours. A *Quick Recalibration* usually can be completed in under an hour and generally takes between 10 and 15 minutes. The calibration process can be stopped at any stage and resumed later.

At the completion of calibration the verification screen is displayed again and the software recommends whether further calibration is required based on the calibration error.

11. Menu and Icon Reference

The E300 software component adds the following types of icons to the Medmont Studio Explorer pane:

E300 Exam – displayed under Patient nodes in the Tree and E300 panes.

Idealized Eye – displayed under Patient nodes in the Tree and E300 panes. This represents an idealized symmetrical, toric ellipsoidal surface derived from one or more actual eye exams.

Contact Lens – displayed under Patient Exam or Idealized Eye nodes in the Tree pane.

Home Tab Items

The E300 component activates the following menu items for the Medmont Studio Home tab:

Corneal Topography – displays the E300 Exam Selection Dialog.

Contact Lens – creates a new Contact Lens for the selected Patient. (see *Fitting Contact Lenses* on page 73).

Configure Tab Items

The E300 component activates the following items in the Medmont Studio Configure tab:

Instrument Setup – Opens the E300 instruments window which allows you to setup, delete and calibrate E300 instruments

Calibrate Instrument – allows you to check the accuracy of the current calibration and recalibrate if required (see *Calibrating the E300* on page 80).

System Settings – allows you to configure to adjust the Eccentricity and Shape Factors, the height and Wavefront errors which affects the attribute values.

View Tab Items

The E300 component adds the items in Medmont Studio to the View tab (note: the View tab is only visible when an appropriate item is selected in the Explorer pane):

Details – displays the details for the selected E300 Exam and allows you to edit them (see *Editing Exam Details* on page 78).

Map – displays a colour contour map or 3D perspective map of up to four selected E300 Exams (see *Setting the Exam View* on page 39).

Combination – displays four different views of the selected E300 Exam (see *Setting the Exam View* on page 39).

Compare – displays a contour map of the difference between two selected E300 (see *Setting the Exam View* on page 39).

Analysis Tab Items

The Analysis tab is added by the E300 component. It is only displayed when a Patient Exam is selected:

Details – displays numerical readouts for apical curvature, sagittal height and shape factor, etc. calculated at a specified meridian and chord diameter for the selected E300 exams (see *Displaying Analysis Details* on page 64).

Ideal Eye – creates an idealized symmetric, toric ellipsoidal surface based on the average values of the currently selected exams.

Composite Eye – Uses the information from the currently selected exams and creates a new map using the combined coverage of the selected exams.

Reset Analysis – clears the analysis of the selected E300 Exams. This forces the software to re-analyse the selected exams.

Recalculate Attributes – recalculates the attributes for currently selected exams. For exam sequences this causes the attributes for all exams within the sequence to be re-evaluated.

Raw Export – creates a set of text files containing raw E300 Analysis data for the selected E300 Exam (see *Exporting the Raw* Analysis on page 71).

Edit – Allows you to edit the E300 exam to highlight and remove artefacts.

Remove Selected – Removes a point(s) that have been highlighted as an artefact for removal.

Display Tab Items

The Display tab is added when a graphical E300 view is selected or taking an E300 exam (see *Setting the Exam View* on page 39).

Reset – resets the zoom and pan to the default settings for the displayed view.

Zoom In – zooms in on the displayed views.

Zoom Out – zooms outwards on the displayed views.

Pan Left – pan to the left of the displayed views.

Pan Right – pan to the right of the displayed views.

Pan Up – pan towards the top of the displayed views.

Pan Down – pan towards the bottom of the displayed views.

Select – set the cursor mode of the displayed views to enable selection of the section indicator and cursor readout.

Pan – set the cursor mode of the displayed views to enable interactive panning using the mouse.

Zoom – set the cursor mode of the displayed views to enable zooming using the mouse.

Planar – image data is displayed as a plan colour map.

Perspective – image data is display a colour map overlayed on a perspective 3D view of the eye.

Reset – Resets the Display tab options back to their default settings.

Map Type – a drop down list box that allows you to select the type of image data to display.

Data – Display data options when the Elevation, Height – Zernike Fit or Wavefront Error: Zernike Fit has been selected from the Map Type drop-down list.

Colour Map Opacity (%) – Set the level of transparency for the Colour Map.

Perspective Scaling – A spin control allows you to display 3D Perspective views with enhanced distortion.

Graph – Adjust the graph display options for *Exam Sequences*

Sim K units – Allows the user to select the units of measurement for keratometric data. Options are: mm (millimetres), D (Diopters), or Auto K, which will automatically select the best unit of measurement based on the chosen map type.

E units – Allows the user to select the units of measurement for elliptical shape factors.

Image – Toggles on/off the raw video image, leaving just the colour map.

Colour Map – Toggles on/off the colour map, leaving just the raw video image.

Numeric Data – Toggles on/off the display of numeric data at specific points on each 30 degree spoke. The data displayed at each point will depend on the chosen map type.

Cartesian Grid – Toggles on/off a one millimetre rectangular grid, centred on the keratoscope axes, overlaying on the colour map.

Polar Grid – Toggles on/off reference ring, centred on the keratoscope axis, overlaying the colour map.

Keratometric Axess – Toggles on/off the display of the Keratometric axes on the map. The steep axis is calculated as the spoke with the highest average axial power whilst the flat axis is always set at 90 degrees from the steep axis.

Annotations – Toggles on/off the display of Annotations for the current exam.

Exam Annotations – Toggles on/off display of annotations for individual exams within an Exam Sequence.

Video Annotations – Toggles on/off the display of annotations for a whole Exam Sequence.

Readout – Turn on/off the readout display

Annotate Tab Items

The Edit tab is added by the E300 component. It is only displayed when a Patient Exam is selected:


Text – add a text annotation to the image.


Callout – add a callout annotation to the image.


Ruler – create ruler annotations; used to measure distances on the image.


Circle – create circle annotations.


Ellipse – create ellipse annotations.


Rectangle – create rectangle annotations


Square – create square annotations.


Polygon – create polygon area annotations.


Curved – create curved area annotations.


Freehand – create freehand area annotations.


Properties – change the properties of the selected annotation.


Delete – delete the selected annotation.


Pupil – allows you re-define the pupil


Iris – allows you to define the iris

Video Tab Items

The Video tab is added by the E300 component. It is only displayed when an E300 Exam Sequence or Tear Film Exam Sequence is selected and Image View mode is active.


Play – sequentially displays each image in the sequence (starting from the current image) then pauses at the beginning of the sequence.


Continuous Play – sequentially displays each image in the sequence (starting from the current image) in a continuous loop.


Pause – pause playing of the sequence.


Start – display the first image in the sequence


Back – display the previous image in the sequence.

Forward – display the next image in the sequence.

End – display the last image in the sequence.

Frame Rate - a dropdown list that selects the playback speed.

Contact Lens Tab Items

The Contact Lens tab is added by the E300 component. It is only displayed when an E300 Contact Lens Exam is selected.

Change – changes the design and/or the refraction for the currently selected Contact Lens Exam.

Edit – changes the design parameters for the currently selected Contact Lens Exam

Save – saves the changes made to the currently selected Contact Lens Exam

Undo – reloads the last saved Contact Lens Exam to undo any changes since the exam was last saved

12. Glossary of Terms

Analysis: The process by which the Placido rings - or segments thereof - are identified on the image, and from their distortions as much of the corneal surface as possible is reconstructed.

Calibrate: The process in which an optimal **calibration** is obtained, such that the overall error in reconstructing the surfaces for the **calibration images** is minimized.

Calibration: A set of parameters used during the analysis of an image to compensate for small variations in the manufacture of the instrument.

Calibration object: A small reflective ball of known radius

Calibration images: A set of (currently 5) images of a **Calibration object**.

Categories: A set of clinician provided descriptions that may be used to describe a particular eye. Examples would be: “pre-op”, “post-op”, “corneal graft”.

Colour scale: A set of colours used to map data values to colours a representation of a surface.

Elevation: The difference between the height and either a best-fit or user-specified sphere.

e: Eccentricity of an ellipse on a plane slicing through the **reference axis** and a specified axis on the surface. The ellipse is fitted to the central point and a specified point on the surface axis. Usually the **steep axis** and **flat axis** are used to give a pair of *e* values.

Flat axis: The axis orthogonal to the **steep axis**.

Idealized eye: A symmetric, toric, ellipsoidal surface based on the average values of one or more surfaces.

Inferior/Superior (IS) index: The **IS** is the difference (measured in diopters) between the average inferior power and the average superior power.

Installed instrument: The instrument (specified by its serial number) that the software expects to use for image capture.

Keratometric power: For a given line through the centre of the surface, this is the axial power at the point on the line where a keratometer would take its measurement (maximized when the given line is the **steep axis**).

Power maps: Axial, tangential and refractive power representations of the surface, measured in diopters.

Reference axis: On the physical instrument, the longitudinal axis passing through the centre of all the Placido rings. In the mathematical 3-dimensional space in which the surface is reconstructed, it is a line passing through the centre of the image, roughly orthogonal to the surface.

Refraction: Summary of the patient's current spectacle prescription. Consists of: *sphere*, *cylinder*, *axis* and *vertex*.

Score: An automatic percentage rating of the quality of an image. Three basic scores are computed for each image, measuring: the amount of *movement*, how well *centered* the eye is, and the *distance* from the eye to the ideal capture plane. A total score, which is the product of the three basic scores, is also computed.

Sim-Ks: Simulated keratometer values, measured along the **steep axis** and the **flat axis** (see **keratometric power**).

Steep Axis: The axis along which **keratometric power** is maximized.

Surface Asymmetry Index (SAI): The SAI is the centrally weighted average of the difference in power between corresponding points at the same chord, 180 degrees apart on the eyes surface.

The weighting value used is:

$$Weight = \frac{1}{R^r}$$

Where; R = radial distance from the keratometer axis

Surface Regularity Index (SRI): This is a calculation of amount of local variation in the power of the eye within the average virtual pupil. The predicted power at a point is calculated as the average of the values of its rectilinear neighbours. The difference between the predicted power and the actual power is averaged over the central 4mm chord area.

The SRI is then given by:

$$SRI = \log(ZERO\_POINT + SCALING\_FACTOR \times avg(abs(\mathrm{Pr}edictedP - ActualP)))$$

Where; *PredictedP* = Predicted Tangential Power (based on the average power of the rectilinear neighbours)

Actual P = Actual Tangential Power

SCALING_FACTOR = 10.0

ZERO_POINT = 0.90

Tear-Film Clearance (TFC): The distance between the surface of the eye and the contact lens at a point.

13. Cleaning, Maintenance and Service

To maintain the life of the components and the accuracy of the instrument, regular maintenance is required in the form of lubrication and cleaning.

Routine Hygiene and Cleaning

All surfaces coming in contact with patients need regular disinfecting. Standard instrument grade disinfectant like IPA (Isopropylalcohol) diluted with 50% water may be used on all external surfaces. Wipe surfaces with a damp cloth only to avoid liquid entering delicate parts and optics. Do not use strong oxidising agents or solvents as they could damage surface coatings. Do not use any aerosols or sprays that could contaminate the optics. Use soft non-abrasive cloth only. Special care of the inside of the cone is required, and is described in the section below.

Cleaning of contaminated Optics

The following optics are externally accessible and subject to contamination from dust, residues from evaporated liquids, body acids and fats, and makeup.

- Cone surface.
- Imaging lens front surface.
- Profile illumination window (on RH channel just inside cone edge).
- Profile image window (on LH channel inside cone edge).

Internal optical surfaces are not accessible without disassembly. Do not attempt to disassemble or turn any of the sealed mounting screws, as the alignment of the optics and the calibration may be altered considerably. Do not put any objects into the cone other than those listed.

Recommended cleaning materials:

- Cotton tips. For Profile windows preferred tapered cotton tips
- Micro fibre cleaning cloth or lint free lens paper
- Non-smear optics cleaner or diluted IPA

The cone assembly is made of polymer products. This means the cone is sensitive to mechanical surface damage (scratches, dents) and may not be chemically resistant to certain solvents.

Do not use any abrasive cloth or strong organic solvents like acetone.

The image lens is positioned near the apex of the cone and difficult to access. Unless the optical performance of the lens is noticeably affected we do not recommend approaching the lens. Dust on this surface is not visible on the

image. Its effect is a lowering of image brightness and overall resolution (not local blurs) only.

The profile windows are 2 x 2 mm in size. To reach the corners of these windows use tapered cotton tips, or if not available from the tip of a standard cotton applicators with tweezers to a pointed rectangular shape and wet slightly with optics cleaner.

The narrow end of the cone can easily be reached with the cotton applicators. For the entrance area cloth or cotton gives a good result.

Calibration Object

The calibration object has a delicate optical surface. After use clean with isopropanol and a lint-free cloth to prevent acid corrosion from fingerprints. Use the same technique to remove any contamination prior to using the object again.

Lubrication

All parts except the exposed horizontal shaft are permanently lubricated and do not require any additional lubricant. The horizontal shaft should be cleaned from dust and old oil residues and oiled every few months. This also protects the shaft from corrosion. The oil used should be acid free fine instrument oil, e.g. sewing machine oil. Apply only a fine film with a lint free cloth.

Service

For servicing and repair, please contact your local agent for advice on suitable and qualified providers. Medmont will make available on request to the service provider circuit diagrams, components, parts lists and instructions etc. as required.

Troubleshooting

The following guide is an aid for the user to help identify, describe and remove certain errors.

Problem	Comment	Action
No video image	12V indicator light is OFF	Instrument ON/OFF switch on? Check power adaptor is fully plugged in. Return back to supplier for repair.
No video image	USB power indicator is OFF	Ensure USB plug is properly connected at both the PC and converter box ends. Return back to supplier for repair.

No video image	Error indicator is flashing	Disconnect and reconnect the USB connection to perform system reset. Return back to supplier for repair.
No video image	**MEDMONT E300 USB** device not displayed in Device Manger	Instrument ON/OFF switch on? Check status lights are showing correct power connection. Check USB port is at least USB 2.0 or higher. Check Windows XP SP2 or higher is installed. Reboot the computer to re-initialise the USB port. Return back to supplier for repair.
No cone illumination	Illumination only comes on for a few seconds, when computer boots up, or when in Capture mode.	Instrument ON/OFF switch on? Check power adaptor and D-plug to frame grabber are not loose Check frame grabber card is firmly in PCI slot
Distance bar in capture window not working, oversensitive or jumping	Blue LED is normally always on when instrument ON/OFF button is on.	Is bright light source present, which contaminates profile signal? If yes: Remove light source, or reposition instrument. If no: Check RH channel from front (look in sideways into small rectangular opening). Is blue light on? *If yes: Has instrument been subjected to excessive shock, vibration or impact?* If yes: check calibration and recalibrate if necessary.

Instrument does not calibrate	Possible reasons: One or more images taken out of distance range One or more images too far off centre One or more of the calibration balls not clean Profile optics misaligned Dirt on profile optics Too much stray light in image Too much movement in image Illumination defect	Identify problem, re-capture affected images if applicable and recalibrate

14. Specifications

Model	E300
Type/Variant	USB
Product Life	Service life 8 years, software support limited (Studio software: current platform only; Operating system: current and previous version)
Method of measurement:	Placido
Coverage:	Diameter 0.25-11 mm
Field of View:	11.5mmH x 11mmV
Illumination:	Red 660nm Green 565 nm Blue 430nm Luminance < 50 cd/m2
Power range:	10-100 Diopters
Number of Rings:	32
Measurement Points	9,600
Analysed Points	102,000
Repeatability:	< 0.1 Diopters
Calibration Object	R8.000mm +/-0.001mm
Footprint:	Width: 350mm Depth: 350mm
Eye level adjustable on unit:	395mm ±15mm
Weight:	8.5kg
Power requirements:	100 – 240 VAC 0.25-0.15 A (PC not included) 12 VDC, 6W via E300 USB Converter
PC and mains powered peripherals:	Compliance with EN/IEC60950 CISPR22 EN/IEC55022
PC:	(See Medmont Studio Manual)
Printer:	Bubblejet/Laser Colour/ Monochrome
Back Up:	CDROM or DVD burner

Operating conditions:	+10° to +40°C max 80% relative humidity
Isolation Transformer	Compliance with EN/IEC 60601-1
Transport/Storage Conditions:	-15° to +40°C 10% to 95% relative humidity 500 to 1060 hPa

15. Declaration of Conformity

EC DECLARATION OF CONFORMITY

medmont

Manufacturer:

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Authorised EU Representative:

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declares, that the manufactured by Medmont Pty. Ltd. product:

Corneal Topographer Model: E300 USB

- **is marketed in the EU from May 2011;**
- **the recorded product serial numbers are commencing from E31890;**
- **is classified as Class I Medical Device and is in conformity with the essential requirements and provisions of the EU Council Directive 93/42/EEC;**
- **is subject to the procedure set out in Annex VII of the EU Council Directive 93/42/EEC;**
- **is in compliance with a current edition of the applicable safety standards:**

IEC 60601-1: ed. 3.0	**Medical electrical equipment - Part 1: General requirements for basic safety and essential performance**
IEC 60601-1-2: ed. 3.0	**Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.**

Nunwading, 5 May 2014

Robert Heavyside
President
Medmont International Pty. Ltd.

16. Representatives

The EU Authorised Representative:

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Your Local Medmont Authorised Agent is: