Dry Eye Analyzer

User Manual

MOPTIM

Dry Eye Analyzer User Manual
Revision History

Publishing details
Moptim
Dry Eye Analyzer

Part Number	Rev	Software Rev	Description	Release Date
	V1.0	V 1.0	The first release	2021.06.18
	V1.1	V 1.0	Update the software interface	2022.04.01

Preface

Hereby, we would like to express our appreciation for purchasing the Dry Eye Analyzer(DEA) of Shenzhen CERTAINN Technology Co., Ltd. DEA engineered by CERTAINN is a novel non-invasive equipment that can be applied to dry eye screening.It is based on the real-time camera system to shoot or record eyelid or eye surface,displaying the image and dry eye diagnosis index via relevant algorithm and computer processing .

DEA is a portable device, which can be used as a separate device or it can be installed on the slit lamp. It can not only measure tear film break up time to evaluate tear film stability, analyze abnormal condition of meibomian gland, measure lacrimal river height to evaluate secretion of tear, but also assess abnormal condition of eye surface by fluorescent staining, which can assist doctors to complete diagnosis and screening of dry eye disease.

DEA software system includes powerful graphics management software, as well as convenient data query, comparison function, effective image optimization processing and measurement .

The purpose of the manual is to provide a training, operating and reference guide for DEA. The users are required to be trained professionally, which includes technical operation and clinical diagnosis. The manual only offers hands-on technical operative training, yet the clinical diagnostic training is not included. All the images acquired clinically must be interpreted by qualified professionals.

Catalog

1. Important Notes

1.1 Declaration

- **Please read the manual thoroughly before any operation.**
- **This manual is only applicable to the Dry Eye Analyzer(DEA) manufactured by Shenzhen CERTAINN Technology Co., Ltd**
- **The information of operating DEA is described in this manual, including Operating procedures, safety precautions and specifications.**
- **Before operation, it is of great importance to understand safety precautions and procedures. Please keep this manual properly just in case.**
- **The equipment can only be operated by professional personnel, and all the operation must be strictly in accordance to the manual.**
- **The maintenance of the equipment can only be operated by qualified personnel who have the authorization of Shenzhen CERTAINN Technology Co., Ltd.**
- **Due to the continuous improvement of our products, without notification, the Shenzhen CERTAINN Technology Co., Ltd.will retain the right to change technical specifications.**

1.2 Safety Notes

This instrument is categorized as following according to IEC60601-1:

- Protection against electric shock: Not applicable
- Degree of protection against electric shock of applicable parts: Not Applicable
- Degree of protection against harmful ingress of water: IPX0.
- Class of operation: Continuous.
- Safety degree when it is used in flammable anesthetic gas mixed with air or mixed with oxygen or Nitrous oxide: Non AP / APG type

Caution: Before operation, please read the safety precautions in this manual. indicated on the equipment to place or transport, otherwise the equipment may lose balance.

Caution: Please operate under the guidance of professionals, non-professionals are prohibited to operate the equipment without authorization.

Caution: Avoid tipping, do not use the equipment in uneven or sloped surfaces.

Caution: The equipment has no special measures to prevent the intrusion of water or other liquids, please do not put the container with liquids on or near the equipment, and do not use sprays near or on the equipment.

Caution: Do not use this equipment for any other purpose other than specified in this manual.

Caution: The equipment is not allowed to work under the flammable, explosive, strong electromagnetic interference circumstances!

Caution: The software and hardware of the equipment have been carefully designed to protect clinicians, users and patients are not subjected to mechanical, diagnosis, or treatment failure potential damage. Unauthorized modifications of the instrument's software or hardware (including peripherals) may jeopardize the safety of operator and patient, as well as performances of the equipment and integrity of patient data. Unauthorized modification will also cause equipment warranty invalid.

Caution: Only Shenzhen CRETAINN Technology Co., Ltd. authorized technicians are allowed to remove the instrument, and the user must not disassemble or repair.(If failure, error messages or operational problem occur, please call customer service of Shenzhen CERTAINN Technology Co., Ltd.: in China, please call 400-688-5339;outside of China, please contact your local distributor.

Caution: Please stop using the device with the patient while it is being serviced or maintained.

Caution: When necessary, Shenzhen CRETAINN Technology Co., Ltd. will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

2. Electromagnetic compatibility (EMC)

(Notes:)

- DEA conforms to IEC60601-1-2:2014 EMC requirements.
- User must install and operate the device based on the provided EMC information.
- Portable or mobile RF communication device might influence the performances of DEA , please avoid strong electromagnetic disturbance. such as mobile phones and microwave ovens, etc.
- The guidelines and the manufacturer's declaration are detailed in the annex.

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable healthcare environments and so on.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

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

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DEA, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7

(EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESS ENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

Technical description

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.
2. Guidance and manufacturer’s declaration -electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The DEA is intended for use in the electromagnetic environment specified below. The customer or user of the DEA should assure that it is used in such an environment:		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DEA 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 A	The DEA is suitable for use in all establishments other than 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	Not applicable	
Voltage fluctuations/ flicker emissions	Not applicable	

The EMISSIONS characteristics of the system make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) the system might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 2

Guidance and manufacturer´s declaration – electromagnetic immunity			
The DEA is intended for use in the electromagnetic environment specified below. The customer or the user of the DEA 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	Contact discharge: ±2 kV, ±4 kV, ±6 kV,± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact discharge: ±2 kV, ±4 kV, ±6 kV,± 8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient/ burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency	Not applicable	Not applicable
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV for line-line ± 0.5 kV, ± 1 kV, ± 2 kV for line to ground	Not applicable	Not applicable

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°,90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	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.			

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6Vrmsc in ISM bands between 0.15 MHz and 80 MHz 3V/m 80MHz to 2.7 GHz and RF bands(See the RF wireless communication equipment table in “Recommended minimum separation	3 Vrms 150 kHz to 80 MHz 6Vrmsc in ISM bands between 0.15 MHz and 80 MHz 3V/m 80MHz to 2.7 GHz and RF bands(See the RF wireless communication equipment table in “Recommended minimum separation	Portable and mobile RF communications equipment should be used no closer to any part of the DEA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150kHz to 80MHz $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.7GHz $d=6\sqrt{P/E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer).

			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 meters(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. The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz,24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. 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 DEA is used exceeds the applicable RF compliance level above, the DEA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DEA.

Table 3

Recommended separation distances between portable and mobile RF communications equipment

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

Rated maximum output of transmitter /W	Separation distance according to frequency of transmitter /m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (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.

Table 4

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency /MHz	Maximum Power /W	Distance /m	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
450	2	0.3	28	28	

710 745 780	0.2	0.3	9	9	Recommended separation distance $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
810 870 930	2	0.3	28	28	
1720 1845 1970	2	0.3	28	28	
2450	2	0.3	28	9	
5240 5500 5785	0.2	0.3	9	9	
Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					

Accessory Equipment

WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

2.1 Product compliance

This product complies with the requirements of EU medical device regulations.

2.2 Symbols and Tags

	**Please read the manual prior to any operation.**
	**Caution:** Consult accompanying documents. **Note:** There are important operating and maintenance instructions found in the manual.
	**Medical Device**
	**European Conformity**
	**Serial number**
	**Catalog number / part number**
	**Model**
	**USB Connection**
	**No Rollover**
	**No Stacking**
	**Non-ionizing radiation**

	Recycle through designated channels

1. The device will be put on the European market after December,2021.
2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment.

Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

When determined that the device is ready for disposal, it is to be recycled following thepolicies and procedures reflecting respective country's requirements. Do not dispose of device as general waste.

2.3 Position of the product label and serial number

The product label is attached on back cover of the equipment:

3. Introduction

3.1 Product structure and composition

DEA(Dry Eye Analyzer) consists of mainframe and the adapters with different functions and need to connect to the computer to work with the operating software. It is available to achieve the function of break up time(B.U.T) measurement, tear height measurement, lipid layer imaging, Meibography, Red eye analysis, etc by changing the adapters, which can help doctor complete the diagnosis and screening of Dry eye.

3.2 Description and intended use

The DEA is intended to do the exams related to the analysis and possible diagnosis of Dry Eye Disease(DED) through the connection of the device to you pc, and particularly.

- Interferometry: records a video to the patient's eye to analyze quantitatively and qualitatively lipid layer of the tear film, to compare it with the related grading scale and save the value;
- Tear Meniscus Hight: The tear secretion of the lacrimal layer was assessed by measuring the height of the tear meniscus;
- NIBUT: recording a video, it allows to evaluate the stability of the tear film between the break up time in a non-invasive way and to save the value;
- Fluorescein BUT: records a video for the evaluation of the tear film's stability, but it is done with instillation of the fluorescein in the patient's eye (invasive) and without cone;
- Meibography: takes a picture of meibomian glands using infrared light. The device can analyze automatically the loss area of the glands to compare it with the related grading scale;
- Additional exams: checks for Bulbar Redness, Blepharitis, Demodex, pupillometry.

All the exams that can be performed with the DEA are of fundamental importance for the ophthalmologist and the optometrist (within their respective professional skins) to study the tear film and for coaching the exams done with the classic instruments (Slit Lamp, Topography, Tonometry, etc.).

3.3 Part description


Fluorescence adapter


MGD adapter


NIBUT adapter

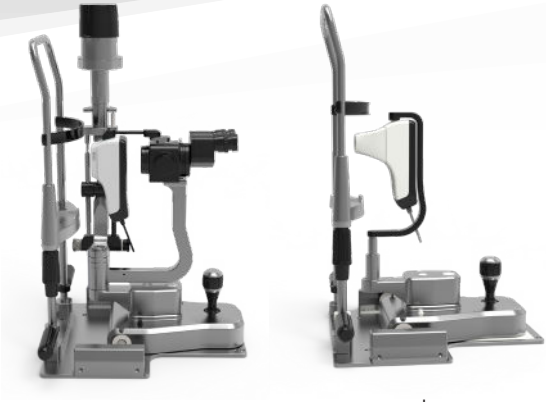

White-light adapter


Remote control

4. Instrument Installation

4.1 Hardware Installation

DEA dry eye analyzer can be used as a handheld device connect the computer via USB3.0 datacable, and it can also be installed on the slit lamp.
If combined with slit lamp,there are two ways to install the DEA
1.Fix the DEA on the slit lamp with a linear bracket,as shown in Figure 4.1a
2.Fix the DEA on the slit lamp with a U-shaped bracket,as shown in Figure 4.1b



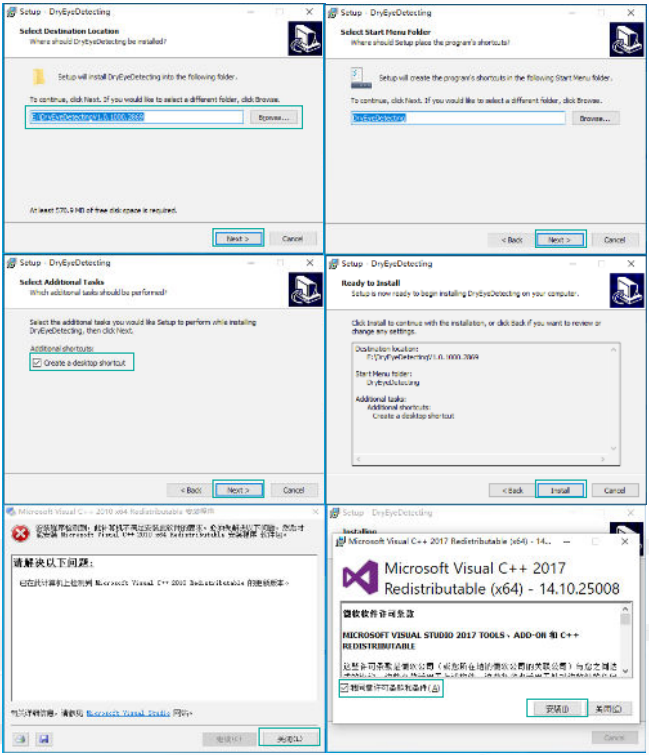
a b

Figure 4.1 Hardware installation(on slit lamp)

4.2 Software Installation

► Run the setup package file

► Choose the installation directory, and Wait for the end of the installation procedure.



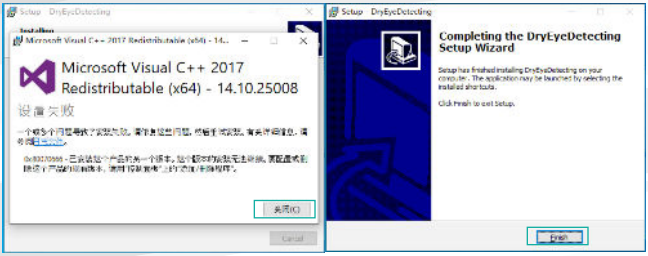


Figure 4.2 Software installation

► Connect DEA's USB cable to the computer, run the software and set up a data storage directory.

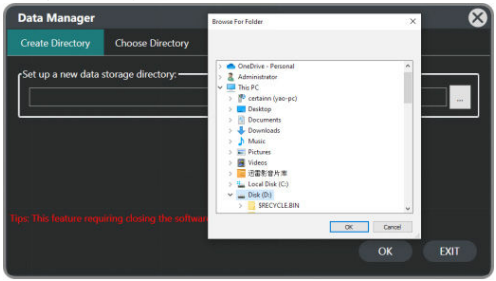


Figure 4.3

5. Guide of use

5.1 Operation procedures

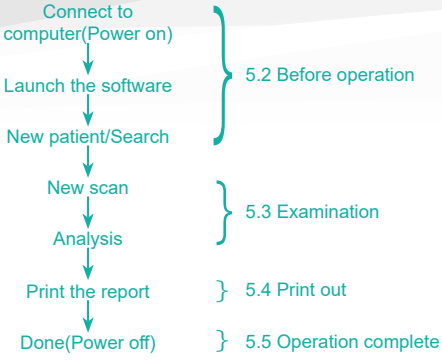


Figure 5.1 Operation procedures

5.2 Before operation

5.2.1. Review the case

Before scanning, it is necessary to review a patient's information, including checking patient's name, date of birth, gender and the eye selected.

5.2.2 Connect the instrument to the computer

The instrument needs to be connected to the computer via USB 3.0 cable to work. Ensure the instrument is connected to the computer before using. If the instrument is mounted on the slip lamp, ensure it is well installed before using.

5.2.3 Launch the software

Double click on the DEA icon on the desktop to launch the software as shown in Figure 5.2.

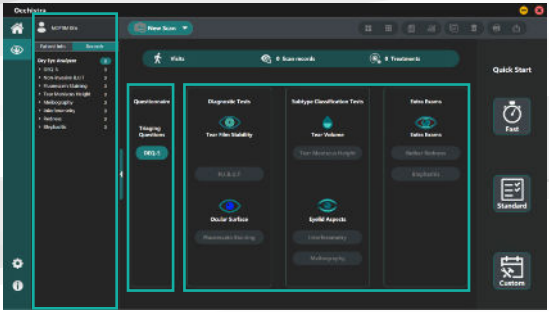


Figure 5.2 Software main interface

1. Create new patient

Click< > and enter the patient profile information list, the fields marked with * are required fields, as shown in Figure 5.3.

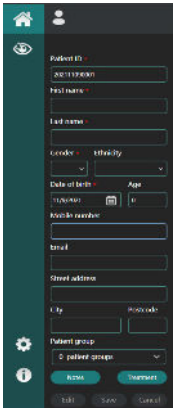


Figure 5.3 New patient interface

2. Search the patient

Double click < > and then enter the patient list

Patient list: If the patient profile already exists, put the key word of the patient information, Click“ ”to search the desired patient.

Patient examination list: Double click the patient and the history examination

of this patient will display on the right bottom.

Captured image display area: In the patient examination list, click the examination to display the acquisition image of this examination.

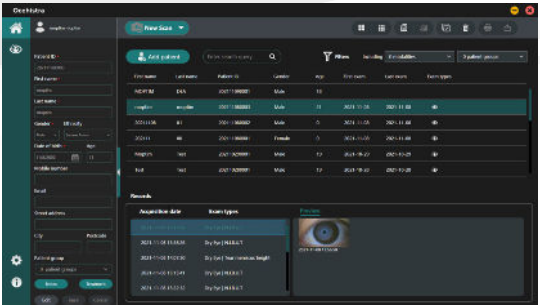


Figure 5.4 Patient list interface

3. Before operation

Instruct the patient to remove the glasses or contact lenses, and then let him sit.(If the device is mounted on the slit lamp, let the patient in front of the slit lamp). Fluorescein sodium dropping is required in B.U.T examination and Fluorescein staining examination.

5.3 Examination

5.3.1 Main interface

Launch the software and enter the main interface.

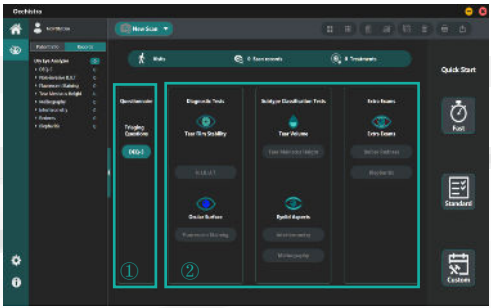


Figure 5.5 Software main interface

1. Questionnaire

5-item Dry Eye Questionnaire(DEQ-5).And the questionnaire result can be used as a reference for further evaluation examination.

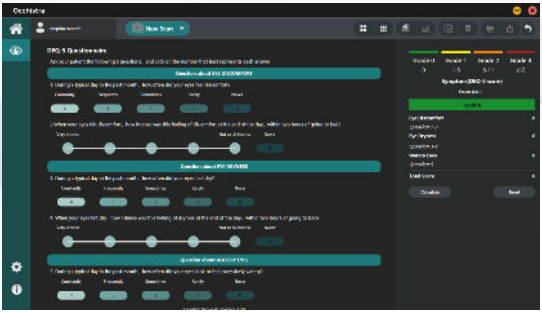


Figure 5.6 Questionnaire

2. Examination patterns

- **N.I.B.U.T:**

Placido cone is applied and a video is recorded to calculate the non-invasive B.U.T to evaluate the stability of the tear film.

- **Fluorescein staining:**

It is used to evaluate the epithelial cells of corneal via Fluorescein staining. Abnormal or missing epithelial cells are stained with fluorescein and observed under the blue light, they appear bright green and the bright green areas of the cornea may indicate dry eye

- **Tear meniscus height:**

Most tears are collected in the inferior and superior tear meniscus.Tear meniscus is used as the main reference of the volume of tears produced to evaluate the tear menisus

- **Meibography:**

The meibomian glands tends to be less or insufficient in patient dry eye. A quantitative analysis of the ratio between the area covered with glands and the total eye-lid area to evaluate the meibomian glands.

- **Interferometry:**

The thickness of the lipid layer can be estimated based on surface reflection patterns and dynamics. the lipid layer may appear like any of the following: amorphous structure, marble appearance, wavy appearance, yellow, brown,

blue or reddish interference fringes. An interferometric analysis of the lipid layer in the tear film is used to evaluate the lipid layer.

- **Extra exams:**

Used for checking the redness, blepharitis, Demodex, pupillometry.

5.3.2 N.I.B.U.T

5.3.2.1 Acquisition

Click <  > in the main interface and select <N.I.B.U.T> in the drop-down box to enter the N.I.B.U.T acquisition interface as shown in Figure 5.8. Before the acquisition, attached the Placido adapter on the device and ask the patient to look straight. When the center point is aligned with pupil, focus on the tear film of the corneal. And then ask the patient to blink once and keep eye open meanwhile take capture until the system automatically records the N.I.B.U.T and the position of first tear film break-up.

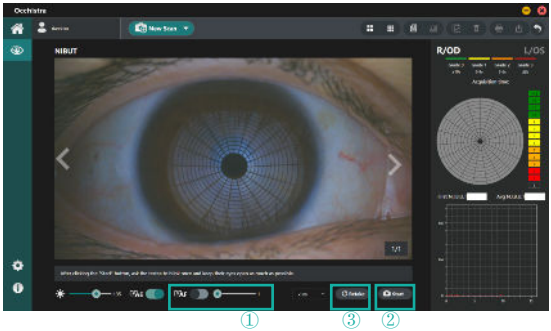


Figure 5.8 N.I.B.U.T Acquisition interface

1. Auto-exposure Two exposure options are available to select. Auto and manual.
2. Start Click <Start> to delete the current acquisition and start a new acquisition.
3. Capture Click <Capture > to start the video recording. And this icon turns to <Stop>. Click <Stop> to complete the scan. The acquisition will be saved automatically.

5.3.2.2 Analysis

The system will automatically calculate the first N.I.B.U.T and the average N.I.B.U.T, as well as display the position as shown in Figure 5.9.

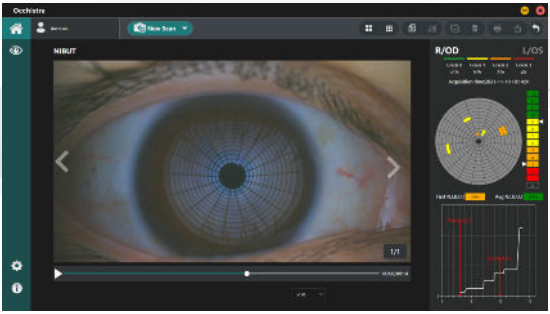


Figure 5.9 N.I.B.U.T analysis interface

5.3.3 Fluorescein Staining

5.3.3.1 Acquisition

Click <  > in the main interface and select <Fluorescein Staining> in the drop-down box to enter the Fluorescein Staining acquisition interface as shown in Figure 5.1..

Before the acquisition, attach the fluorescence adapter(to block the yellow light) on the device.

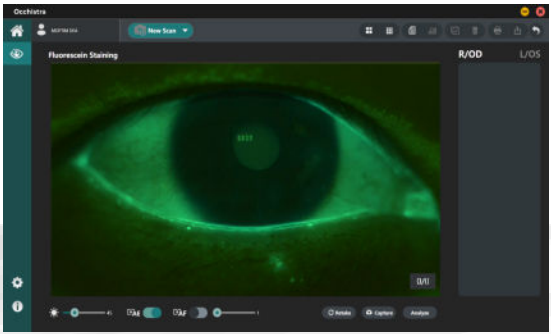


Figure 5.10 Fluorescein Staining acquisition interface

5.3.3.2 Analysis

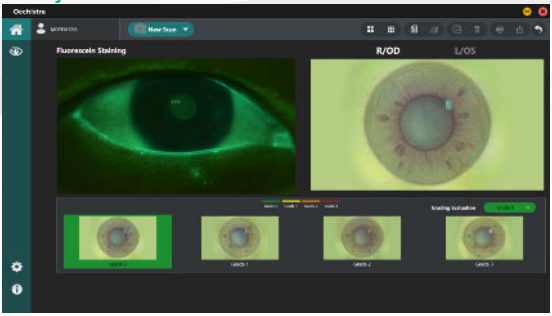


Figure 5.11 Fluorescein Staining analysis interface

There are four grading example images on the right which are used as the reference to help doctor diagnosis.

5.3.4 Tear meniscus height

5.3.4.1 Acquisition

Click <  > in the main interface and select <Tear meniscus height> in the drop-down box to enter the Tear meniscus height acquisition interface as shown in Figure 5.12.

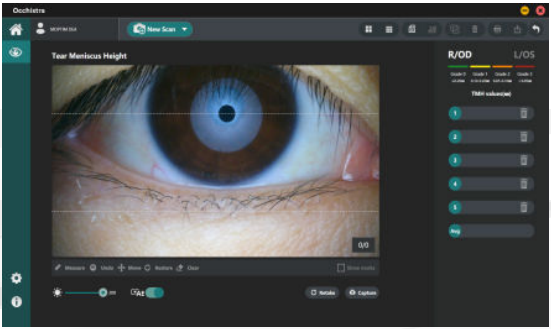


Figure 5.12 Tear meniscus height acquisition interface

5.3.4.2 Analysis

Click < Measure > on the tool bar below. Mark the borders of tear meniscus manually with the mouse and the height can be calculated by the system automatically. The measurement is up to five and the system will also calculate the average value of the measurements as shown in Figure 5.14

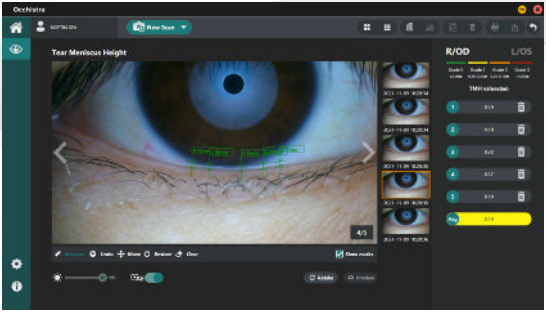


Figure 5.13 Tear meniscus height analysis interface

5.3.5 Meibography

5.3.5.1 Acquisition

Click < > in the main interface and select <Meibography> in the drop-down box to enter the Meibography acquisition interface as shown in Figure 5.14.

Before the acquisition, attach the MGD adapter on the device.

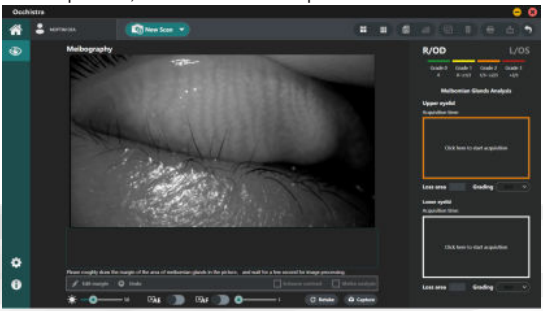


Figure 5.14 Meibography acquisition interface

5.3.5.2 Analysis

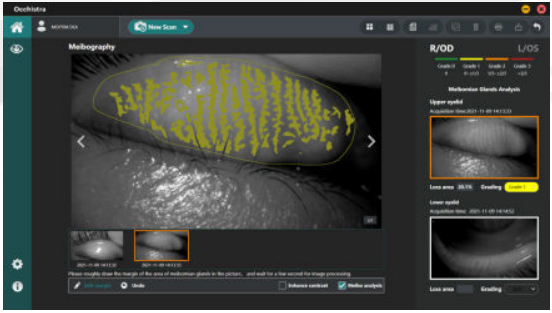


Figure 5.15 Meibography analysis interface

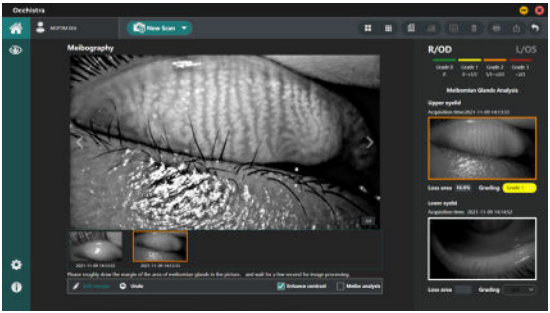


Figure 5.16 enhance contrast

Meiboscore grading of glands loss area
Grade 0: glands loss area=0
Grade 1: 0 < glands loss area≤1/3
Grade 2: 1/3 < glands loss area≤2/3
Grade 3: glands loss area > 2/3
The loss area can be margined automatically by the system. Manual detection is also available to draw the desired shape and the glands area will be highlighted with yellow color.

5.3.6 Interferometry

5.3.6.1 Acquisition

Click <  > in the main interface and select <Interferometry> in the drop-down box to enter the Interferometry acquisition interface as shown in Figure 5.17.

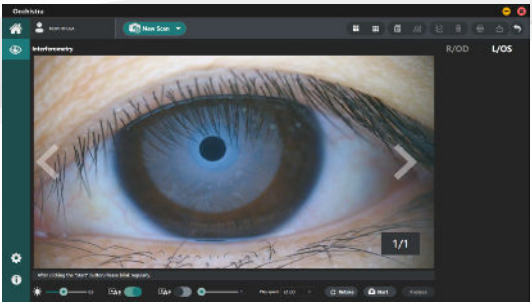


Figure 5.17 Interferometry acquisition interface

5.3.6.2 Analysis

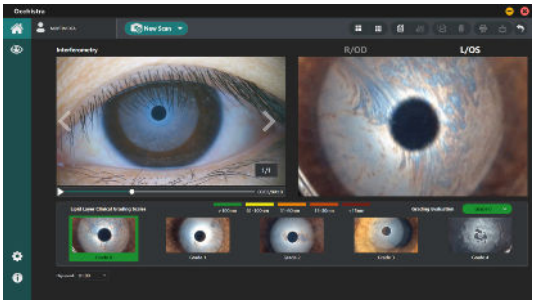


Figure 5.18 Interferometry analysis interface

5.3.7 Data preview

Click <  >, it will display the history examinations preview interface. It can be grouped by examination mode or by date. It also supports multiple images displaying in one page, 4 images displaying, 9 images displaying, as shown in Figure 5.19, Figure 5.20 respectively.
In the history examination list preview interface, double click the examination to enter the corresponding analysis interface.

Figure 5.19 4 images displaying

Figure 5.20 9 images displaying

5.3.8 Progress analysis

In the analysis interface, click<  > to enter the progress analysis interface. The history examination with the same acquisition mode and the corresponding trend analysis graph will display on the progress analysis interface.

5.4 Printout

In the analysis interface, click<  > to enter the printout preview interface as shown in Figure 5.21.

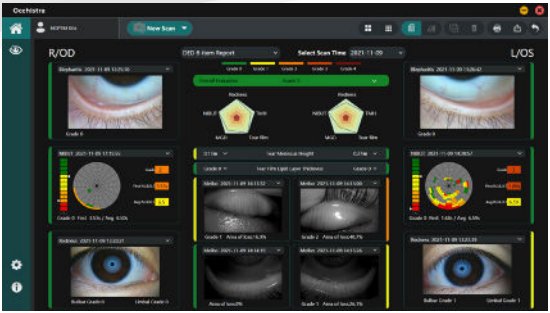


Figure 5.21 Printout preview interface

In the preview interface, click <  > to print the report.

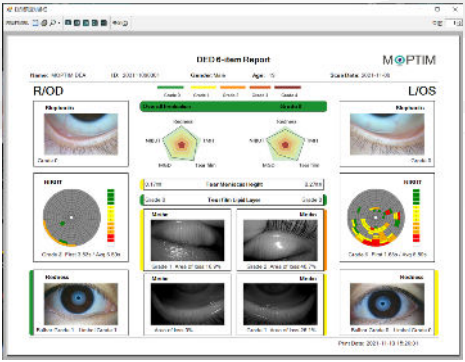


Figure 5.22 Report interface

5.5 Operation complete

1. Close the operating software
2. Turn off the computer.
3. Put the protection cover on the objective lens.

Warning: Put the lens protection cover on the objective lens and put a dust cover on the instrument when the device is not in use.

6. Packaging and Maintenance

6.1 Packaging

Check if there is obvious damage on the packaging material, if any please contact the distributor intermediately.
Open the packaging box, take out the device, user manual, accessories and the configuration list. And check the accessories according to the configuration list.
If the instrument needs to be transported safely, it is recommended to use the original packing material to avoid damage and unnecessary loss.

6.2 Cleaning

Turn off the instrument before the cleaning
If the instrument case is stained, wipe it with a soft cloth.
For stubborn stains, please use a soft cloth dipped in water diluted neutral detergent to wipe, dry, and then wipe with a soft cloth.

⚠ WARNING: The instrument has no special measures to protect against harmful ingress of water or other liquids. To avoid damage to the instrument and a safety hazard, cleaning solutions, including water, must be applied sparingly, with a non-lining cloth that is dampened only—not dripping wet ! Aerosols can not be used on the instrument.Do not use solvents containing acetone or xylene, and do not use detergents containing abrasive materials. Use only ordinary cleaners.

If the equipment is not used for a long time, it also needs to be maintained every month, cleaned, disinfected and started to check whether it is normal.
If the warranty period is exceeded, it is recommended to purchase a service contract of Shenzhen Certainn Technology Co., Ltd. for details, please contact the service agency of Shenzhen Certainn Technology Co., Ltd.

6.3 Adapters cleaning

The adapters include MGD Adapter,NIBUT Adapter,White light adapter,Fluorescence Adapter.
If the adapter is stained with fingerprints or contaminated due to other reasons it will impact the image quality.It is recommended to inspect the adapter in advance before the acquisition as the procedures are shown below.

1. Visually inspect the adapter lens for dust or stains
2. Use the blown balloon to blow the dust or stains off.
3. If the stain adheres to the lens, please wipe it with absorbent cotton dipped in absolute alcohol from the center to the periphery until it is clean.

Note: Wipe gently and carefully to avoid scratching the lens.

4. Visually inspect the adapter lens again for dust or stains.

6.4 Environment

Storage and transportation environment

Temperature	-20℃ ~ +55℃	Atmospheric Pressure	86 kPa ~ 106 kPa
Humidity	≤93%		

Working environment

Temperature	5℃ ~ 40℃	Voltage	5V
Humidity	≤80%	Atmospheric Pressure	86 kPa ~ 106 kPa

7. Trouble shooting

If the equipment does not work properly, please check the table below. If the problem is still not solved, please contact the manufacturer authorized local representative.

Problem	Possible Causes	Remedy
Unable to collect expected image on fundus	• Bad contact of USB • Bad contact of adapter	Unplug the interface and reconnect
No clear image	• Fungus or dust deposit on optics	• Clean dust & fungus

8. Configuration

Standard Accessories

Item	Quantity
DEA(Dry eye analyzer mainframe)	1
User manual	1
NIBUT adapter	1
Remote control	1
Certificate of qualification	1
Warranty Card	1

Optional Accessories

Item	Quantity
MGD adapter	1
White-light illumination adapter	1
Fluorescence adapter	1
Type A connector for Slit Lamp	1
Type B Connector for Slit Lamp	1

9.1 Limited Warranty

This Warranty gives you specific legal rights, and you may have other rights, which vary from state to state. For one year from the date of delivery (the “Warranty Period”) to the original purchaser (“You,” “Your,” “Purchaser”),Shenzhen Certainn Technology Co., Ltd. (“CERTAINN,” “Seller,” “We,” “Our,” “Us”) warrants its DEA(Dry Eye Analyzer), excluding components and software as stated below (the “DEA(Dry Eye Analyzer)”) to be free from defects in material or workmanship. In the event of failure, seller's obligation is limited to repairing or replacing on an exchange basis the parts that have been promptly reported as defective by Purchaser during the Warranty Period and are confirmed as defective by Seller upon inspection. This Warranty covers all parts, labor, travel and expenses for the Warranty Period, except as otherwise stated herein. This Warranty only applies to the original Purchaser and shall not, in any way, be transferable or assignable.

The procedure for warranty claims shall be as follows: when you believe the DEA(Dry Eye Analyzer) is defective, promptly report the defect to CERTAINN. Whenever possible, we will provide “in the customer's office” service to repair your DEA(Dry Eye Analyzer). However, at our discretion, repairs may be made in our repair department. In this case, we will pay all shipping costs unless your DEA(Dry Eye Analyzer) is found upon inspection not to be eligible for repair under this Warranty, in which case you will be responsible for one-half the shipping costs. If your DEA(Dry Eye Analyzer) is ineligible for repair under Warranty, we will notify you, and any repairs you authorize will be performed at our normal rates. All replaced parts will become the property of CERTAINN.

This Warranty specifically covers the DEA(Dry Eye Analyzer). This Warranty does NOT cover: consumable items such as operating supplies, paper or storage media, or the servicing of any external printer. Those items will be covered by their manufacturer's warranty and arrangement for service must be made through that manufacturer. This Warranty will NOT apply if repair or parts replacement is required because of accident, neglect, misuse, acts of God, transportation or causes other than ordinary use, or supplies or accessories that do not meet the proper operating specifications of CERTAINN. This Warranty does NOT apply to any articles that have been repaired or altered except by CERTAINN.

All data stored on the hard disc, magneto-optical and/or floppy discs are the

Purchaser's records, and it is your responsibility to preserve the integrity of these files. CERTAINN is not responsible for the loss of patient files stored on the hard disc, floppy discs, backup magneto-optical discs or backup floppy discs.

You bear the entire risk as to the quality and performance of the software. CERTAINN does not warrant that the software will meet your requirements, that the operation of the software will be uninterrupted or error-free, or that all software errors will be corrected. You assume the responsibility for the installation, use and results obtained from the DEA(Dry Eye Analyzer)T and programs.

The Warranty does NOT extend to any removable media that has been damaged as a result of accident, misuse, abuse, or as a result of service, or modification by anyone other than CERTAINN. Should such software prove defective following its purchase, you (and not CERTAINN) assume the entire cost of all necessary service, repair, or correction. CERTAINN has no liability or responsibility to any person or entity with respect to any claim, loss, liability, or damage caused or alleged to be caused directly or indirectly by any software supplied with the DEA(Dry Eye Analyzer) or by CERTAINN.

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Acknowledgment

You acknowledge that you have read all the provisions in this Chapter, including this License and Limited Warranty, understand them, and agree to be bound by their terms and conditions.

10.Service Commitment

Thank you very much again for purchasing our Dry eye analyzer(DEA).
CERTAINN has established a set of strict quality control system, to engineer excellent quality of products, but because it is a complex high-tech equipment, fail to follow operating procedures may cause errors, even damage to instrument. Therefore, we have to remind you: please read and comprehend this manual before use, and operate strictly in accordance with our rules.
If you have any questions while using our equipment, please contact us.
If you feel that our instruments have any room for improvement, please contact us.
If our instrument has any trouble, please call us.
If you have good suggestions or criticism for our products or work, please feel free to tell us.
If you no longer use our instruments, dispose them according to the local and national laws.
Our staff will welcome your call with full enthusiasm, and answer your questions in the most
sincere attitude, solve your problem as soon as possible, and sincerely accept your criticisms and suggestions.

Manufacturer: Shenzhen Certainn Technology Co., Ltd.

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