3nethra classic

User Manual

CE
0843

Make sure you read this manual before using the device.
Keep this manual in a safe place so that you can use it in the future.

Template Revision History

Ver. No.	Ver Date	Prepared By	Reviewed & Approved By	Issued By	Affected Sections & Summary of Change
1.0	29th Oct 2013	Sushma	VP-Engineering	MR	Initial Release

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Ver. No.	Ver. Date	Prepared By	Reviewed & Approved By	Issued By	Affected Sections & Summary of Change
1.0	20-01-2016	Divya	Sanojkumar	MR	Initial Release
1.1	20-07-2016	Divya	Sanojkumar	MR	Manual gain slider procedure added in section 4.4 & updated screenshots In sections 4.4.3 & 4.5

Note

• Please contact your sales representative or local Forus dealer to install the device.

• The desktop or laptop used with 3nethra classic must conform to IEC60601-1 or IEC60950.

• All electrical equipment used with the product must comply with the system standard IEC 60601-1. If in doubt, consult your sales representative or local Forus dealer.

• It is advisable to use an isolation transformer conforming to IEC60601-1 when a desktop or laptop conforming to IEC60950 is used.

• The user is responsible for the use and maintenance of the product.

• A dedicated individual should be responsible for maintenance, to ensure the product is kept in good condition and used safely.

• The electromagnetic waves caused by certain electrical devices can cause the product to malfunction. It is recommended to place the device in isolation from other electrical equipment.

• In no event shall Forus be liable for direct or indirect consequential damage arising from an abnormal use of this product. Forus shall not be liable for loss of image and other data for any reason.

• The reading of images and storage of data must be performed in accordance with the laws of the country where the product is being used. The user is responsible for maintaining the privacy of image and other data.

• The power adapter supplied is designed to be used solely with this camera. Do not use it with any other product.

• Forus reserves the rights to change the specifications, configuration and appearance of the product without prior notice.

•The content of this user manual may be changed without prior notice, for any questions regarding the user manual please contact your local Forus dealer or sales representative.

Device Classification

Protection against electric shock – Class II Electrical Device as Per IEC 60601-1

Degree of protection against electric shock – Type BF

Degree of protection against ingress of water – IPX0

Operating mode – Continuous

Standards

IEC60601-1: Medical electrical equipment – Part 1: General requirement for basic safety and essential performance.

IEC60601-1-1: Safety requirements for medical electrical systems.

IEC60601-1-2: Electromagnetic compatibility

IEC60601-1-6: Usability

ISO15004-1: Ophthalmic instruments – Part 1: General requirements applicable to all ophthalmic instruments.

ISO15004-2: Light hazard protection

ISO10940: Ophthalmic instrument fundus camera

ISO10993-1: Biocompatibility of medical devices

IEC62304: Medical device software life cycle processes

IEC62366: Application of usability engineering to medical device

ISO14971: Application of risk management to medical device

Table of Contents

1. Introduction

1.1 Intended Use

The 3nethra is a non-mydriatic device for imaging the posterior and anterior surfaces of the human eye. It assists clinicians in the evaluation, diagnosis and documentation of visual health.

1.2 Indications For Use - IFU: 3nethra classic

The 3nethra classic is a non-mydriatic and non-contact device to acquire, display, store and transmit digital images of the posterior and anterior surfaces of the human eye, in-vivo conditions. It assists clinicians in the evaluation, diagnosis and documentation of visual health. The device acquires only images and does not provide any pathological analysis or diagnosis for treatment.

1.3 Purpose of this manual

The purpose of the user manual is to provide the user with a comprehensive guide for understanding the installation, working principle and disassembly of the device.

1.4 Minimum System Requirements

The 3nethra comprises an imaging system and a processing system, which is a laptop or desktop computer. The recommended minimum configuration for the processing system is as follows:

a) 2.2 GHz or better dual-core processor.

b) 2 GB main memory (RAM) for Windows 7, 4GB main memory (RAM) for Windows 8 and above, 500GB free hard disk space.

c) Additional hard disk space will be required to store captured images. (Approximately, 50 images will require 1GB of storage space.)

d) Colour display supporting 1366x768 pixels.

e) USB 2.0 / 3.0 Port.

f) Minimum 1.2Mbps internet connectivity.

g) Laser printer or inkjet printer, with a minimum of 600 dpi.

h) Microsoft Windows based operating system (Windows7/8/8.1/10)

i) Acrobat Reader.

1.5 Product Description

The 3nethra is a compact, portable and easy to use non-mydriatic digital imaging device. It is designed to acquire, display, store and transmit images of the posterior and anterior surfaces of the human eye. The images assist clinicians in the evaluation, diagnosis and documentation of visual health.

1.6 Safety

Please ensure that the equipment is installed and operated in a controlled environment, under normal conditions. The recommended operating environmental parameters are:

- Temperature: 5-40 °C
- Humidity: 30-90%
- Atmospheric Pressure: 70-106 kPa

Ensure that the 3nethra is setup in a clean dust-free and moisture-free environment.

Install the machine on a flat level surface, to avoid damage by moving parts to device and people around it.

Ensure that the exposed objective lens is free of stains, dust and fingerprints. **DO NOT** use any liquid to clean the objective lens.

Before the device is used for each patient, ensure that the base of the chin rest, forehead and handle are cleaned with IPA (Isopropyl Alcohol). Alternately, for the chin rest, use chinrest soft tissues for every patient.

Use the recommended rated power supply only. A higher voltage may damage the power adaptor.

When not in use,

- Switch off the power supply and remove the adaptor from the plug point.
- Cover the objective lens with the cap.
- Shut down the computer connected to 3nethra device.
- Lock the camera mount and place the device over 3nethra device.

The 3nethra device works in close proximity to human eyes. Only trained technicians may operate it.

1.7 Electromagnetic Emissions

3nethra classic complies with IEC 60601-1-2 standard for EMI and EMC compliance. The 3nethra classic is intended for use in the electromagnetic environment specified below. The user of the CF-1 should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment–Guidance
RF emissions CISPR11 EN55011	GROUP1	The 3nethra device 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 electromagnetic equipment.
RF emissions CISPR11 EN55011	Class A	3nethra Device is suitable for use in all establishments other than domestic, and may also be used in domestic establishments and those directly connected to the public low-voltage power supply network, supplying buildings used for domestic purposes, subject to the following warning: **Warning:** This equipment/system is intended for use by healthcare professionals only. It may cause radio interference or may disrupt the operation of nearby equipment. In such situation re-orient or relocate the 3nethra device or provide shielding to the location.
Harmonic emissions ENIEC61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions ENIEC61000-3-3	Complies	

1.8 Warning labels

Important warnings are placed on the product to provide warning indications to encourage safe use and prevent any danger to the operator and existing facilities. The following section provides the meaning of each label placed on the 3nethra device. We recommend that individuals using the 3nethra device read the following information about labels, icons and understand their meanings relating to “Safety Precautions” to be followed.

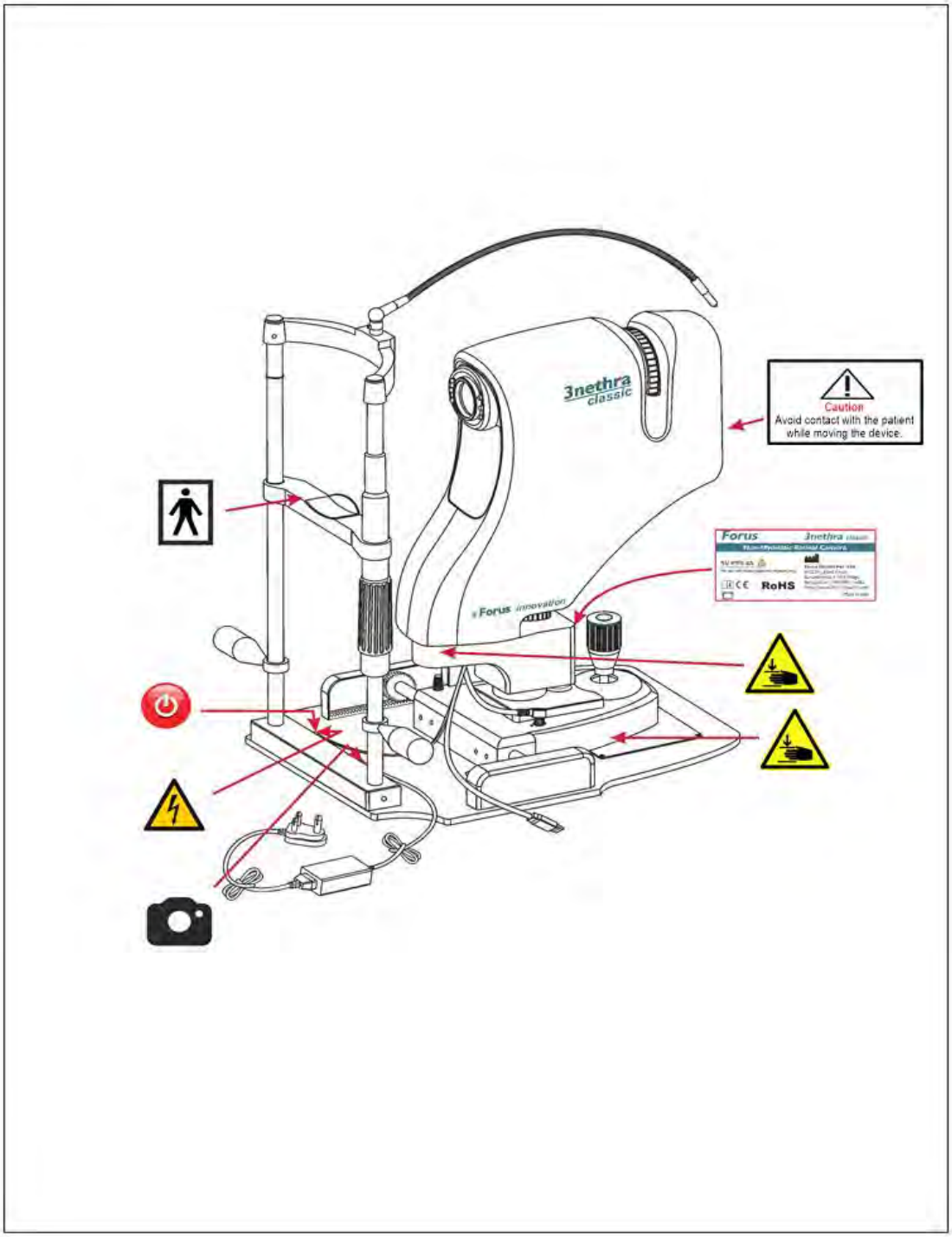


Figure 1: Warning labels and positions

1.8.1 *Meaning of labels*

Label	Meaning
WARNING	Ignoring or disregarding this label may lead to death or serious injury.
PRECAUTIONS	Ignoring or disregarding this label may result in personal injury or severe damage to the instrument or other facilities.

Figure 2: Warning labels

1.8.2 *Safety symbols*

This instruction manual details the safety precautions that need to be observed to prevent accidents. Always observe them and use the instrument correctly.

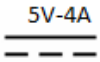
Symbol	Description
	To avoid potential injury to the patient while moving the instrument,always keep the instrument at a safe distance from the patient
	To avoid potential injury, do not place your hand or fingers into the area between the instrument body.
	To avoid the potential injury while installing the device.
	Type BF protection
	Direct Current
	To avoid risk of electric shock, do not attempt disassembling, rebuilding and/or repairs.
	Tricam connection

Figure 3: Safety symbols

1.9 Operating Conditions

3nethra device captures non-mydriatic posterior and anterior surface images of the human eye. Good natural dilation of the eye, as occurs in low lighting, is necessary to capture clear posterior images.
Place the equipment in a low lit room, dimmed by lowering window shades or switching off lights.
Even in a low lit room, there should be provision to turn on the lights quickly with a nearby switch, to enable easy movement of examinee and operators after completing the use of the device.

It is recommended that the 3nethra device and the laptop or desktop monitor be placed on a height-adjustable table. Two chairs or an examination stools will be needed for the operator and the patient. Please refer to the specifications section 6 of this manual for the recommended size of table for placing the devices.

1.10 User Maintenance

To ensure safe and proper operation of the 3nethra device, unless otherwise specified in this manual, all maintenance activities should be carried out by a trained service technician. The following maintenance tasks can be performed by the user. Please get familiar with the 3nethra device parts by referring Figure 8.

1.10.1 *Cleaning the 3nethra*

The objective lens may be cleaned by the user.
To check the objective lens, darken the room to examine it from the front and at an angle. Shine a torch on it at an angle. The condition of the objective lens can be improved as described in the section below:

• Dust and dirt on the lens surface
a) Blow off dust with an air blower.

Caution: Do not let the tip of the air blower touch the objective lens.

• Fingerprints and oil spots on the surface
a) Blow off any large particles with an air blower
b) Take the cleaning cloth provided with the device, lightly wipe the objective lens spirally from the centre outward. Continue until the stains have been completely removed.

1.10.2 *Precautions while cleaning the 3nethra*

• Do not wipe off or rub the objective lens when there is dust or other substances on it, as this could scratch the lens surface.

• Never wipe the objective lens with disinfecting ethanol, eyeglass lens cleaner or cleaning paper containing silicon, as the lens surface could be damaged or incompletely wiped off.

• Never use alcohol, benzene, thinner, or other solvents to clean the case of the instrument. These could damage it.

• Never use disinfecting ethanol, glutaraldehyde or other solvents to clean the outside of the instrument, except the forehead rest and the chin rest base. This could damage it.

• If the chin rest paper will not be used, be sure to disinfect the chin rest base for each patient before use. Disinfect using IPA (Isopropyl alcohol).

• The case should be cleaned with soft cotton cloth. The cloth can be slightly moist, or a mild detergent liquid can be used for cleaning the surface of the case.

• Avoid spraying water or detergent liquid on the case of the device, as droplets can go into the device and affect its functionality. Do not use ethanol or other solvents while cleaning the equipment.

1.11 Storage and Transportation

3nethra device and stand are neatly packed in the packaging provided for delivery.
After packaging, the device should be stored in a place where the environmental conditions are within the specified limits as below.

• Temperature: 5-40 °C
• Humidity: 30-90%
• Atmospheric Pressure: 70-106 kPa

Environmental conditions should be maintained as mentioned above during transportation. Care should be taken while handling the equipment during transportation.

2. Packing List

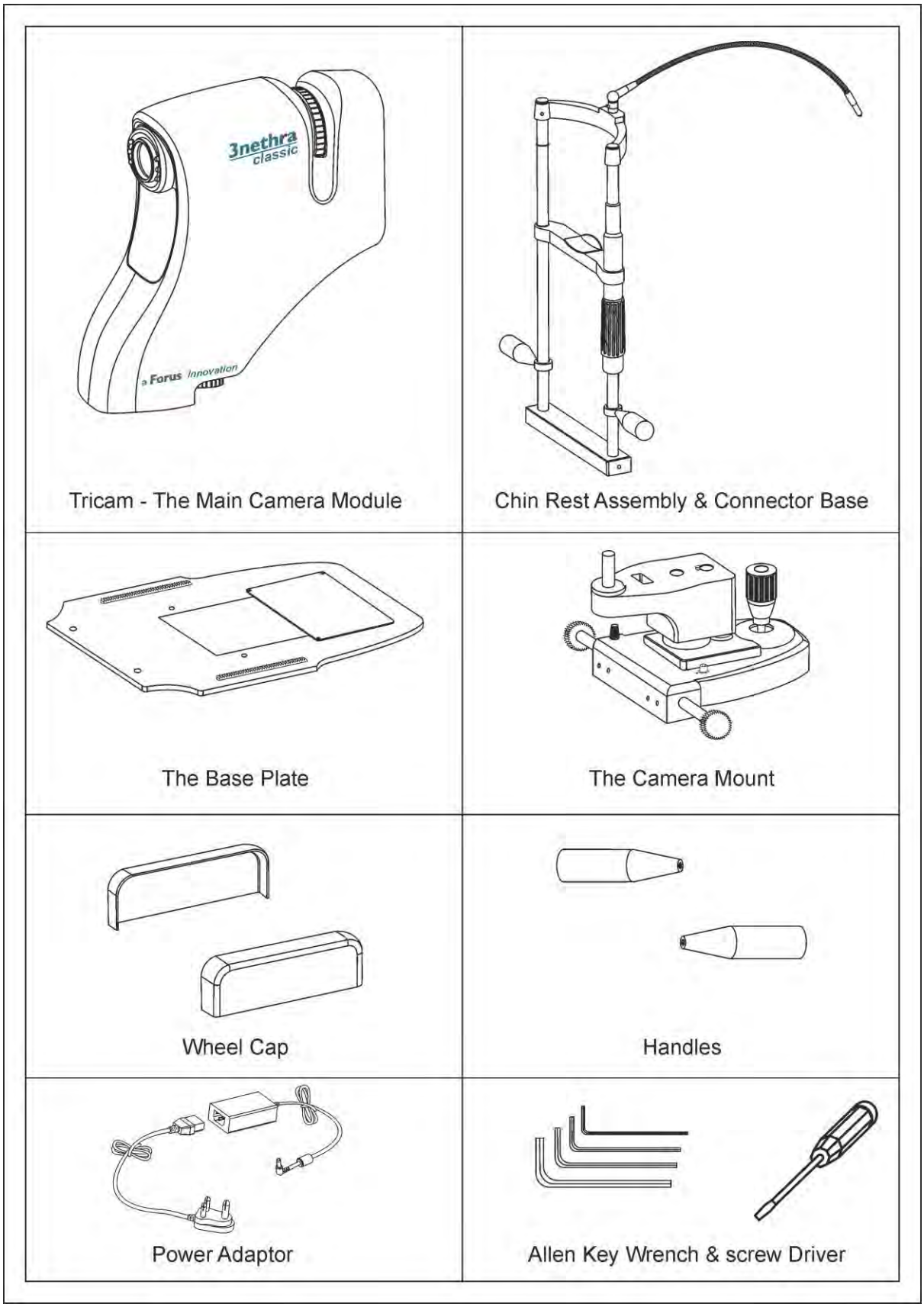


Figure 4: Packing List

2.1 3nethra Parts List

The 3nethra tricam, stand assembly, tools & accessories are packaged in specially designed suitcases and packaging materials which are enclosed in corrugated cardboard.
The list of items packaged is as follows. (Please refer to:
Figure **4**)

- Tricam
- Stand Assembly
- The Camera Mount
- Chinrest Assembly with External fixation LED
- Base Plate
- Wheel Cap
- Handles
- Allen Keys
- Screw Driver
- Power Adaptor
- Sterile Tissue
- Lens Cap
- Device cover

3. Getting Started

The Initial installation is performed by Forus trained personnel in the presence of a customer/client provided technician.

3.1 Operator Skills and Competency

A 'Trained Technician' is a person who has received training as necessary by Forus, to install, assemble, disassemble, maintain and operate the device.

The trained technician shall be responsible for the future assembly, disassembly, operating and maintenance of the device. The skill and competency required by technician operating the 3nethra device includes:

1. People skills to handle examinee to seat and position examinee chin on to the chin rest of the device.
2. Operate the 3nethra device to capture eye images.

3.2 Assembling Stand

Carefully remove the components from the packing box. Remove styrofoam and sponges used for absorbing shocks during transportation. Assemble as shown in

Figure 5

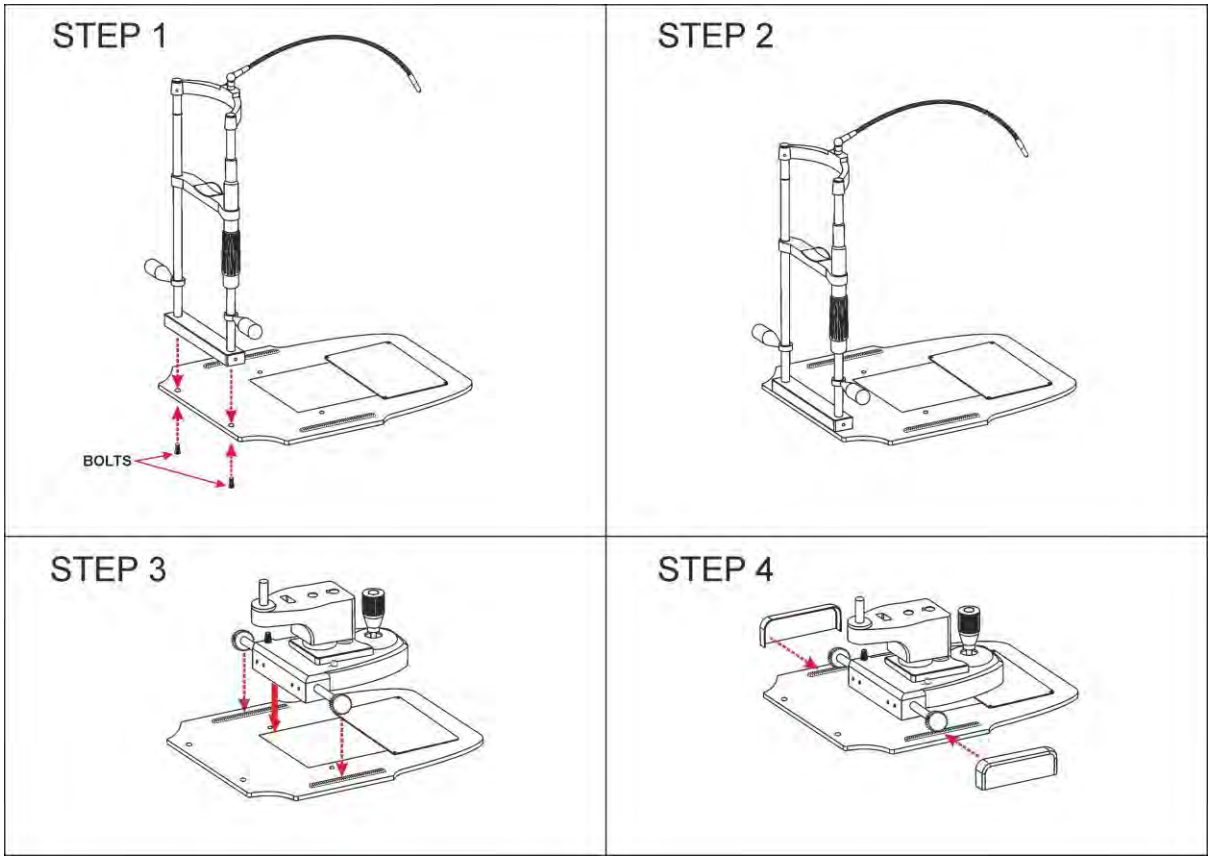


Figure 5: Assembling 3nethra Stand

3.3 Assembling 3nethra Device onto Stand

Place 3nethra device onto the mount. Gradually lower it in such a way that the shaft on the mount fits smoothly onto the hole in the device as shown in

Figure **6**.

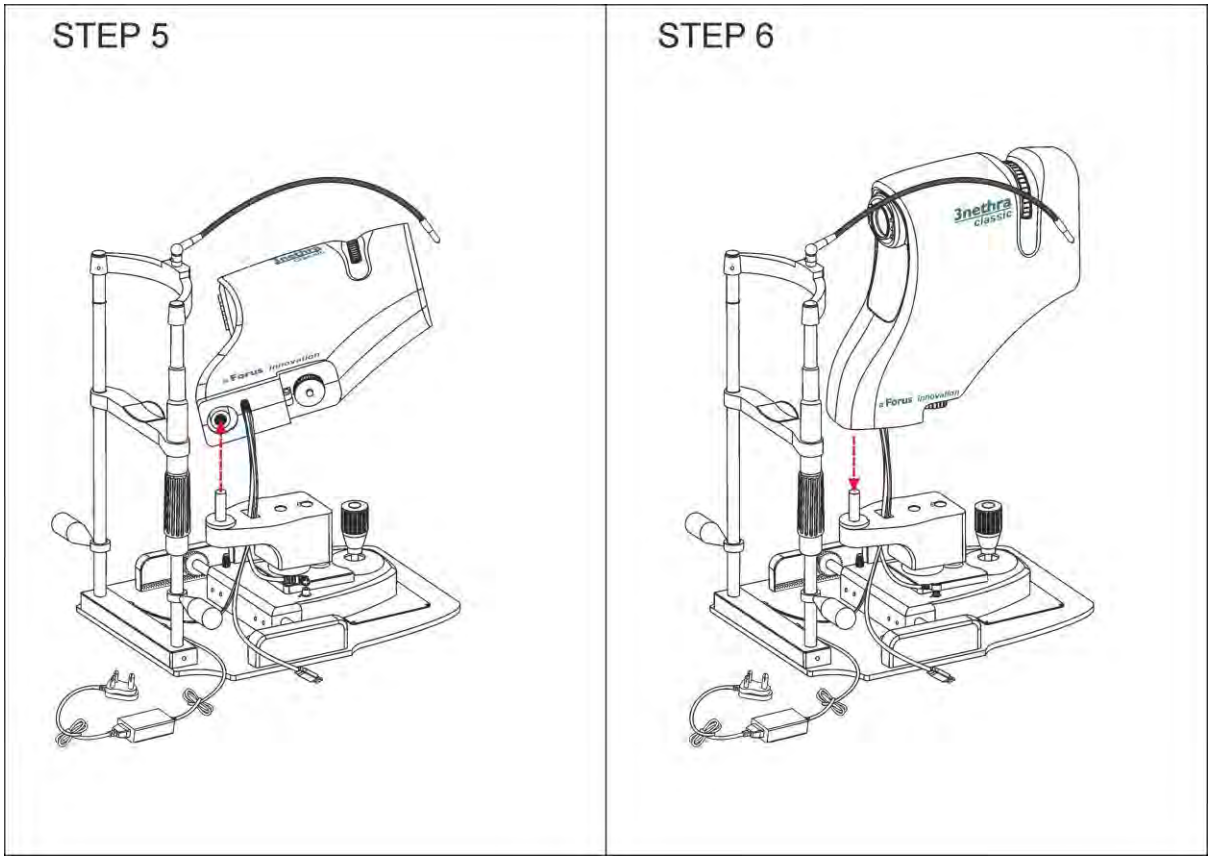


Figure 6: Assembling 3nethra Device onto Stand

3.4 Connections on 3nethra

Note: All the socket input output (sip/sop) must be 5volts.

1. Connect the power adaptor supply to the base of chin rest (Figure 7).
2. The main connection from the power supply goes into the base of the chinrest.
3. Connect the power cable coming out of the device to the base of the chinrest.

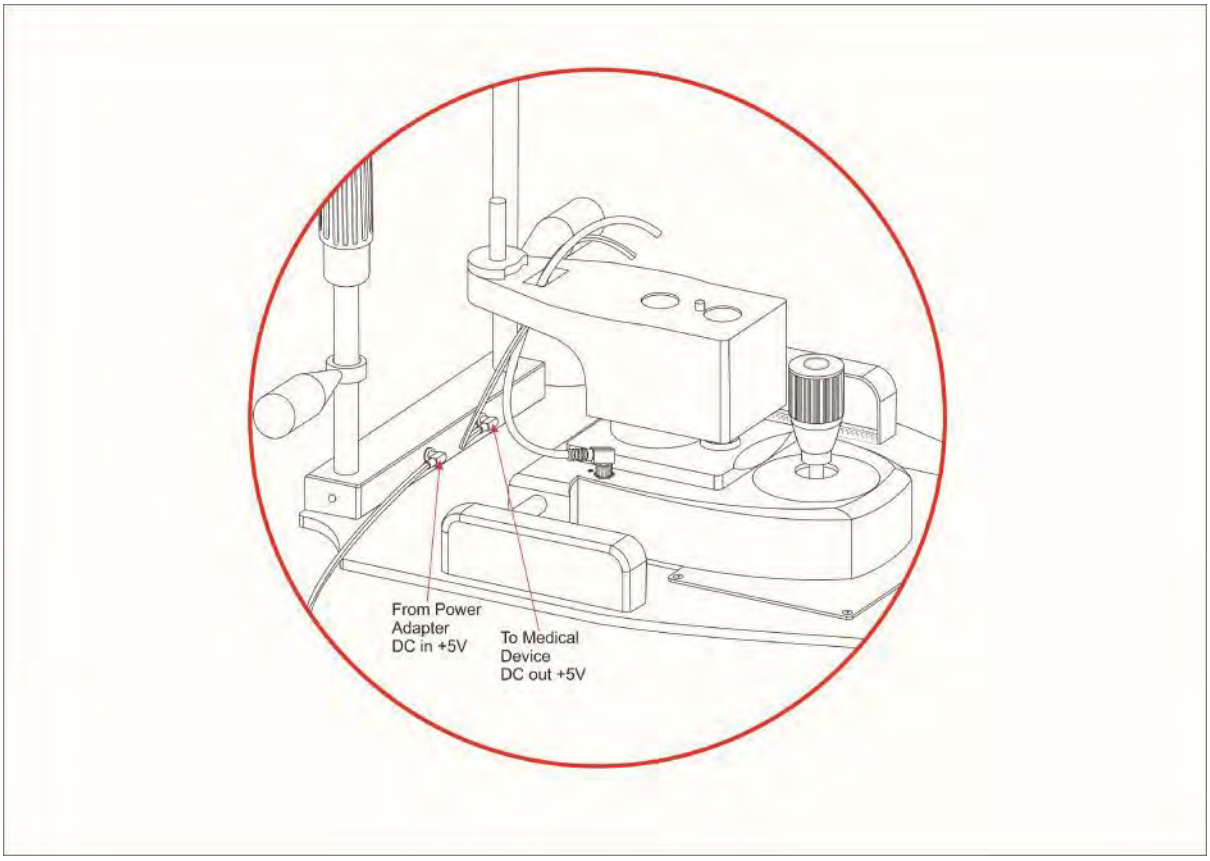


Figure 7: Connector to base of the chinrest.

4. Connect the trigger cable coming out of the device to the camera mount.
5. Connect the USB cable coming out of the device to the desktop or laptop.

3.5 Getting Familiar with the 3nethra

Get to know the parts and their names (Figure 8) to better understand explanations in this manual

3.5.1 *Applied parts*

Below is the list of applied parts for the 3nethra classic device. Please refer to (Figure 8)

1. Forehead Rest
2. Chin Rest
3. Handles

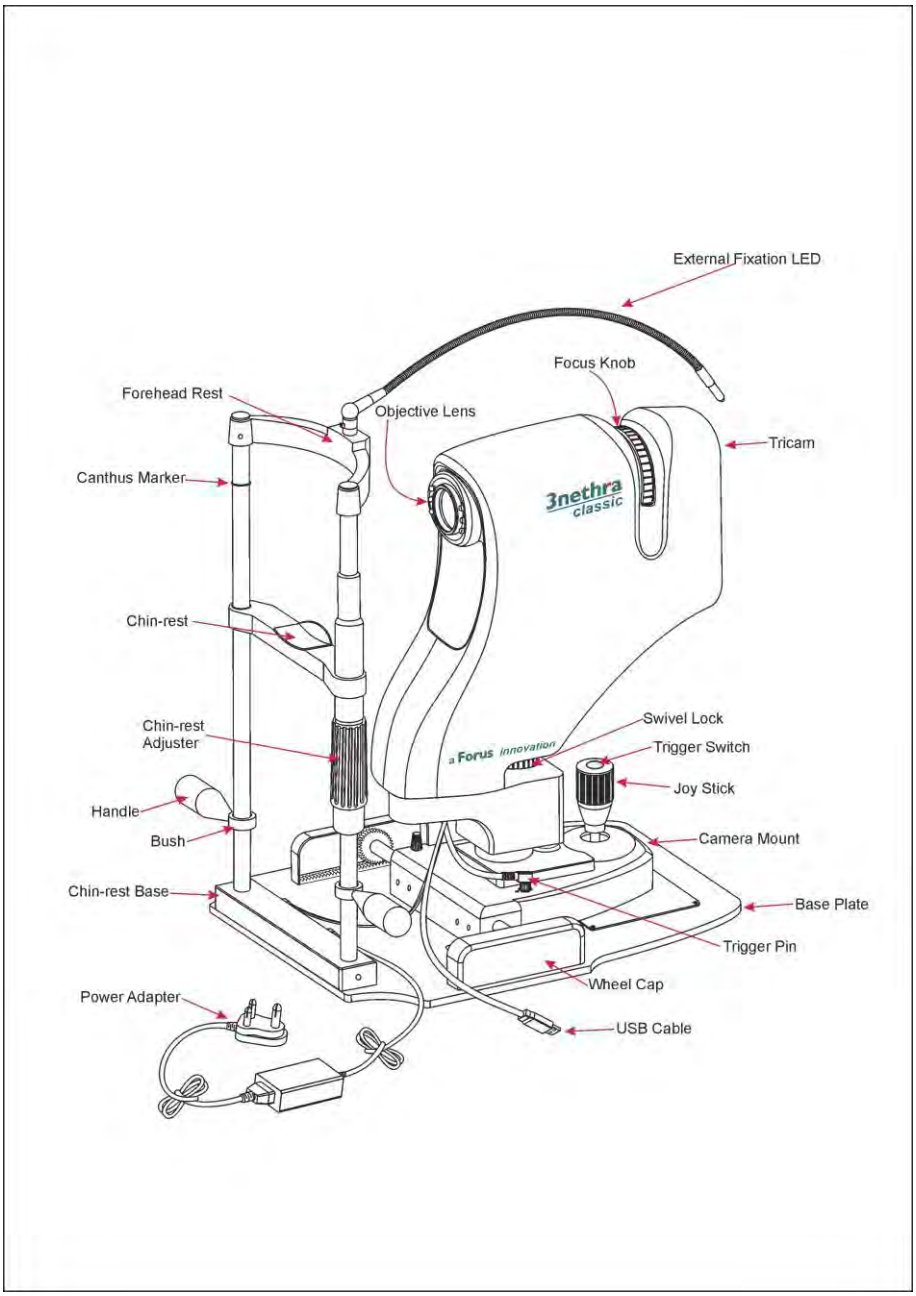


Figure 8: Components of 3nethra classic

3.6 Powering Up

Follow these instructions to power on the 3nethra device:

1. Remove the objective lens cover.
2. Double check and ensure the following connections:
   - Power connector from mains
   - Power cable from tricam to stand
   - Trigger cable from tricam to camera mount
   - USB connector from tricam to laptop or desktop
3. Ensure the power cord is connected correctly
4. Ensure the swivel lock is not released so that the tricam is in fixed position
5. Turn main power switch on
6. Ensure the software is correctly installed. The system can be used only with the accompanying software
7. Please check the following for the correctness of connections:
   a) The external fixation LED turns on
   b) On the right hand top corner of the 3nethra application screen, the power indicator light glows green.
8. If any of the above fails contact your sales representative or local Forus dealer.

3.7 Software Installation

Please refer to the Software installation guide provided with this unit to install the 3nethra software.

3.8 External Fixation LED

The External Fixation LED is provided to ensure the examinee looks at the red light emitting from the tip of the External Fixation LED. This will enable the operator to focus the device camera and beam the light on the anterior eye surface or into the fundus of the eye through the pupil. By moving the fixation LED the examinee's eyeball position can be moved to enable viewing different anterior and posterior parts of the eye.

3.9 Operating on 3nethra, Stand and Joystick

The 3nethra device mounted on the stand has two dimensional motions. By using the Joystick:

1. The device can be moved horizontally.
2. The device can be moved vertically.
3. The device can be moved diagonally.
4. The Joystick knob can be rotated to move the 3nethra tricam up or down
   a. Rotating Joystick knob anticlockwise the tricam will move down
   b. Rotating Joystick knob clockwise the tricam will move up
5. The focussing knob on top of the device enables focusing of the image
6. The Joystick enables movement of the device on the stand

7. The Image is captured by the trigger button on top of the joystick

3.10 Swivel, Swivel Lock and Joystick

The tricam can be turned to the left or the right after releasing the swivel lock. This motion will allow focussing into different regions of the fundus.

The Joystick can be rotated in clockwise and anticlockwise directions up and down respectively (Refer to Figure 9).

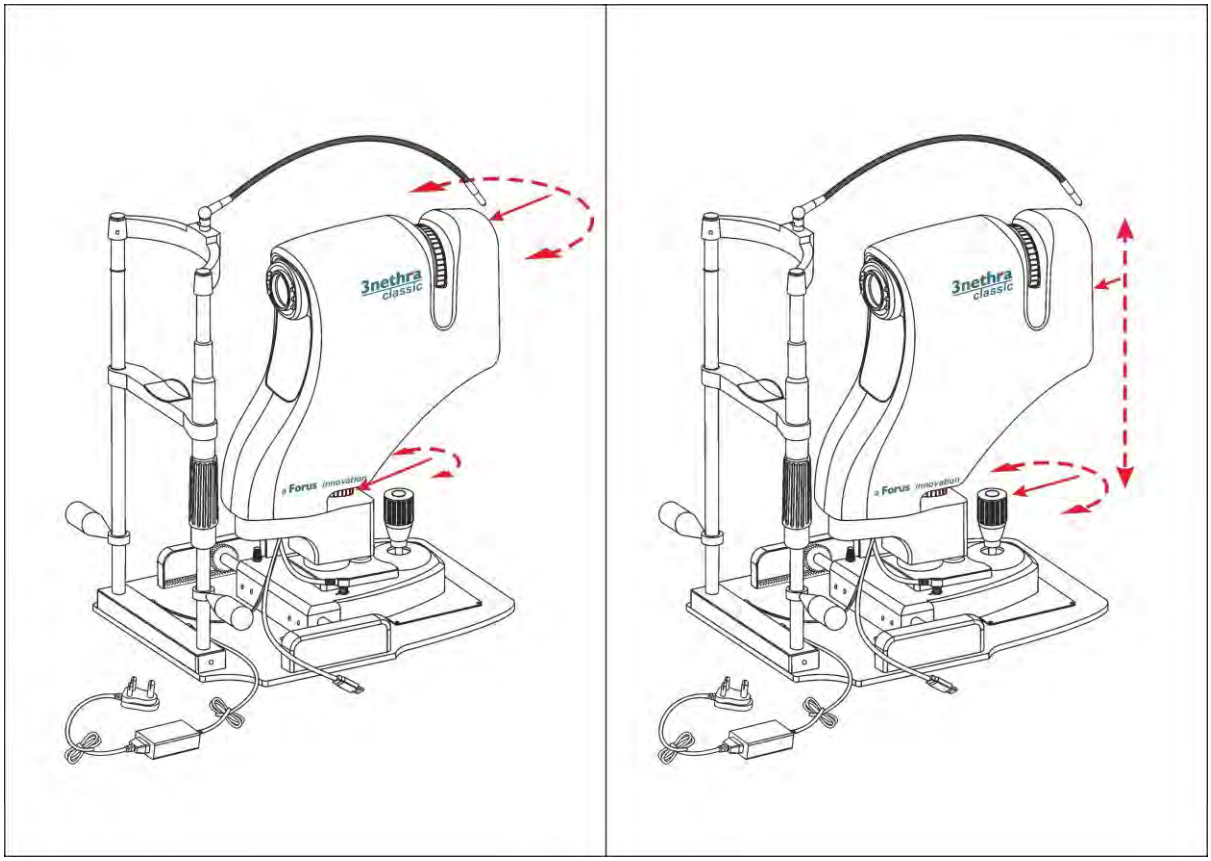


Figure 9: Swivel lock and Joystick

3.11 Trigger

By pressing the trigger button on the joystick the Photograph (image) is captured.

3.12 Disassembling the 3nethra

1. Switch off the power supply.
2. Disconnect and carefully remove the:
   - AC-DC adapter connector connected to the chin rest base on the stand
   - Pin connector connecting the chin rest base to the 3nethra device
   - Four pin connector cable from 3nethra device connected to the camera mount
   - USB connector from laptop or desktop connected to the device
3. Lock the camera mount using the camera mount lock.
4. Slowly remove 3nethra device from the camera mount
5. Remove the wheel caps attached to the rail on the base plate of the stand

6. Take the camera mount out from the base plate, carefully so that it doesn't cause any damage
7. Remove the fixed chin rest from the base plate. Use the supplied Allen wrench to loosen the screws.
8. Remove the handles from the side of chin rest

Note: After disassembly of the 3nethra is completed, store the disassembled parts in the provided 3nethra suitcase.

4. Working with 3nethra classic

Software application undergoes frequent upgrades. The software installed on your laptop/desktop may not be the same as described in the user manual. For any further queries regarding specific software version, kindly contact your sales representative or local Forus dealer.

4.1 Operator Responsibility

The operator should possess the skill and competency to handle the device in the following ways, if not; he/she should undergo training provided by Forus service engineer:

- Bring the examinee to sit, and position the examinee's chin on device chin rest
- Prepare the device to capture an image
- Operate the device to capture an Image
- Capture posterior image of eye
- Capture anterior image of eye

4.2 Software

The 3nethra works with "3nethra"software. To work with 3nethra software, ensure that the 3nethra device is connected with the processing device (laptop/desktop). Switch on the processing device, and follow the instructions provided in the "7.3.3_ENG_053_Software Installation Guide_TrisoftUS1.1.0.pdf" (Provided on the installation USB). After successful installation of the software, the 3nethra icon will appear on the processing device.

Double click on the "3nethra" icon on the desktop to launch the application. While the application is launching the following screen will appear:

Figure 10: 3nethra launching screen

After the software application has completed loading, the main window (“Study Screen") for registration of examinee will appear as in Figure 11; if the 3nethra device is not powered ON, a red light appears in the right top corner of the window along with the device not powered message.

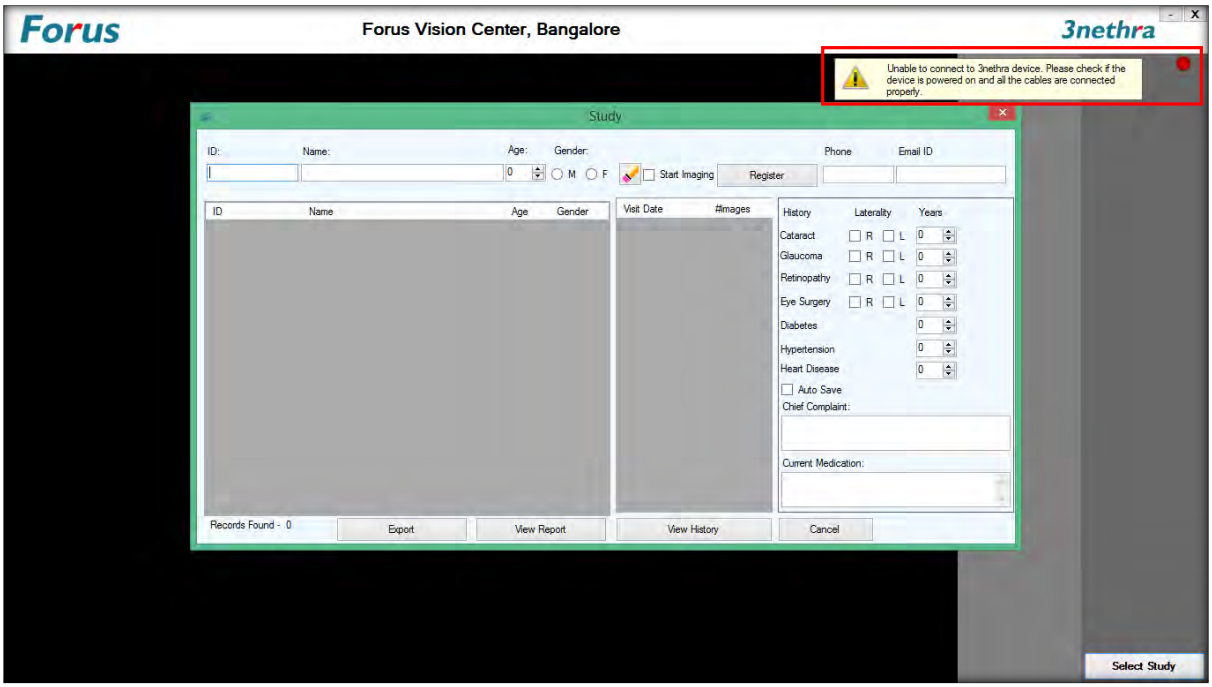


Figure 11: Main window (when the device is not connected, or not powered up)

When the 3nethra device is connected and powered on, a green light appears on the right top corner of the device as shown in Figure 12 below. The device not powered message will automatically disappear.

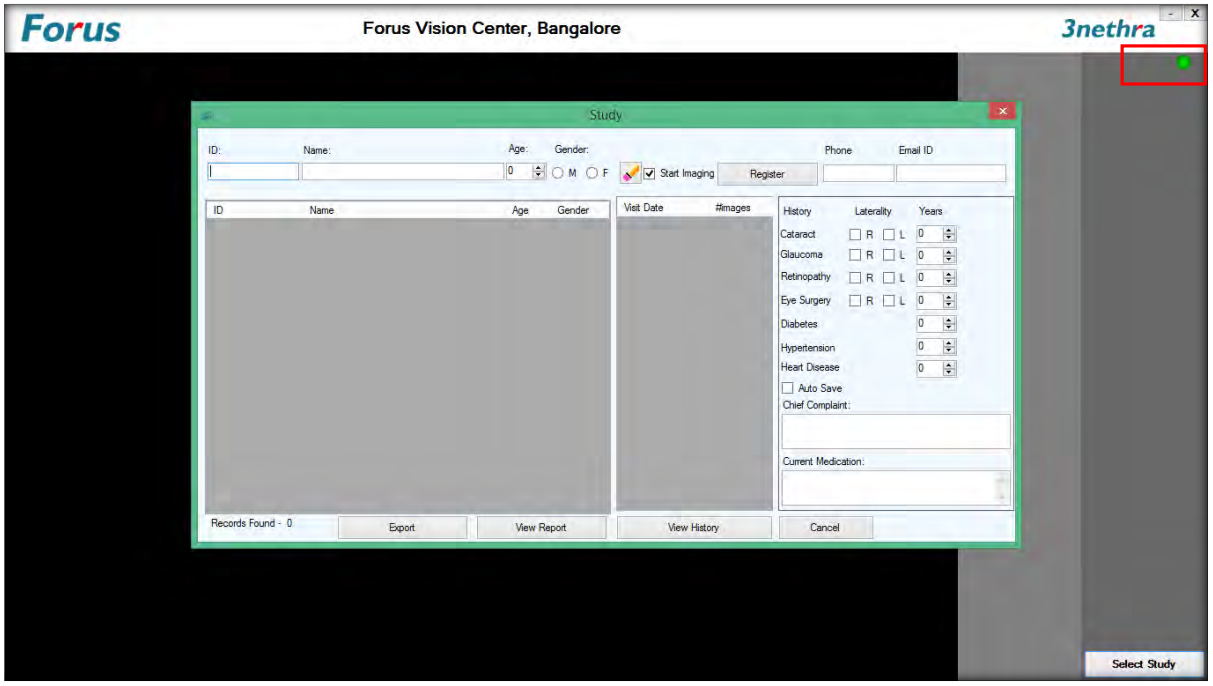


Figure 12: Main window (when the device is connected and powered up)

4.3 Using 3nethra software for Registration of Examinee

The registration of the Examinee can be performed on the processing device (laptop/desktop). The registration screen as in Figure 13 appears after the device is turned on and is connected to the processing device. Registration can be performed in two options:

1. New registration: For an examinee whose eye image is to be captured for the first time
2. Existing examinee: For a registered examinee whose details are available on the database

4.3.1 New Registration

To register new examinee

- Go to the main window (Study Screen) Registration Screen Figure 13.
- Enter the demographic details of the examinee
- Click on “Register”

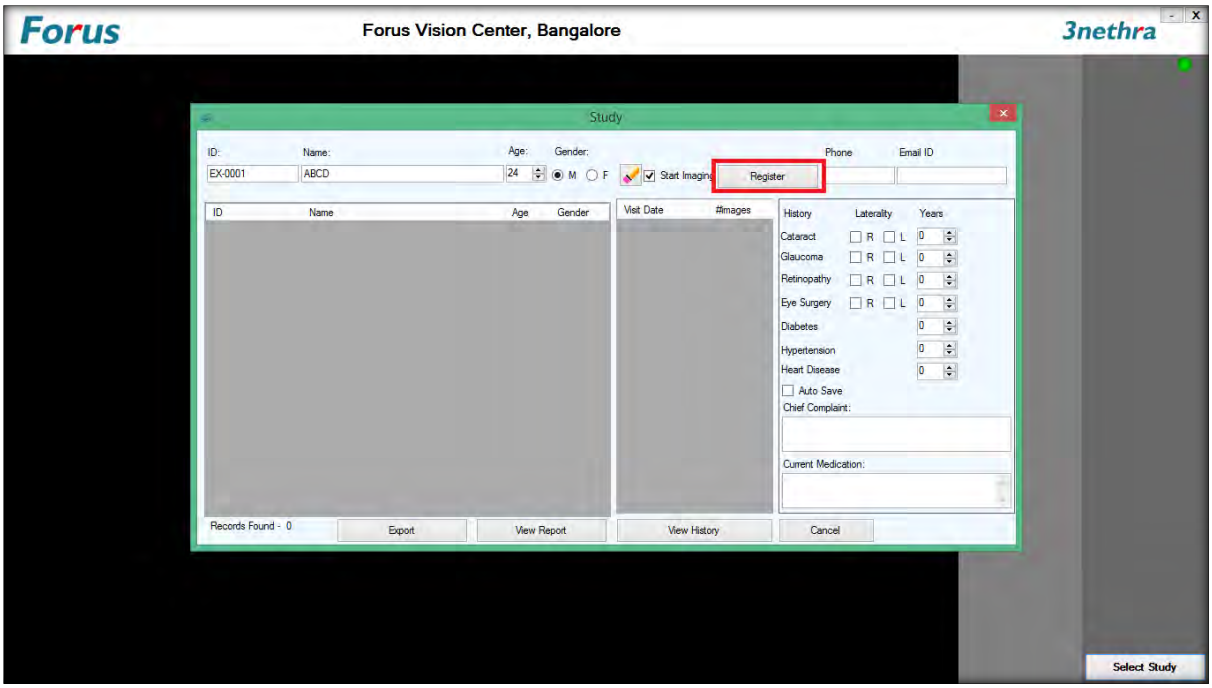


Figure 13 3nethra registration window

4.3.2 Existing Registration

Capture images of individual whose name and details are registered in the system

1. Search for the individual registration by entering at least the first three characters of the name or the ID number, in the relevant field as shown in Figure 14.

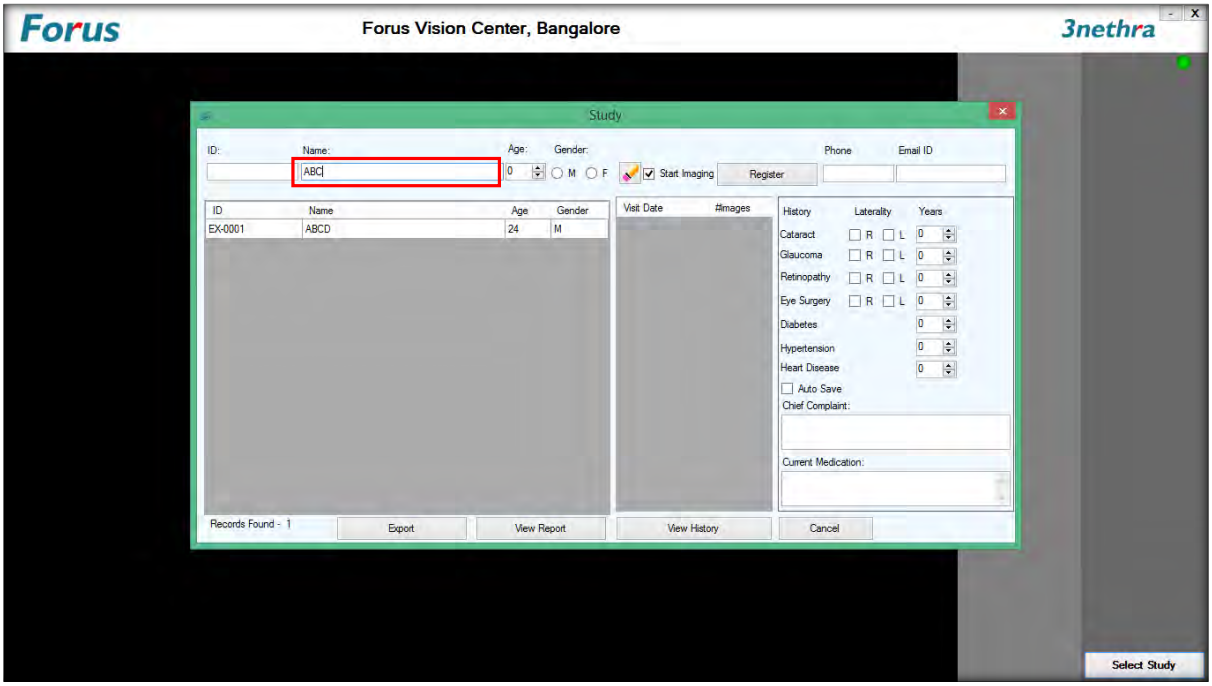


Figure 14: Search based on Name

2. All registered names starting with the first 3 characters entered will appear on screen as in Figure 15.

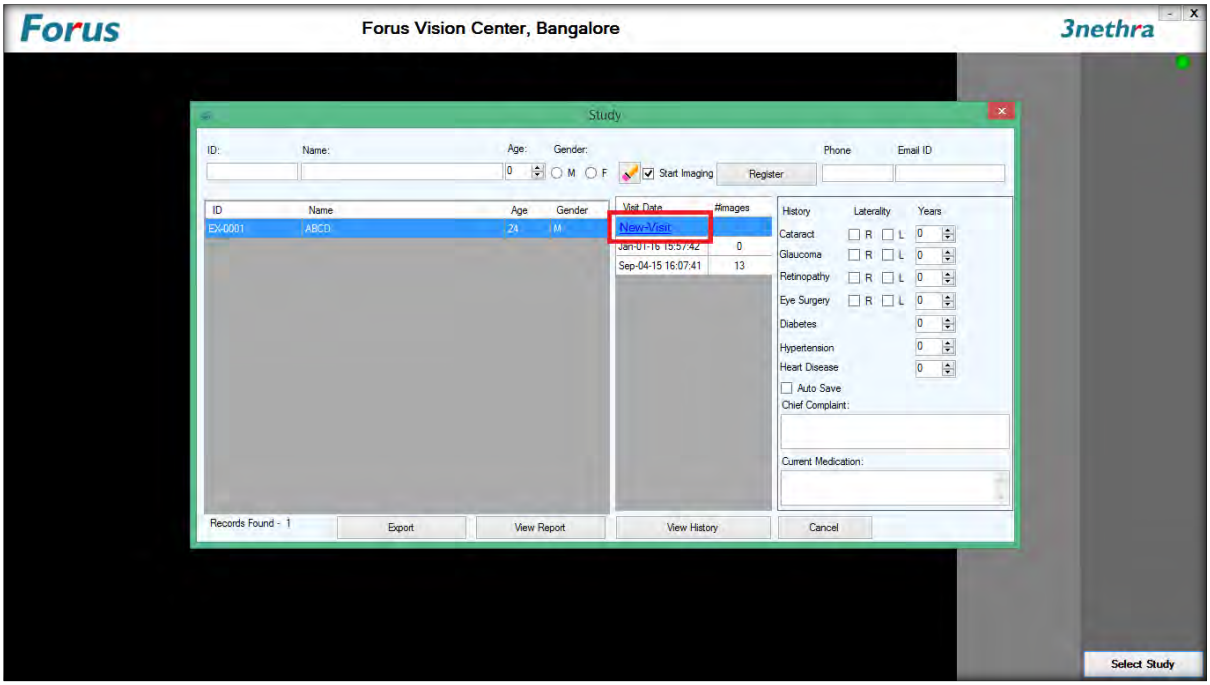


Figure 15: Study List

3. Select the correct patient name
4. Double click on the patient name or single click on “New Visit”. This will launch a window as shown in Figure 16
5. Following operations can be performed on the pop-up screen. Refer Figure 16
    a. “Use Existing Visit”
    b. “Create New Visit”

c. “View Report”

d. “View History”

e. “Cancel”

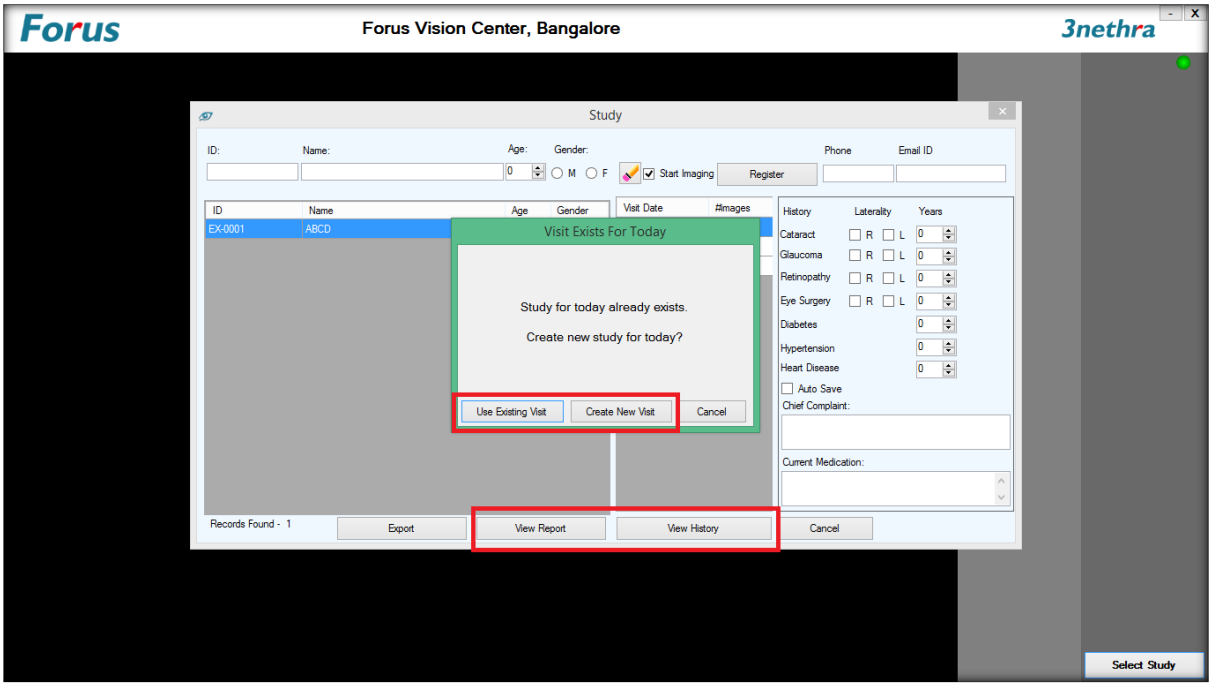


Figure 16: New Visit Dialog Box

4.4 Capturing Images

To capture Images of Examinees Eye follow the steps below:

1. Prepare 3nethra processing device (laptop / desktop) to capture images of eye
2. Prepare Examinee posture for capturing images of eye. Align the device with anterior /posterior position of eye to view, focus and capture the eye using the Joystick, trigger and focus knob.
3. Save image on laptop / desktop
4. Captured Images can be brightened using brightness slider bar which is placed at bottom right corner of the application. The Default value is set to 7 and can be manually adjusted from 0-10 as desired by the examinee. Click Left button of the mouse to adjust the Manual gain control.
5. Once Image is captured in Posterior mode with default value 7, if the captured image looks over saturated then the image can be enhanced by moving the brightness slider bar towards left corner of the slider bar.
6. Once Image is captured in Posterior mode with default value 7, if the captured image looks dark then the image can be brightened up by moving the brightness slider bar towards right corner of the slider bar.
7. Repeat operation to capture the other eye image
8. Captured images gets stored in both .png and .jpg formats respectively.

4.4.1 Preparing Examinee posture for capturing eye image

Seat the examinee comfortably on an examination chair/stool. The examinee's face must be positioned close to the 3nethra device, to enable alignment of the camera with the eye. Place the examinee chin on the chinrest and ensure the forehead touches the forehead rest at all times, until the Imaging is complete.

Adjust the table height or chair height so that the examinee can rest the chin comfortably on the chin rest. It is recommended that the examinee holds on to the handles so that the sitting position is stable and head and eye movements are controlled.

Adjust the height of the device by turning the Joystick knob. The chin rest position can be adjusted using the chin rest adjuster. Adjust it to bring the corner of the eye in line with the canthus marker on the chin rest (Refer to **Figure 17**).

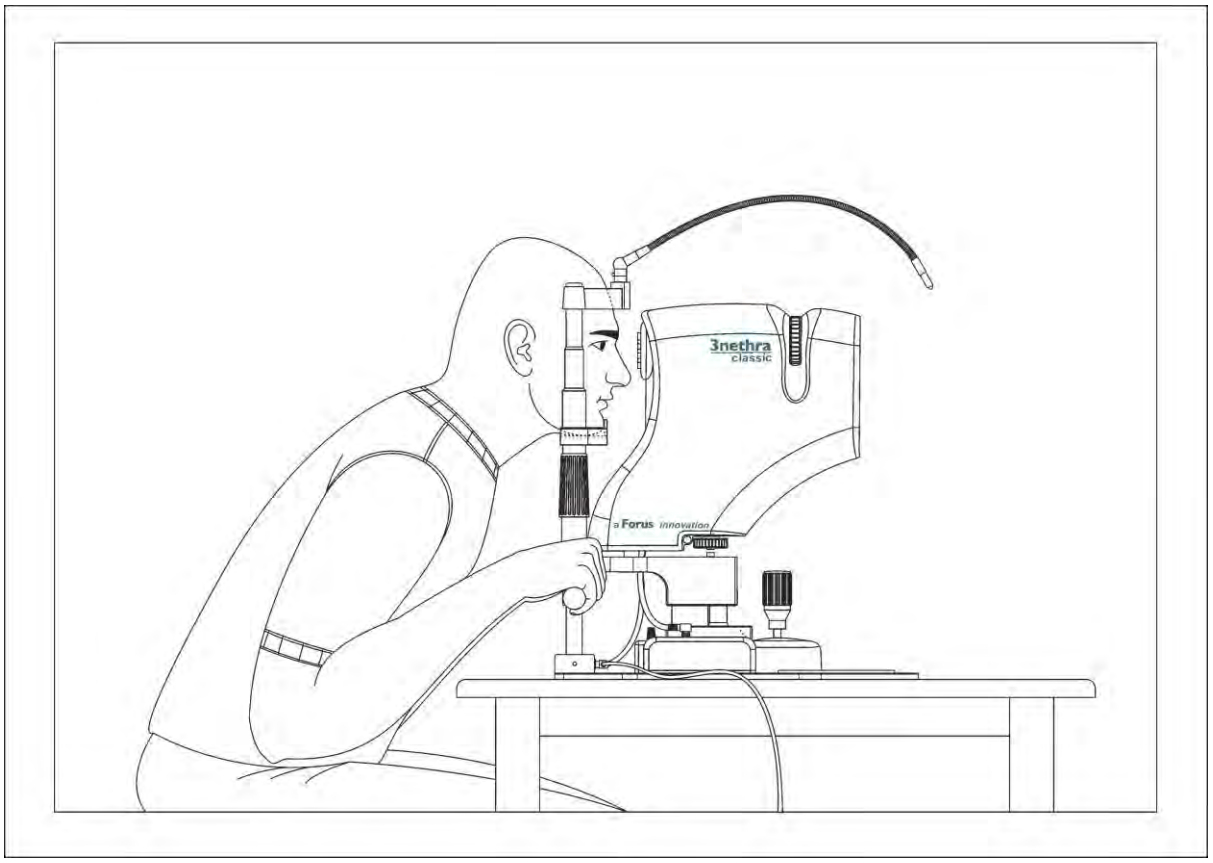


Figure 17: Positioning the patient

On the computer screen you will see a black and white live feed from the camera lens in front of the eye of the examinee when the eye is aligned with the canthus marker. Do finer height adjustments using the joystick. Clockwise rotation raises the device, and anticlockwise rotation lowers the device. It is good to keep the device position in the mid-level and away from the chin rest stand (close to the operator) before each examination so that there is flexibility of moving the device.

- Seat the examinee on a chair/stool in front of 3nethra device
- Have the examinee rest the chin on the chinrest and forehead on the forehead rest
- Make the examinee to look at the external Fixation LED (refer section 4.4.3.2)
- Position the device away from the examinee and align the device in front of the examinee eye.
- Move the joystick in front until the eye and the pupil are clearly visible on the processing device screen.
- Adjust the device and focus on to the eye anterior surface for anterior imaging. Adjust the device and Focus onto the pupil until a clear image of the fundus is visible for posterior imaging.

4.4.2 Selection of eye to be imaged

Before capturing posterior image of eye the examiner should ensure that the button clicked [i.e., Left or Right] and the eye being imaged are the same as shown in Figure 18.

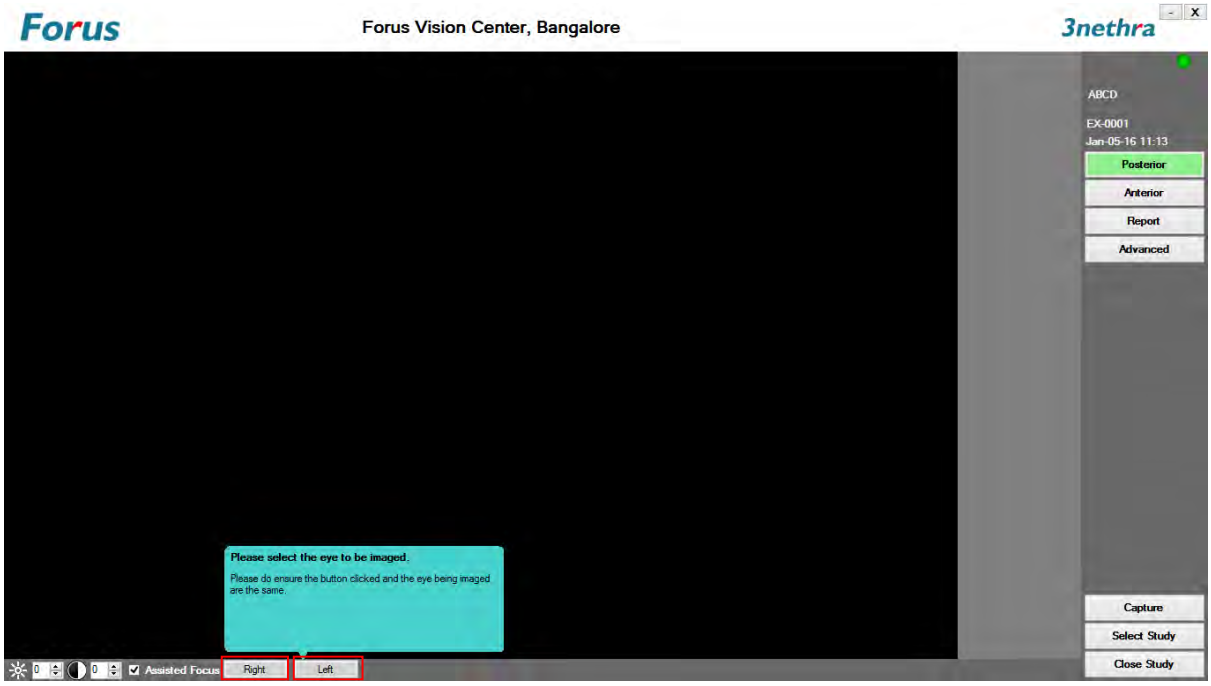


Figure 18: Selection of eye to be imaged

4.4.3 Capturing Posterior Image of Eye

Prior capturing posterior image of eye, In addition with *Assisted Focus*, cross markings are also provided in the centre of the grid, this tool helps the user to centre the pupil before entering into the posterior segment. Centring the pupil will help the user achieve uniform illumination more easily (see Figure 19: Positioning the pupil).

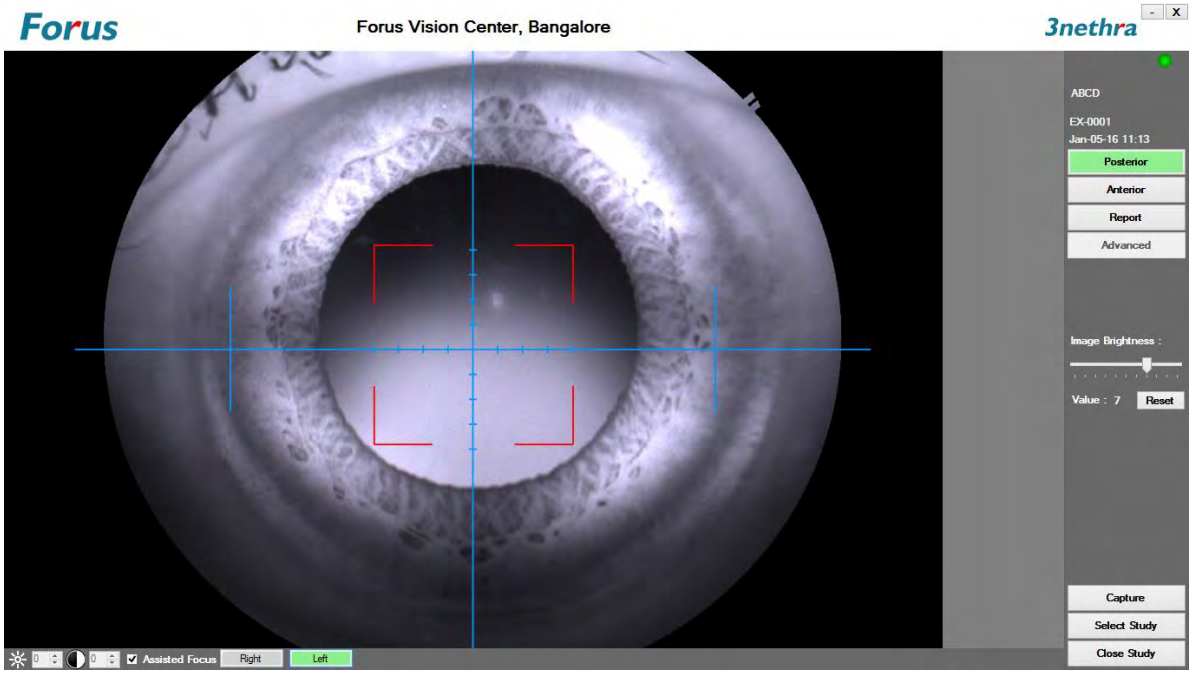


Figure 19: Positioning the pupil

Focus on the posterior segment of the eye as in Figure 20; a rectangle grid is displayed for *assisted Focus*. The colour of the rectangle toggles between red, white and green to indicate the current readiness for imaging, as described in the following section:

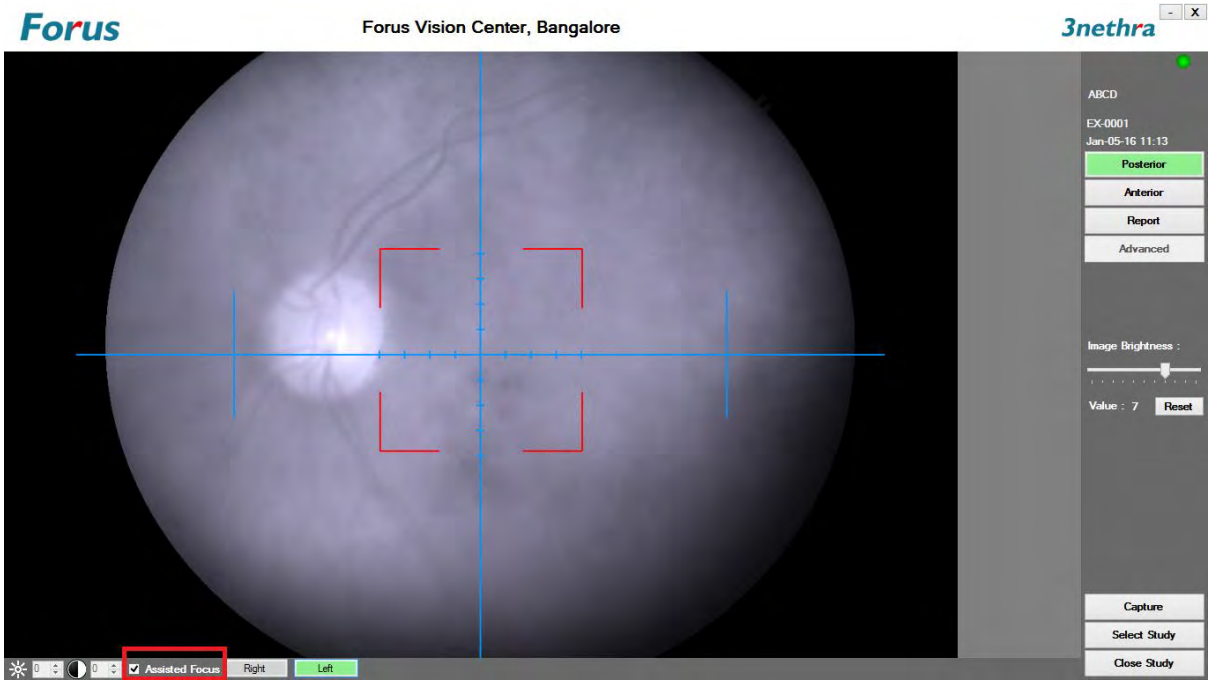


Figure 20: Focusing on posterior segment

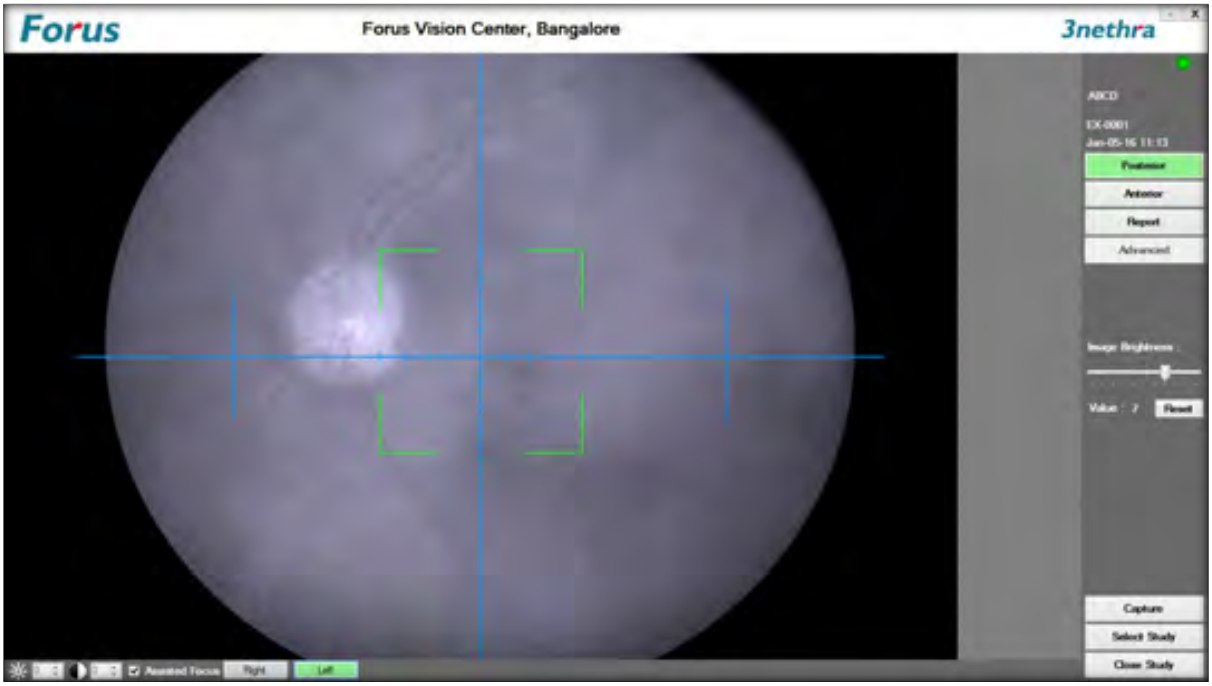


Figure 21: Focused on Posterior segment (with uniform illumination of light)

4.4.3.1 Assisted Focus for Posterior segment Mode

In image capturing mode for posterior segment images, the software adds assistance to indicate the state of readiness for Imaging which is enabled by checking the 'Assisted Focus' selection at the bottom tab of the window as in Figure 20.

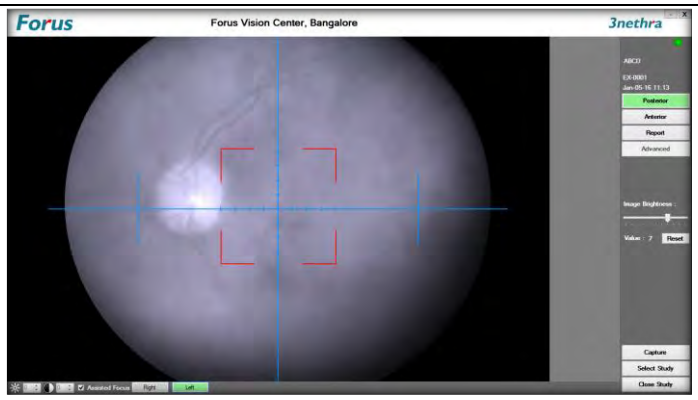
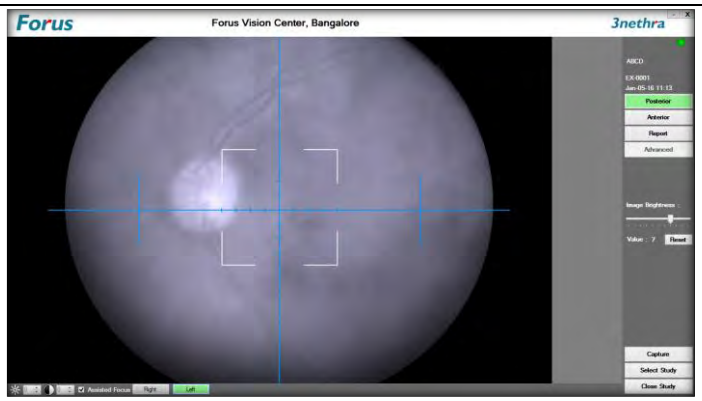
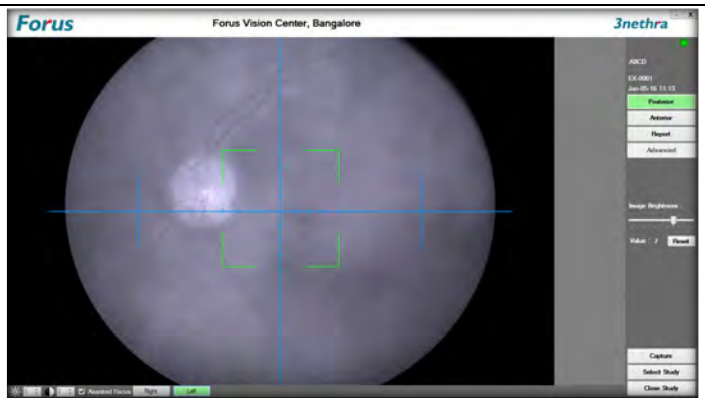
Uniformity of illumination indicator	Type
	Non uniformly illuminated: Square is red.
	Uniformly illuminated but not focused: Square is white.
	Uniformly illuminated and focused: square is green.

Figure 22: Assisted Focus Illustration

4.4.3.2 External Fixation LED

Use the External Fixation LED to get the optic disc in the desired position. When you move the LED up, the optic disc on the computer screen goes down. When you move the LED to the left, the optic disc on computer display will move right, and so on.

Using a combination of external fixation LED light and joystick, move the device to capture the focussed image of the anterior surface and posterior surface as desired.

4.4.3.3 Capturing image of the posterior segment

Using the joystick, move the camera toward the examinee's eye. As you move closer, you will see the image on the screen zooming in. The camera lens needs to be about 25cm away from the eye.

Caution: Move the device slowly. Moving it fast may cause the lens to hit the examinee, which may cause damage to the examinee and the device.

Loosen the swivel lock to move the device in left and right direction for viewing into different posterior segment of eye at the desired angle.

Adjust the focusing knob to get the clearest picture while watching the black and white image of the fundus on the screen. Once you get the desired clarity, press the trigger button on the joystick. Once the image is captured, live feed from the camera stops and the screen steadily displays the new fundus image. Sample figure provided in Figure 23. After you have captured the left fundus image, pressing the trigger button returns the camera into live mode.

NOTE: The trigger should be pressed for capturing the next image. This will only happen after the current fundus image is fully displayed. No intermediate image will be captured if the trigger is pressed continuously.

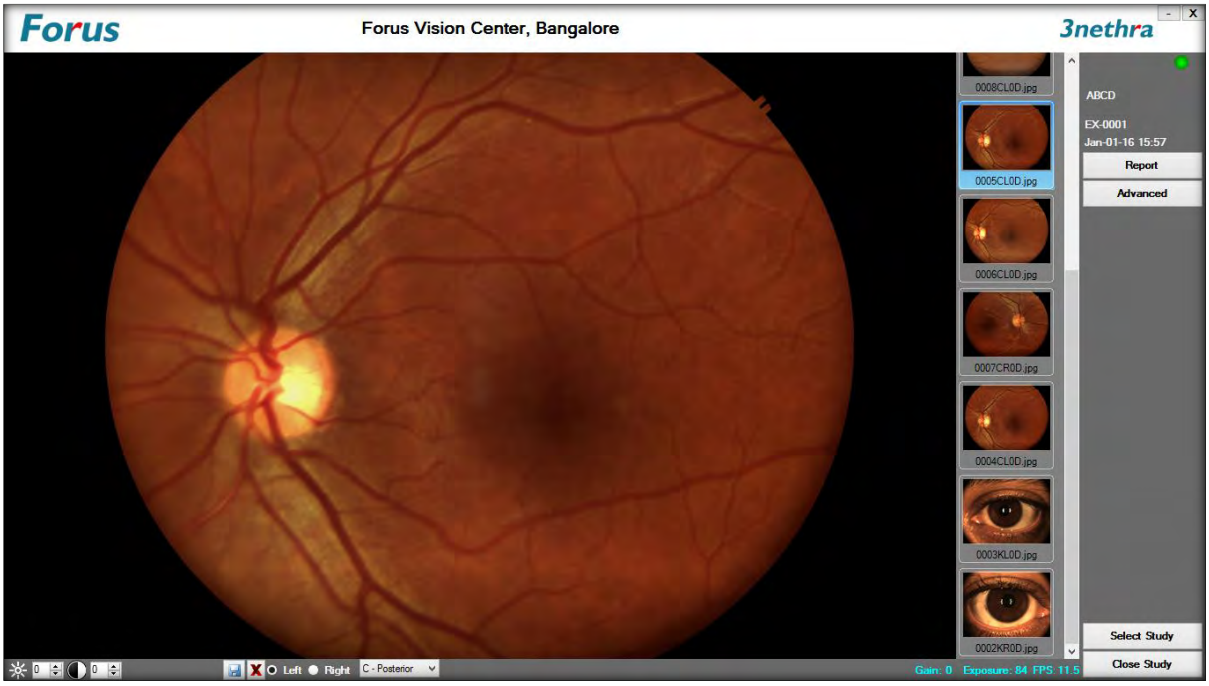


Figure 23: Capturing a fundus Image

4.4.4 Capturing Anterior Surface Image

- Once the posterior imaging is completed, select the anterior Imaging option.
- Use the External Fixation LED to get the examinee eye positioned at a desired position.

The camera needs to be moved around 8cm closer to the eye to get full view of the anterior segment. Selecting the “Anterior” button on the main image capture screen will enable

anterior imaging. A guidance mark as shown in Figure 24 should be used to position the pupil appropriately.

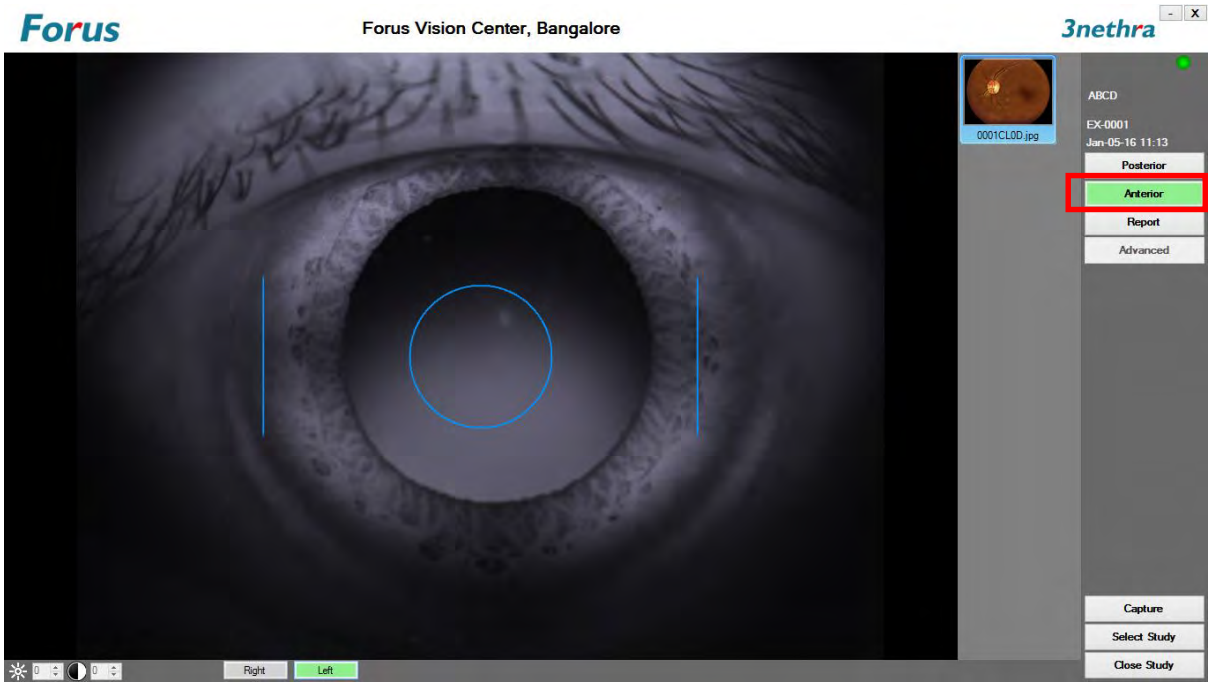


Figure 24: Guidance mark

Once the pupil is correctly positioned and focused capture the anterior image. Refer Figure 25

Figure 25: Anterior surface imaging

Focusing on the anterior surface, different parts of the eye become clear at different positions.

4.4.5 **Functions in History mode**

Posterior: Selecting Posterior button from horizontal palette will allow the examinee to alter anterior image name to Posterior. Converted images will automatically be renamed as shown in Figure 28.

Figure 26: Selection of Posterior Image in History Mode

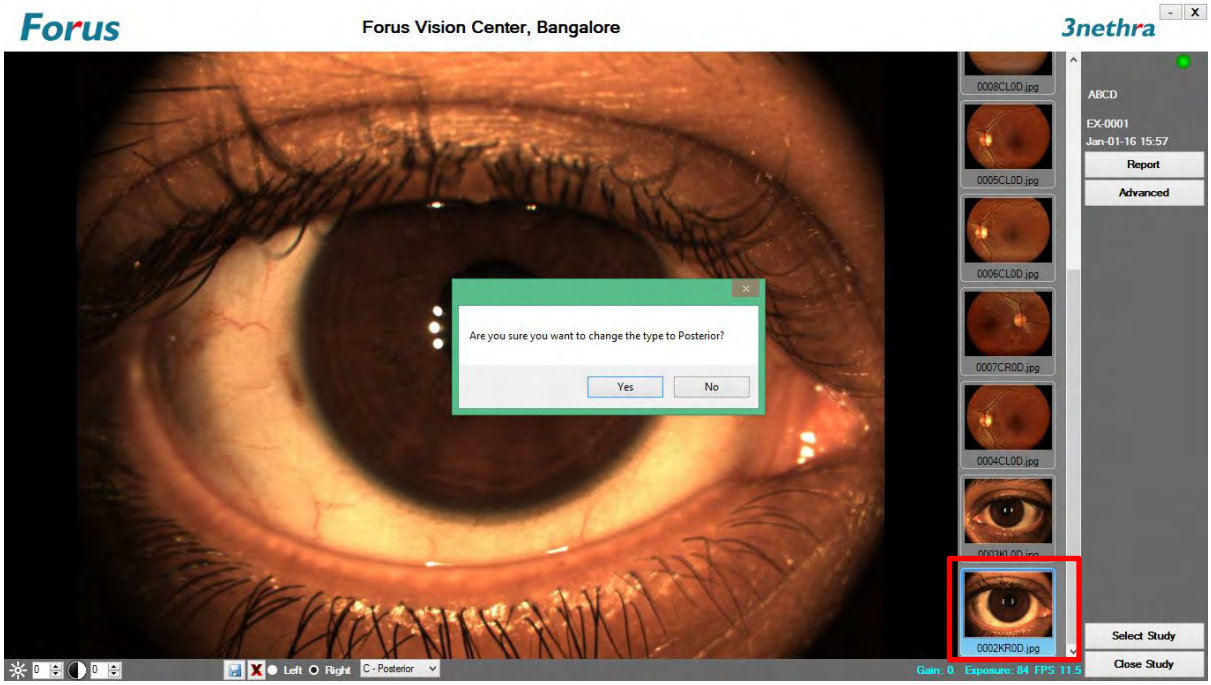


Figure 27: Changing Type to Posterior Image in History Mode

Figure 28: Posterior Image after selecting C-Posterior in History Mode

Anterior: Selecting anterior button from horizontal palette will allow the examinee to alter Posterior image name to anterior. Converted images will automatically be renamed as shown in Figure 31

Figure 29: Selection of Anterior Image in History Mode

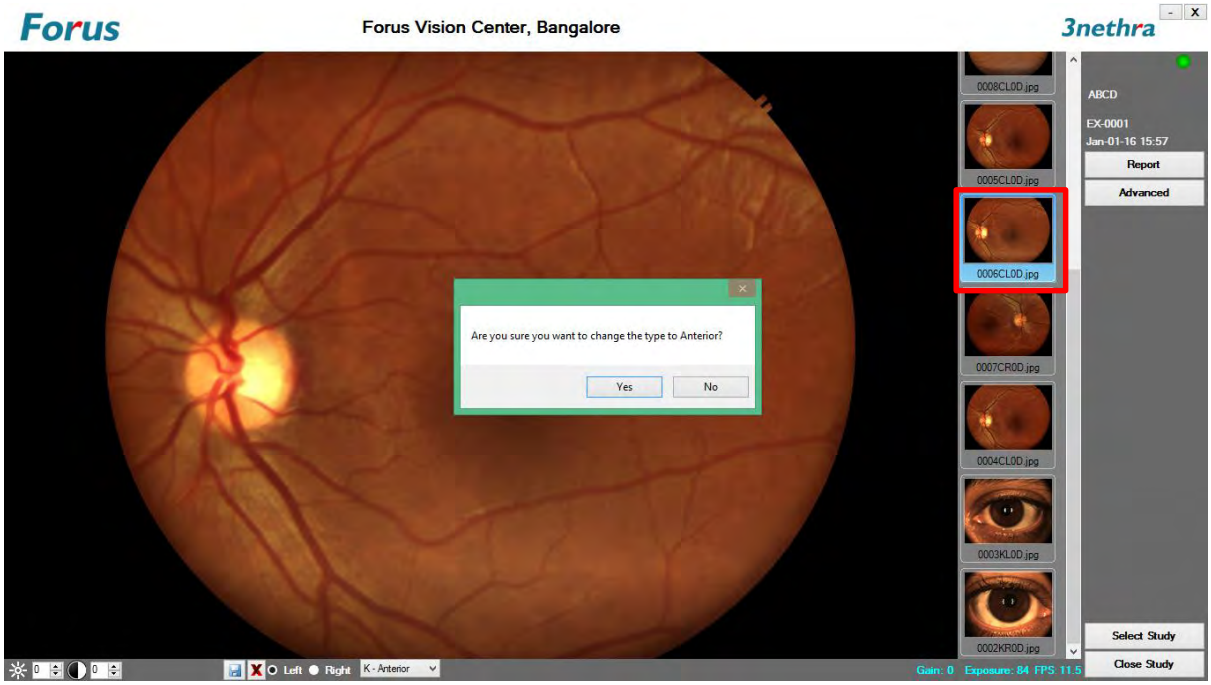


Figure 30: Changing Type to Anterior Image in History Mode

Figure 31: Anterior Image after selecting K-Anterior in History Mode

Save: Left Clicking the mouse button will automatically save the images once the changes to image is done as shown in Figure 32.

Delete: Left clicking the mouse will pop up a dialog box as shown in Figure 32 below. Once the dialog box appears on screen, Clicking on "Yes" option will allow the selected image to delete.

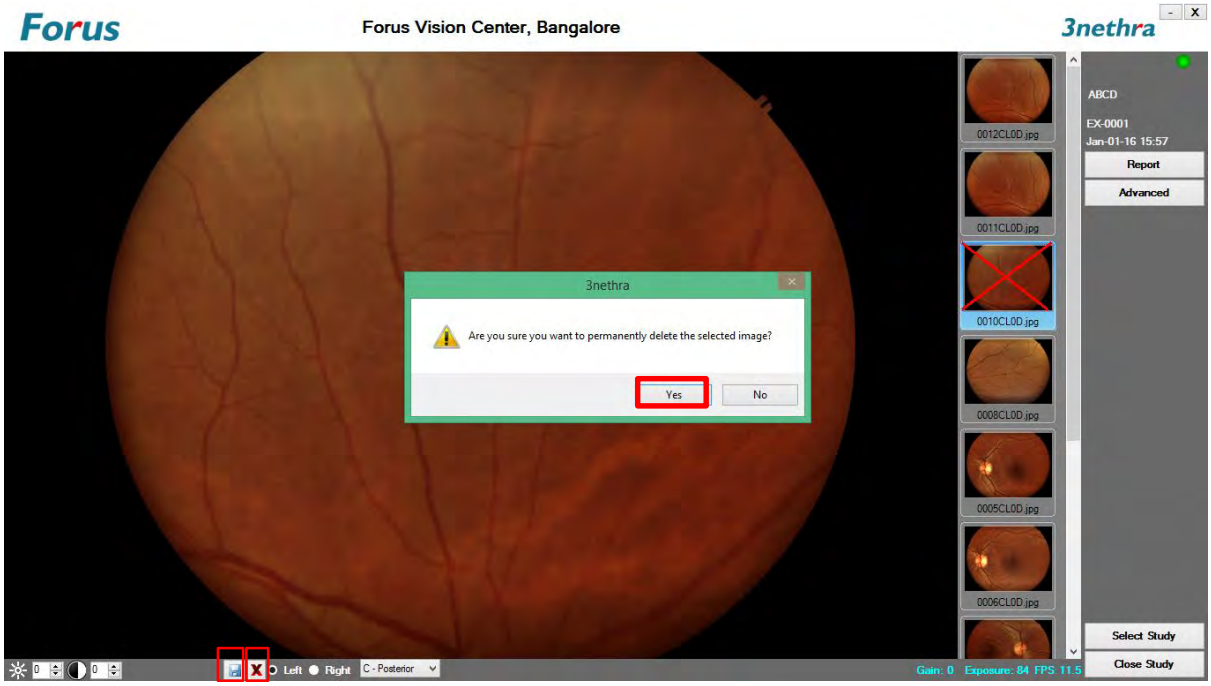


Figure 32: Deleting Image in History Mode

Brightness: By using this option  lightness or darkness of the image can be easily attained. Left clicking the mouse button will enable to increase or decrease the brightness from Upper limit +8 to lower limit -8. Brightness can be varied both in live feed and History mode.

Contrast: Increasing the contrast  makes the light areas become more lighter, and the dark areas becomes darker. Left clicking the mouse button will increase or decrease the contrast from upper limit +8 to lower limit +8. Contrast can be varied both in live feed and History mode.

4.5 Report

Once the Report button is pressed, the software pop's up a dialog for selecting the report template.

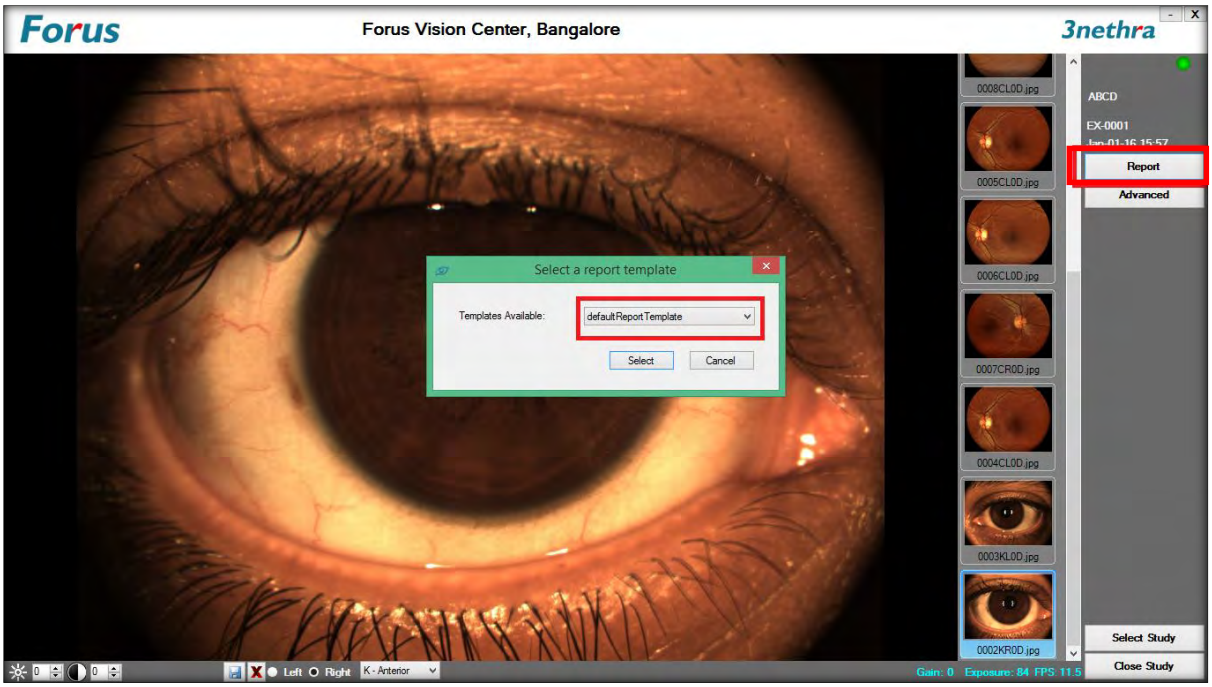


Figure 33: Report Template Selection

a. If you select the Default report template, a dialog opens as in Figure 34.

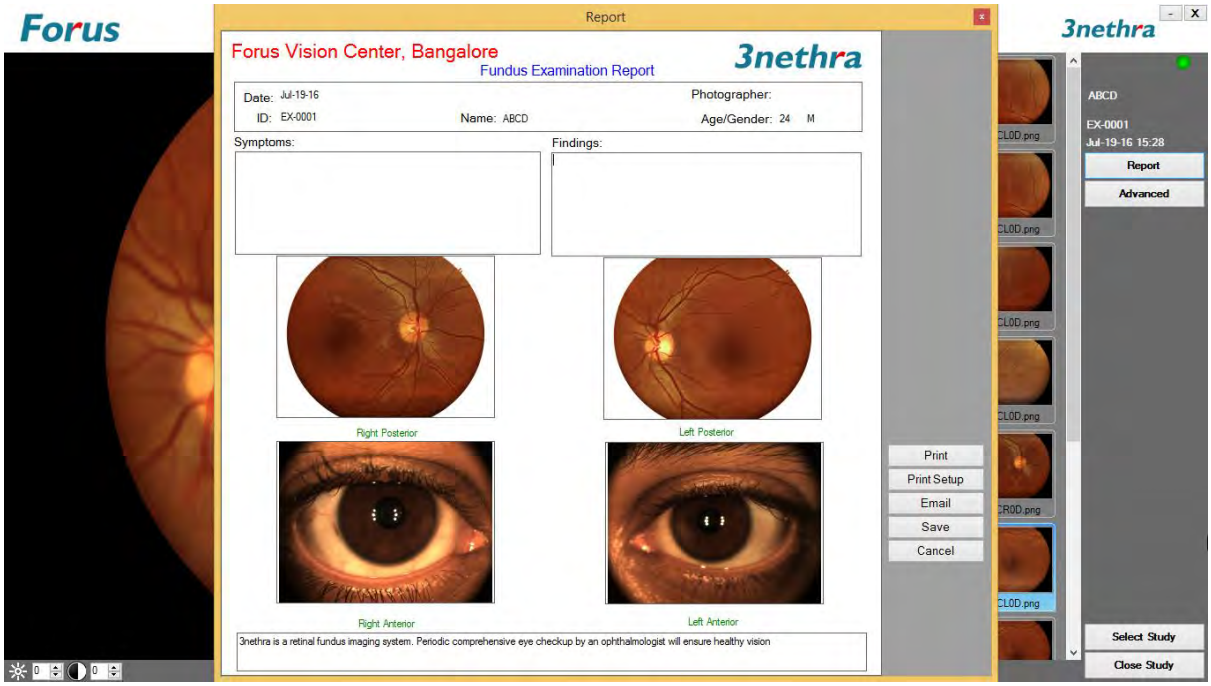


Figure 34: Default report template

b. If you select the Landscape report template from the drop down list as shown in Figure 35 , a dialog opens as in Figure 36.

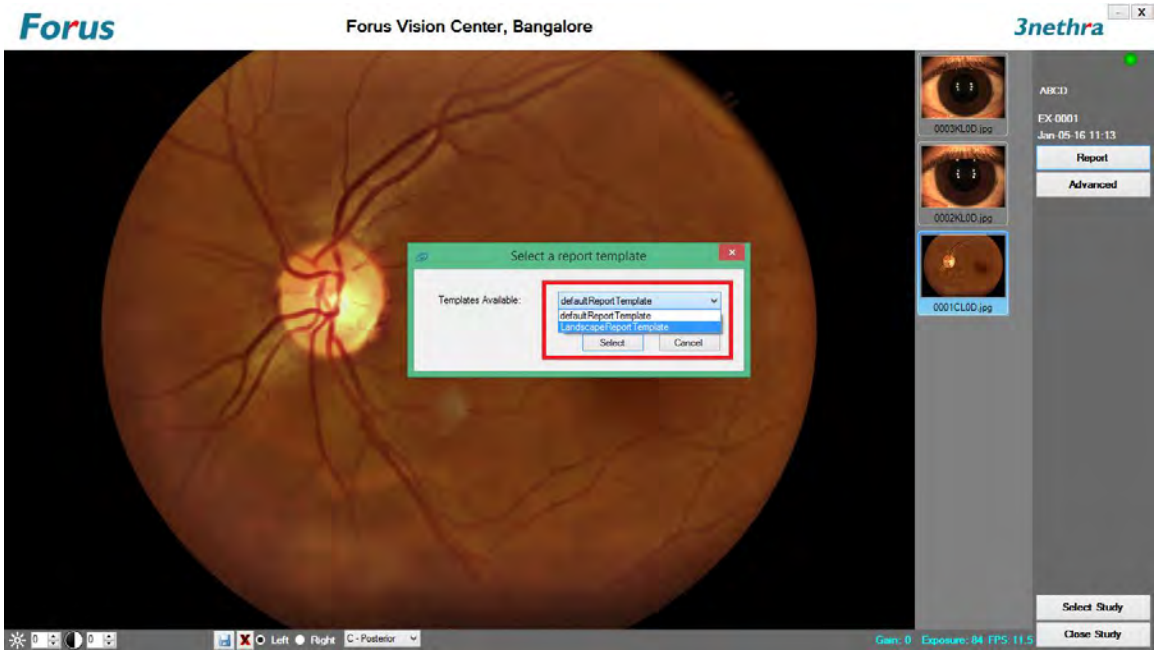


Figure 35: Landscape report template selection

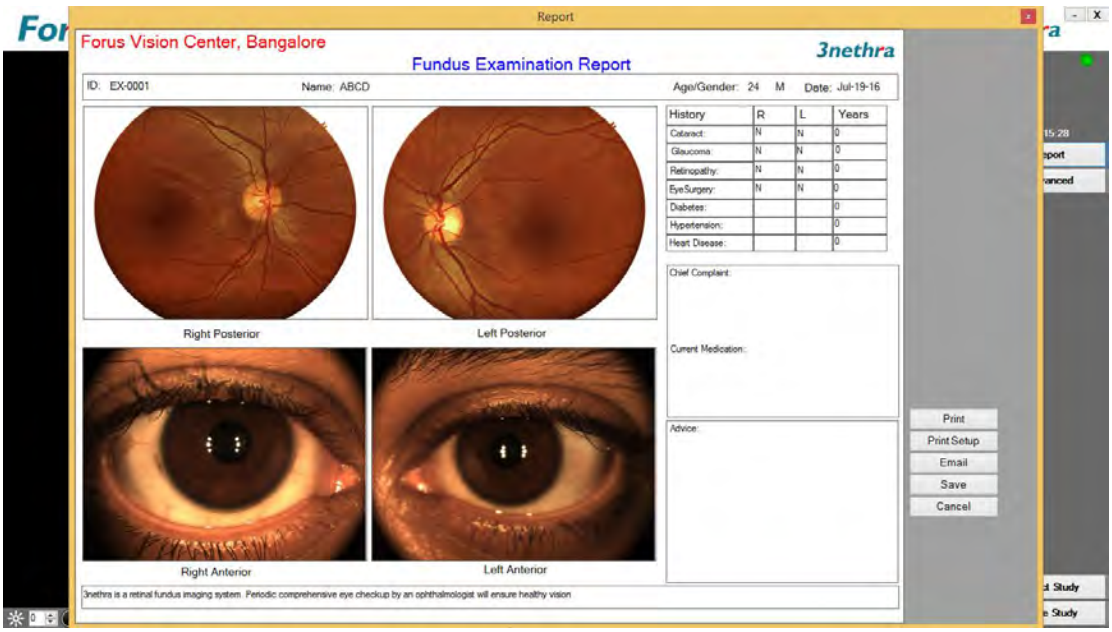


Figure 36: Landscape report template

In the report, you can change the images by double clicking on the image box. If you have captured multiple images, pick and choose the images that you want to include in the report.

Here you can either print, save, e-mail report to the doctor.

On clicking <Print Setup> button, the following dialog appears where you can modify printing parameters such as Red tone, Green Tone, Blue Tone etc., see Figure 37.

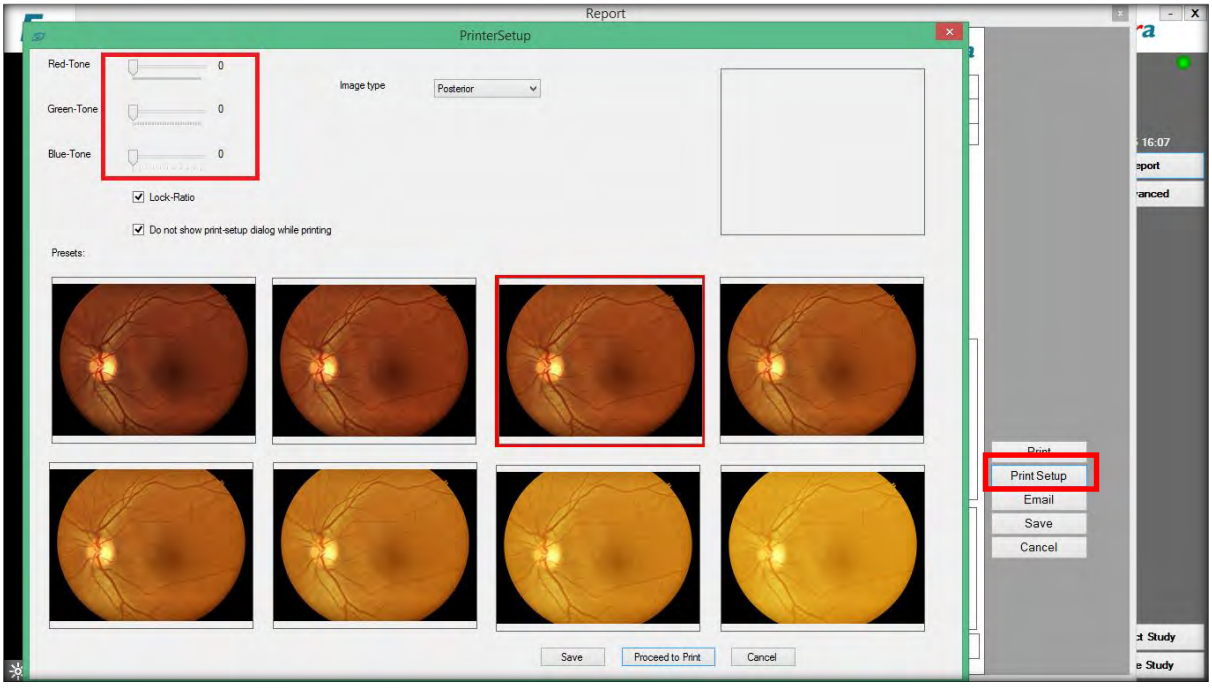


Figure 37: Image type selection

You may email this report to a doctor by clicking the <Email> button. In the email interface, enter necessary information such as recipient name and email address, and click on the <Send> button to send the email.

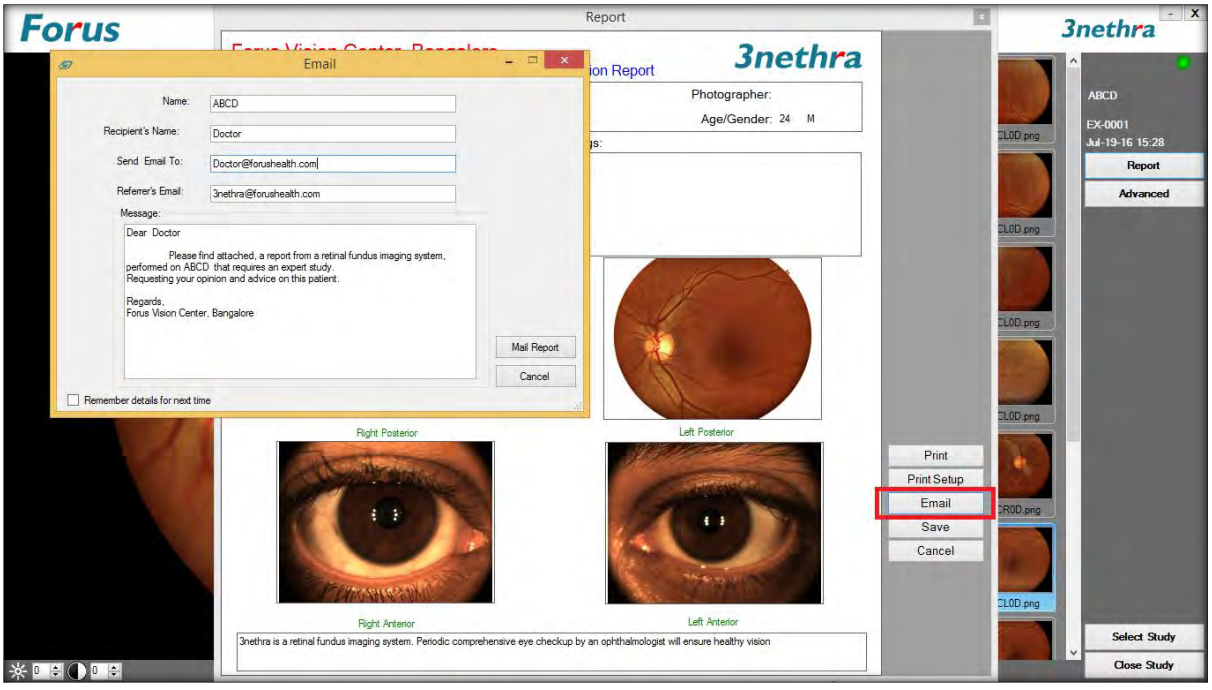


Figure 38: Emailing Report

Once the email screen disappears, you will be taken back to the report screen. Click on the <Cancel> button on the report screen to go back to the initial screen as in Figure 12 where you are ready for another pre-screening session.

4.6 Advanced Options

4.6.1 Remote Assistance

On clicking <Advanced> on the top right hand side of the window in anterior mode (Figure 31) or posterior mode (Figure 28), a popup menu appears as shown in Figure 39

In the unlikely event of a problem where assistance from the Forus service team is needed, you can invoke Remote Assistance quick support by selecting Options tab, then clicking on the <Remote Assistance> button. As in the Figure 39.

Note: Internet connection is a must for using remote assistance.

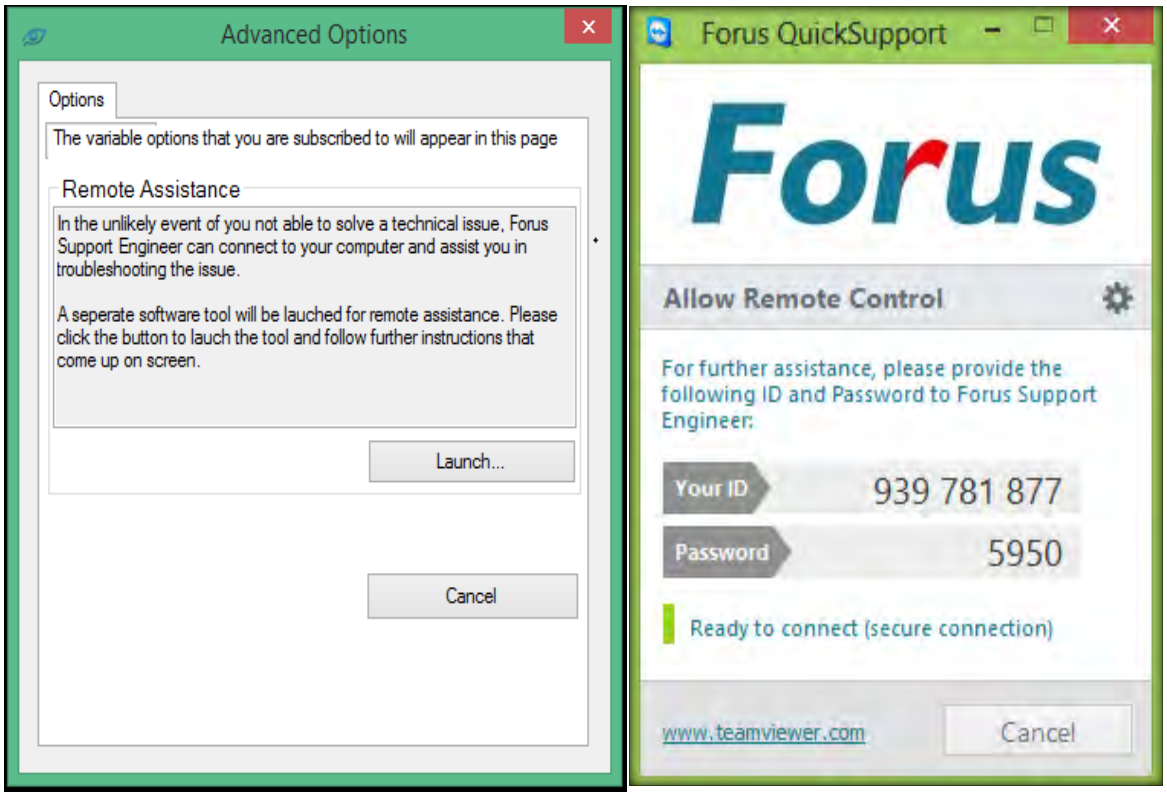


Figure 39: Remote Assistance

1. Once clicking on the remote assistance button window appears asking for “User Account Control”, click on “Yes”
2. A disclaimer window will appear for user’s acceptance before continuing further.
3. On accepting the disclaimer, team viewer quick support window will be displayed. The ID and password will appear automatically; this needs to be shared with the service engineer to initiate remote assistance. As in Figure 39.

Note: Since remote assistance also exposes the computer system completely to the remote user, caution needs to be exercised while using this feature.

5. Tweaking and Tuning

5.1 Troubleshooting

⚠ WARNING	• To avoid the risk of electric shock, do not attempt disassembling, rebuilding or repairs. Consult your dealer for repairs.

1. When you power up, if the external fixation light does not come up:
   - Test whether you have a power supply at the plug point by connecting some other device to the same plug point, such as a table lamp. If the power supply is missing, get it fixed by a qualified person.
   - If the power supply is working, check all the connections in the Section 3.4 “Connections on 3nethra” of this manual.
   - If the fixation light still does not come up, call the 3nethra technical support number listed in section 8 of this manual.
2. When you press the trigger button, if it doesn’t take an image:
   - Check all connections in the Section 3.4 “Connections on 3nethra” of this manual.
   - Do you see the red external fixation LED light up?
   - If the LED is on but the trigger does not work, call the 3nethra technical support number listed in section 8 of this manual.
   - If the LED is not on, there may be some problem with the connectors. Double check the connector cables. If still the problem persists, call the 3nethra technical support number listed in section 8 of this manual.
3. When you press the trigger button, a software error message is flashed:
   - Ensure that the Operating System and computer is as per the recommended configuration.
   - Ensure that the software is installed as per the instructions given in the software installation manual.
   - Still if you are not able to rectify the problem, call the 3nethra technical support number listed in section 8 of this manual.
4. If you cannot get the optic disc into the desired position:
   - Use the swivel to focus on the optic disc
   - You may ask the examinee to look at a different object.
   - Examinee may have a squint. You may need to experiment and find out the optimal position for the external fixation LED.

5.2 Daily Maintenance

1. When the device is not in use, tighten the lock on the camera mount so that the wheels are not freely moving.
2. When the device is not in use, cover the camera with the lens cap.
3. Once a week, apply one drop of machine oil to the camera mount lock.
4. Protect the machine from dust by covering the whole setup using the device cover provided with the 3nethra.

6. Specifications

Picture angle	40 degrees
Working distance	40 mm (from objective lens to Anterior segment)
Optical Resolution	20 microns
Focusing method	Manual
Light source for observation	Infrared Light Emitting Diode with fixed intensity
Light source for photography	White Light Emitting Diode (Flash) with fixed intensity
External fixation target	Red Light Emitting Diode
Horizontal movement	60 mm (back and forth), 80 mm (Left and Right)
Vertical movement	30 mm
movement	80 mm (up and down)
Interface	Universal Serial Bus 2.0 and 3.0
Image Sensor	3 Megapixel
Power supply	AC 100-240 V, 50/60 Hz (for DC power adaptor 5V/4A)
Power consumption	5-10 Watts
Dimensions / Weight	340 (W) x 498 (D) x 620 (H) mm / 20 kg
Accessories	Objective lens cleaning cloth Device cover Allen keys Chin rest tissue papers Screw driver Lens cap
Software Applications	Image Storage and Retrieval Patient Records Management Image Enhancement Print Ready Report Generation
Optional	
Paper copy of Report	Colour Printer
Table	Height Adjustable Table: 700(W), 500(D), 640-800(H) mm, Minimum
Not Included, but required	
For running 3nethra software	MS Windows 7 (or newer) based laptop or a desktop with minimum of 2GB RAM, 2.2GHz CPU. For MS Windows 8 and above minimum of 4GB RAM (Forus recommends to use a CE marked laptop or a desktop)
Power	Uninterruptible AC Power Supply for 5V DC Adaptor
Report Viewing	Uninterruptible AC Power Supply for Laptop / PC Acrobat reader, Microsoft Office 2003 or newer version

Figure 40: Specifications

*Although every attempt is made to meet or exceed the above performance standards, specifications are subject to change without notice.

7. Labelling Information of the Device and Package

The various labels present on the 3nethra device and packaging box are shown in Figure 41 and Figure 42 below

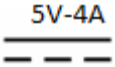
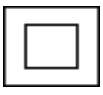
Symbol	Explanation
	CE Logo with Notified Body Number
	Manufacturer Name and Address
	EC Representative
	Manufactured date
	Batch
	Consult instruction for use
	Keep Dry
	Warning Symbol
	Temperature limitation
	Type BF
	Direct Current
	Connection from 3nethra tricam
	Fragile
	Class II Electrical Equipment as per IEC 60601

Figure 41: Labelling Details

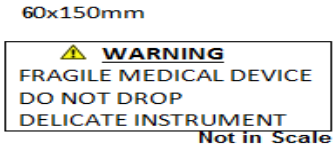
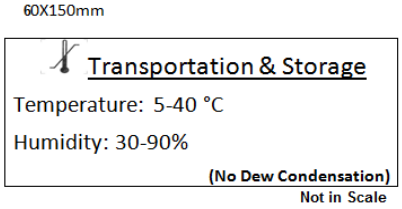
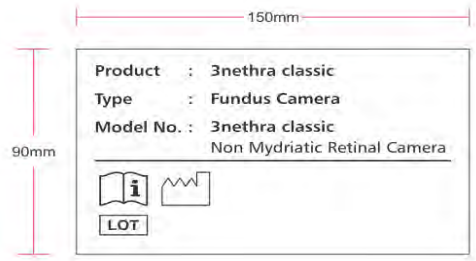
SL NO.	Labels
1	
2	
3	
4	

Figure 42: Labels on the Packing Box

8. Quick Reference

In case of	What to Do?
System Does not behave as expected	Refer to Trouble Shooting Guide
A Software Error message appears	Refer to Trouble Shooting Guide
You could not fix the problem by yourself	Seek help from Customer Support: Phone: + 91-80-41624042 Email: support@forushealth.com

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