
ConfoScan4™

Operator's Manual

CE
0123



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Notice

This manual is primarily for eye specialists. Authorized personnel of Nidek Technologies will give an introduction to the operation and handling of the instrument itself. The introduction will be in the form of a basic training during installation. In the interest of the patient's safety only specially trained personnel are permitted to operate the instrument.

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Before bringing this machine into service, please read this document carefully and in full. You should keep this important information in a safe place for later reference.

Manufacturer

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Intended purpose and classification

The ConfoScan4 Confocal Microscope is indicated for use as a diagnostic tool for observation of cell layers of the anterior parts of the eye.

According to directive 93/42/EEC, the medical device "ConfoScan4" is a Class I device with a measuring function. This device shall be operated by professionals authorized by the local regulations.

IP classification: according to the degree of protection provided by the enclosure with respect to harmful ingress of particulate matter or water, the unit is classified IPX0.

According to IEC 601-1, the equipment can be connected continuously to the supply mains and is provided for continuous operation.

Precautions

For safety, it is important that the operator be well-trained in the use of the device and pays particular attention to the position of the lens relative to the eye.

Operator's Manual Information

Revision: 7

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General information.

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The covers or the control panels are not to be removed. If the covers and/or the panels are not in their proper position, the instrument should not be used.

Certification.

Notified agency: TÜV Product Service GMBH Identification no. 0123
Certificate CE No.: G2M 05 04 44899 005 valid until 2009-07-21

Electromagnetic compatibility.

This device is classified in class B according to IEC60601-1-2.

This instrument has been tested and found to comply with the limits for medical devices to the IEC60601-1-2 and Medical Device Directive 93/42/EEC. These limits are intended to provide reasonable protection against harmful interference in a typical medical installation. This instrument generates, uses and can radiate radio frequency energies and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the system does cause harmful interference to other devices, which can be determined by turning the system off and on, try to eliminate the interference adopting one or more of the following measures:

- reorient and/or relocate the receiving device;
- increase the distance between the devices;
- connect the system to an outlet on a different circuit than that to which the other devices are connected;
- consult the manufacturer or field service technician for help.

Safety Notices

An electrical outlet that is not correctly wired could place hazardous voltage on metal parts, or the device attach to the CS4.

It is the responsibility of customer to ensure that the outlet is correctly wired and grounded to prevent an electrical shock.

Before installing signal cables, ensure that the power cord for the CS4 is unplugged.

During an electrical storm, do not connect or disconnect any cables.

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1. Product overview and indications.

The CS4 (ConfoScan4) is a fully digital confocal scanning microscope that allows to view and image human corneal layers in vivo, in a non-invasive way.

The operator can view, magnify and measure individual layers of the transparent structures and tissues of the cornea.

One examination records automatically a sequence of images of the cornea, which can be transferred to an external computer for digital storage and review.

The CS4 performs also no-contact endothelial microscopy.

The CS4 features pachymetry and locating of intra-corneal structures.

1.1. Total scan of cornea

The CS 4 records a sequence of corneal images starting from the anterior chamber and then moving the optical head back and forth throughout the entire cornea.

The lens used for this type of exam is a 40x water immersion objective; therefore it is necessary to apply a transparent gel to the front lens to perform exams.

The gel is in contact with the eye.

1.2. Pachymetry measurement

The CS4 records a sequence of corneal images starting from the anterior chamber and then moving the optical head back and forth throughout the entire cornea.

The lens used for this type of exam is a 40x water immersion objective, therefore it is necessary to apply a transparent gel to the front lens to perform exams.

To perform a pachymetry measurement it is necessary to equip the CS4 with the Z-Ring system, an additional sensor to increase accuracy of the measurement.

The Z-Ring contacts the eye.

1.3. Endothelial microscopy

The CS4 automatically records a sequence of endothelial and posterior stroma images.

The lens used for this type of exam is a 20x in air objective, which does not require any gel.

There is no part of the microscope in contact with the eye.

2. The equipment



Figure 1 – CS4 views

2.1. The microscope head

The microscope head contains the lamp, the b/w camera, the confocal scanning system, the entire floating plate where the lens is mounted, the safety sensor, a motor moving the lens back and forth during the scans and all optical parts, including the fixation targets.

After ten minutes from the last brightness adjustment (automatic or manual), the system moves the head in HOME position and turn off the lamp (the head HOME position is a stand-by position).

2.2. The microscope body

The body contains the power supply, the embedded microprocessor with internal memory and the 3-axis robot used to move the microscope head up, down, left, right, back and forth.

The embedded microprocessor hosts the CS4 embedded program.

Other external parts of the instrument body are the display, the joystick, the touch panel, the main switch, the power cable and the communication cable.

2.3. Forehead and chin rest

On the patient side of the equipment the following parts are located: forehead rest, dual chin rest including the knob for height regulation and OD/OS sensors.

2.4. Microscope lenses

Warning. The microscope shall use the lenses described in this paragraph.

The microscope is provided with a water immersion 40x lens. Working distance is 2 mm.

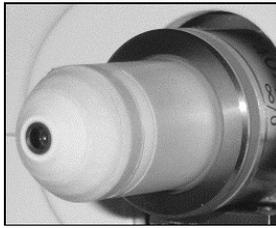


Figure 2 – 40x lens

As an option CS4 can be also equipped with a 20x lens, for no contact endothelial scans. Working distance is 12 mm.



Figure 3 – 20x lens

The Z-Ring system is a CS4 option provided for contact exams when accurate pachymetry measurements are needed.

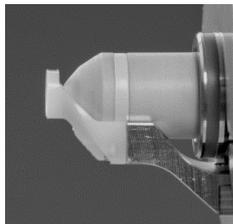


Figure 4 – 40x lens with Z-Ring system

The Z-Ring is for exclusive use together with the 40x lens.

The Z-Ring works in contact with the eye.



3. Safety, emergency and contra indications.

3.1. Precautions

Only personnel who have been specifically trained on the system should be permitted to operate the unit. The system should under no circumstances be exposed to water, due to the possibility of fire or electrical shock. Check to make sure all cables are properly connected. Never pull out a plug by the cable and avoid any excessive strain on the cable.

3.2. Installation and relocation

The CS4 is tabletop equipment, it must be stably placed over a table. A very stable and solid table is required. Do not hit the table or the equipment during the exam operations.

Warning. If the table is wavering or the CS4 is not perfectly stable, the movement can cause some unpredictable problems. For example,

- the Eye protection system can be triggered, in such case it stops the exam;
- the Z-Ring can press for a few moments on the eye with a little increase or decrease of pressure;
- It is possible to have a small discontinuity during the cornea scan.

3.3. Immediate stop push button

At any moment it is possible to press the red *Immediate Stop* button located on the right of the display in order to immediately stop any head movements.

To reset the *Immediate Stop* push button, turn the button in the direction indicated by the RESET label.



Figure 5 - Immediate Stop push button.

3.4. Generic dangerous condition

If there is smoke in the CS4, or if water falls over the equipment, or for whatever reason the operator thinks appropriate, when it is necessary to resolve a dangerous situation the operator must move away the patient and then cut off the electrical power.

Electrical power can be cut off by turning the power on/off switch or by disconnecting the power cord from the electrical outlet.

3.5. Eye protection system

The CS4 has a security system in order to prevent damages from physical contact of the lens with the eye. When the sensor detects a mechanical push on the lens above a pre-set emergency threshold, the CS4 immediately moves the head of the microscope in the HOME position, and stops the scan or the alignment.

3.6. Optical radiation precautions

There are no optical radiation hazards by the CS4.

It is recommended that the intensity of the light directed into the patient's eye be limited to the minimum level necessary for the exam.

The level of brightness is different for the 20X lens or for the 40x lens. See Chapter 5 "Standalone operations" in this manual for more information.

The average duration of a normal exam is around 1-2 minutes for the 20X exam, and 3-4 minutes for the 40x with Z-Ring exam.

3.7. Restrictions of patient groups

Corneal confocal microscopy should be avoided in eyes that underwent recent corneal surgery and are not yet completely re-epithelized. Pathologic corneas with damaged epithelium should be examined only after medical approval.

4. Preparing for an exam

4.1. Informing the patient

In order to maximize patient's comfort, ease of acquisition and obtain the best quality images, the operator shall inform the patient about what to expect at each stage of the examination.



The operator shall stress, in particular, the following:

- The patient will experience a bright light that is slightly flashing and tinted yellow, which can cause some dazzling after the exam is over.
- The ophthalmic gel may cause a transient slight blurring of the vision.
- Both symptoms will disappear in 10 - 15 minutes after the end of the exam.
- Patients should not drive until the above mentioned symptoms have completely disappeared.
- Patients should not scratch/push the examined eye with the fingers, following the application of the anesthetic, as sensitivity will be reduced for several hours.

4.2. Disinfecting the front lens and the Z-Ring (40x lens only)

This procedure must be performed before each exam, on the 40x lens and on the Z-Ring.



Microscope lenses and Z-Ring cannot usually be sterilized by heat and sterilization by gas can also lead to damage of the lens. Also, the use of UV-light is not an adequate precaution against viruses. The operator shall use the following disinfection procedure:

- Remove the residual gel from previous exam (if the gel is dry, remove it using a wet soft cleaning-tissue);
- Unscrew the lens from the microscope optical head;
- Screw the lens on the cover of the original container;
- Immerse the front lens 10-20 mm deep in a 70% Isopropanol solution for 10 minutes: do NOT completely immerse the lens in the container;



- Remove the lens from the container and wash it with water for injection (WFI);

- Mount the lens back on the microscope. During this operation care should be taken in order to avoid contact with the disinfected part handling the lens on its metal cylinder.

When the front lens is completely dry an examination can begin.

Disinfect the Z-Ring in the same manner.

When the Z-Ring is completely dry, look for its integrity.

If the Z-Ring gets somehow damaged and sharp edges are seen during visual inspection, it must NOT be used anymore.



The 40x lens and the Z-Ring are provided as not sterilized: the operator must clean and disinfect both at first use.



Figure 6 - Label "NON STERILE", on the bag of Z-Ring and 40x.

4.3. Turning on the unit

Insert the device plug, turn the main switch ON and wait for the system to complete the boot sequence. The system is ready when the acquisition screen appears on the display.



Figure 7 – Detail of display after the start up (acquisition screen)

4.4. Ergonomics

Patients should be examined in a relaxed position, with the forehead and chin pressed firmly against the forehead/chin rest. The patient should look inside the front lens and should be asked to fixate at the internal, light blue, fixation circle.

The operator shall assess before the beginning of the examination whether the patient wears contact lenses. It is not advisable to carry out an examination with contact lenses, because the cool temperature of the gel spreads out quickly on the surface of the eye. This can result in the patient's eye becoming irritated and cause the patient to blink.

Also, soft hydrophilic contact lenses present an additional problem in that they absorb and bind with the contents of surrounding media. Since it is necessary to use an immersion gel, these types of lenses should not be worn during an examination. Similarly, hydrophilic disposable lenses should not be used due to anesthetic build up in the contact lens material.

The same applies to wearers of hard contact lenses even though the absorption of foreign substances is a lot less critical with these lenses. Since the heat conductivity of hard contact lenses is less than that of hydrophilic contact lenses, examinations with hard contact lenses without anesthetic is possible in exceptional cases. The lenses, however, should be thoroughly cleaned after the procedure.

After the examination, patients should not insert their contact lenses until the tear film has washed the anesthetic and immersion gel away. This usually happens after approximately 15 to 30 minutes.

The operator should be sitting on the joystick side, controlling the joystick with the right hand and using the left hand for speed and light controls.

The optimal viewing angle for the embedded display is obtained when the operator is sitting, not standing.



Examinations should be performed in a non-full-daylight room.



The automatic OD/OS detection relies on the vertical pressure applied by the patient's chin. If the patient does not load enough weight on the chin-rest, undetected OD/OS may result.



4.5. **Anesthetizing the eye** (40x lens only)

This procedure shall be performed regardless the presence or not of the Z-Ring.

This procedure shall not be performed in the case of the 20x lens.

Warning. The examiner should pre-assess if the patient is hypersensitive or allergic to the anesthetic drops.



The operator must consider possible side effects of every type of product against the benefit of the examination.

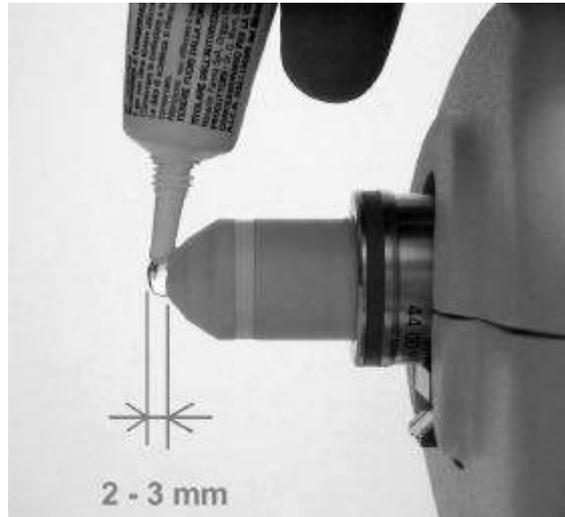
Shortly before an examination, it is advisable to anesthetize the target eye by means of a superficial anesthetic; otherwise the cool gel applied to the front lens could induce blinking. In such a case, eyelids will easily wash away the gel.

Since several anesthetic solutions are available in the ophthalmic market, the operator will decide upon a solution based on his/her own medical knowledge.

4.6. **Applying gel to the front lens** (40x lens only)

Before approaching the patient's eye, it is necessary to apply a transparent gel to the front lens.

The operator shall apply a drop of gel, 2-3 mm in diameter, onto the tip of the front lens, starting from the top of the front lens and until the drop completely covers the lens.



The front lens should be well covered with the gel. Avoid air bubbles or contaminants inside the gel; this may interfere with light transmission, making the image blurred and unclear. After placing the gel on the front lens, the operator should inspect the droplet for air bubbles to ensure proper operation of the device. If in the landing phase, debris seen as white specks are observed in the gel, the use of that gel should be discontinued.

The examiner should pre-assess if the patient is hypersensitive or allergic to the gel.



The following gels are commonly used:

- GenTeal Gel (in the US market) from Novartis Ophthalmics.
- Viscotirs Gel (in the Italian market) from CIBA Vision.

The 40x lens is a water immersion lens that shall only be used with a gel or a other media with similar refractive index.



5. Standalone Operation

The equipment can work as a standalone unit, without any other device connected.

When performing a scan in standalone mode, any previously acquired examination is overwritten. It is possible to save only one examination, in case the equipment needs to be switched off (see Exam review, SAVE command).



It is also possible to review the last exam and configure the settings of the CS4 embedded program.

Attachment of an external computer, enables permanent storage and review capability (see 6. **Connecting to NAVIS**).

5.1. Standard exam (40x lens)

Configuring exam parameters

There are mainly three parameters which the operator needs to check/select before starting any exam:

1. Scan mode
 - semi-automatic (SEMI): the operator selects scan depth (i.e. the depth of the section to be scanned, in microns) and scan step (the distance in microns along the scan direction between two adjacent pictures);
 - Automatic (AUTO): the operator selects only scan step: in this case the program will automatically detect the anterior chamber and tear film and perform a full corneal scan;

Default values for scan depth and step are respectively 800 μm and 5 μm . The minimum value for step is 1.5 μm .

2. Auto-Alignment option (AA): Status = ON or OFF (To change the type of AA, "Normal" or "Screening", please refer to Settings chapter)
3. Fixation target (FIX): central, peripheral (8 different positions), OFF.

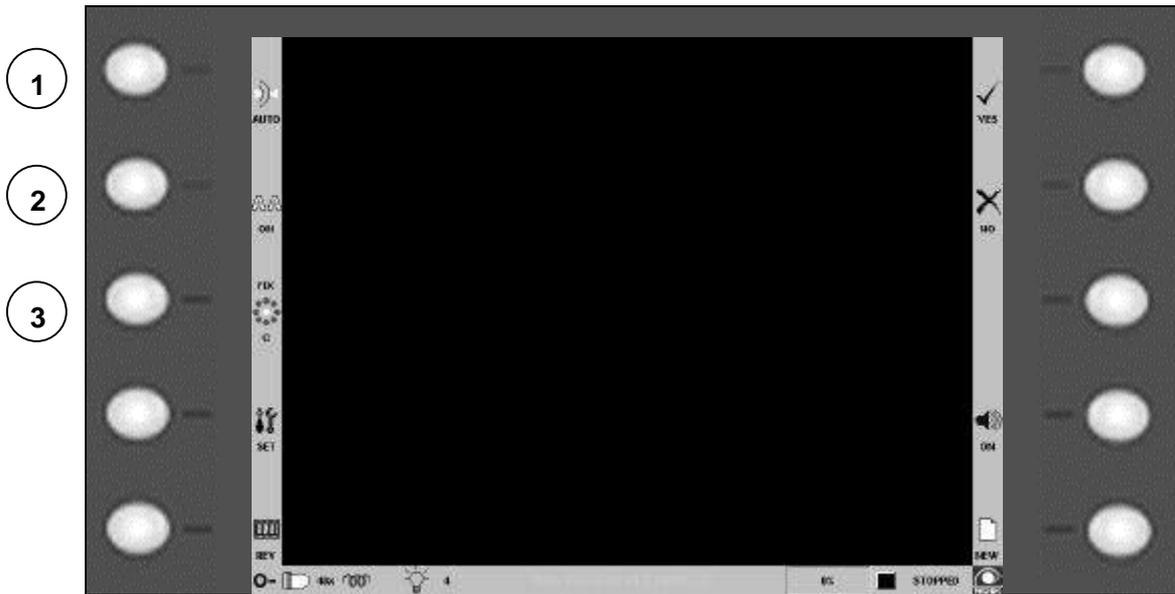


Figure 8 – Display and touch-panel

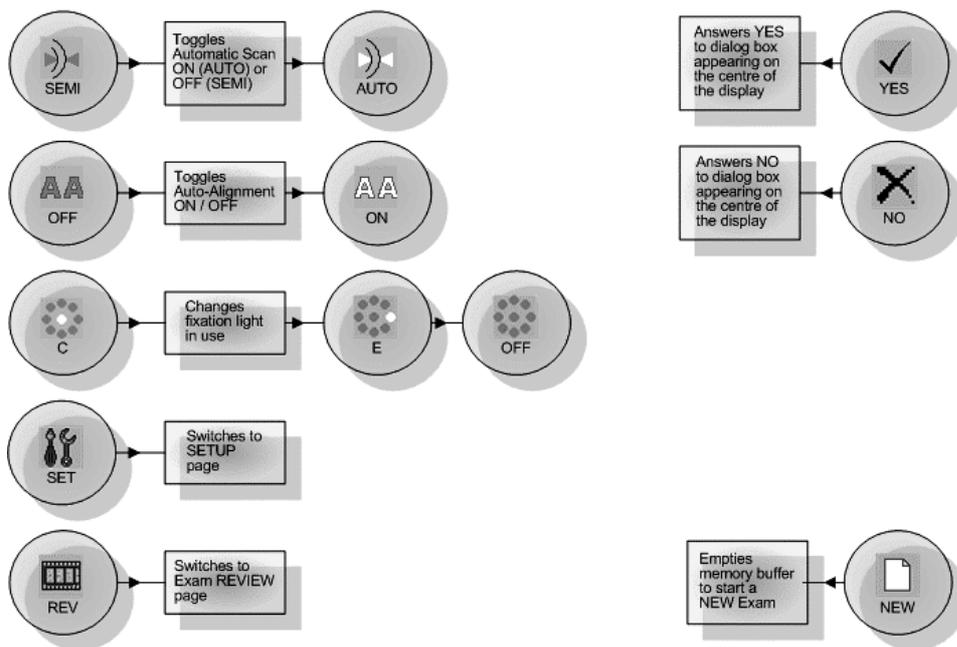


Figure 9 – Synoptic of symbols in acquisition screen

Positioning the patient

Now proceed to position the patient as described at 4.4.

Before approaching the patient's eye it is necessary to check the lamp level. Lamp brightness can be tuned by means of the LIGHT knob located on the joystick: the actual lamp brightness is shown on the display, at the lower left corner, beside the bulb symbol.

Standard values for 40x exams are 70-90. Maximum is 100, but at this setting, the light level, while safe, may be uncomfortable to the patient and the life of the lamp may be shortened.

Lamp brightness can be manually adjusted during the exam if image brightness appears too dim or bright.

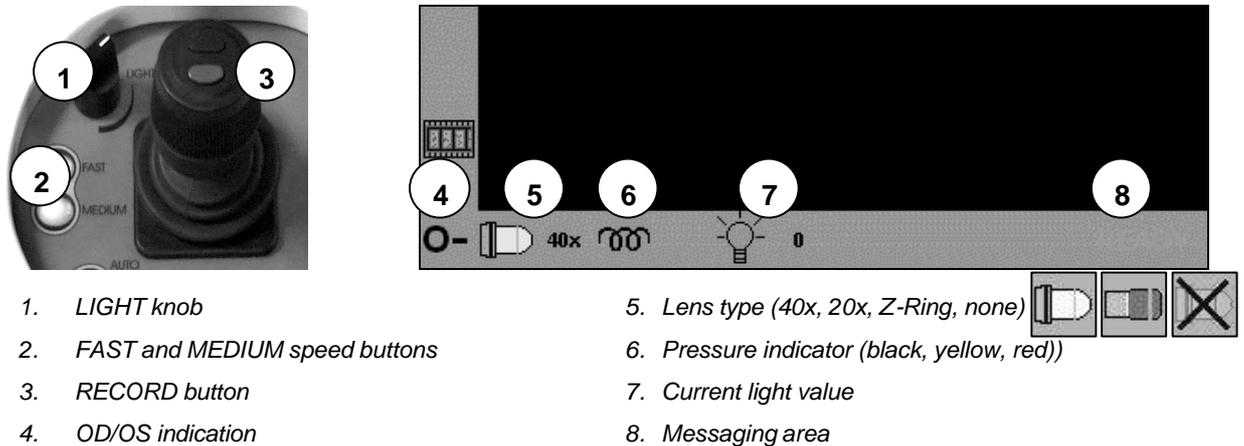


Figure 10 – Joystick commands and display indicators

The Landing process

Landing consists in manually moving the optical head from the home position with the joystick in 3 directions, X, Y, and Z, so that:

- a. lens apex and corneal apex are aligned as much as possible vertically and horizontally,
- b. contact is established between the gel and the cornea (also called “approach” phase),
- c. further forward movements (and vertical / horizontal adjustments, if needed) make the layer of interest appear on the display. Refer to paragraph Landing & Alignment rules below for more details.

Landing can be performed manually or automatically, by activating the Auto Landing function¹ (see p. 30).

Landing (manual or automatic) precedes Alignment (manual or automatic).

A sound tone will play (see activating Audio Feedback option, p. 30) if any bright image, normally corresponding to some corneal layer, is seen during the approach to the cornea; such a sound informs the operator that landing has completed and alignment can start.



Frequency of such sound tone is proportional to the brightness of the images.

If the Audio Feedback option is disabled the Auto Landing function is also automatically disabled.

Use the joystick to move the microscope head towards the patient: the head will follow the joystick movements. Up and down motion is achieved by rotating the joystick around its vertical axis.

¹ only available since software v1.1.0 and only for 40x mode

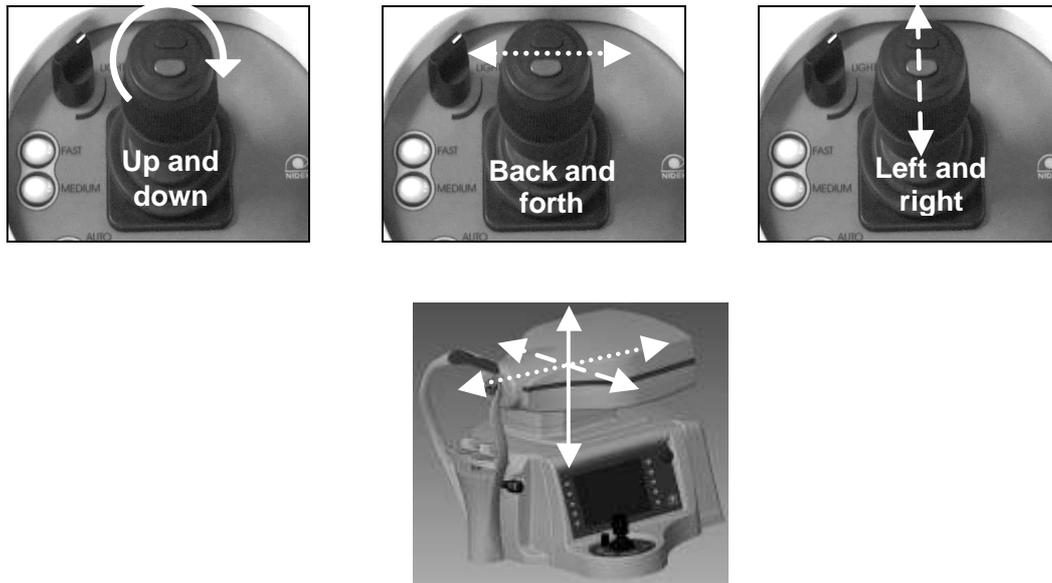


Figure 11 – Head directions vs. joystick actions

Align the head so that the front lens apex is aligned to the center of the pupil. While approaching the eye, you may use the “FAST or “MEDIUM” speed by pressing the corresponding button on the joystick pad. Drive the head at about 3-5 mm from the corneal apex.

Be sure that you will from now on only use the “Normal” speed, which is automatically set when none of the two speed buttons is pressed.



Adjust the front lens position in the vertical and horizontal directions, then move the microscope head forward until the gel drop touches the surface of the cornea. If Auto-landing has been enabled, press the green joystick button. Else move the lens forward by about 1 – 1.5 mm.: dim images (normally stroma) should be seen on the display.

The Alignment process

Alignment consists of fine tuning the position of the front lens apex with respect to the corneal apex in the vertical, Y, and horizontal, X, directions to achieve the best possible centering, so that corneal layers are homogeneously illuminated and uniformly visible across the picture.

At the end of the alignment process recording can start.

Alignment can be performed manually or automatically by activating the Auto Alignment function.



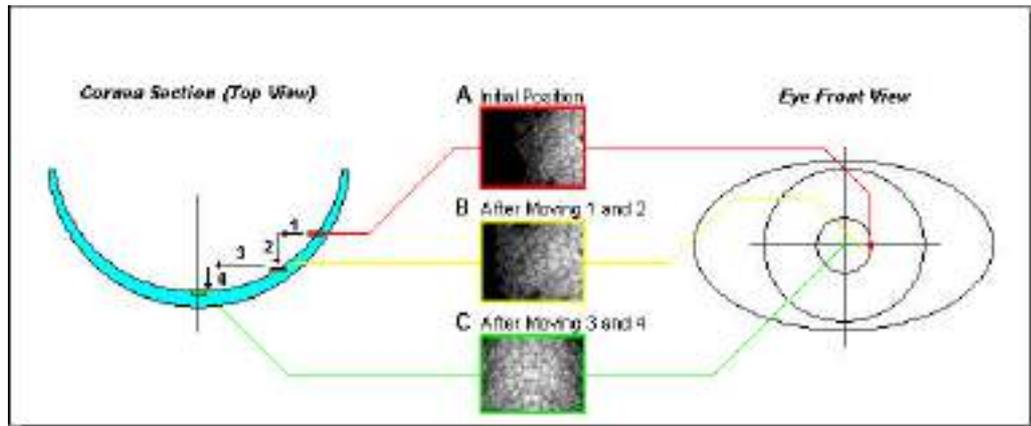


Figure 12 – Alignment concept

As a general rule for manual alignment, dark areas at the sides of the images indicate the direction to move, along each axis, to improve centering to the apex. The Auto Alignment software also employs this same concept. 

Landing & Alignment rules

The following rules shall be kept in mind when landing during the 40x exam (no Z-Ring).

There are several different scenarios:

1. Auto Landing ON, Auto Alignment ON

This is the easiest way to operate the unit and is the factory default. The operator just needs to move the optical head forward until contact between gel and cornea is established and then press the green button to start automatic landing. When the auto landing process is completed, automatic alignment starts and eventually recording.

Refer to the Auto Landing paragraph below for more details on this function.

2. Auto Landing OFF, Auto Alignment ON

The operator needs to perform manually the landing sequence. Alignment in X and Y of the lens with the corneal apex is performed with the joystick. Then the lens is advanced toward the cornea until any corneal layer is seen on the screen (stroma or endothelium). The green button is then pressed to start the auto alignment. When the auto alignment is completed, recording starts.

It is not necessary to reach the endothelium to start the auto alignment. 

3. Auto Landing ON, Auto Alignment OFF

This combination is not of practical interest.

4. Auto Landing OFF, Auto Alignment OFF

The operator needs to perform manually both the landing and alignment sequences. Pressing the green button will in this case start recording.

When using the AUTOMATIC scan mode, the green button should be pressed when proper alignment conditions are reached and endothelium is seen on the screen.

When using the SEMI AUTOMATIC scan mode, the green button can be pressed whenever the layer of interest is seen: the scan will proceed backward from the starting position, according to the programmed scan step and scan depth.

Auto Landing

Auto landing makes the optical head move forward by 750 μm or until an image of the cornea is detected.

Should such movement NOT be enough to image any corneal layer, the operator must press the green button until a sound informs that auto landing has completed and corneal layers are seen on the screen.

Typically contact with the gel is established when the focal plane is 1-1.5 mm far from the superficial layers; therefore at least two Auto Landing initiation steps are normally required to land with a corneal image.

The Auto Landing function is automatically disabled if the operator has the lamp level set below 70 before pressing the green button.

The Auto Landing function is automatically disabled if some bright object such as a bubble or gel debris is detected during the approach phase. Contaminated gel and bubbles in the gel should be avoided.



If the Auto Landing function is for any reason NOT active, pressing the green button will start Auto Alignment or a recording, depending upon the settings selected by the operator.

Auto Landing can be re-enabled at any time by pressing the HOME command button.

Starting the scan

Once the green RECORD button on the joystick (see Figure 10) is pressed, the scan will start.

IF Auto Alignment is ON when pressing RECORD, it will complete the alignment along all directions and bring the optical head to the anterior chamber, just behind the endothelial layer prior to start scanning.



At this point a “beep” sounds, the display messaging area says “RECORDING” and the microscope starts scanning. A progress bar on the bottom of the display will highlight the scan progress (0-100%).

During recording the Forward/Backward control of the joystick is disabled, while Left/Right and Up/Down movements are allowed (only at minimum speed) in order to refine the alignment, if necessary.

It is possible to stop recording at any time by pressing the STOP button on the base of the joystick. To re-start recording without discarding previously acquired images, press again the RECORD button. To re-start recording and discard all previously acquired images, press the NEW button on the right of the display, confirm data loss, and press the RECORD button on the joystick.



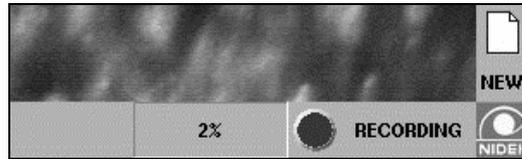


Figure 13 – Lower right corner of display during scan

When the recording phase has completed (350 pictures maximum), a “beep” plays: press the HOME button on the base of the joystick to move the microscope back to its resting position.

The patient can now be released.

5.2. **Pachymetry exam** (40x lens + Z-Ring)

The contact exam, performed with the Z-Ring, involves:

- All steps described at chapters 4.1 through 4.5 for preparation;
- Z-ring disinfection;
- Z-ring mounting;
- Application of gel, as in 4.6;
- All steps described at 5.1.

Refer to chapter 4.2 for the disinfection procedure.

The Z-Ring shall be mounted (magnetic attachment) before applying the gel to lens. Gel is applied afterwards, by pouring the drop from the top, as shown below.



Figure 14 – Gel insertion point for Z-Ring exam

The CS4 automatically detects the Z-Ring.

At the start of Z-Ring exam, when the CS4 is moving from the HOME position, it displays the following message: “PLEASE CONFIRM THE PRESENCE OF Z-RING ADAPTER (YES/NO)”.

The operator has to check if the Z-Ring is present and if it is correctly hooked to the CS4 and to press the YES push button to acknowledge it.

If there is any problem, the operator has to push the NO push button and discontinue the exam.

After the above confirmation the CS4 displays another message:
“PLEASE PUSH THE FRONT LENS TO CHECK THE EFFECTIVENESS OF SAFETY FEATURES”.

The operator has to gently push the metal support of the Z-Ring with a finger (see fig. below), the CS4 detects the contact and the Eye Protection System moves the head of the microscope to the HOME position, and displays the message “SAFETY FEATURES CHECK OK”.

Only at this point the operator can perform the exam.

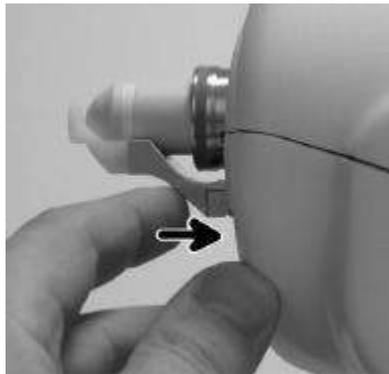


Figure 15 – Pushing of metal support of the Z-ring.

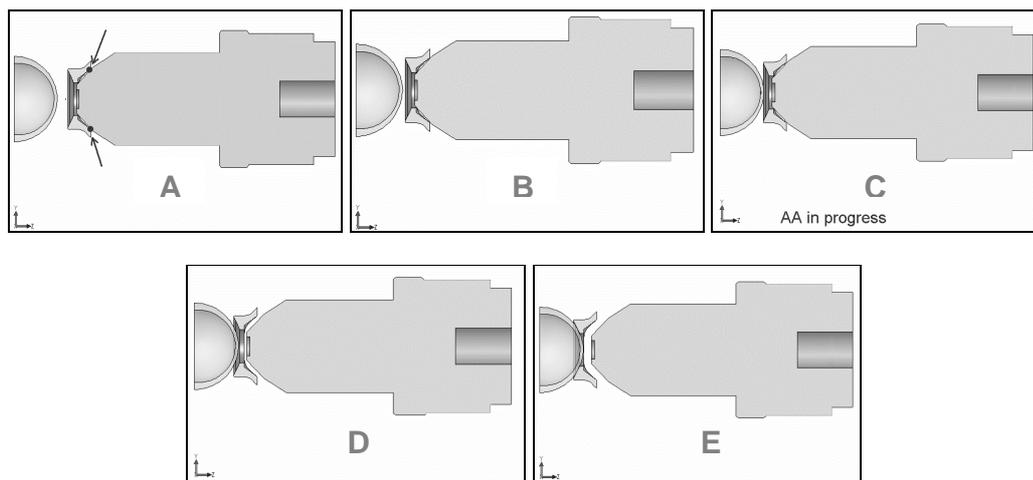
Landing rules

Basically, landing rules are the same as described for the standard 40x exam.

Particular attention should be paid in achieving accurate centering in X and Y before establishing any contact with the cornea.



Following is an explanation of the entire landing/alignment sequence for this kind of exam.



- A. Initial position, with lens touching the Z-Ring.
- B. Lens and Z-Ring are manually moved in all directions to achieve centering and so that eventually the focal plane intersects the cornea. At this point RECORD is pressed (if auto-alignment is ON).

- C. Auto-alignment (or manual if auto-alignment is OFF) is in progress along X, Y and Z. There is no contact yet: the Z-Ring and the lens are still moved synchronously, i.e. the entire head is moving.
- D. When AA is completed the Z-Ring is automatically moved forward, contact is established, pressure grows and the lens is simultaneously and automatically moved backward so to keep the focal plane stable on the endothelium.
- E. When pressure reaches a pre-set level the scan starts.

5.3. No contact endothelial scan (20x lens)

The no-contact endothelial exam, performed with the 20x lens, involves a simplified sequence with respect to the standard 40x exam and specifically:

- Removal of the 40x lens and mounting of the 20x lens;
- Ergonomics described in chapter 4;
- All steps described in 5.1, with the following differences:
 - light shall be now tuned to 35-40,
 - only the SEMI-automatic mode is available, with scan depth set by default to 500 microns and scan step set by default to 5 microns.
 - check the landing rules as they are specific for this kind of exam (see below).

Landing rules

The following rules shall be observed when landing during the 20x exam:

- IF Auto Alignment is OFF: land on the endothelium and then press RECORD. Landing on the epithelium or on the stroma will cause the endothelium NOT to be visible in the acquired images!
- IF Auto Alignment is ON (any mode): land on the tear film (this will normally produce image full saturation) and then press RECORD. Landing on the stroma will make the exam slower. Landing on the endothelium will make the Auto Alignment fail.

The principle of the Auto Alignment is different in the 20x exam: alignment is done at very low light level on the tear film layer and finally the optical head moves forward to the endothelium and the scan starts.



The 20x exam acquires fewer images than the 40x exam, therefore the examination is shorter.

5.4. Exam review

Press the Review (REV) button to review the acquired scan.



There are two different review modes: the Z-Scan curve and the full-screen mode.

Z-Scan curve

The Z-Scan is a plot of the average brightness in the central portion of the image, therefore it provides the operator with a corneal reflectivity profile.

Z-Scan is the default review mode and it is automatically selected when entering the review screen.

The Z-Scan curve allows an easy review of the corneal scan: as the operator moves the cursor along the curve (+/-) the image corresponding to the cursor specific location is displayed.

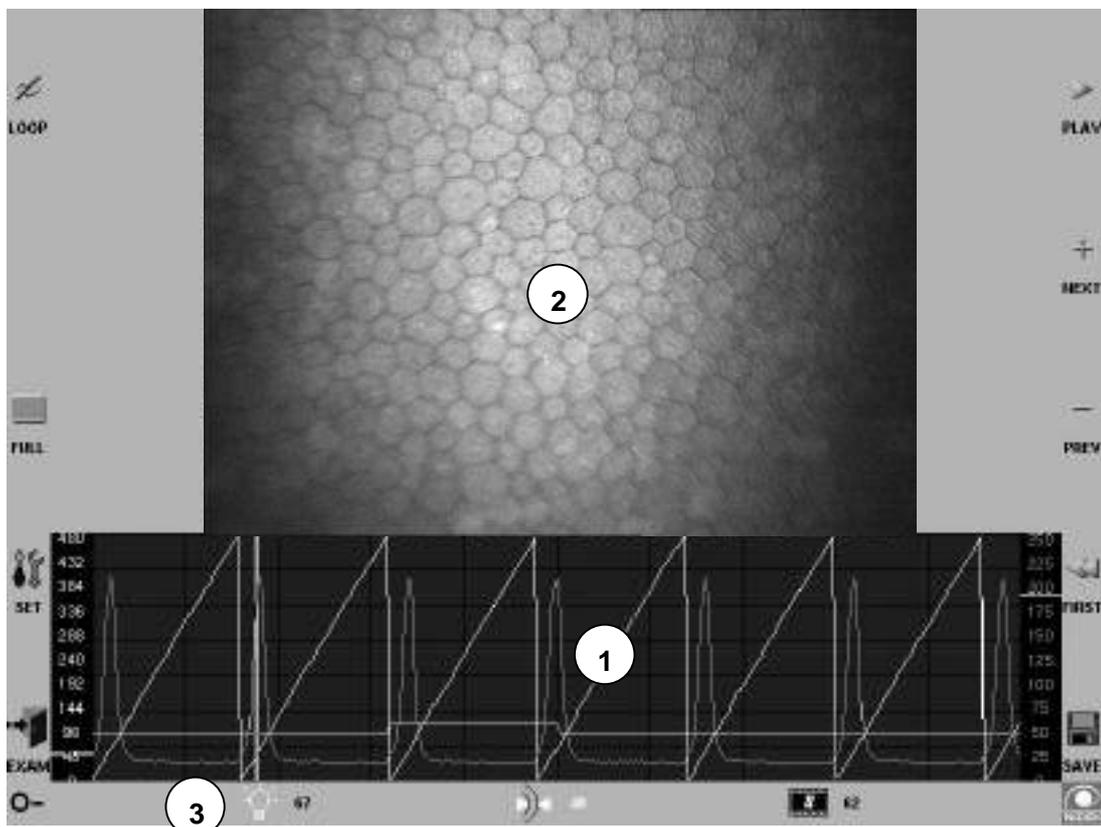


Figure 15 – Z-Scan review

1. Graph

The graph plots the intensity and the Z-position of each image:

- The green curve (Intensity Profile) represents the average brightness of the central portion of each image.

- The white saw-tooth curve (Position Profile) represents the relative Z position (i.e. along the direction of scan) at which each image was captured. In the semi-automatic mode, the Position Profile ranges from 0 to the programmed scan depth.
- The yellow curve represents the applied pressure during the contact exam (Z-Ring exams only).

2. Image Area

The image of the sequence corresponding to the cursor position in the graph.

3. Image Data

Numerical data corresponding to the selected image. From left to right:

- Eye information (OD/OS) associated to the current image: if the patient is not correctly positioned on the chin-rest, undetected eye (O-) appears.
- Lamp brightness when the selected image was captured (0-100).
- Z-position of the current image relative to the first image of the sequence (in microns).
- Image number within the scan (1-350).

Full-Screen mode

In this mode recorded images are shown at full size, allowing the operator to view all details.

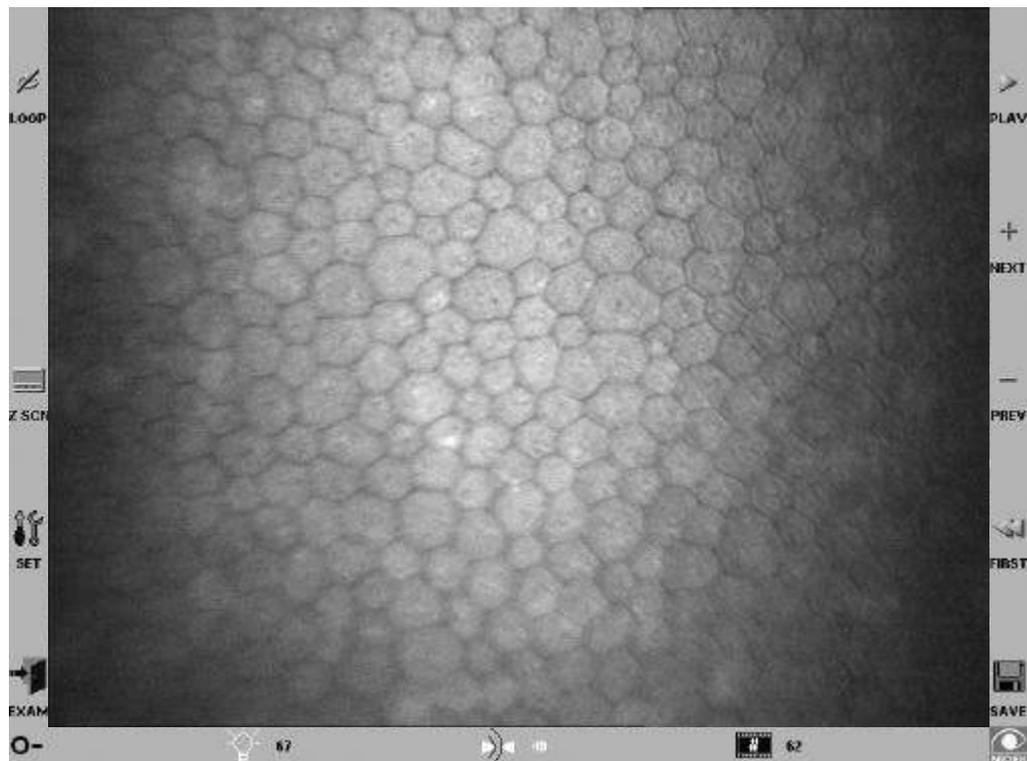


Figure 16 – Full screen review

A short description of commands available in this mode follows.

On the left-hand side of the display, top to bottom:

- **LOOP** – enable/disable loop mode during playback;
- **Z-SCN / FULL** – toggle between Z-Scan and Full-Screen modes;
- **SET** – go to the Settings (see 5.5);
- **EXAM** – back to exam acquisition screen;

On the right-hand side of the display, top to bottom:

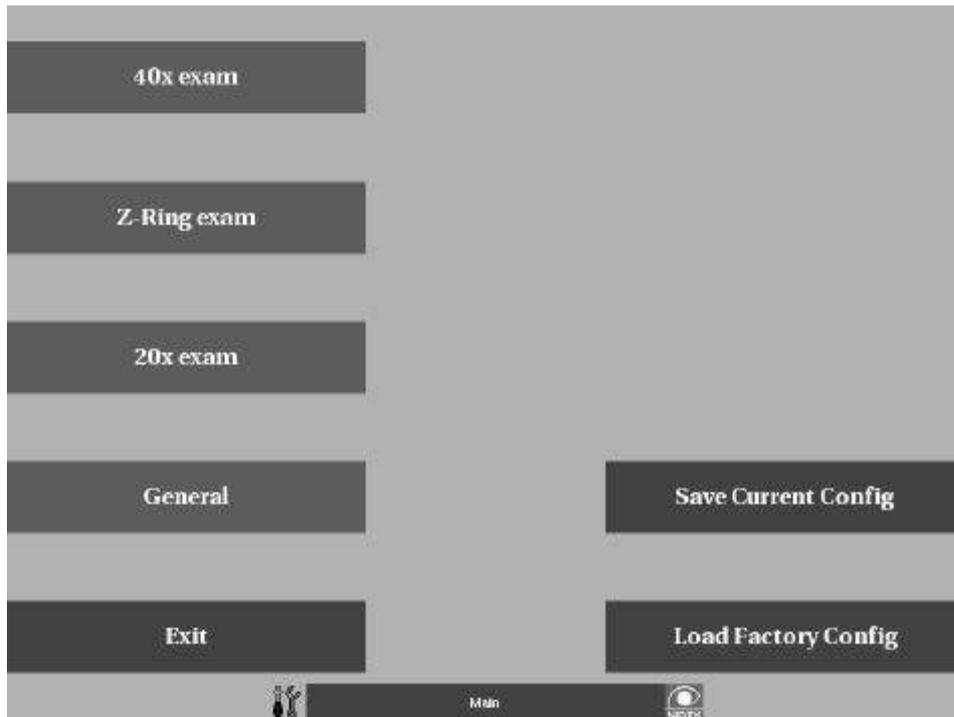
- **PLAY-PAUSE** for playback of the image sequence; in the Z-Scan mode the cursor will “sweep” during playback across the Position Profile and Intensity Profiles.
- **NEXT** – browse the image sequence one by one in the forward direction;
- **PREV** – browse the image sequence one by one in the backward direction;
- **FIRST-LAST** – back to first / jump to last;
- **SAVE** the exam to the internal memory, allowing to switch-off the device without losing data: next time the device is turned on, the exam will be reloaded (see Warning).

If there is a problem with eye identification, after the **SAVE** option, the CS4 displays the message: “WARNING: THE EYE INFO IS PARTIALLY OR COMPLETELY MISSING”.



5.5. Settings

Press the Settings (SET) button on the left-hand side of the display to enter the main settings screen.

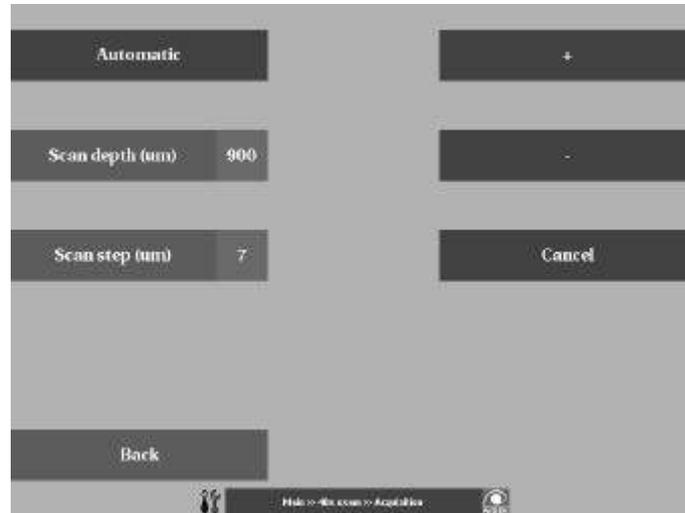


A description of the different options accessible through the main settings screen follows.



- Acquisition: press this button to enter in the *40x Acquisition settings screen* (see below).
- Auto Alignment: press this button to enter the *40x Auto Alignment settings screen* (see below)
- Audio Feedback: press this button and then the +/- buttons to toggle OFF / ON the Audio Feedback functionality. Default setting is ON.
- Auto Landing: press this button and then the +/- buttons to toggle OFF/ON the Auto Landing functionality. Default setting is ON.

40x exam acquisition settings screen



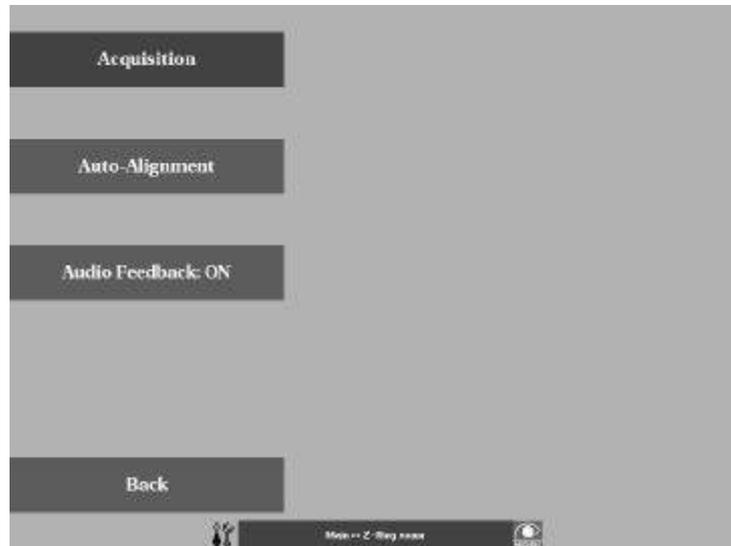
- Automatic / Semi-automatic: press this button and then the +/- buttons to toggle the scan mode
- Scan depth (semi-auto mode only): press this button and then the +/- buttons to set the total scan depth of the semi-auto scan.
- Scan Step: press this button and then the +/- buttons to set the distance between adjacent recorded images

40x exam Auto Alignment settings screen



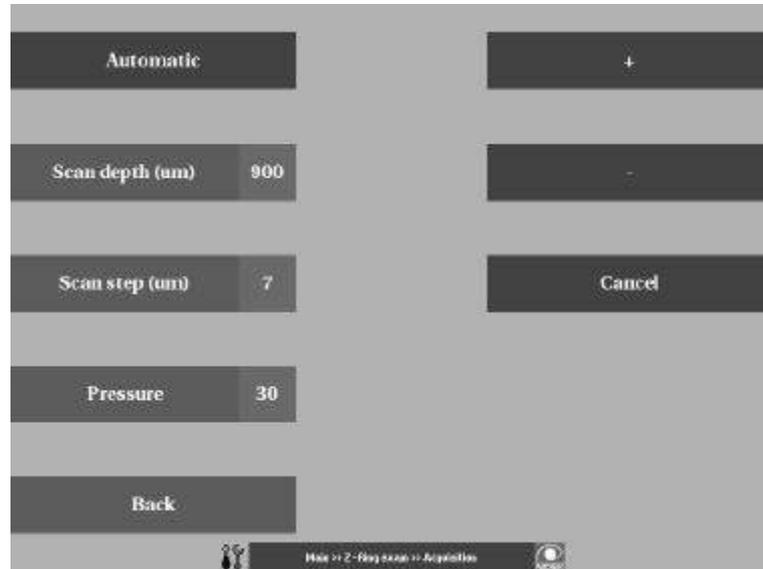
- Status: press this button and then the +/- buttons to enable or disable Auto Alignment functionality
- Mode: press this button and then the +/- buttons to set the Auto Alignment type (NORMAL /SCREENING).
 - NORMAL: after 30 s, if optimum alignment has not been reached, the algorithm stops, a message displays "Auto Alignment failed" and the device waits for the operator's intervention (either manual alignment or new start of Auto Alignment);
 - SCREENING : after 15 s if optimum alignment has not been reached, the algorithm accepts current alignment and starts scanning / recording anyway.

Z-Ring exam



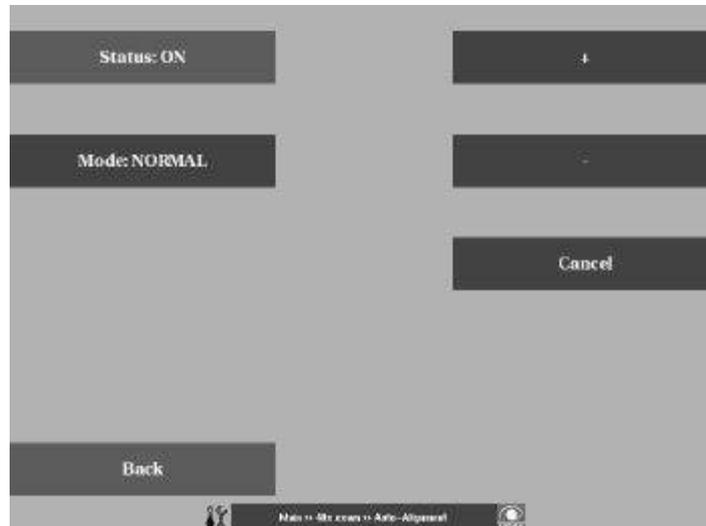
- Acquisition: press this button to enter in the Z-Ring Acquisition settings screen
- Auto Alignment: press this button to enter the Z-Ring Auto Alignment settings screen
- Audio Feedback: press this button and then the +/- buttons to turn OFF /ON the Audio Feedback functionality.

Z-Ring exam acquisition settings screen



- Automatic / Semi-automatic: press this button and then the +/- buttons to toggle the scan mode.
- Scan depth (semi-auto only): press this button and then the +/- buttons to set the total scan depth of the semi-auto examination scanning.
- Scan Step: press this button and then the +/- buttons to set the distance between adjacent recorded images.
- Pressure: press this button and then the +/- buttons to set the Z-Ring exam pressure on the eye. Range is from 10% to 65% of the maximum pressure, when the safety plate is completely retracted.

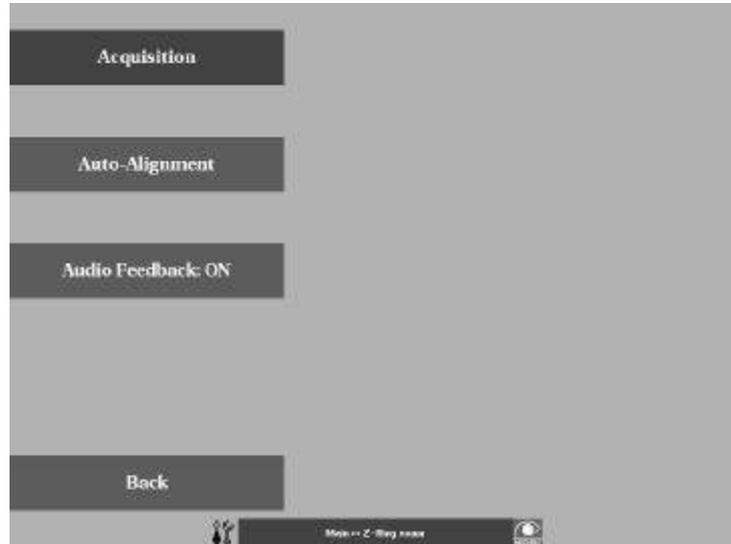
Z-Ring exam Auto Alignment settings screen



- Status: press this button and then the +/- buttons to enable or disable Auto-Alignment functionality
- Mode: press this button and then the +/- buttons to set the Auto-Alignment type (NORMAL /SCREENING).
 - NORMAL: after 30 s, if optimum alignment has not been reached, the algorithm stops, a message displays "Auto Alignment failed" and the device waits for the operator's intervention (either manual alignment or new start of Auto Alignment);
 - SCREENING : after 15 s if optimum alignment has not been reached, the algorithm accepts current alignment and starts scanning / recording anyway.

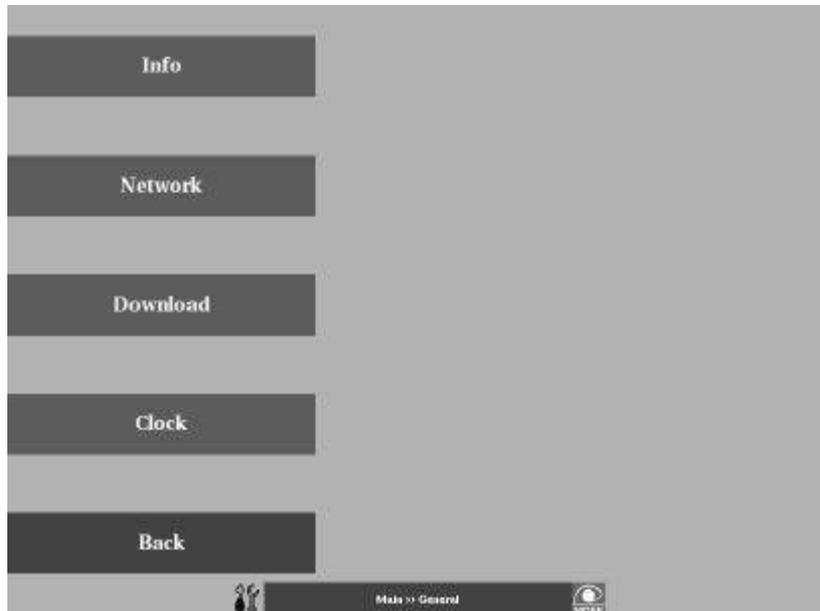
Such Screening mode is designed for a situation where, due to different reasons (non cooperative patient, specific pathologies, etc..), the optimal alignment is hard to achieve. When the operator is not experienced enough to decide when to accept a partial alignment and press the joystick black button, the screening mode is particularly helpful, in that it eliminates any decision by the operator and records an exam in any case, even if not perfectly aligned.

20x, no contact, exam



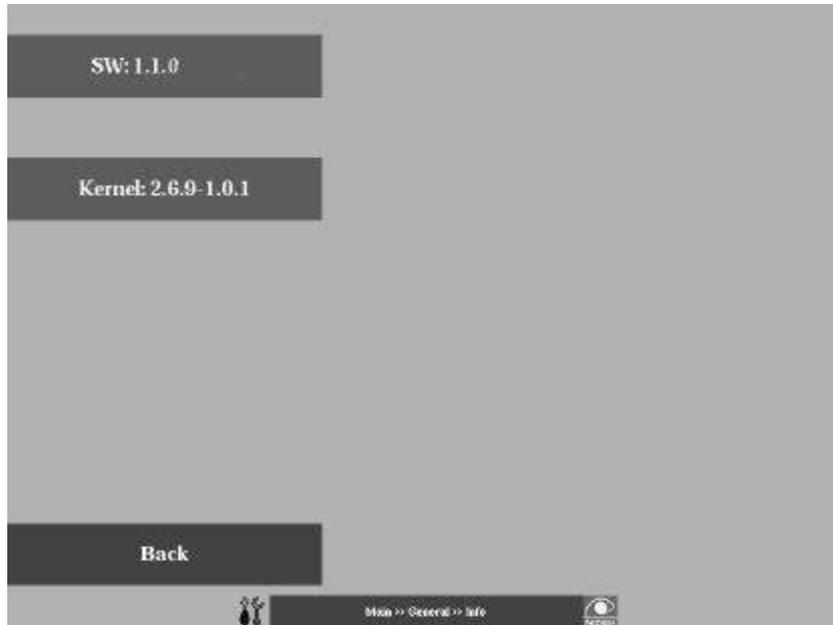
- Acquisition: press this button to enter in the 20x Acquisition settings screen
- Auto Alignment: press this button to enter the 20x Auto Alignment settings screen
- Audio Feedback: press this button and then the +/- buttons to turn OFF /ON the Audio Feedback functionality.

General



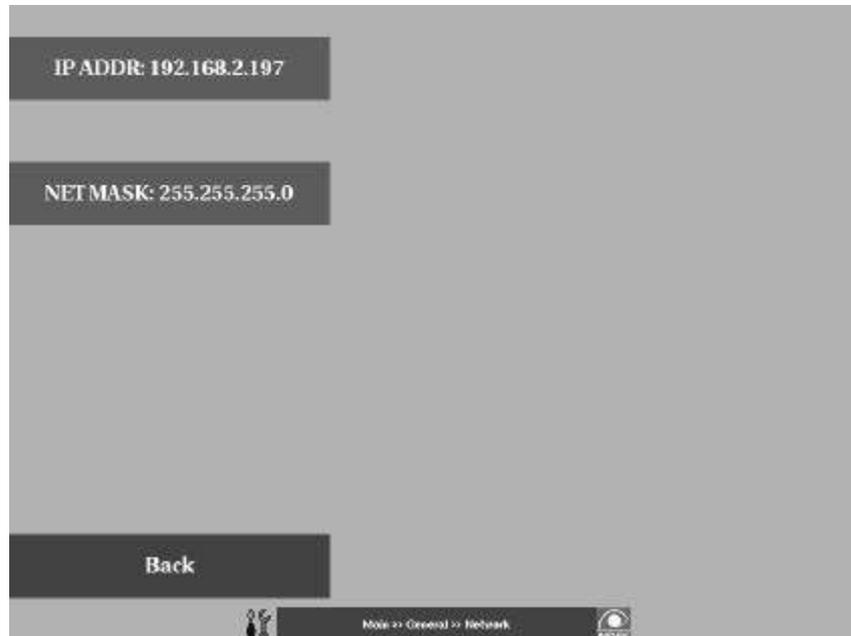
- Info: press this button to enter the Software information screen
- Network : press this button to enter the Network information screen
- Download: press this button to enter Download settings screen
- Clock: press this button to enter the Clock settings screen

Software information screen



- SW : this label shows the CS4 internal software version
- Kernel: this label shows the CS4 internal operative system version

Network information screen



- IP ADDR: (only for NAVIS external PC connection) this label shows the address of the CS4 network card. This same address should be used in the NAVIS CS4 Import Module settings.
- NET MASK: (only for NAVIS external PC connection) this label shows the network mask of the CS4 network card. This same mask should be used in the NAVIS CS4 Import Module settings

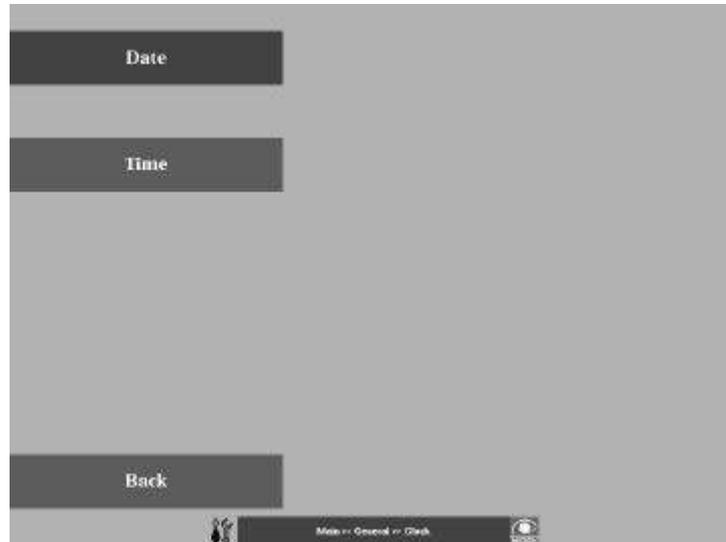
To change the CS4 network card configuration (static or dynamic IP, static IP address number, mask....) please contact Nidek Technologies' authorized personnel.

Download setting screen



- Min Intensity: (only for NAVIS external PC connection) press this button and then the +/- buttons to set the “black level”, which is the minimum intensity under which an image is discarded because it is too dark. Default is 0.
- Max Intensity: (only for NAVIS external PC connection) press this button and then the +/- buttons to set the “white level”, which is the maximum intensity above which an image is discarded because saturated. Default is 255.

Clock settings screen



- Date: Press this button to enter the screen for date setting
- Time: Press this button to enter the screen for time setting

6. Connection to NAVIS

The CS4 standalone unit cannot permanently store more than one examination.

To store captured examinations and to access other advanced analysis functions, it is necessary to transfer the acquired data to a NAVIS PC by means of a network connection using the CS4 NAVIS application. 

6.1. Starting the CS4 application

To start the CS4 NAVIS application, run NAVIS, login by selecting a user from the user list and double-click the CS4 icon.

The patient list appears, waiting for operator input: it is now possible to either create a new patient or select an existing one. Finally press the *Select* button.

The CS4 NAVIS application starts and the *CS4 Import Module* appears, waiting for operator input:

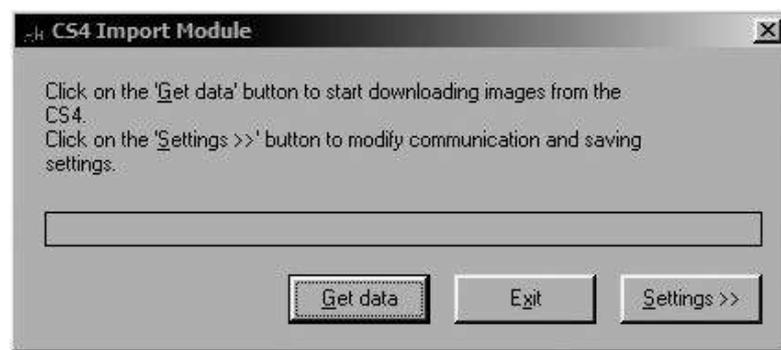


Figure 17 – Import module

6.2. Transferring the exam

The first time an exam transfer is performed, it might be necessary to verify if the CS4 IP address is correctly set on the settings panel (see [Advanced Import module](#)).

To start downloading an exam from the connected CS4 unit, check that the CS4 unit is in the *Exam Review state*: download is only possible when this condition is accomplished. 

Press the *Get data* button.

When the download is complete (progress bar disappears), the Import module will automatically close and the images will be visible in the CS4 NAVIS application main screen.

Warning.

If there is a problem with eye identification, after the download option, NAVIS sends the message: "WARNING: THE EYE INFO IS PARTIALLY OR COMPLETELY MISSING"

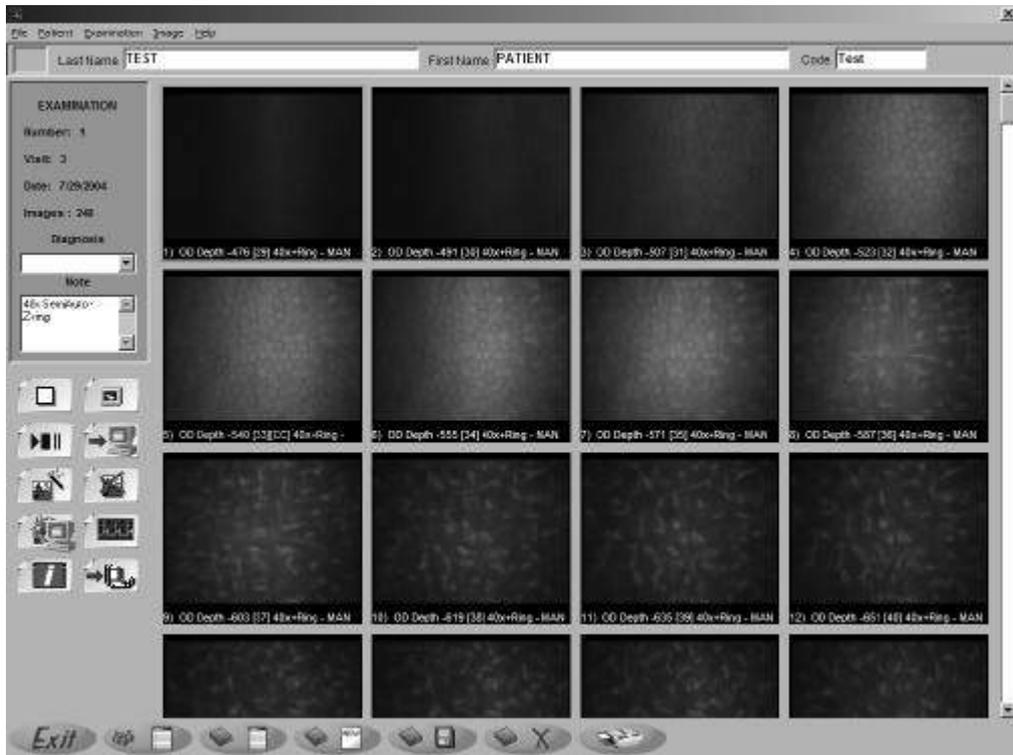


Figure 18 – Downloaded exam displayed in the CS4 NAVIS application main screen

It is possible to partially retrieve an exam by pressing the Cancel button while downloading: in such case the application will ask whether or not to save the downloaded images.



To download a new exam, press the *Patient list* button to select or create a new patient, then press the *Import* button to re-open the Import module and proceed as above.



Figure 19 – *Patient list* and *Import* buttons

6.3. Advanced Import module

This section explains how to modify the Import settings.

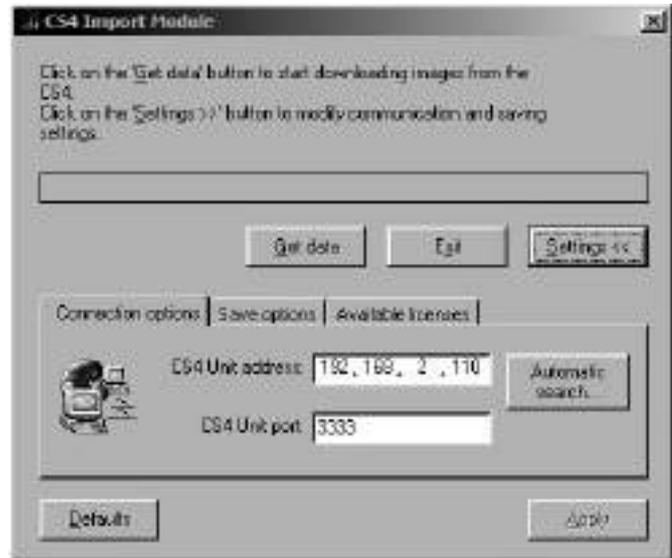
To access such advanced settings, press the *Settings >>* button located on the Import module.

Connection options

Allows checking and configuring the CS4 unit address (IP address).

The default address of any CS4 unit is 192.168.2.99.

The actual address of a specific CS4 unit can be checked in the CS4 embedded program settings (see 5.5).



Save options

This panel allows changing the format of imported images.

It is possible to save images in uncompressed format (bitmap) or compressed (jpeg low or high quality).

The default format is: Jpeg High Quality (recommended).



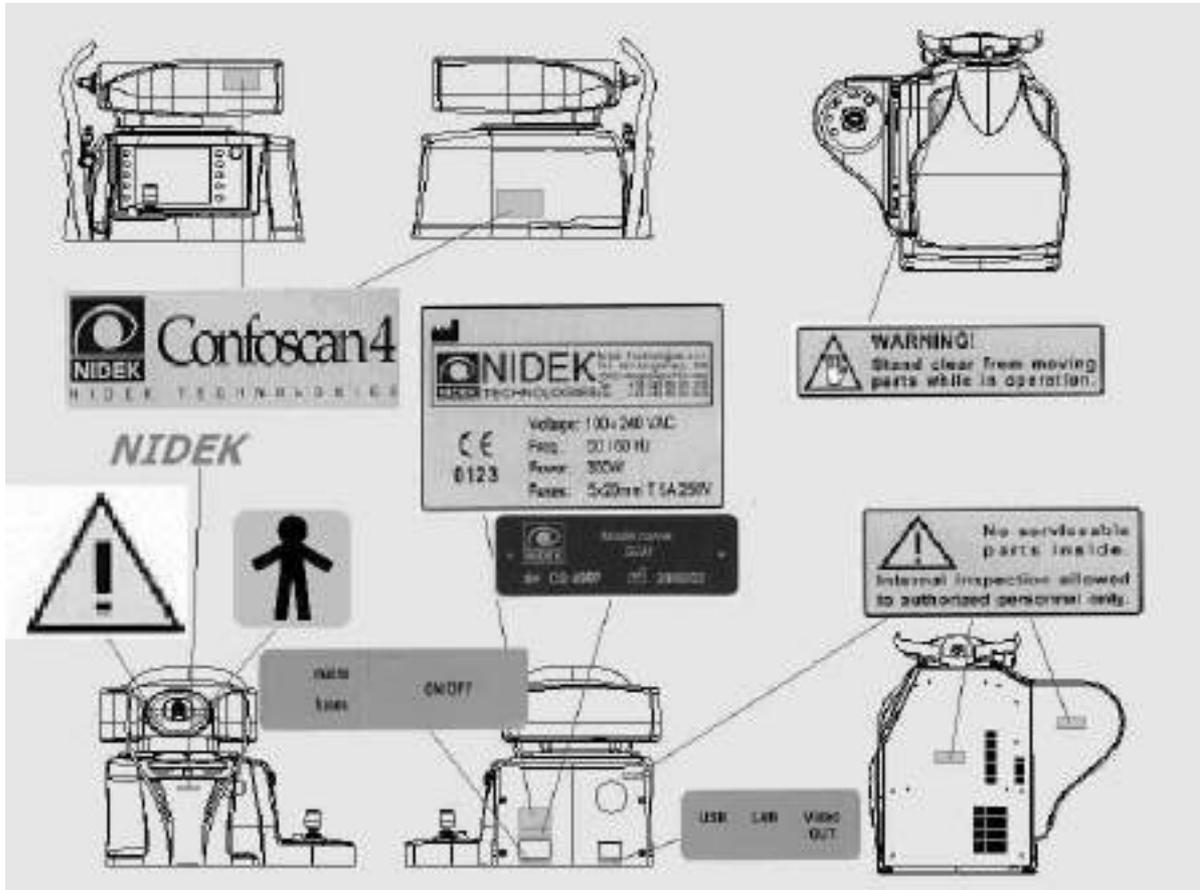
7. Technical Specifications²

Size	55 x 48 x 60 cm - Inch: 22" x 19" x 24"
Weight	32 kg - 70 lbs
Regulations	CE mark according to Medical Devices Directive 93/42/EEC; conformity to EN 60601-1, EN 60601-1-2, EN ISO 14971, EN ISO 15004, EN ISO 10993-1
Class and Type	Class I with a measuring function (according to Medical Device Directive 93/42/EEC) Isolation Class I, type B applied part (according to EN 60601-1)
IP classification	IPX0 (according to the degree of protection provided by the enclosure with respect to harmful ingress of particulate matter or water)
Power Supply	From 100 to 240 VAC; 50 / 60 Hz
Detachable power supply cord	1,5 mm ² - 100-240 VAC
Main Fuse	Type 5 x 20 mm, T (delayed) 5 Amperes (100-240 VAC) Compliance with: EN60127.2.III / VDE 0820 / CEI 32.6.2 / BS 4265 / SEMKO 104 / DIN 41661
Power Consumption	300 W
Lamp	Osram Xenophot HLX 64625 FCR 12V, 100W, GY6.35
External Conditions	Temperature: 10/40° C – 50/104° F Atmospheric Pressure: 700 hPa - 1060 hPa Relative Atmospheric Humidity: 30 % - 85 % (not condensing)
Refractive Index of gel (Visidic)	1.34

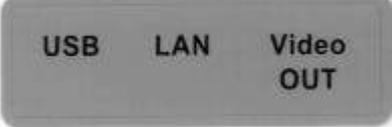
Feature	40x mode	20x mode
Image acquisition speed	25 fps	25 fps
Image size	768 x 576 pixel	384 x 576 pixel
Inspected field	460 x 345 µm	460 x 690 µm
Magnification (on 15" display @ 1024x768, 1:1 zoom)	500x	250x
Lateral resolution	0.6 µm/pix	1.2 µm/pix
Number of images	Up to 350	Up to 200
Programmable depth of scan	Yes	Yes
Minimum axial step	1,5 µm	1,5 µm
Working distance	1.98 mm	12 mm
Instrumental accuracy of pachymetry (with Z-Ring)	± 5 µm	-

² Specifications are subject to change without notice for improvements

8. Labelling



	<p>Localized in the rear, near the power switch.</p>
	<p>Two labels on the lateral sides.</p>

 <p>WARNING! Stand clear from moving parts while in operation.</p>	<p>On the operator side.</p>
 <p>No serviceable parts inside. Internal inspection allowed to authorized personnel only.</p>	<p>On the lateral side and under the base.</p>
	<p>On the rear, near the power switch.</p>
	<p>Near the lens.</p> <hr/> <p>It means: Attention, consult ACCOMPANYING DOCUMENTS.</p>
	<p>On the rear, near the power switch.</p>
	<p>On the rear, near the cables.</p>
	<p>Near the lens.</p> <hr/> <p>It means: TYPE B APPLIED PART.</p>
	<p>On the patient side.</p>
	<p>Separate collection for WEEE</p>

9. **Cleaning**

The system should be cleaned regularly.

The use of harsh cleaning agents can damage the device, especially the objective lenses, and must not be used.

The front lens should be cleaned only with alcohol.

Warning. After each examination, the chin rest and forehead rest shall be cleaned using ethanol solution or other similar cleaning agents.

For the rest of the system use normal household cleaners intended for synthetic surfaces. Make sure that the electronic parts of the instrument do not come into contact with water.

10. **Transport and storage.**

Range of environmental conditions for transport and storage of equipment.

Ambient temperature range of 0 °C to 50 °C.

Ambient relative humidity of 10% to 85%.

Atmospheric pressure range of 70 kPa to 106 kPa.

11. Customer Satisfaction assessment

(to be filled at the end of the installation)

	Not Satisfied at all	Partially satisfied	Satisfied	Very satisfied	Excellent
1. Commercial support and knowledge of the salesman during the deal.					
2. Relationship between price and product/service we offer.					
3. Quality of technical description during the deal.					
4. Quality of documentation, operator's manual, brochures, technical descriptions.					
6. The effectiveness of installation.					
7. Overall satisfaction level with our services.					

12. Report on the initial use of ConfoScan4 and introduction to system operation

(Client's copy)

ConfoScan 4 Serial Number _____

The system was set up by a specially trained and Nidek Technologies' authorized person.

The installation began on _____ at _____ until _____.

The unit was in perfect working order.

The operator-in-training's attention has been drawn to the importance of heeding the precautions and the specific precautions regarding light emission as well as the contents of the Operating Instructions.

A visual examination of the cornea should last no longer than two minutes.

The operator-in-training was informed about the safety mechanisms such as the contact with the forehead rest as well as the floating objective lens mounted on springs. It has been made clear that direct contact with the cornea itself needs to be treated with maximum care.

The operator has been given a detailed explanation on how to operate the unit.

Name, Date and Signature of the Nidek Technologies' authorized person:

Name, Date and Signature of the person(s) as well as details of the institution, where the introduction of the instrument has been carried out:

Report on the initial use of ConfoScan4 and introduction to system operation

(Nidek Technologies' authorized personnel's copy)

ConfoScan 4 Serial Number _____

The system was set up by a specially trained and Nidek Technologies' authorized person.

The installation began on _____ at _____ until _____.

The unit was in perfect working order.

The operator-in-training's attention has been drawn to the importance of heeding the precautions and the specific precautions regarding light emission as well as the contents of the Operating Instructions.

A visual examination of the cornea should last no longer than two minutes.

The operator-in-training was informed about the safety mechanisms such as the contact with the forehead rest as well as the floating objective lens mounted on springs. It has been made clear that direct contact with the cornea itself needs to be treated with maximum care.

The operator has been given a detailed explanation on how to operate the unit.

Name, Date and Signature of the Nidek Technologies' authorized person:

Name, Date and Signature of the person(s) as well as details of the institution, where the introduction of the instrument has been carried out:

13. Regular Maintenance

13.1. Equipment operation

The customer is invited to request to the NT Authorized Service Center one periodic check on the equipment every year.

During the periodic check, the technician of the NT Authorized Service Center will perform accurate checking of the following items:

- the cooling fans,
- the software boot of the equipment,
- cleaning of lenses,
- the setting of the covering,
- the eye system protection mechanisms,
- the labeling,
- the network interface,
- the test of all the functions, with TRIAL EYE Tool.

At the end the technician will fill a report of the intervention.

13.2. Safety

In order to prevent electrical accidents, the customer is invited to request every two years to the NT Authorized Service Center or to the clinical engineering service the following checks:

- continuity of protective grounding test,
- leakage current test for ground, enclosure and patient, according to EN 60601-1.

14. Installation and Initial Use of equipment.

Without exception, only a Nidek Technologies' authorized person is allowed to assist in the initial installation and first time use of the system.

It is advised to leave the equipment on the installation place the necessary time for the acclimatization.

15. Disposal

The system consists of materials like plastics, varnishes, aluminum, and electronic components: to dispose of the system or accessories, comply with local ordinances and regulations regarding disposal or recycling.

15.1. Separate collection for WEEE

The European Directive 2002/96/EC, amended by the European Directive 2003/108/EC in force the 13th august 2005, establishes the separate collection for Waste of Electrical and Electronic Equipment (WEEE).

The users of Electric and Electronic Equipment (EEE) have not to dispose of WEEE as unsorted municipal waste, they have to collect such WEEE separately.

The available return and collection system is defined by the local public administration, or in alternative an authorized company can recycle the WEEE.

Please refer to public administration about the separate collection, if this information is not available, contact the manufacturer of the equipment.

The users have a fundamental role to contributing to reuse, recycling and recovery of WEEE.

The potentially dangerous substances contained in the WEEE, can pollute the environment and produce harmful effects to the human health.

Below, there are a few indications of specific dangers of some substances, which may leach in the environment and in the water system.

Lead: damages the nervous system of humans, it affects the endocrine system, the cardiovascular system and kidneys. It accumulates and is very toxic for animals, plants and micro-organisms.

Cadmium: accumulates with a half-life of 30 years and can damage the kidneys and cause cancer.

Mercury: is easily accumulated in organisms and concentrates through the food chain. It has chronic effects and can cause brain damage.

Chromium (Hexavalent): easily absorbed into cells with toxic effects. The results can be allergic reactions, asthma and it is considered to be genotoxic (damages the DNA). Especially dangerous when incinerated.

Brominated Flame Retardants: widely used to reduce flammability (eg cables, connectors and plastic cases).

The Electronic Electrical Equipment shall be marked with the symbol of a crossed-out wheeled bin, as shown below.



Separate collection for Waste of Electric and Electronic Equipment (WEEE).

16. Servicing and Support Information

A Nidek Technologies' authorized person should regularly service the system. It is advisable to have the first servicing performed 6 months after the instrument has been installed, with further servicing every 6 to 12 months.

A proper servicing agreement must be signed with Nidek Technologies or its authorized service company.

For any request or question, please contact us at:

Nidek Technologies Srl

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Email: nidektechnologies@nidektechnologies.it

Web: www.nidektechnologies.it