maia

Macular Integrity Assessment

OPERATING MANUAL

MANUAL INFORMATION

Date of release:	June 12th, 2019
Revision number:	35_EN
Reference software version:	v2.6
Manufacturer:	CenterVue S.p.A. Via San Marco 9/H, 35129 Padova – ITALY Tel. +39 049 501 8399 Fax +39 049 501 8398 centervue

SUMMARY

1. INTRODUCTION

The Macular Integrity Assessment (MAIA) is intended for use as a diagnostic device to aid in the detection and management of diseases affecting the macula, including, but not limited to, macular degenerations. MAIA provides measurements of threshold sensitivity, fixation site and fixation stability as well as confocal images of the retina.

At this purpose the primary function of MAIA is to provide:

- images of the central retina over a field of view of 36°,
- a quantitative evaluation of macular function based on threshold sensitivity,
- a quantitative evaluation of macular function based on fixation analysis,

allowing the reader for the detection and follow-up of any degenerative process affecting the macula.

Threshold sensitivity and fixation measurements are compared with normative data to provide an indication of presence of functional alterations (results “within normal limits” / “suspect” / “outside normal limits”).

The main clinical outcome to be evaluated is any of a series of different macular degenerations with particular interest in age-related macular degeneration (AMD) as well as amblyopia and any other condition which reduces macular sensitivity.

The clinical interpretation of MAIA results is restricted to licensed eye care practitioners.
The process of making a diagnosis using MAIA is the responsibility of the eye care practitioner.

A device specific training is required for any operator to become able to use the system.

2. SYSTEM

MAIA - 2013 Edition (ATMARME002)

Fig. 1 – MAIA side view

The system is made of the following main components: optical head, touch-screen display, instrument body, push-button, chin-rest, forehead-rest.

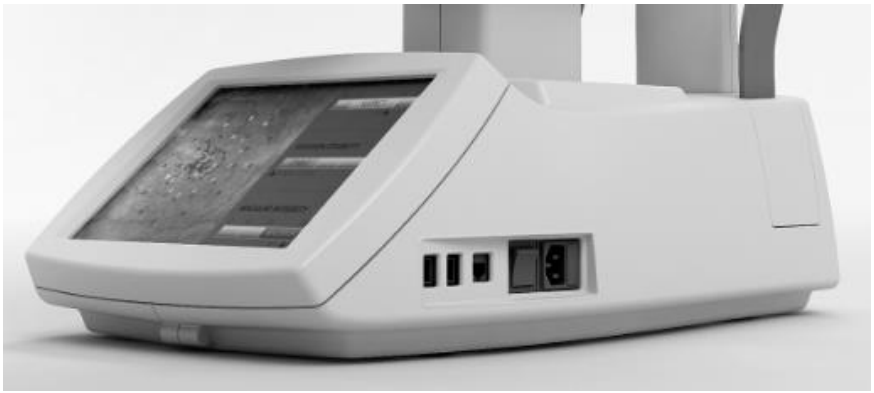


Fig. 2 – USB and Ethernet connectors, power inlet and main switch

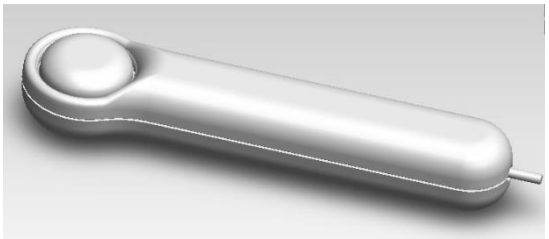


Fig. 3 – Push-button = applied part

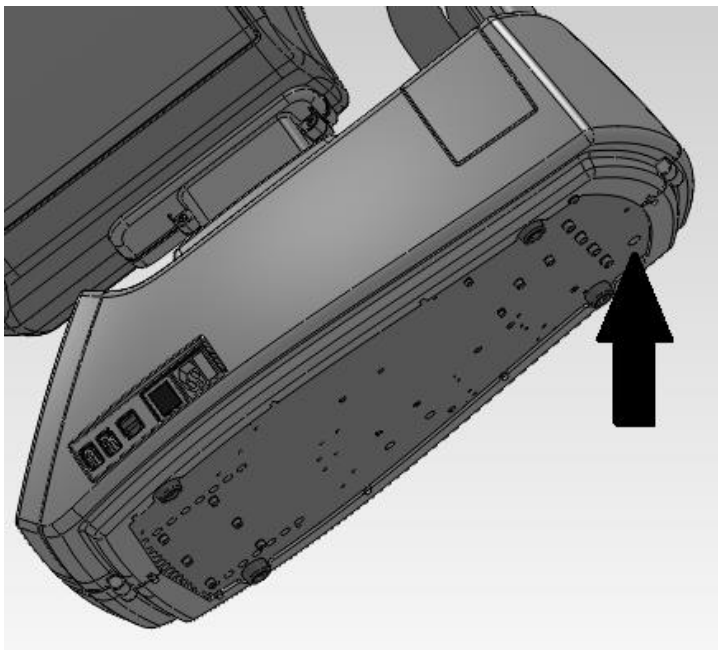


Fig. 4- Push-button plug

MAIA 2013 Edition is supplied with:

- power cord
- push-button
- lens cap
- spare fuses
- dust cover
- forehead-rest silicone pad
- Eye Occluder
- this operating manual

MAIA - 2009 Edition (ADMITME001)

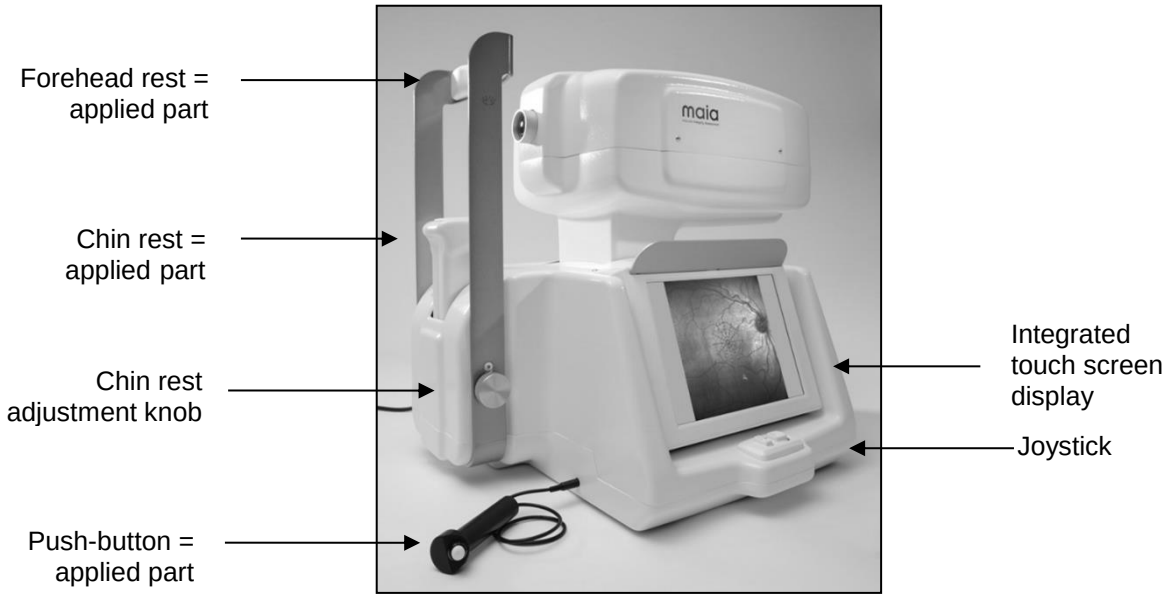


Fig. 5 – MAIA front view

The system is made of the following main components: optical head, touch-screen display, joystick, instrument body, push-button, chin-rest, forehead-rest.

Fig. 6 – USB and Ethernet connectors (left) / power inlet and main switch (right)

MAIA 2009 Edition is supplied with:

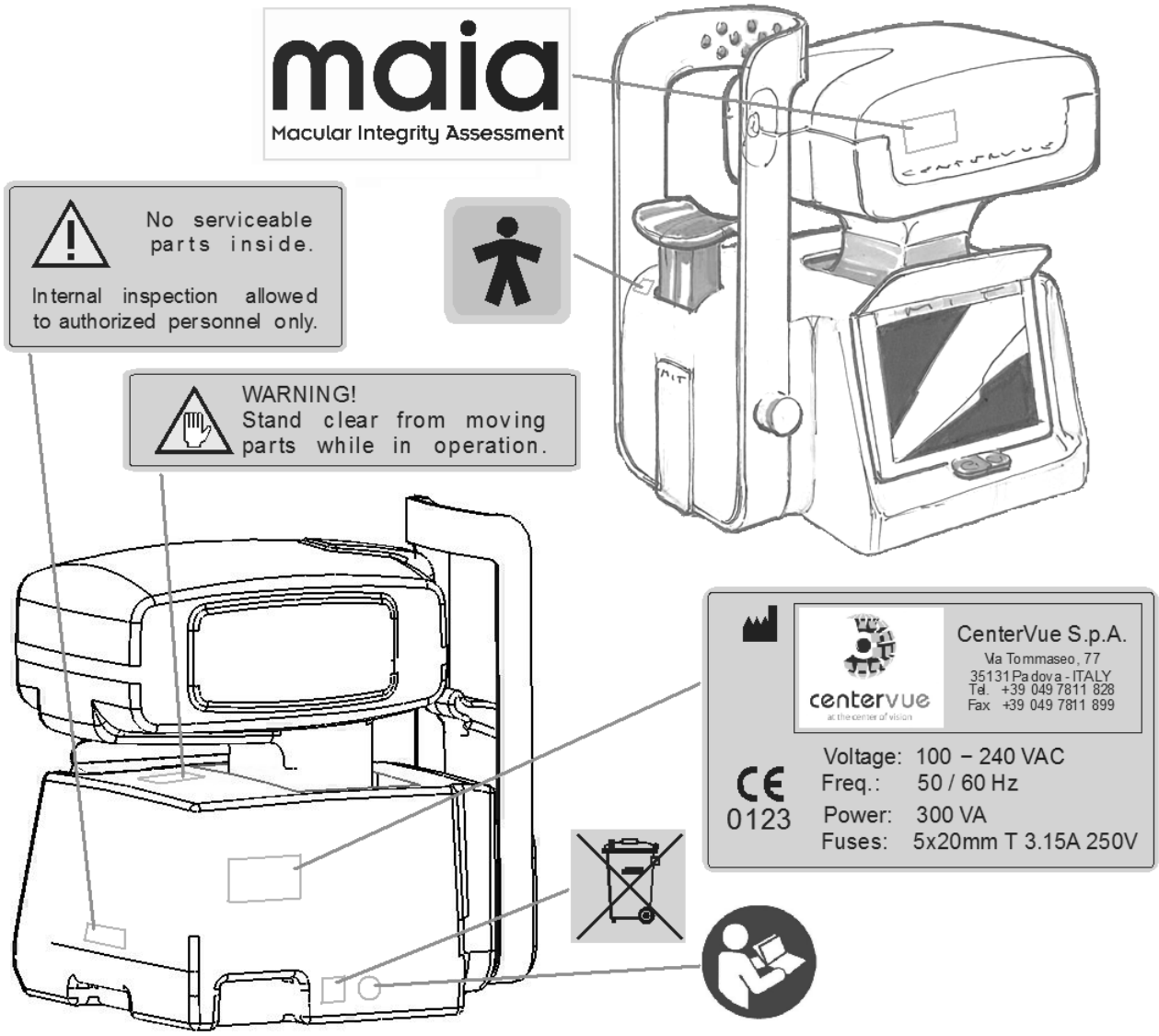
- power cord
- push-button
- lens cap
- spare fuses
- USB keyboard
- dust cover
- this operating manual

3. LABELING

MAIA - 2013 Edition

Class I laser product conforming with IEC 60825-1.

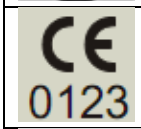
MAIA - 2009 Edition



Class I laser product conforming with IEC 60825-1.

4. SYMBOLS

Symbols adopted in this manual.

Symbol	Explanation
	Manufacturer Data
	Manufacturing Date (year month of production)
	Electronic and electric devices must be recycled.
	Refer to Instruction Manual
	CE mark: the device complies with the essential requirements of the European Medical Devices Directive 93/42/EC
	Warning: stand clear from moving parts
	Type B Applied Part
	Generic Warning
	Important information

5. WARNINGS AND PRECAUTIONS

The following precautions are particularly relevant to the device safety:

- CAUTION – Federal law restricts this device to sale by or on the order of a physician.
- The clinical interpretation of MAIA results is restricted to licensed eye care practitioners.
- A device specific training is required for any operator to become able to use the system.
- Do not open the device: this could lead to electric shocks or damage to the system.
- Do not use the instrument in the event that the cover or other parts of the device have been removed.
- Only technicians authorized by CenterVue may service MAIA. CenterVue cannot be held responsible for system safety should MAIA be opened, repairs carried out, third parties software be installed, or parts be replaced by un authorized persons.
- Do not expose the device to water: this could lead to fire or electric shock.
- Stand clear from moving parts during operation.
- All parts in contact with a patient's skin need to be disinfected after use (see par. 14).
- The instrument is supplied with an earth ground by means of a protection conductor contained inside the power supply cable. To replace such cable, only use a cable provided by CenterVue with current rating of 10A and conductor size of 1mm^2. Before turning on the system, make sure the power supply socket is correctly grounded to avoid the risk of electric shock.
- The room where MAIA is operated must respect local or national safety standards relative to medical use of a room or area, such as IEC or ISO safety standards.
- MAIA must NOT be used in an oxygen rich environment or in presence of flammable anesthetics.

The following precautions are particularly relevant to prevent use errors:

- Before performing any exam check that the push-button is functional by checking that the “Button” indicator on screen turns orange when the button is clicked: If the push-button is not functional no patient response will be detected and wrong threshold values will be recorded.
- Before performing any exam check that the stimulus is projected at the center of the central fixation target. The stimulus is automatically enabled when entering the exam interface (pressing “New Fast/Expert Exam”). If the stimulus is not centered the exam outcome will be unreliable.
- The device must be placed in a room which is not exposed to adverse chemical-physical conditions, such as the presence of sulfur, salt, dust, direct sunlight, lack of ventilation, high humidity, sudden temperature drops or peaks. The safety and/or effectiveness of the instrument cannot be guaranteed if these conditions are not fulfilled.
- MAIA needs to be operated under the following environmental conditions:
  Temperature: 10°C - 40°C (50°F – 104°F) / Humidity (max): 90% not condensing
- MAIA needs to be stored under the following environmental conditions:
  Temperature: -10°C – 60°C (14°F - 140°F) / Humidity (max): 90% not condensing
- **MAIA outcomes are not sufficient to identify a treatment option: further diagnostic assessments such as dilated fundus photography, optical coherence tomography, etc... are needed in case MAIA results indicate presence of a functional alteration. During its clinical evaluation MAIA showed specificity and sensitivity above 90% to early and intermediate age-related macular degeneration, indicating that false positives and false negatives are possible.**
- Do not leave the front lens uncovered while the system is not in use.

The MAIA display is a **touch screen panel**: wherever this manual says “click on...” it means “point the finger on the display on...”

This updated version of the Operating Manual mainly refers to MAIA – 2013 Edition. Some of the features and components are available on only one of the two models and are clearly indicated throughout the manual.
Due to the different resolution of the monitor of MAIA – 2009 Edition, some screenshots might be slightly different than what can be seen (in terms of presence and position of some buttons). However, if the related function is available in the 2009 Edition, it will be easy to identify them.

6. PREPARING MAIA

We recommend to read carefully and thoroughly par. 5 - WARNINGS AND PRECAUTIONS before proceeding with first use.

To make MAIA functional you need to:

- extract the system from its box;
- place it on a suitable electrical table[1] (see dimensions at par. 17);
- connect the power cord provided with the unit to the power inlet (see Fig. 2 or Fig. 6);
- connect the push-button to the push-button connector (see Fig. 4 or Fig. 5): the push-button is used by examined subjects during the test, as explained at par. 7, item 8;
- optionally connect the 3D joystick to any of the USB ports (see Fig. 2 or Fig. 6): the joystick can be used to align the patient as a complement to the touch screen (see 8.4.5);
- optionally install the Eye Occluder (see Par. 6.1) ***[available for 2013 Edition only]***;
- optionally connect a compatible printer to any of the USB ports (see Fig. 2 or Fig. 6).

For the list of compatible printers please contact the manufacturer or visit www.centervue.com

- attach the silicone forehead-rest (included in the tool box) on the head-rest frame as shown in the pictures below (Fig. 7 and Fig. 8) ***[available for 2013 Edition only]***;

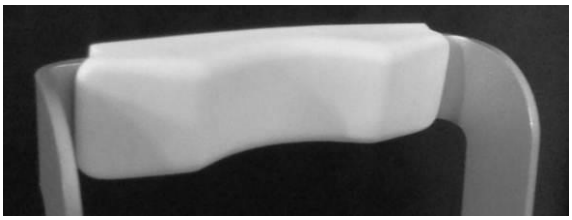


Fig. 7 – Forehead rest patient side

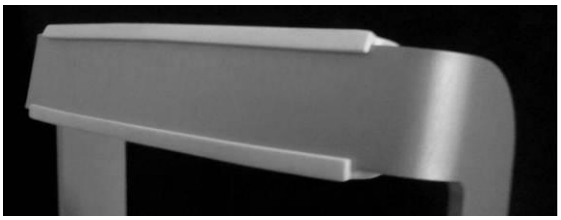


Fig. 8 – Forehead rest rear side

The room where MAIA is operated shall remain in semi-darkness during the test, as direct light sources hitting the front lens or a patient's eye would affect the result of the exam.

6.1 Mounting and installing the Eye Occluder

The Eye Occluder is a device ***[available for 2013 Edition only]*** to be installed on MAIA forehead rest. It is to be used to mask the contralateral eye during exam, as a non-invasive alternative to an eye-patch. Its use is advisable when the environment can affect the concentration of the patient during exam (e.g. other persons in the room), and the patient is not comfortable with keeping the contralateral eye closed.

[1] Not provided with MAIA

The black screen is to be fixed to the mobile arm by two automatic buttons: always attach and detach first the button on the short part of the arm, then the one on the long part (see Fig. 9 and Fig. 10).

Fig. 9 – Mobile arm and black screen

Fig. 10 – Eye Occluder mounted

To install it, simply remove the silicone rest from the forehead rest, and assemble it on the side opposite to the patient with the two provided screws and with the provided 2 mm Allen key, as depicted in Fig. 11.

Fig. 11 – Eye Occluder installation

The Eye Occluder shall be free to rotate from one eye to the other, passing over the top of the head-rest, so not to interfere with patient's nose (see Fig. 12).

Fig. 12 – Possible directions of rotation

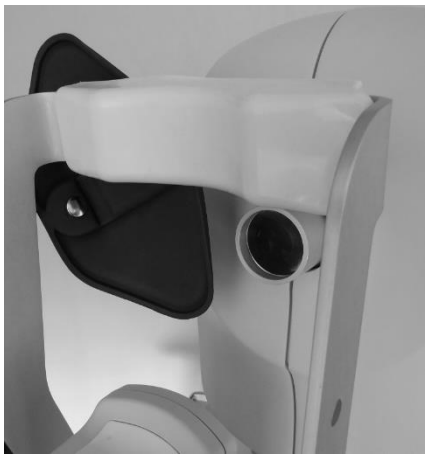


Fig. 13 – Eye Occluder position when examining the right eye

After the Eye Occluder is installed, the forehead rest can be installed over it. Always turn the Eye Occluder to the contralateral eye before starting the exam (see Fig. 13).

The Eye Occluder is designed not to touch the patient during the exam. Anyway, if needed, the black screen can be easily removed for disinfection. Multiple replacement screens can be ordered as needed.

7. PREPARING THE SUBJECT

This paragraph explains how to prepare a subject for the MAIA test. There are no restrictions as to the selection of the subjects undergoing MAIA testing, but since the test requires the subject to maintain concentration and follow the below instructions for several minutes, very young subjects (before primary school) as well as mentally diseased persons may to not be able to co-operate appropriately.

The subject should not wear spectacles while being examined, otherwise artifacts may appear in the retinal image.
MAIA does not compensate for a subject's astigmatism. Subjects with astigmatism within $\pm$ 4 diopters can be tested normally. Testing a subject with astigmatism outside the above range may result in inaccurate measurements.

MAIA compensates a subject's spherical refractive error in the range -15 to +10 diopters: testing a subject presenting a spherical error out of the above range may result in inaccurate measurements.

MAIA is a non-mydriatic device (minimum pupil diameter 2.5 mm), so there is no need to dilate the subject.
Patient contacting parts are indicated in Fig. 1 and Fig. 3.

Before the test inform the subject about the following:

1) *MAIA will test your ability to perceive light and look at a steady target;*
2) *the test is non-invasive, in particular the system will never touch your eye and you will only see some red and white light;*
3) *do not move and maintain concentration throughout the test;*
4) *the test will last approx. 5 minutes per eye;*
5) *find a comfortable position, keeping the chin and forehead firmly pressed against the rests;*
6) *look for a small red circle inside the instrument and always keep fixating at its center;*

Fig. 14 - fixation target as seen by the subject over the background

7) *during the test you can blink;*
8) *you will be given a push-button: press it with the thumb should you see, or believe you see, a whitish small spot appearing anywhere;*

Fig. 15 – spot as seen by the subject over the background

9) *It is absolutely normal that you do not see many of the spots, so do not worry.*

During the test:

- inform the subject when the test is about to start, following the initial alignment and setup;
- periodically inform the subject of the approximate time to completion;
- repeat recommendations 6) and 8);
- finally, inform the subject when the test is over.

NOTES FOR THE OPERATOR

No specific clinical knowledge is required to operate MAIA. However, a device specific training is required to use the system.

The operator needs to be acquainted with the following concepts:

- pupil: the central part of the external surface of the eye, through which light goes in;
- retina: the internal surface of the eye ball;
- macula: the central portion of the retina;
- fixation / fixating: the ability of a subject to stare at a specific point in space;
- optic disk: a specific portion of the retina characterized by a roughly circular shape and by outgoing / incoming vessels (see Fig. 16);
- sensitivity threshold: the minimum intensity of a light stimulus that is perceived by a subject as emerging from the background;
- alignment: the action of moving the top part of the system so that optics are aligned with a subject's pupil.

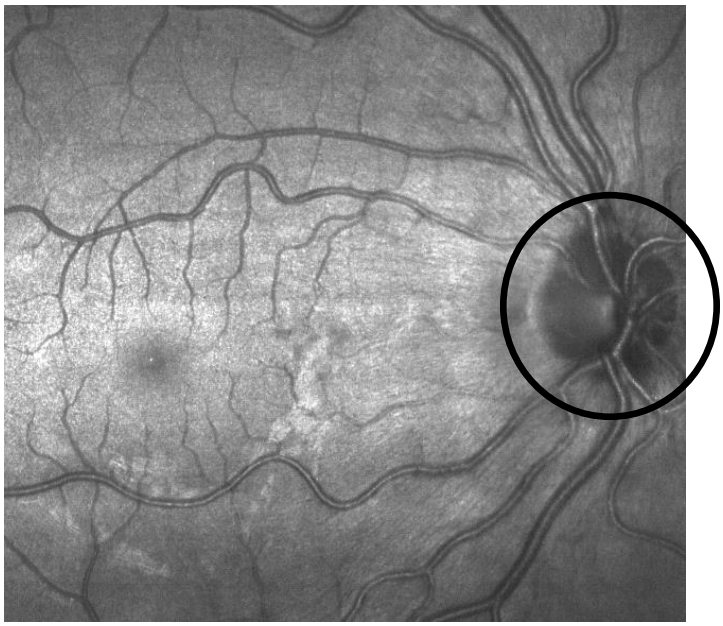


Fig. 16 - The optic disk (indicated by the black circle)

Acquaintance with the basic concepts of standard automated perimetry is helpful for an effective use of some of the features of the MAIA device and for the interpretation of its results.

8. PERFORMING THE EXAM

This paragraph explains how to operate MAIA to perform any of the available tests.
Turn the instrument on and wait until the software loads and the startup screen appears (see Fig. 17). The complete boot procedure takes approximately 1 minute.

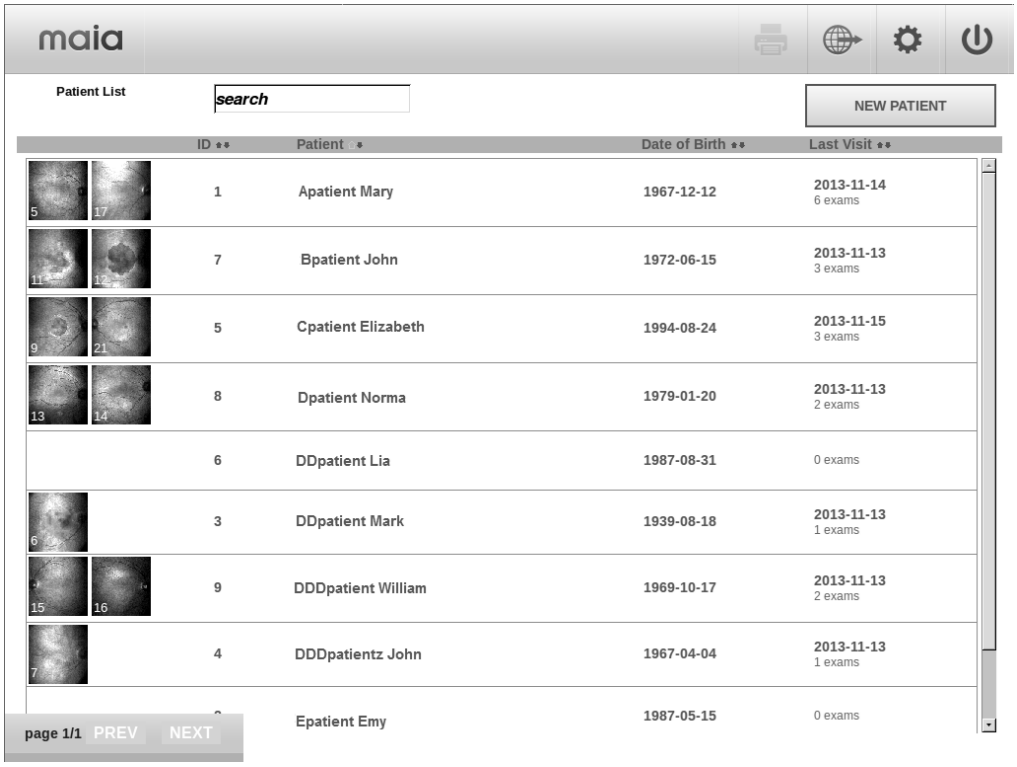


Fig. 17 – Startup screen showing patients list

8.1 Projection System checkup

MAIA Projection System is the internal assembly responsible of projecting the stimuli on the desired positions of the retina depending on the test grid and the information coming from the Retina Tracking System.
It is suggested to check at least daily (see Par. 19 – Maintenance) that the Projection System is correctly calibrated. At every boot, MAIA will request the operator to check the position of the white stimulus and confirm that it is correctly positioned.
The operator shall look into the front lens and check that the center of the white dot is located inside the external border of the fixation target (see Fig. 18 for a graphical representation), and press the button corresponding to the outcome of the check.

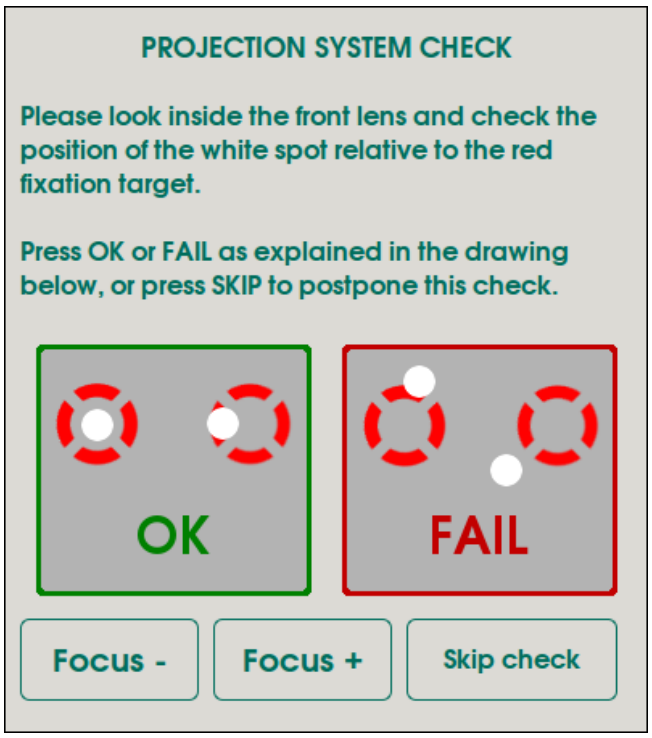


Fig. 18 – Projection System Check

If the operator reports that the stimulus is not within the accepted area, the device shall be verified by a CenterVue Authorized Service Representative because the Projection System might be out of calibration.
In this situation it is recommended not to perform any exam because its outcome would be unreliable or inaccurate, as indicated by high Fixation Losses indexes in most exams.

8.2 Adding a new patient

To add a new patient to the list, click on the **NEW PATIENT** button (see Fig. 17) and type the last name, the first name and the date of birth: these data are all mandatory, while the gender selection is optional (Fig. 19). A unique numerical ID is automatically assigned to any new patient.

The assigned patient ID is unique but may not be persistent: in particular, it will change when restoring a backup archive in APPEND mode (see 11.7).

The date format is the following throughout the software: YYYY-MM-DD.

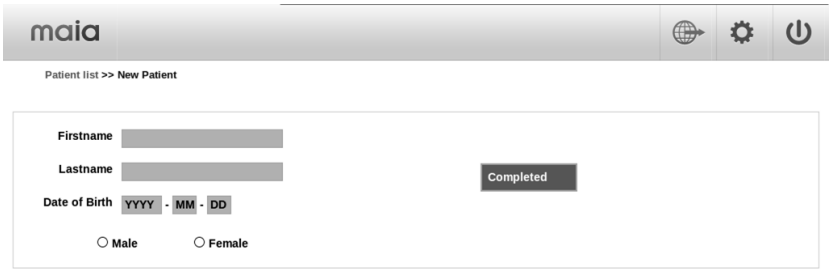


Fig. 19 – Patient demographics insertion screen

If a patient with the same Lastname, Firstname and Birthdate is already present in the system, a warning message will inform the operator and ask whether to open the existing patient or to create a duplicate (see Fig. 20).

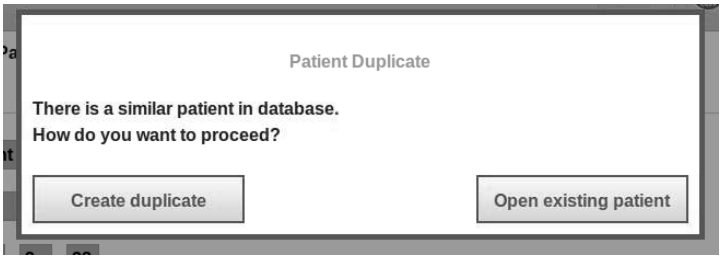


Fig. 20 – Duplicate patient warning

Once created, the new patient's record will open (see Fig. 21).

8.3 Selecting an existing patient

Click on any of the names appearing in the startup screen: the corresponding patient's record will open. The **Search** box can be used to search a specific patient by last or first name, while the arrows in the header row allow to sort the list by ID, last name, date of birth of date of last visit.

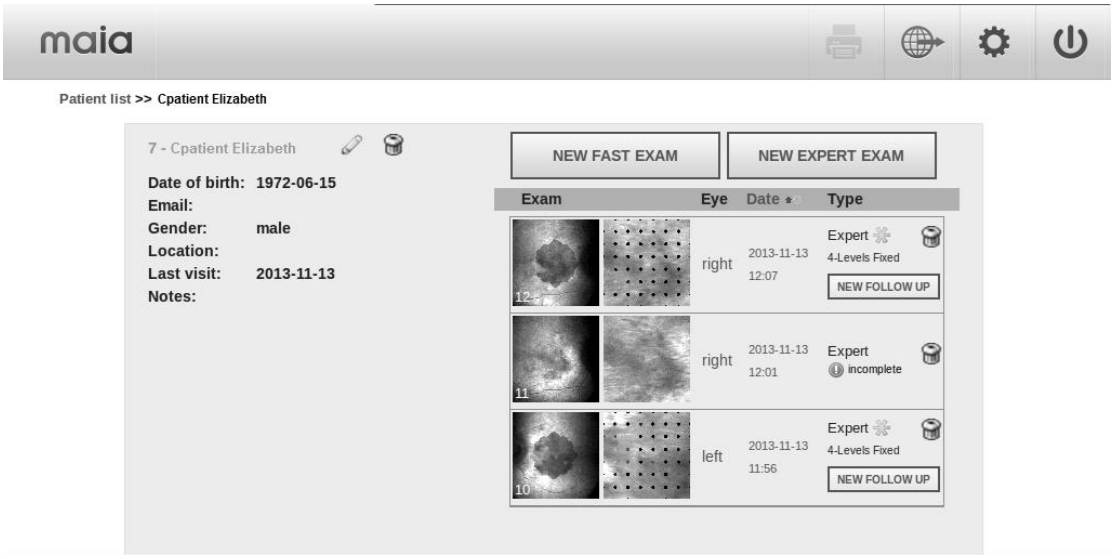


Fig. 21 – Patient Record screen

8.4 Performing the exam

In the patient record screen, the following options are available:

- **NEW FAST EXAM**: performs a quick assessment of the macular sensitivity and fixation stability, reporting whether the results are: within normal limits / suspect / outside normal limits. The fast test takes 2 to 3 minutes per eye and does not provide actual threshold values.

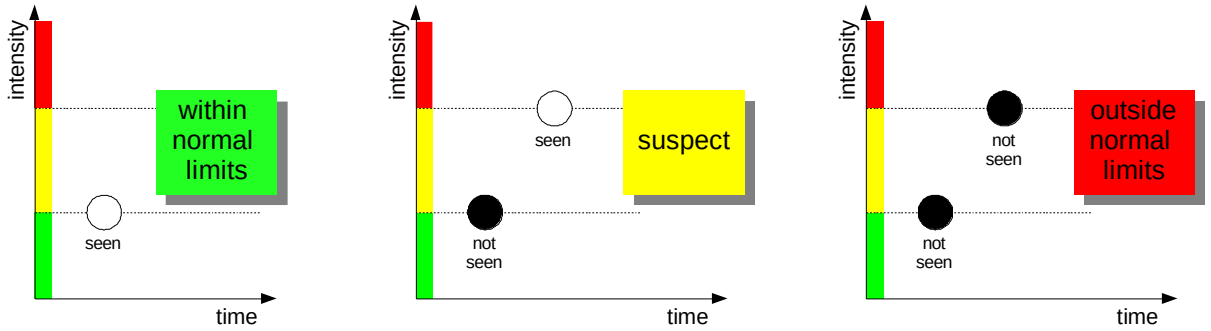


Fig. 22 – Fast test projection logic

- **NEW EXPERT EXAM**: performs a complete assessment, determining macular threshold sensitivity and fixation stability. Three threshold convergence strategies are available:
    a. **4-2** strategy (default): a full-threshold test used to examine retinal sensitivity in detail;
    b. **Four Levels Fixed** strategy (4LF): this strategy has been developed to reduce the examination time, as in supra-threshold perimetric tests. Only 4 intensities are tested (0 dB, 5 dB, 15 dB and 25 dB), hence this test does not measure the actual threshold but rather a supra-threshold response consisting of one of the following options: “not seen at 0 dB”, “seen at 0 dB”, "seen at 5 dB", "seen at 15 dB", "seen at 25 dB"; this strategy can be used on patients presenting significantly reduced thresholds as compared with reference values.
    c. **Scotoma Finder** strategy: this strategy has been developed to significantly reduce the examination time too, as in supra-threshold perimetric tests. Only one intensity is tested (0 dB), hence this test does not measure the actual threshold but rather a supra-threshold response consisting of one of the two following options: “seen at 0 dB”, “not seen at 0 dB”. This strategy can be used on patients presenting significantly reduced thresholds as compared with reference values, including areas of absolute scotoma (i.e. unable to perceive the 0 dB stimulus).
    d. **Fixation Only** strategy: this strategy allows to collect only the fixation data measured by the retinal tracking, without projecting any stimulus. The duration of the exam can be set at the beginning, from 10 sec. to 5 min., with 10 sec. steps. This strategy allows to perform analysis on the fixation skills of the patient.

  The exam reports whether fixation stability overall results are within normal limits / suspect / outside normal limits.
  If 4-2 strategy is applied, the exam also reports whether macular threshold sensitivity overall results are within normal limits / suspect / outside normal limits. The ***4-2*** expert test takes 4 to 7 minutes per eye, while the ***4-Levels Fixed*** test or the ***Scotoma Finder*** test take about 1 to 4 minutes per eye.

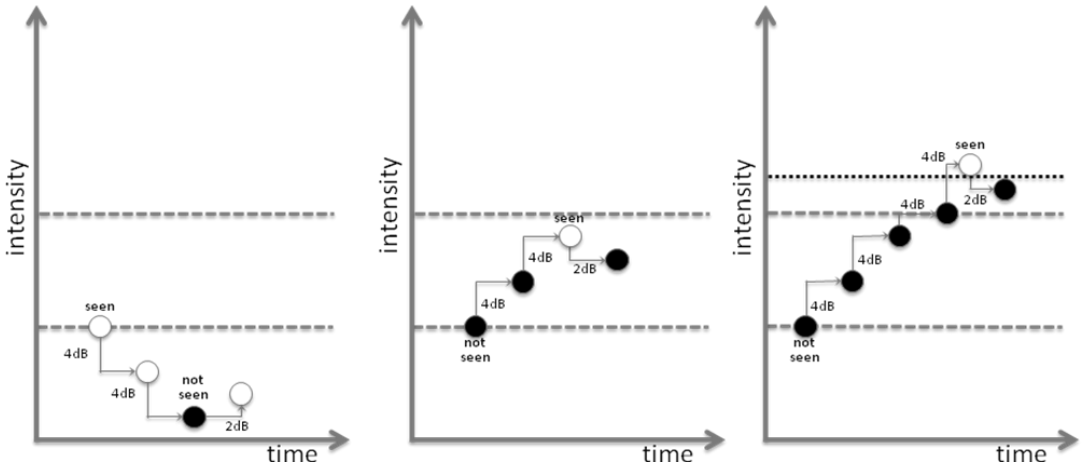


Fig. 23 – Expert test projection logic (4-2 strategy)

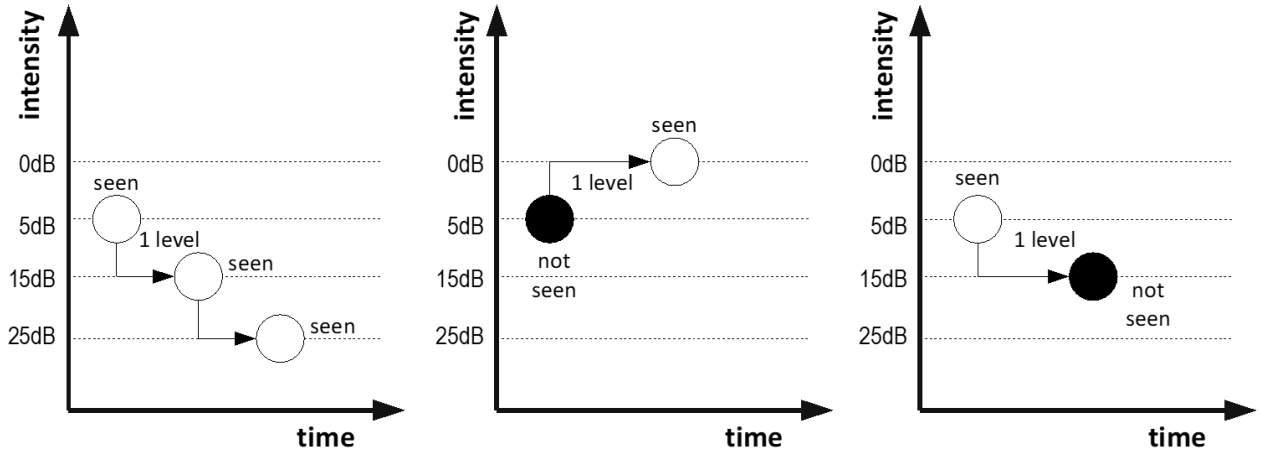


Fig. 24 – Expert test projection logic (4-Levels Fixed strategy)

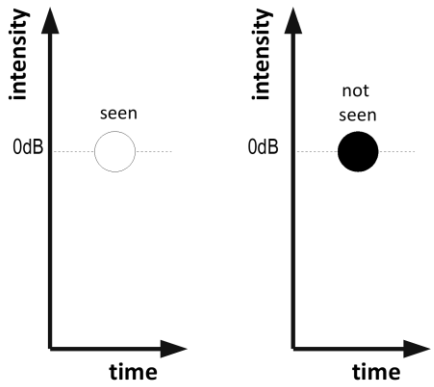


Fig. 25 – Expert test projection logic (Scotoma Finder strategy)

- **NEW FOLLOW-UP EXAM** (only available when an expert test was made): repeats the baseline expert test by accurately re-measuring the same points.

See here below for FAST or EXPERT exam, and par. 8.5 for FOLLOW-UP exam.
For a complete description of the outcomes of the different exam options, see Par. 9.

8.4.1 Checking push-button operation

After clicking on any of the 3 buttons listed above (**new fast exam**, **new expert exam**, or **new follow-up**), the test screen opens (see Fig. 28).
Before proceeding with the test, verify that the push-button is functional by checking that the "Button" indicator on screen (see Fig. 26) turns orange when the button is pressed. This has to be repeated before each exam session, also to check patient's ability to operate the push-button.

If the push-button is not functional no patient response will be detected and wrong threshold values will be recorded.

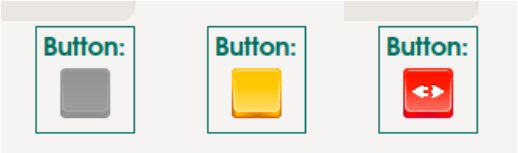


Fig. 26 - Push-button status indicator **on screen** by icon color: *not pushed, pushed, unplugged*

In MAIA 2013 Edition only, the software automatically detects whether the push-button is missing or improperly plugged, and it warns about this situation with a message (see Fig. 27): in such a case re-check proper connection by unplugging and fully plugging again the jack of the push button (see Fig. 4).

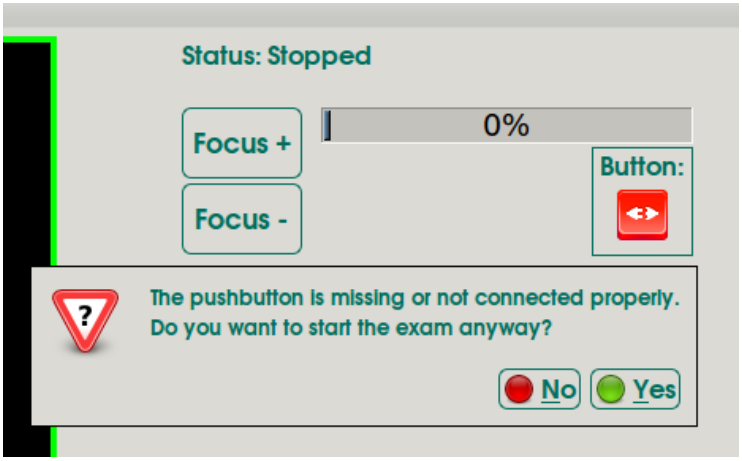


Fig. 27 – Message for unplugged push-button

The pushbutton detection is a hardware feature ***missing in MAIA – 2009 Edition***: as a consequence, the owners of this model are strongly suggested to check that the pushbutton is connected and working before starting any exam.

At this point it is also suggested to check the Projection System status by looking into the front lens and checking the stimulus position (see Fig. 18).

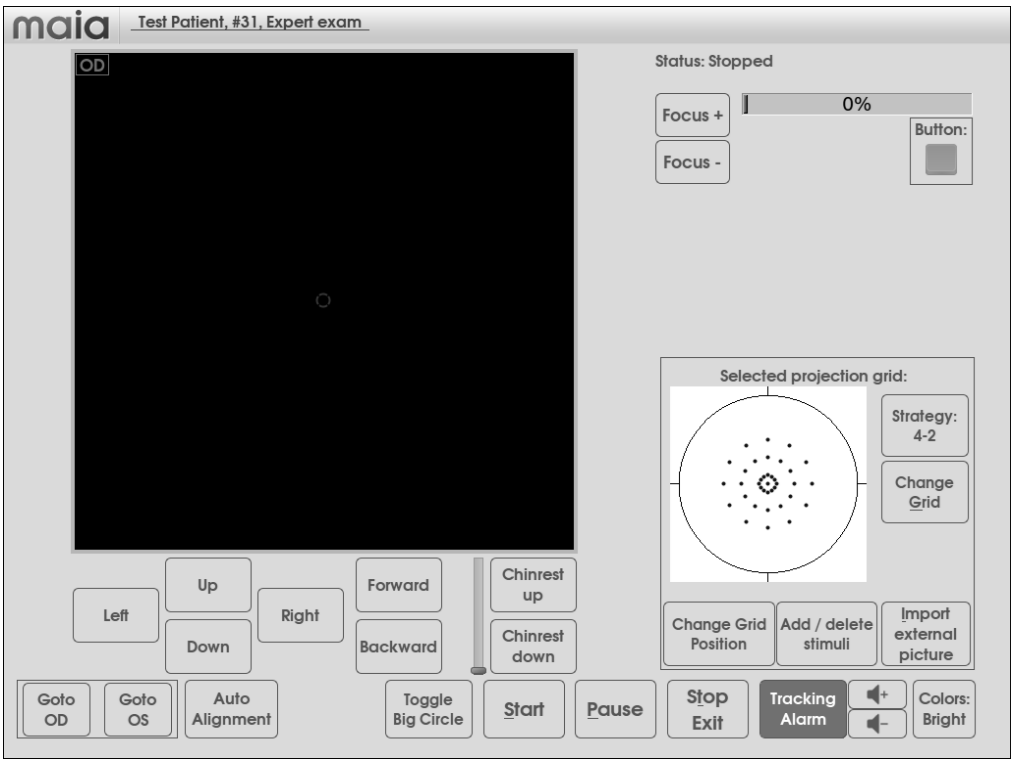


Fig. 28 - Test screen

8.4.2 Dark mode

As described in Par. 5, the MAIA test shall be performed in semi-darkness: in some environments indirect light from MAIA display reflected by the environment could adversely affect this requisite. In such a case, the operator can reduce the light diffused by MAIA display by clicking on the **Colors:Bright** button (Fig. 28), which will toggle into **Colors:Dark** changing the screen background to black as shown in Fig. 29, and also turning off the blue led inside the Joystick (Fig. 32).

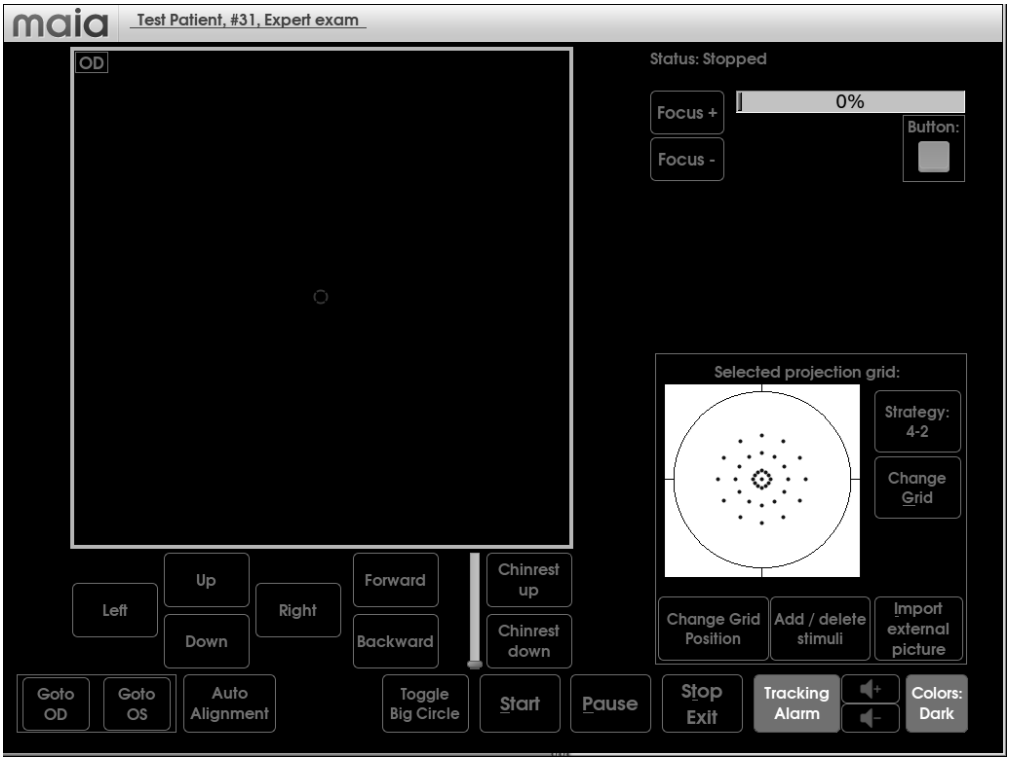


Fig. 29 - Dark mode test screen

8.4.3 Choosing the strategy

When performing an expert test it is possible to select the exam strategy by clicking on the three-state button “Strategy:”. The three available choices for strategy are:

- Strategy: 4-2 (default)
- Strategy: 4-Levels Fixed
- Strategy: Scotoma Finder

Comparison with a Reference Database, and therefore the index “Average Threshold” and the index “Macular Integrity”, are only available when using the **4-2 strategy** with the default 10° stimulus grid (see par. 9.2).
The “Macular Integrity” index are not available when using the 4-Levels-Fixed and Scotoma Finder strategies.

8.4.4 Choosing the grid

When performing an expert test, it is possible to select the stimuli grid by clicking on the Select Grid button (see Fig. 30). The default grid is the first one in the list (37 points, 10° macular coverage). The following additional grids are available:

- 6° macular coverage, 37 stimuli: compared with the default grid, provides a higher resolution measurement of a smaller region; the 3 stimuli rings are located respectively at 1°, 2° and 3° from the center;
- 20° macular coverage, 41 stimuli: provides measurement of the entire macular region;
- “10-2”, 20° macular coverage, 68 stimuli: same grid as in the Humphrey 10-2 test; measures more locations that the previous grid;
- “Manual”: an empty grid used in conjunction with command **Add/delete stimuli** to create custom perimetric grids that are specific for a certain patient.

The following combinations are available:

- choosing one of the predefined grids (including an empty one);
- possibility to set the center of the selected grid (by enabling the option **Change Grid Position**). This option will prevent the grid to be automatically centered on the PRL;
- possibility to add “custom” points to the selected grid by locating them directly on the retinal image (option **Add/delete stimuli**).

Changing any of the above options will result in a grid different from the default 10° grid for which reference values are available, therefore no comparison indices (“Average Threshold” and “Macular Integrity”) will be available.

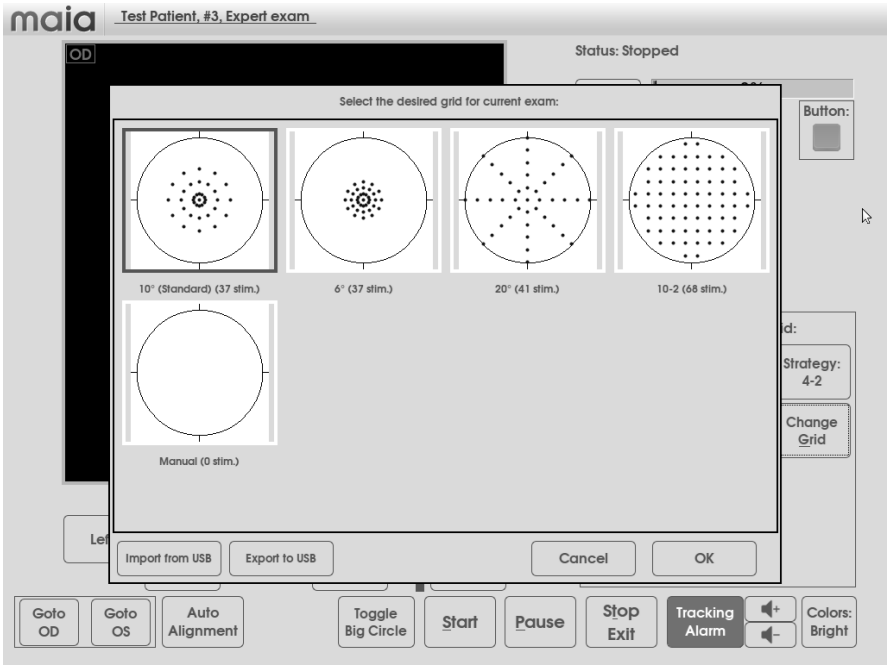


Fig. 30 – Grid selection screen (only available for expert test)

The 5 grids shown in Fig. 30 are the default grids coming with MAIA software. More custom grids can be created as desired as .xml files.
The .xml file can be imported from a USB device using the "**Import from USB**" button and then can be stored with the "**Export to USB**" button. If no custom grid is currently installed on the unit, the "**Export to USB**" button stores a sample xml file called ***MaiaPatternsSample.xml***, containing 2 sample grids and instructions on how to edit an XML to compose the desired testing grid. For further details on how to edit an XML file to create a MAIA grid, please refer to ***APPENDIX A: MAIA grids XML format***.

Please note that only the custom grids can be exported (not the 5 default grids); similarly, when importing new grids you will be asked if you want to append them or to overwrite your custom grids: if "overwrite" is selected, only the custom grids will be replaced by the ones contained in the .xml file, leaving the 5 default grids untouched.
If more than 8 grids are present, it will be possible to scroll among all the grids by swiping your finger up and down in order to reach the projection grid desired for the exam.

8.4.5 Alignment

The patient shall now place his head over the chin-rest and his forehead in contact with the forehead-rest pad (see Fig. 7). In order to have faster alignment phase, the chin-rest height shall be adjusted so to have the patient's eye aligned with the eye marker placed on the side of the head-rest support. The chinrest can be adjusted vertically using the **Chinrest Up/Down** screen buttons on 2013 Edition only (see Fig. 32-Left), and rotating the adjustment knob on 2009 Edition only (see Fig. 5).
In order to perform the exam, the front lens shall be aligned to the eye to be examined, and at the proper distance, that is 30 mm away from the cornea.
The software provides a self-alignment aid, which attempts to move the MAIA head in front of patient eye and to align it (right-left and up-down).

Click on **Goto OS** (Fig. 31) to perform the test on the left eye, or on **Goto OD** for the right one: the head will move towards the average position of the pupil for the selected eye.

It is then possible to align the patient manually or aided by the **Auto Alignment** system.

Pushing the **Auto Alignment** button will start the detection of the eye currently highlighted in the upper left corner of the live image (see Fig. 28), which is the one currently nearest to the MAIA head: the **Auto Alignment** button gets highlighted to make evident the operation in process.

Fig. 31 - Self-alignment buttons

It does not make any difference to start with the right eye or with the left one, when examining both eyes. MAIA can test one eye only, too.

Any manual intervention on the motion, either clicking on one of the **Left/Right, Up/Down, Forward/Backward** buttons (Fig. 32-left) or acting on the optional 3D joystick (as illustrated in Fig. 32-right), or on the joystick of 2009 Edition (Fig. 33), will stop the automatic alignment (the **Auto Alignment** button is no more highlighted) and return manual control to the operator.

To perform a manual alignment, look for a bright circular spot (the patient's retina seen through the pupil) as shown in Fig. 34A and Fig. 34B and use either the buttons on the touch screen (**Left/Right, Up/Down**) or the optional 3D joystick to bring the spot towards the center of the image.

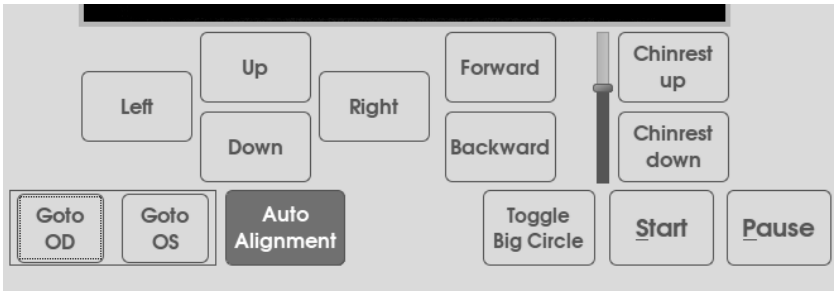
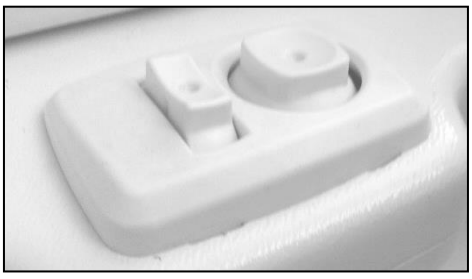


Fig. 32 – Buttons on the touch screen of 2013 Edition (left) and 3D Joystick operation (right)



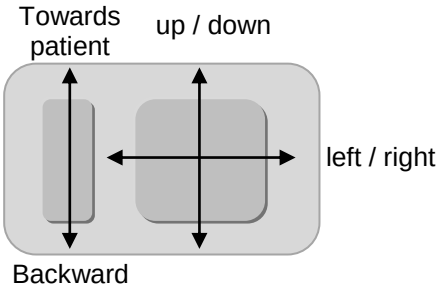


Fig. 33 – Joystick operation of MAIA – 2009 Edition

By moving the optical head to the RIGHT, the retinal image will shift to the LEFT and viceversa. Similarly by moving the head UP the retinal image will shift DOWN.

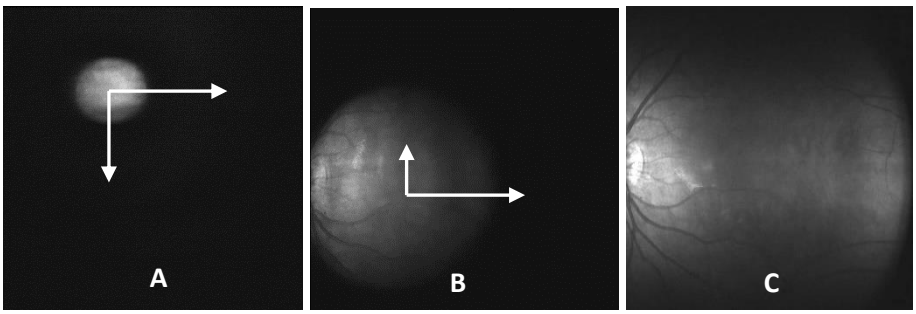


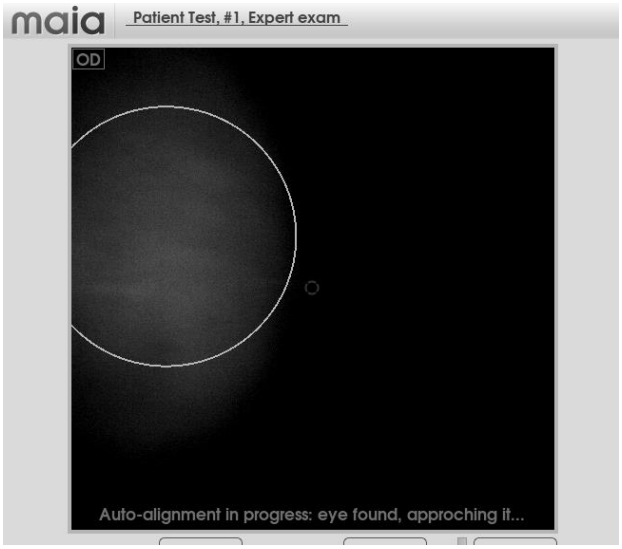
Fig. 34 – retina alignment

The self-alignment consists of 4 steps, reported by a message superimposed to the live image, and they are:

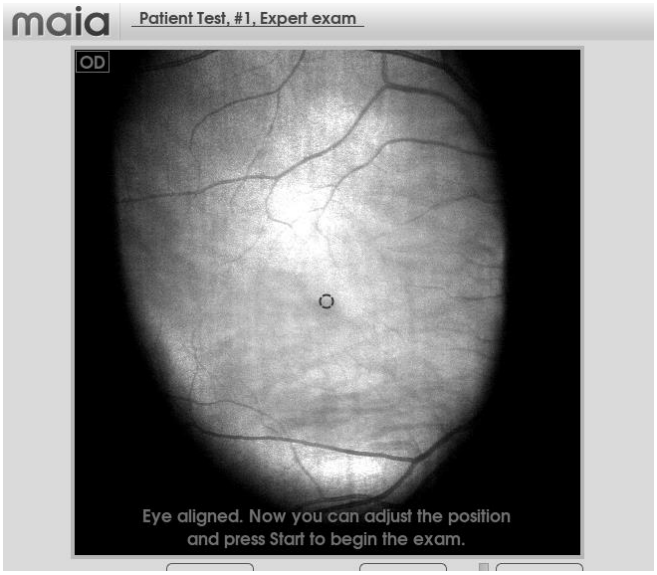
1) **Eye Reaching**: the head moves to an average position for the selected eye. The message is: ***"Auto -alignment in progress : moving towards OD / OS...";***

2) **Eye Searching**: the head performs vertical movements while changing the focus to find the pupil. The message is: ***"Auto-alignment in progress: searching the eye..."*** . As soon as the pupil is identified (in the live image it gets highlighted by a green circle), comes the next step;

3) **Eye Approaching**: the head starts to align itself to the pupil, so to bring it to the center of the image, and, at the same time, it makes a coarse scan of the focus to increase the brightness. Then, always keeping the pupil at the center, it begins to approach moving towards patient's eye, performing small corrections in alignment. The message is: ***"Auto-alignment in progress: eye found, approaching it ..."***. Once the size of the pupil takes up about 70% of the image, it passes to the final stage;



4) **Eye-aligned**: the motors stop, the message becomes ***"Eye Aligned"***, and the **Auto-Alignment** button gets unlighted.



With poorly cooperative patients or with adverse environment light condition (direct spots to the front lens), it could be the case that the procedure does not stop, and continues trying to align. In such a case ask to the patient to stare in front of him, correct environment light and, if not enough, align manually.

If during one of the steps the eye is lost (i.e. it disappears from the field or cannot be recognized), the procedure restarts from step 1.
If the eye is out of the field reachable by the head (because the patient is badly positioned on the forehead rest, or because the chin rest is too high or too low), a message will say: ***"Eye is unreachable: Please adjust chinrest and/or patient head."*** Act on the chin rest, or reposition the patient to get self-alignment proceeding.

When the optical head stops moving, the operator shall manually adjust the position, that is to move forward until the retinal image is fully framed, with **no black areas in the periphery** (see Fig. 34C), using the button "**Forward**" (or pushing forward the optional 3D joystick) and performing needed small adjustments in alignment, in order to get the full image of the retina in the live image, avoiding corneal reflexes and dark bars on the image itself.

Once you are all set click on the **Start** button. (See Fig. 35)

8.4.6 Auto-focus

MAIA will now automatically focus the retina: the auto-focusing process requires around 10 seconds. During this phase also the Auto-brightness adjustment takes place: if the acquired retina image appears overexposed, the power of the light source is decreased in order to reduce exposure.

The light source power can be adjusted in order to reach the desired image brightness during the entire exam, acting on the "**Bright +/-**" buttons, which will increase/decrease the power in 5% steps with respect to the calibration value. Note that the maximum value corresponds to different power levels during the alignment/focusing phase and the stimuli projection phase.

8.4.7 Fixation target selection

You will then be prompted to select the fixation target.

Should the image be not properly focused, the buttons for manual focusing can be used, that are **Focus +** and **Focus –,** to adjust the focus before proceeding.

The small center circle and the twenty crosses, plus the large circle surrounding them, represent the available fixation targets (see Fig. 35). Such circle and crosses appear on the screen with color blue when they are off (not visible to the patient), red when they are on (projected onto patient's retina underlying area).

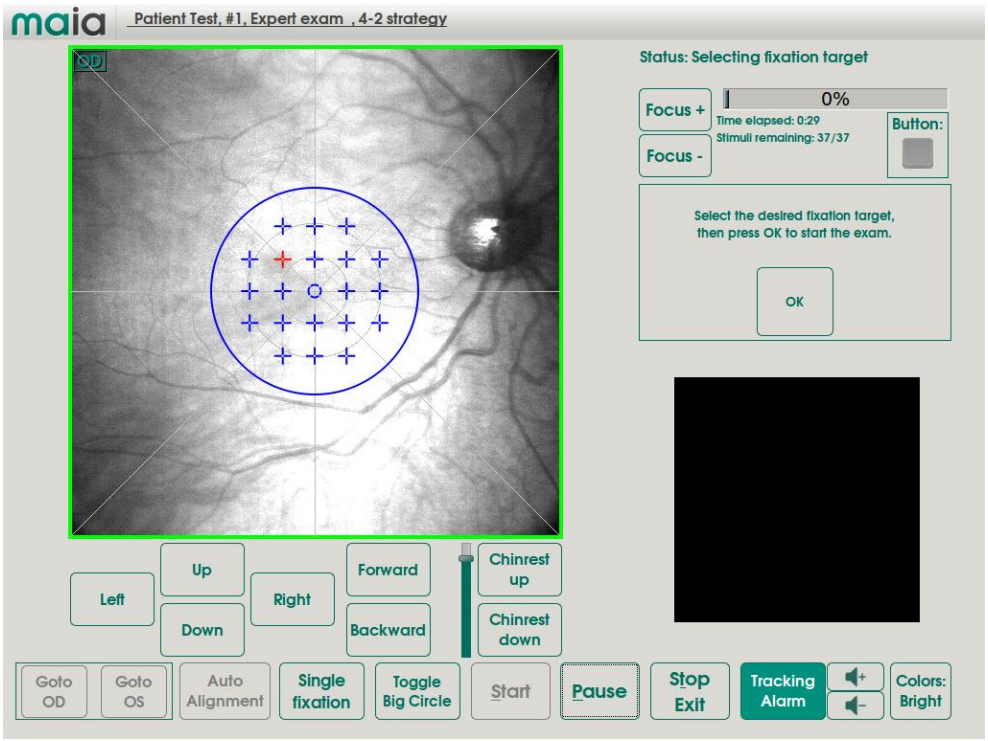


Fig. 35 - Fixation target selection

The button "**Single fixation**", if clicked toggles, to "**Multiple fixations**" (see Fig. 36), thus allowing to choose the fixation target selection mode:

- **Single fixation mode**: when this option (which is the default) is selected, by touching the screen and dragging the finger over it, the fixation target (small circle or cross) nearest to the touched point is turned on, while any other small target is turned off. The effect, moving the finger onto the retina picture, is to drag the fixation target position accordingly, stepping between the allowed positions. The large circle is turned on or off independently by the small targets by clicking the "**Toggle Big Circle**" button.
- **Multiple fixation mode**: when this option is selected, by touching onto the screen any small fixation target (small circle or cross) is toggled between on and off, without changing the state (on – off) of any other small target. This way, as many targets as desired can be turned on simultaneously. The large circle is turned on or off independently by clicking the "**Toggle Big Circle**" button.

The Multi-fixation target is a hardware feature available only on the 2013 Edition. In order to help patients to see the fixation target, the owners of 2009 Edition can choose to use the standard 1° circular target, the larger 12° big circle, or both by using the "**Small/Big/Both Fixation**" on-screen button.

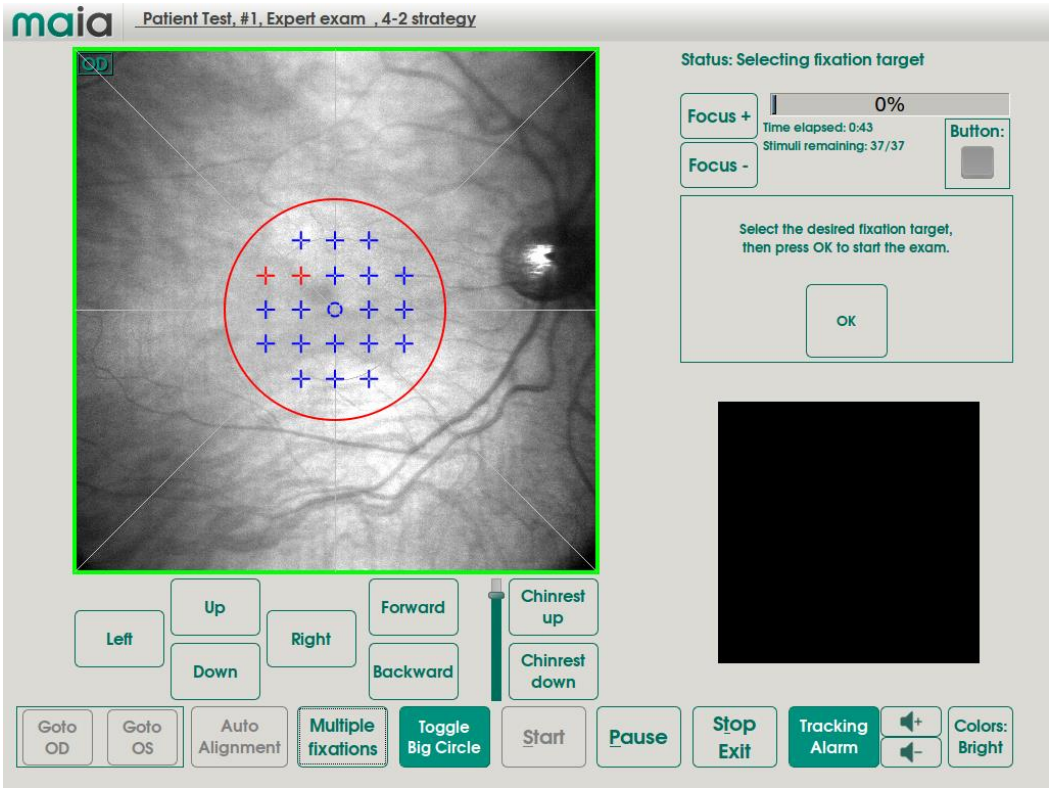


Fig. 36 - Fixation target: multiple selection

8.4.8 Dynamic Multifixation (DMF) Target Operation ***[optional, available on 2013 Edition only]***

The following procedure suggests how to use the additional feature given by the additional eccentric fixation targets (crosses).
In cases of large central scotoma, patients may have difficulties to see the standard fixation target. In such cases the operator may select an eccentric target. Once the eccentric fixation target is visible by the patient, the operator shall move the target towards the center of the target array trying to make visible the central standard fixation target, as described in the following procedure.

1. As a first attempt, the operator shall ask to the patient whether he is able to see the small red circular fixation target located in the center of the MAIA ocular.

   If the patient is able to see the small central fixation target, the MAIA examination can be performed.

2. If the patient is not able to see the standard fixation target, the operator can select an eccentric fixation target (red cross) located outside of the scotoma area (the scotoma area is normally created by a Geographic Atrophy in the retina and it is seen in the SLO image as a hyper reflective area, that is a bright area).

3. Once the patient is able to see the selected eccentric target, the operator shall try to move that eccentric target towards the center.

4. If the central fixation target is visible, the MAIA exam shall be performed. Otherwise, the MAIA exam shall be performed with the visible cross target closest to the central circular target.

As an aid to fixation, in order to help the patient to keep tracking the chosen target, click on **Big Fixation**: this will switch ON the peripheral 12° circle.

8.4.9 Reference image selection

When the most suitable fixation target is selected, be sure that **just one** fixation target is on (not considering the large circle, which can be either off or on, and can be used as a boundary to help the patient to find again the desired fixation target, if he loses contact with it).

Please consider that reference database data, and related indices, will be available only using the central standard fixation target.

When ready, click on "**OK**" button to proceed with the exam.
If multiple fixations are on, a prompt will ask to re-check and turn off any target but one (Fig. 37)

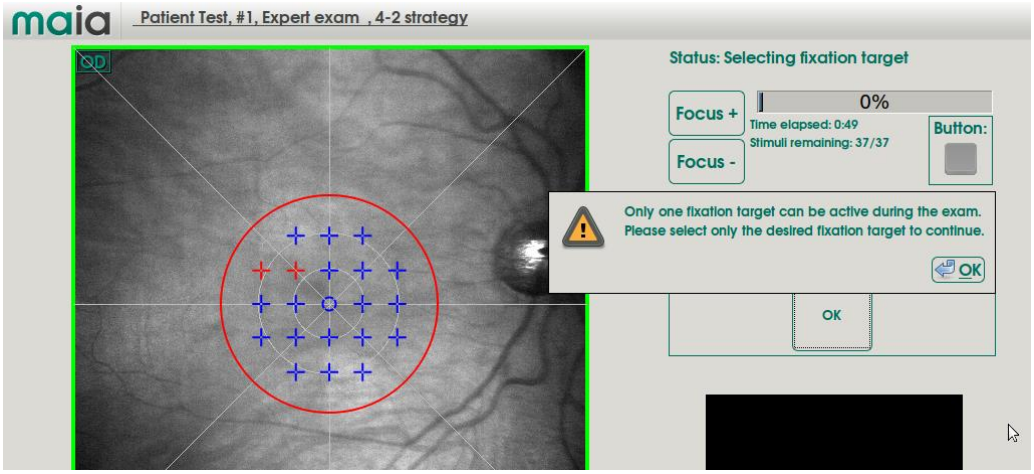


Fig. 37 - Too many targets selected

MAIA will now capture one retinal image to be used as the exam reference, called ***Still Picture***.

You will then be prompted to accept or reject the acquired image: should the image be clear and focused, click on **Yes**. If not, for instance because the subject moved or blinked, or because focusing or brightness was unsatisfactory (see Fig. 40), click **No**. Then it is possible to retry the Autofocus procedure with the **Re-run autofocus** button, or to adjust focus and brightness manually clicking on **Manual focusing**. In Manual Focusing, use the **Bright +/-** and the **Focus +/–** buttons until the image quality is satisfactory, and then press **OK** to acquire a new ***Still Picture*** to be confirmed.

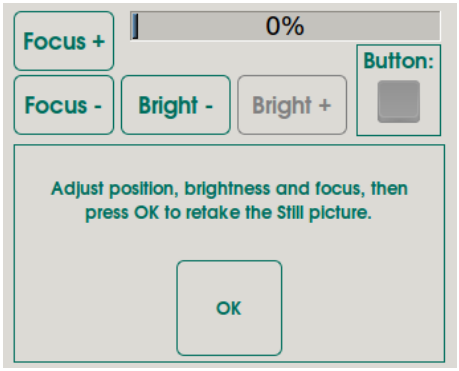


Fig. 38 - Manual focusing

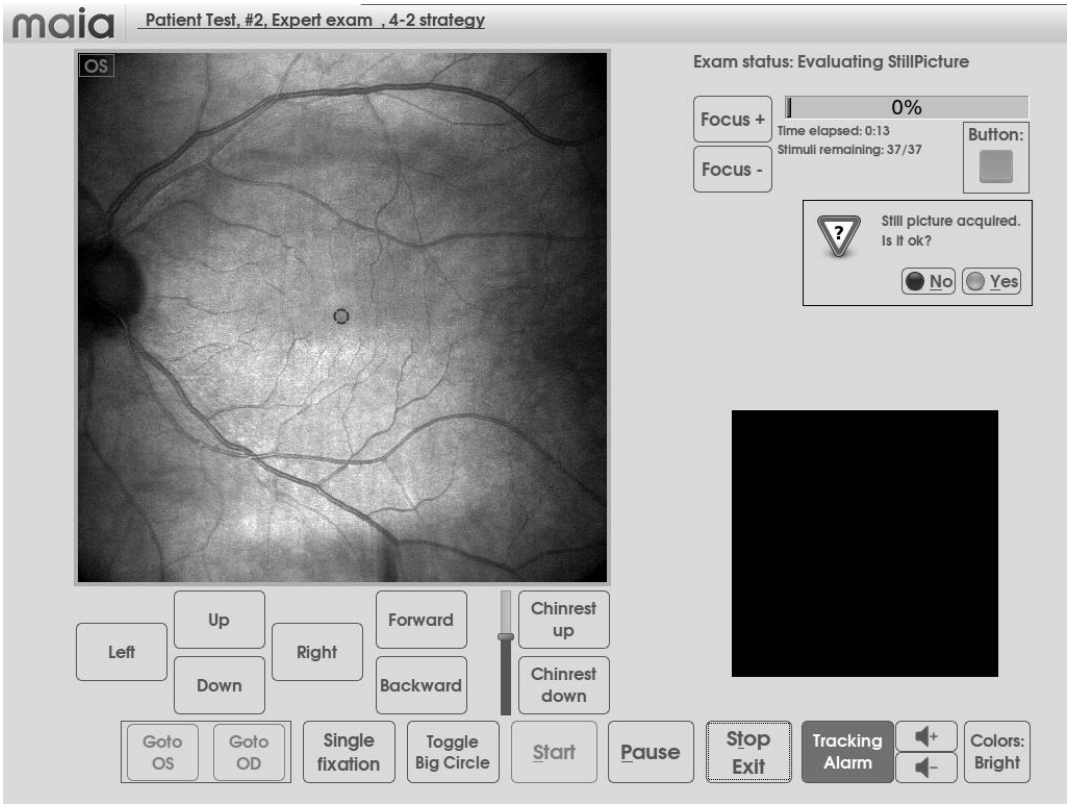


Fig. 39 – Reference image evaluation

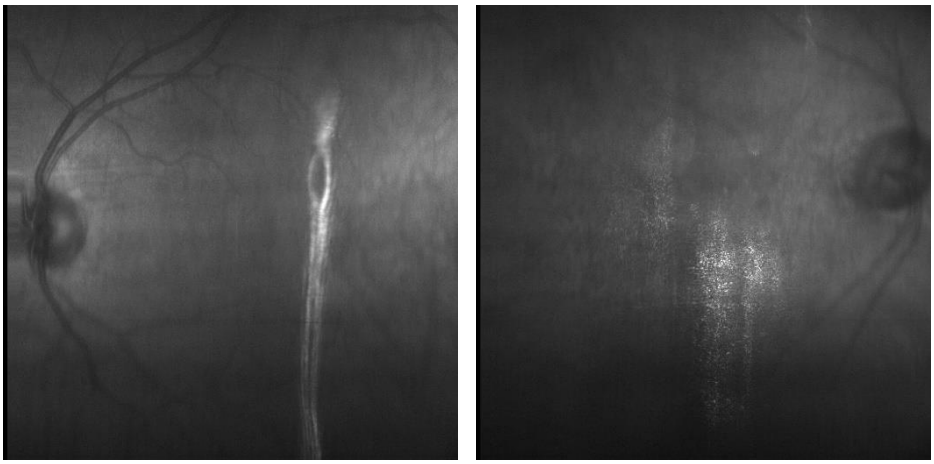


Fig. 40 - Images of insufficient quality to effectively run the test, because of corneal reflections (left) and/or wrong focusing (right)

When the image is focused also the patient will see the target in focus, viceversa if the image is NOT well focused the patient will NOT see the target in focus and this may alter the test results.

8.4.10 Grid centering (optional)

This option allows to test retinal areas different from the default macular area.
If the **Change grid position** option is selected you will be asked where to set the center of the chosen grid by clicking on the desired point on the retinal image. Note that all stimuli outside a circle of 30° of diameter will be rejected. Then click on **Ok**.

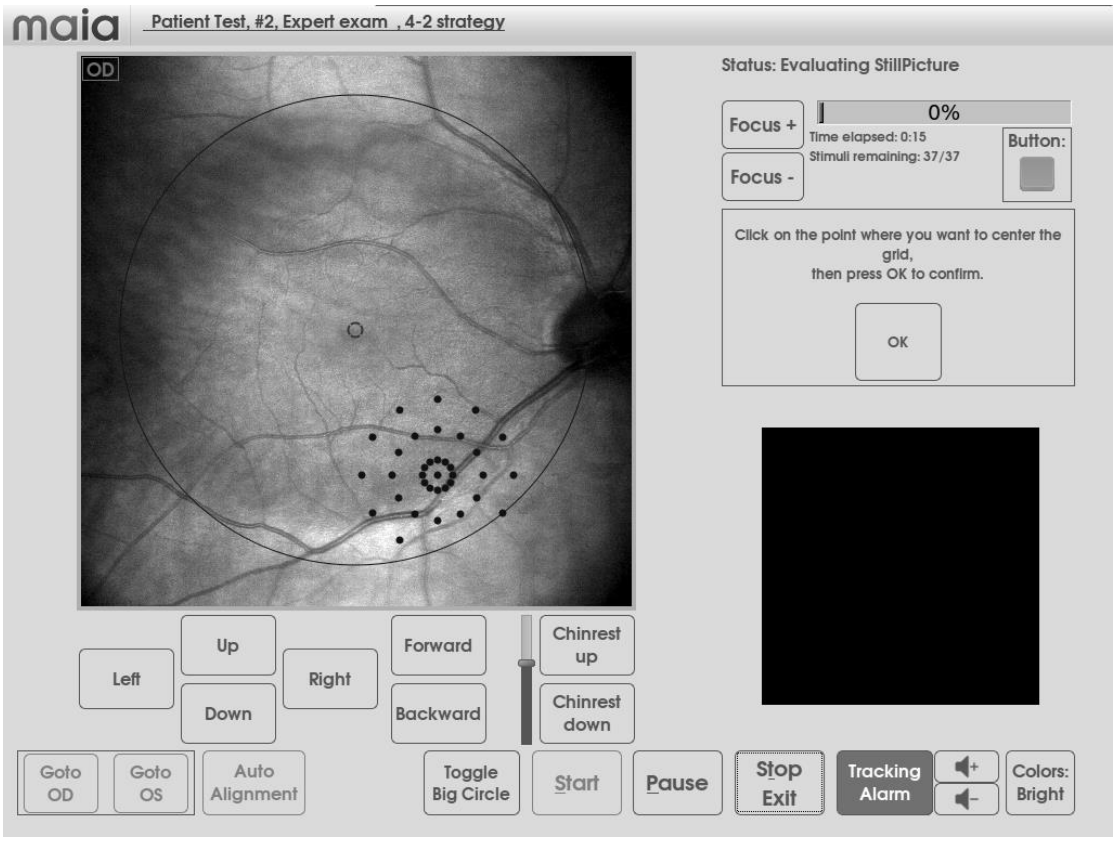


Fig. 41 – decentered grid

8.4.11 Adding custom stimuli (optional)

This option allows to test retinal areas different from the default macular area.
If the **Add stimuli** option is selected, you will be allowed to place custom stimuli over the image. Depending on which button is active, you can **ADD** or **DELETE** custom stimuli.
Stimuli can be placed by clicking in the desired position on the retina image, within a 30° circle and cannot be placed closer than 0.5° to each other.
The last stimulus added will be displayed in orange color; in the lower right frame a zoomed view of the last stimulus placed will be displayed, with 4 arrow buttons allowing to shift it in the 4 directions for fine-positioning (see Fig. 42).
If the **DELETE** button is active, tapping on a point on the retina image will delete the closest stimulus to the point clicked.

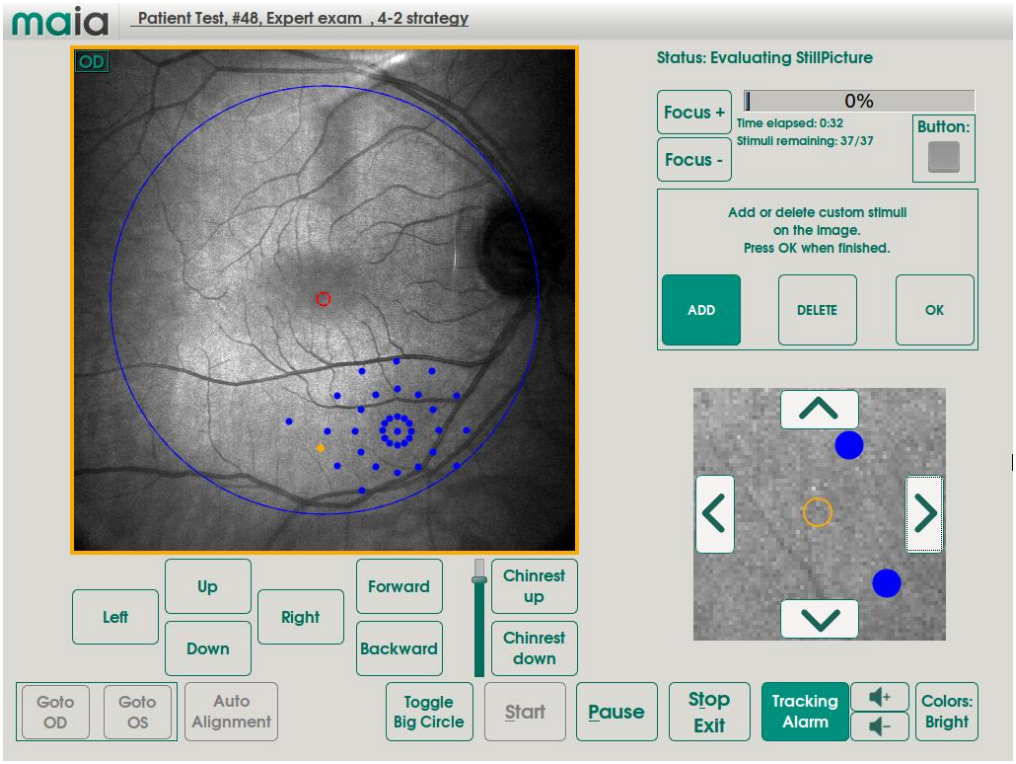


Fig. 42 - custom stimuli editing

8.4.12 Identifying the optic disk

You will then be asked to click on the center of the optic disk. Then press **Ok**. Incorrect identification of the disc center may result in erroneous fixation losses counts, with the test being possibly falsely considered inaccurate.

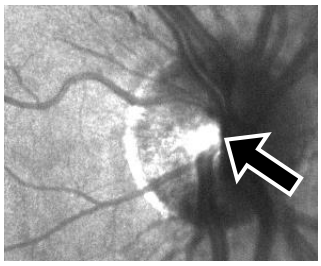


Fig. 43 – Optic disk center location

	Once this operation is done, MAIA will start recording the eye movement with the automatic **eye tracking** system**.** It is normal that the image suddenly becomes slightly darker at this point.

The image displayed on the left half of the screen is an **eye tracker-stabilized live image**, while the image on the right half is the original, untracked, live image (see Fig. 44).

8.4.13 PRL-initial assessment

During the first 10 seconds of the test the system records the patient's fixation activity (approx. 250 points), the center of which is used to estimate the preferred retinal locus (***PRL-initial***) in which to center the stimuli grid (unless option **Change Grid position** is enabled). During this phase the patient must only concentrate in fixating the center of the fixation target.

For patients showing difficulties in recognizing the fixation target, it is suggested to activate the "**Enhanced Fixation**" feature (in the **Settings** menu: see paragraph 11.1) which will project a blinking stimulus at the center of the fixation target in order to help its detection. This blinking stimulus is only present in this phase and will disappear when the PRL-initial has been determined.

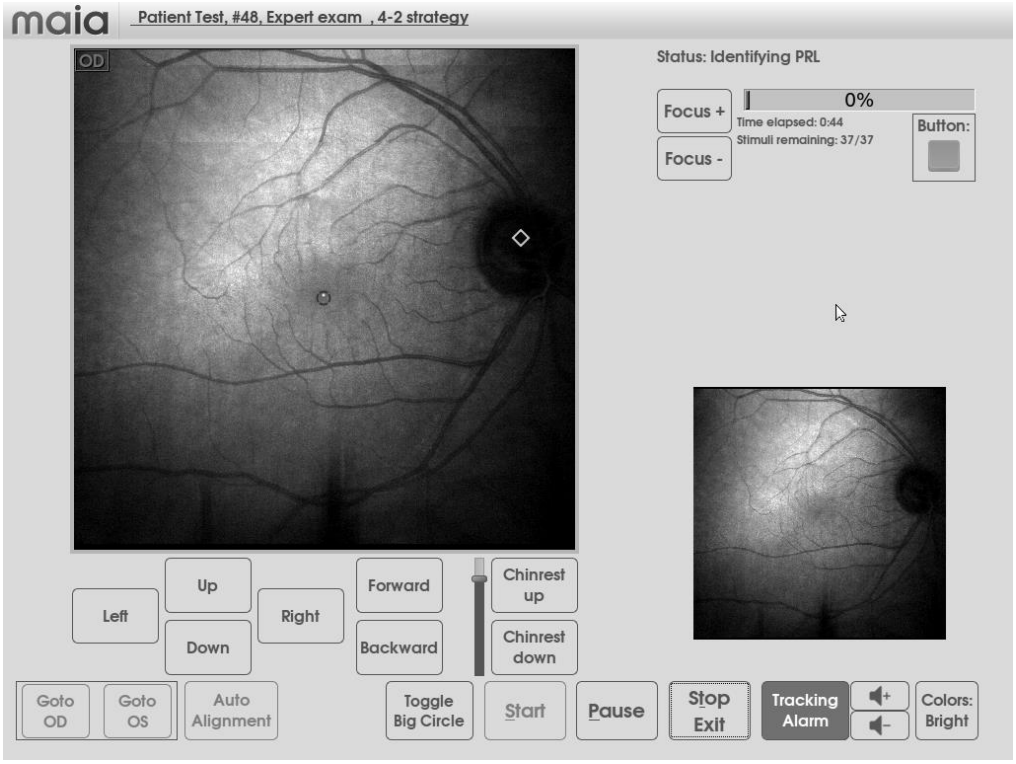


Fig. 44 – PRL-initial assessment

8.4.14 Training session

Then perimetric projection starts, with the first stimuli being used as a training session for a patient to understand his task. Such stimuli are not considered in the test results. When/if two of such training stimuli are responded, the true test stimuli start. If the patient does not respond to eight of such training stimuli, the test will start anyway.

8.4.15 Initial stimuli intensity (pre-test)

In case of *expert* exam (***4-2*** and ***4-Levels Fixed*** strategies only), MAIA initially measures the threshold at 4 points to tune the initial intensity of the subsequent stimuli to the patient under exam. Such pre-analysis allows to reduce the test time in case of lower than normal sensitivity.

8.4.16 Monitoring the test

Test progression can be monitored by (see Fig. 45):

- reading the "remaining stimuli" indication;
- checking the "estimated remaining time". This information is present only in Expert/Follow-up exams and appears only when at least 25% of the stimuli have terminated (in order to collect enough data for the estimation).
- checking when the push-button is pressed, based on the corresponding signal;
- looking at the retina images: the small one on the bottom right of the window shows the **live** image (just like it is being acquired by the camera); the bigger one on the left shows the **stabilized** image (i.e. shifted using the information coming from the eye-tracking). The small yellow dot displayed on the stabilized image represents the current fixation point (the point of the retina which is aligned to the center of the fixation target in this very moment).

- watching the current eye-tracking status: the border of the stabilized image turns GREEN if the eye-tracking is correctly detecting and registering the eye movements, while it turns RED otherwise (e.g. during eye blinking or in presence of a strong misalignment due to excessive head movement). It turns ORANGE if the exam is paused.

When the eye-tracking is unable to locate the retinal image (RED frame) the stimuli projection is paused.

If this situation persists for more than 4 seconds, an intermittent beep sound is emitted to alert the operator that the patient has moved and needs to be re-aligned to the front lens.

This alarm can be turned off de-selecting the **Tracking Alarm** button, and the volume can be adjusted with the nearby buttons.

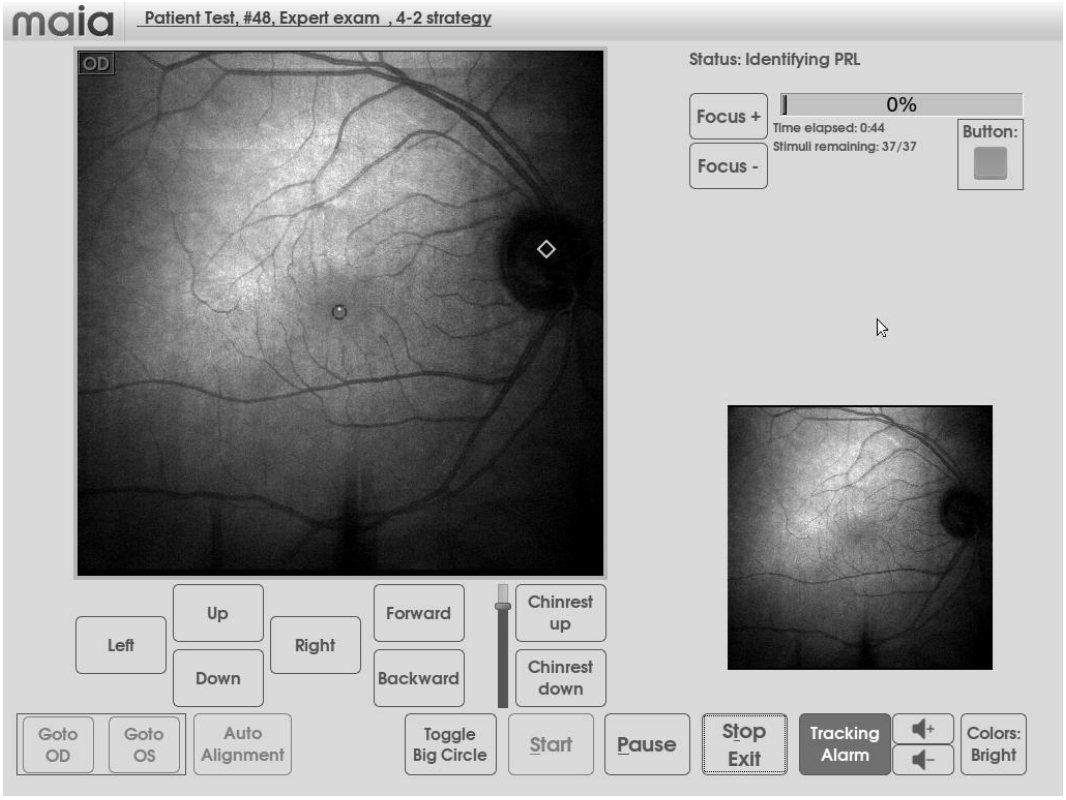


Fig. 45 – Exam interface

The meaning of the symbols appearing on the image during projection is the following:

- stimulus being projected, no response;
- stimulus projected and seen (patient response received).

A stimulus intensity ranges from 0 to 36 dB, according to the following scale:

Fig. 46 – Stimuli color scale

A stimulus marked with the symbol ***"<0"*** indicates that the maximum intensity (0 dB) has not been seen by the patient: this means that the underlying zone has no sensitivity at all (scotoma).

For the ***4LF*** strategy, displayed colors have the following meaning:

seen at 25dB

seen at 15dB – not seen at 25dB

seen at 5dB – not seen at 15dB

seen at 0dB – not seen at 5dB

not seen at 0dB

For the ***Scotoma Finder*** strategy, displayed colors have the following meaning:

seen at 0dB

not seen at 0dB

The test can be paused and restarted at any time by clicking on **Pause** without the data being compromised.
The test can be stopped at any time by clicking on **Stop**. If a test is stopped before completion it is flagged as “incomplete” and only partial results are available.

Once the test is completed the data will be saved on the disk and the Exam review page will appear in about 10 seconds.

8.5 Running a follow-up test

If an Expert test has been performed to certain a patient, a **follow-up** assessment is possible. To run a follow-up, select the desired patient (see Fig. 21) and click on the **New Follow-up** button in the corresponding expert test (the baseline exam). Then proceed as explained at 8.3: MAIA will re-test the same points tested during the baseline test.

In case of a follow-up test, the stimuli grid is NOT centered on the PRL (which may move with respect to the baseline test) but is centered at the same point as in the baseline test.

The follow-up mode is not available for fast tests.

9. REVIEWING RESULTS

In the patient list click on the desired patient, then click on the desired test from the list on the right: the test results screen will show up as in Fig. 47.

9.1 Results of the *fast* test

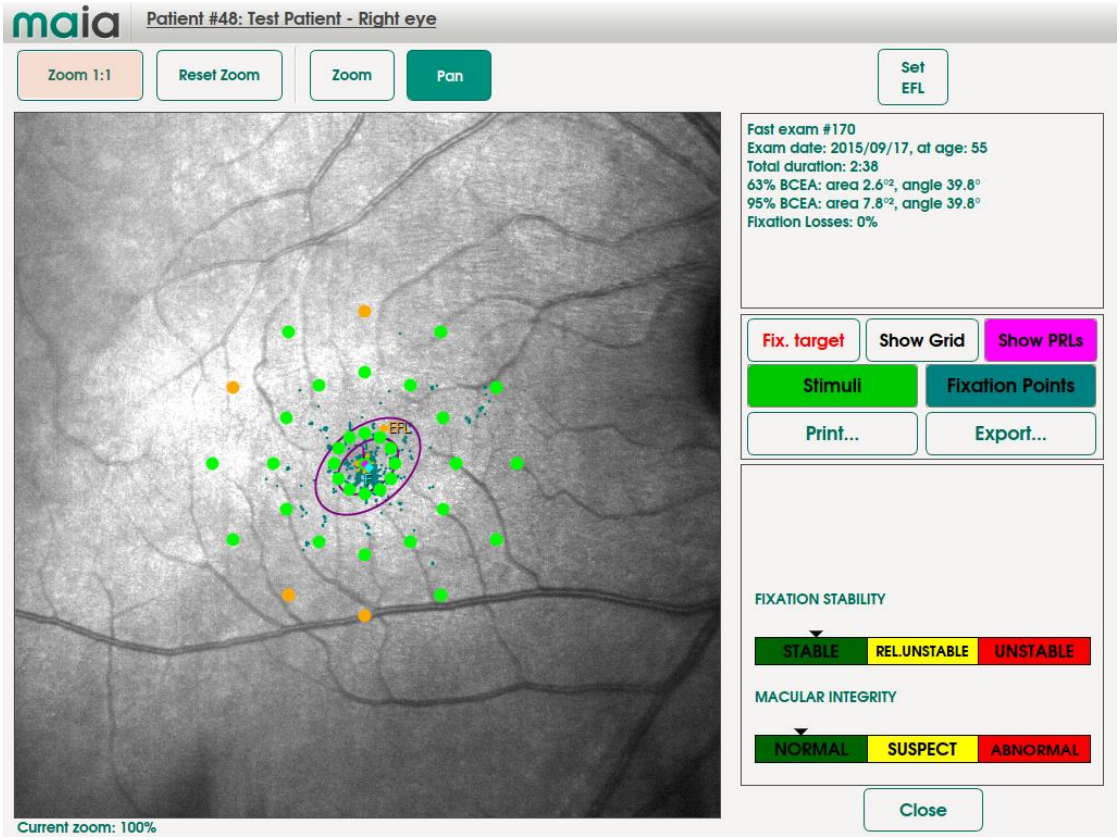


Fig. 47 – Fast Test results screen

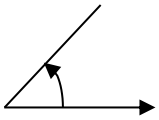
Displayed information include:

- Patient number, last name and first name, eye information (top bar);
- Exam number, type of exam, date of exam, patient age, exam duration in minutes and seconds and ***Fixation Losses*** index (top-right panel): such index provides the percentage of control points projected at the optic nerve which were seen by the patient (ideally 0%);

While ***fixation losses*** over 30% indicate that the test is not reliable, the above index is based only on the percentage of fixation losses. This device does not provide other indicators of reliability such as the percentage of false positives and false negatives.

- Fixation points: they represent all the points of the retina used throughout the whole exam to fixate the target: the orange ones are the points used during the first 10 seconds of the test (a.k.a. the Registration phase), the blue ones the ones used during the rest of the exam.
- BCEA analysis: the “63% Bivariate Contour Ellipse” (the smaller ellipse in the plot) represents the ellipse describing the statistical distribution of 63% of all fixation points. Its area (expressed in squared retina degrees) and the angle between the major axis and the horizontal axis (measured counter-clockwise, as in figure below) are displayed in the exam

info frame. Similarly, “95% BCEA” (the larger ellipse in the plot) represents the ellipse describing 95% of all fixation points.

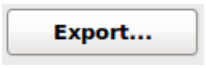


- PRLs: the magenta one (INITIAL, marked as “I”) is calculated as the center of the fixation points recorded by the eye-tracker in the initial 10 seconds of the test; the cyan one (FINAL, marked as “F”) is calculated as the center of the fixation points recorded in the rest of the exam;
- Stimuli and related threshold. Colors have the following meaning: green = “seen at 27 dB”, orange = “seen at 25 dB”, red = “not seen at 25 dB”. According to the MAIA normative database, 27 dB represents the 90th percentile on normals, while 25 dB represents the 97th percentile;
- Index FIXATION STABILITY, based on the following:
    - If more than 75% of the fixation points were located within a 2° diameter circle centered in the gravitational center of all fixation points, the fixation is classified as **stable**.
    - If less than 75% of the fixation points were located within a 2° circle, but more than 75% of the fixation points were located within a 4° circle, the fixation is classified as **relatively unstable**.
    - If less than 75% were located within a 4° circle, the fixation is classified as **unstable**.
- Index MACULAR INTEGRITY, indicating whether measured threshold values are normal, suspect or abnormal. Such indication is derived by comparison with age-matched normative data and relies upon a statistical analysis of the number of points that are seen at normal intensity (green dots, perceived at an intensity corresponding to two standard deviations below the normal average), at suspect intensity (orange dots, perceived at an intensity corresponding to three standard deviations below the normal average) or are not seen at all (red dots, NOT perceived at an intensity corresponding to three standard deviations below the normal average).
    - The sensitivity of this method has been clinically assessed and found to be higher than 90%;
    - The specificity of this method has been clinically assessed and found to be higher than 90%;

In case of a SUSPECT result, the test should be repeated.

Available functions include:

- Image zoom and pan, zoom to stimuli grid and restore to full image (Reset Zoom)	
- Allows to set the position the Estimated Fovea Location (EFL) marker over the retinal image	
- Enabling / disabling display of the fixation target	
- Enabling / disabling display of the PRLs and the EFL	
- Display stimuli / hide stimuli / display stimuli with their IDs (3 options)	

- Display all fixation points recorded during the test / display only fixation points recorded during stimuli projection / disable display of fixation points (3 options)	
- Print (on paper, USB key or shared folder): generates a PDF file containing the report of the exam (see 10.PRINTING)	
- Export (to USB key or shared folder): generates a PNG file of the entire retina, with the overlapped layers currently selected for visualization	

	The EFL (Estimated Fovea Location) marker is a landmark that can be placed over the retinal image, at the discretion of the operator, in order to evaluate the position of the fovea with respect to the PRLs (Initial and Final). It has no effect in the calculation of the Fixation Indexes and the BCEAs.

9.2 Results of the *expert* test

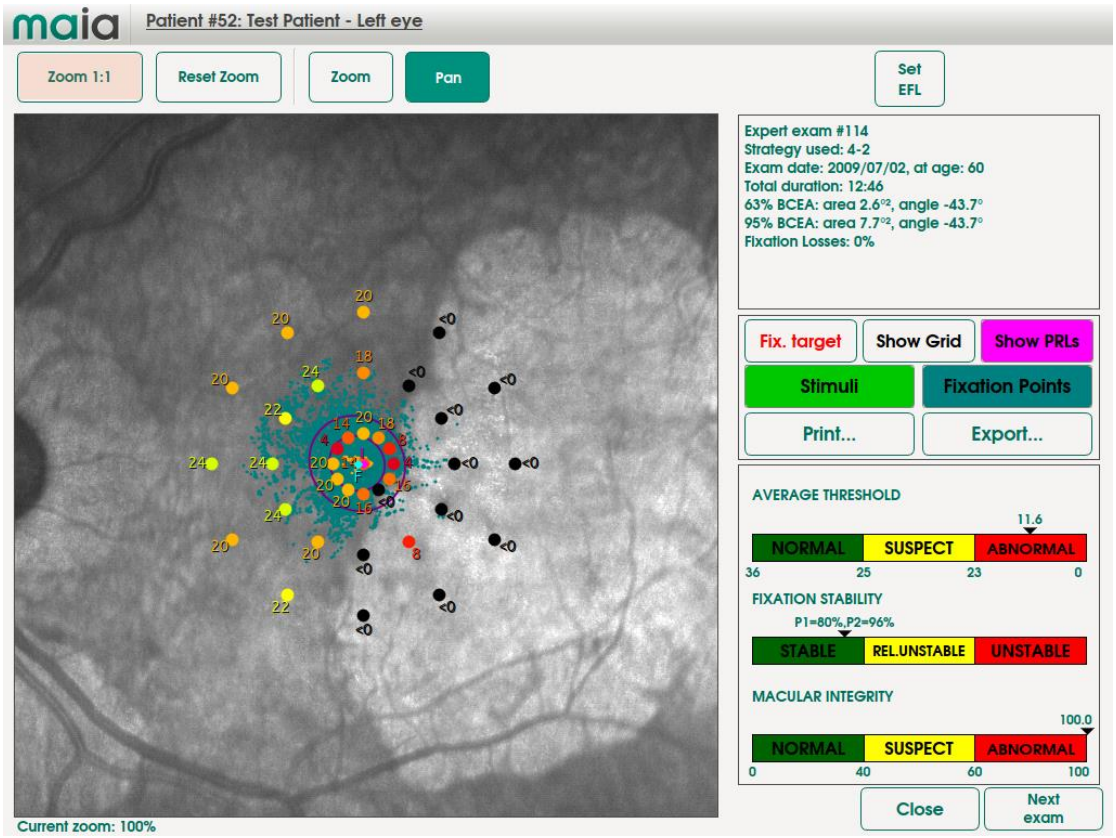


Fig. 48 – Expert Test results screen: 4-2 strategy

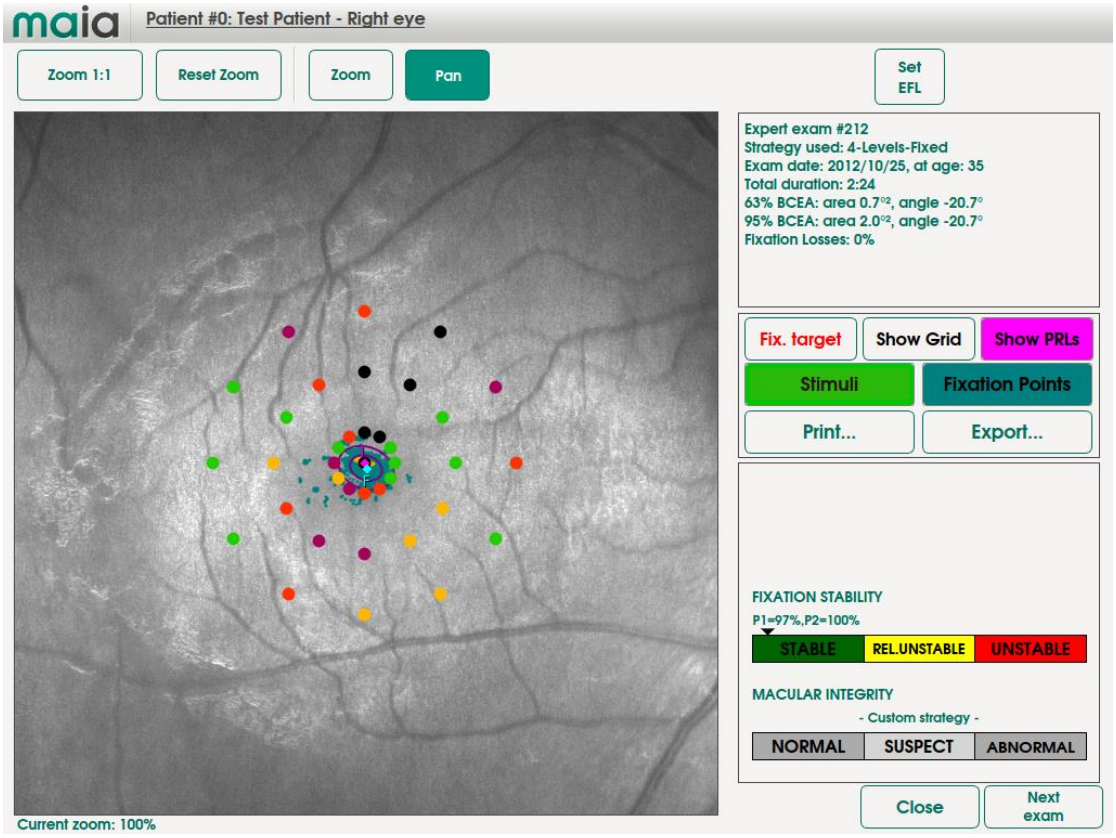


Fig. 49 – Expert Test results screen: 4-Levels-Fixed strategy

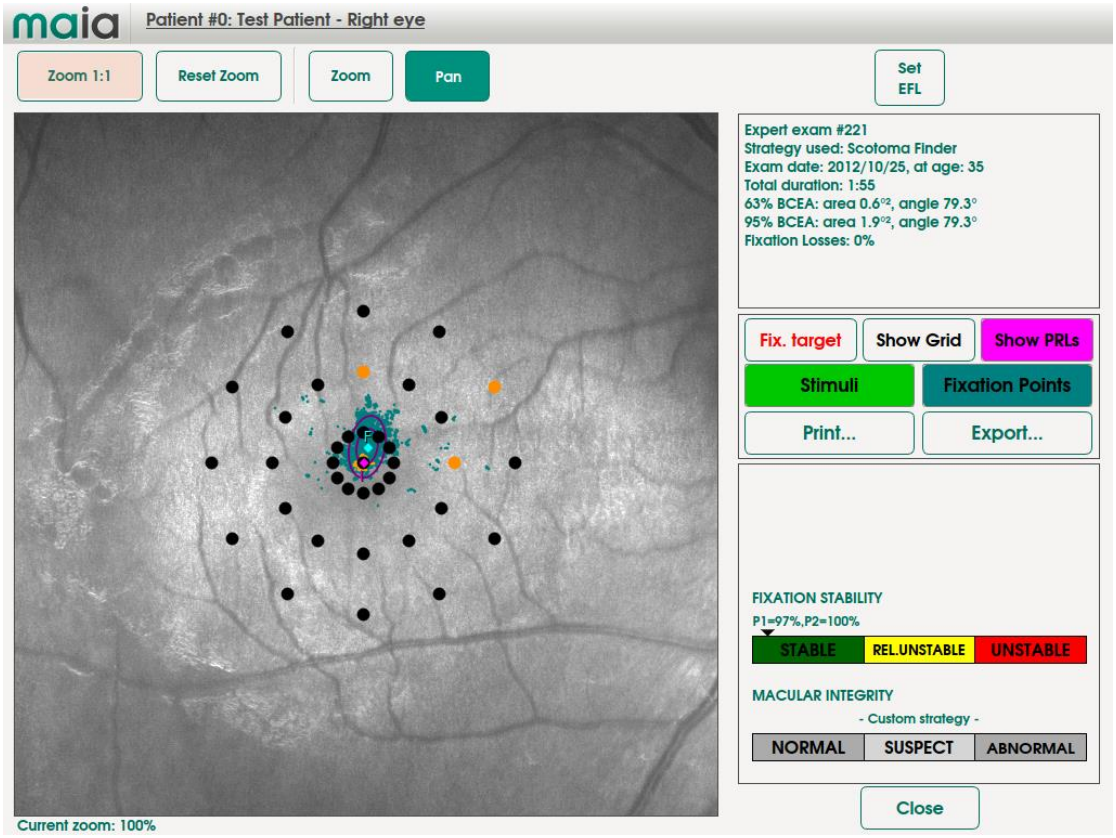


Fig. 50 – Expert Test results screen: Scotoma Finder strategy

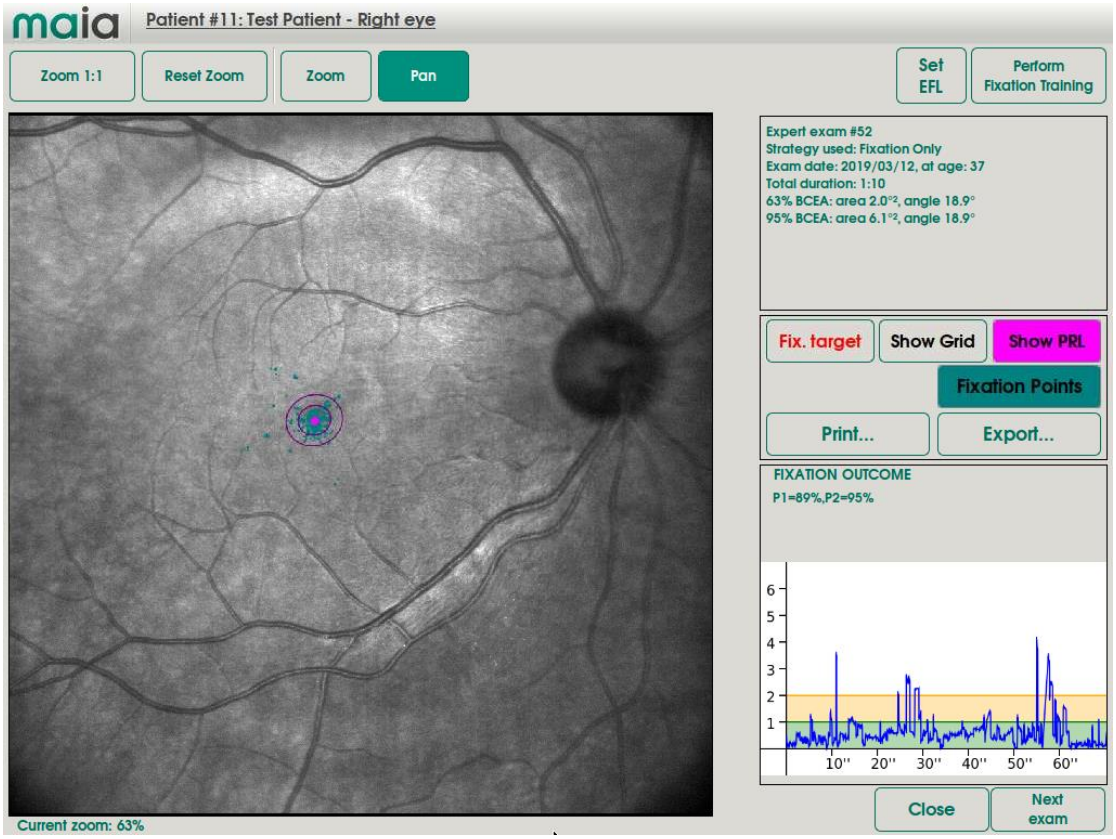


Fig. 51 – Expert Test results screen: Fixation Only strategy

Displayed information include:

- Patient number, last name and first name, eye information (top bar);
- Exam number, type of exam, date of exam, patient age, exam duration in minutes and seconds and ***Fixation Losses*** (top-right panel): such index provides the percentage of control points projected at the optic nerve which were seen by the patient (ideally 0%);

While fixation losses over 30% indicate that the test is not reliable, the above index is based only on the percentage of fixation losses. This device does not provide other indicators of reliability such as the percentage of false positives and false negatives.

- Fixation points, BCEA analysis and PRLs (just like the ***Fast*** exam); the Fixation Only strategy provides the Fixation Outcome chart, which plots the distance of each fixation point from the PRL-f over time;
- Stimuli and related threshold in dB: it is possible also to view the interpolated sensitivity map (see Fig. 52), a 2D map representing the sensitivity on each point of the retina using the information coming from the nearby stimuli;
- Index AVERAGE THRESHOLD (only for ***4-2*** strategy): by comparison with age-adjusted normative data, this graph shows whether the computed average is normal (less than two standard deviations from the normal average), suspect (between two and three standard deviations from the normal average) or abnormal (beyond three standard deviations);
- Index FIXATION STABILITY, based on the following:
    - If more than 75% of the fixation points were located within a 2° diameter circle centered in the gravitational center of all fixation points the fixation is classified as **stable**.
    - If less than 75% of the fixation points were located within a 2° circle, but more than 75% of the fixation points were located within a 4° circle, the fixation is classified as **relatively unstable**.
    - If less than 75% were located within a 4° circle, the fixation is classified as **unstable**.

  The displayed values, indicated as P1 and P2, represent the percentage of fixation points located respectively within the 2° and 4° circles.
- Index MACULAR INTEGRITY (only for ***4-2*** strategy): uses a neural network multivariate model (the EYEdB™) that includes age, average threshold value, a measure of points with threshold below 25 dB and all measured threshold values. The neural network has been trained on normal as well as pathologic exams.

The Macular integrity index is a numerical value (not dB) that describes the **likelihood** that a patient's responses, as processed by the neural network, are normal, suspect or abnormal when compared to age-adjusted normative data.

The macular integrity index does not represent the severity of the disease process. Higher numbers suggest a greater likelihood of abnormal findings, while lower values suggest a greater likelihood of normal findings.

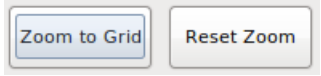
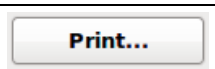
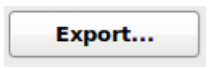
There is no direct relationship between the average threshold value (dB) and the macular integrity index. In fact it is possible for the average threshold to be normal while the macular integrity index is abnormal, as other variables in the data (besides the average threshold value) may be causing the abnormal finding.

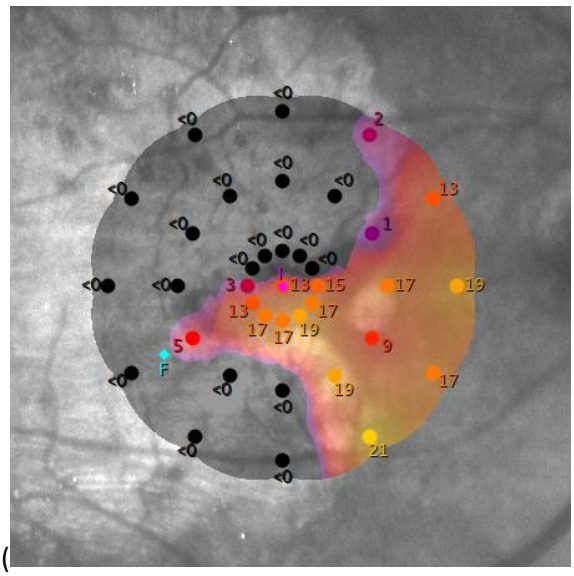
The sensitivity of this method has been clinically assessed and found to be higher than 90%;

The specificity of this method has been clinically assessed and found to be higher than 95%.

Since its calculation is based on MAIA's reference database, the Macular Integrity index for Expert exams is available only using the ***4-2*** strategy and the ***standard 10°*** grid, without moving the grid position (i.e., leaving it centered on the PRL-i).

Available functions include:

Image zoom and pan, zoom to stimuli grid and restore to full image (Reset Zoom)	
- Allows to set the position the Estimated Fovea Location (EFL) marker over the retinal image	
Enabling / disabling display of the fixation target	
Enabling / disabling display of the PRLs and the EFL	
Display stimuli and the corresponding threshold values / display stimuli and interpolated sensitivity map (see Fig. 52) / disable display of stimuli / display stimuli IDs [preceded by "#"] (4 options)	
Display all fixation points recorded during the test / display only fixation points recorded during stimuli projection / disable display of fixation points (3 options)	
Print (on paper, USB key or shared folder): generates a PDF file containing the report of the exam (see 10.PRINTING)	
Export (to USB key or shared folder): generates a PNG file of the entire retina, with the overlapped layers currently selected for visualization	



(

Fig. 52 – Interpolated sensitivity map (4-2 strategy)

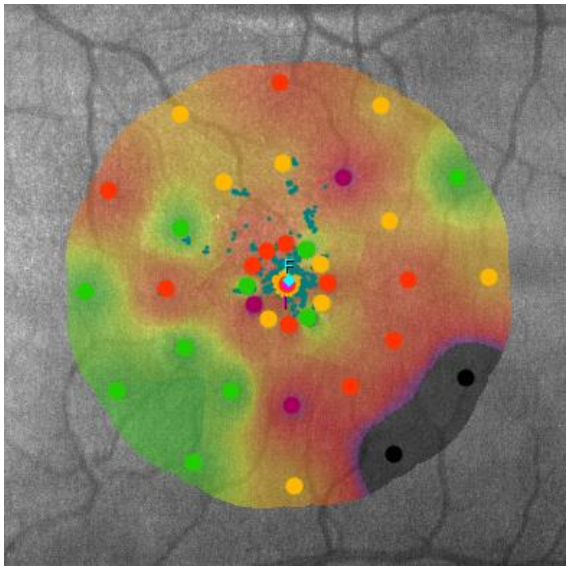


Fig. 53 – Interpolated sensitivity map (4-Levels-Fixed strategy)

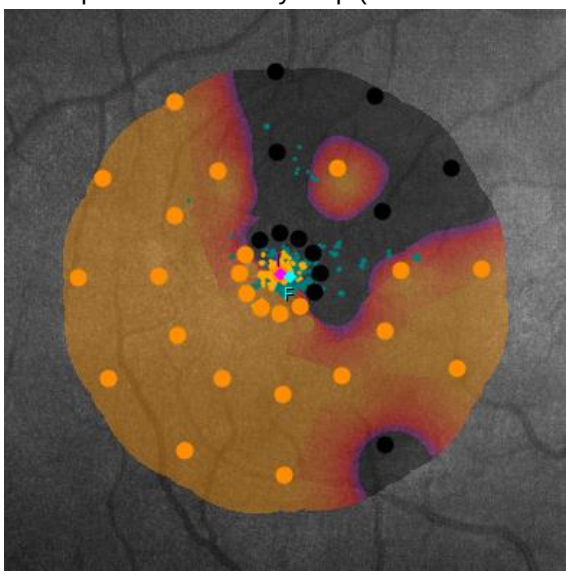


Fig. 54 – Interpolated sensitivity map (Scotoma Finder strategy)

9.3 Follow-up results and differential map

In presence of follow-up exams, it is possible to display differential values between two consecutive test and the time changes of the numerical indices provided by MAIA (average threshold, fixation stability and macular integrity).

	Follow-up tests are displayed underneath the corresponding expert test and are slightly shifted on the right.

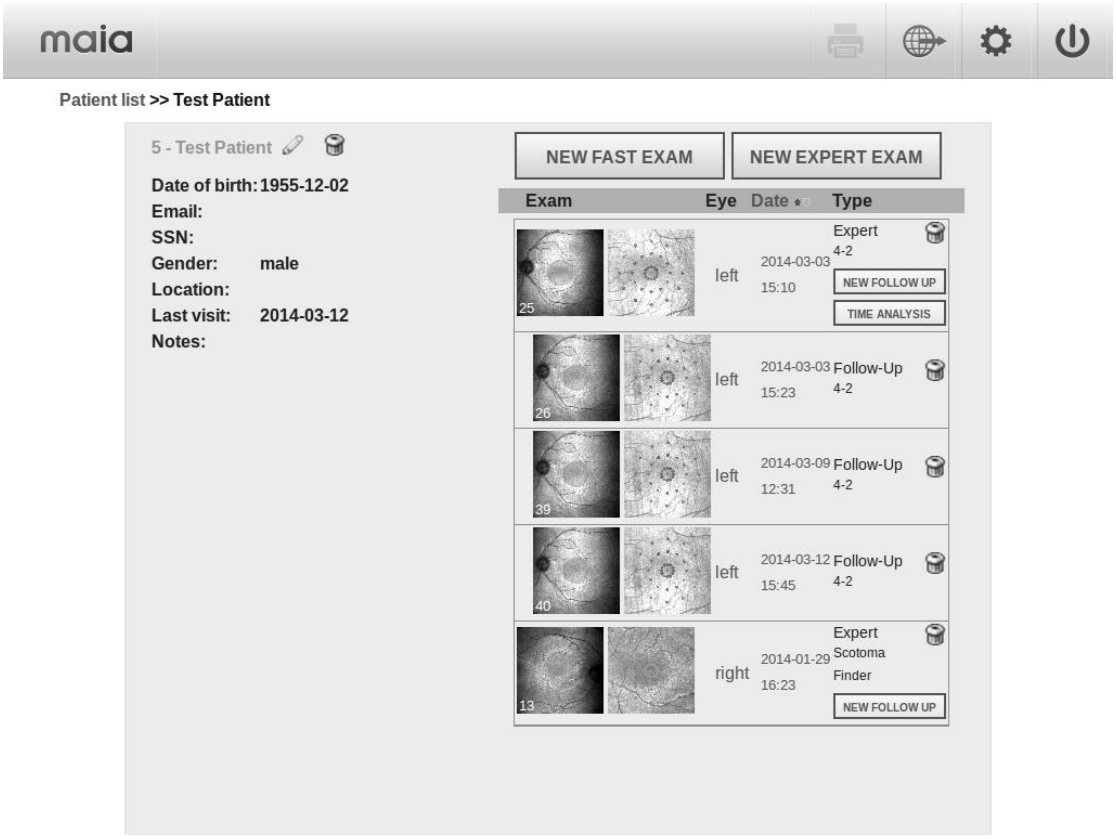


Fig. 55 - patient record with 3 follow-up exams

To access the differential map click on the **TIME ANALYSIS** button.

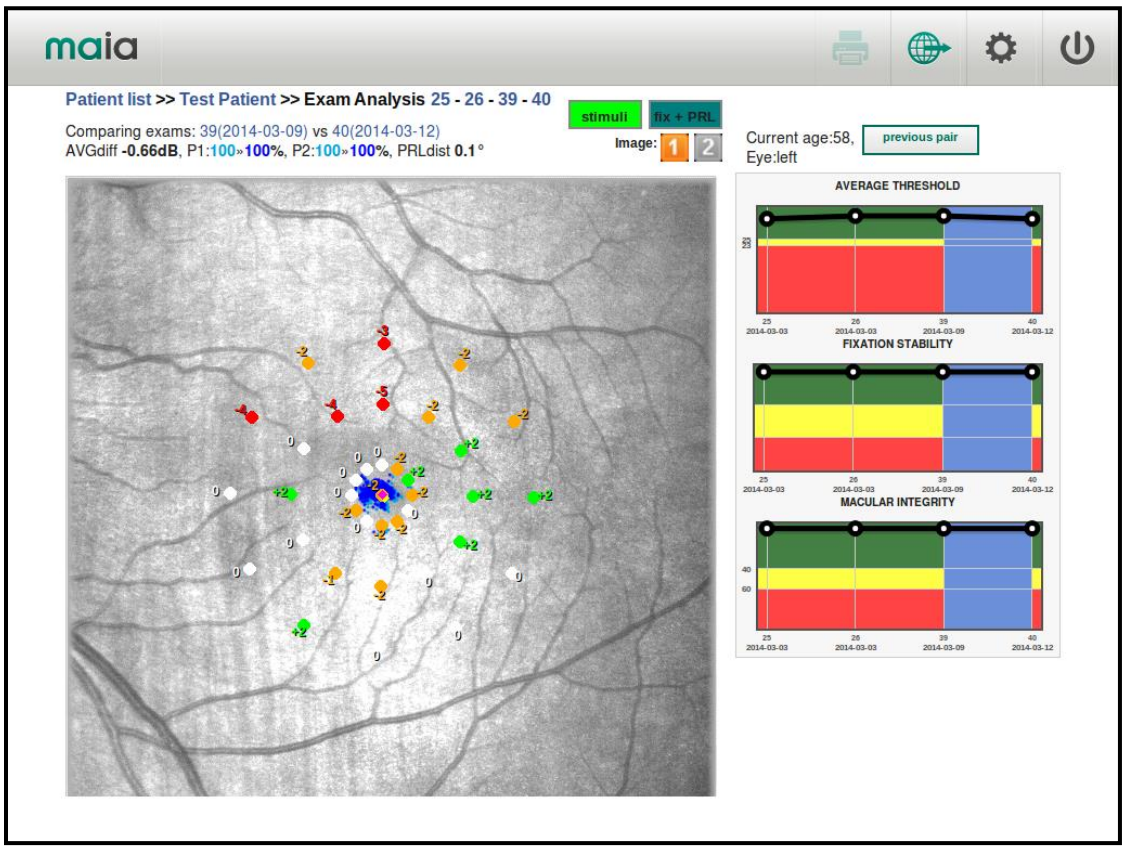


Fig. 56 - time analysis screen: 4-2 strategy

On the right, for the ***4-2*** strategy, such screen shows a time plot of indices AVERAGE THRESHOLD, FIXATION STABILITY and MACULAR INTEGRITY. The horizontal axis represents time and the vertical one the values of the indices. The normal, suspect and abnormal areas are colored in green, yellow and red. The blue bar highlights the two consecutive exams that are compared on the left of the screen.

The retinal image displayed on the left is that of the first test of the two being compared. Values represent the threshold differences between the second and first test:

- Green indicates a threshold increase;
- White indicates a 0 dB change in threshold;
- Orange indicates threshold decrease of 2dB at maximum;
- Red indicates threshold decrease beyond 2dB.

Click on the **Image: 1** or **2** buttons to choose whether to display the differential values respectively over the image of the first or second test. This function can be used to verify proper registration between the images of the two tests being compared.
If stimuli appear at remarkably different retinal locations in the two images, a poor image registration has occurred. In such case results of the two exams are correct but differential threshold values should be regarded with care, as different retinal locations were measured in the two exams.

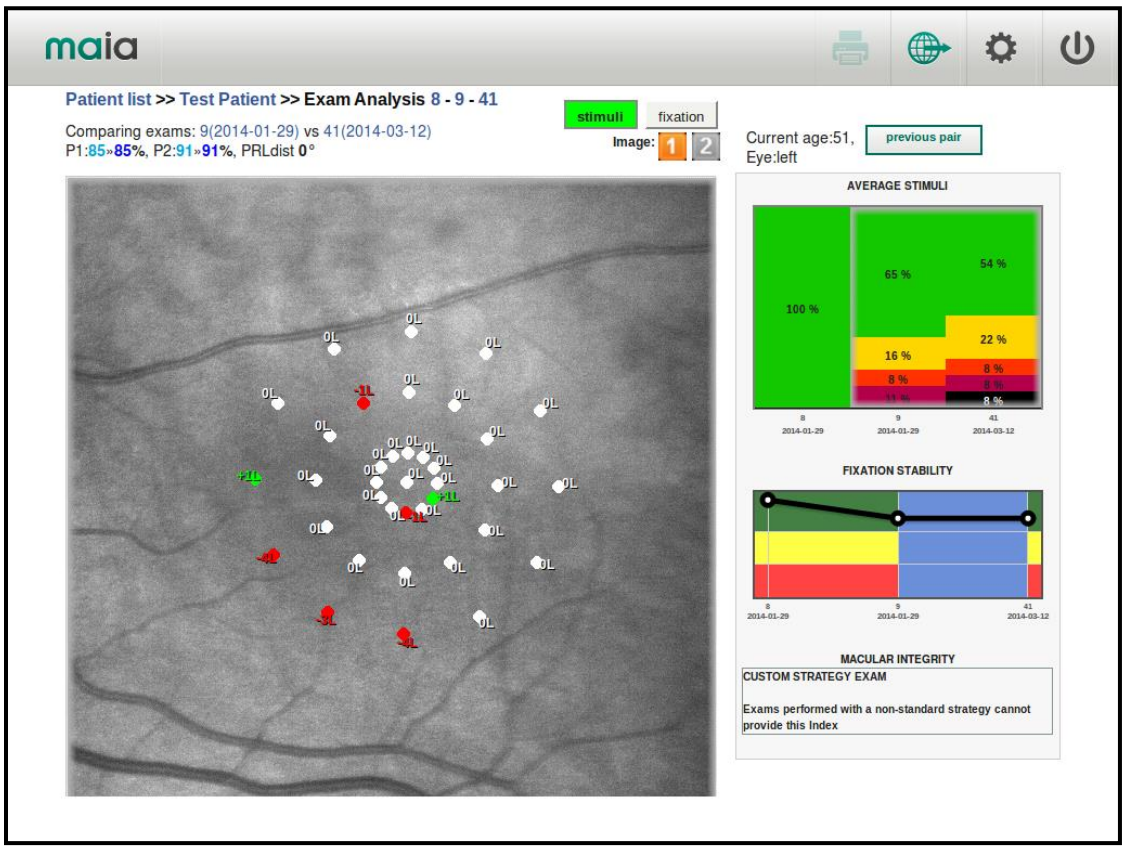


Fig. 57 - time analysis screen: 4-Levels-Fixed strategy

In case of ***4-Levels-Fixed*** strategy the right section of the screen shows two graphs:

- AVERAGE STIMULI depicts by an histogram, for each exam, the percentage distribution of the four different responses (black means: 0 dB not seen),
- FIXATION STABILITY is a time plot of the related index, where the horizontal axis represents time and the vertical one the values of the index. The normal, suspect and abnormal areas are colored in green, yellow and red. The blue bar highlights the two consecutive exams that are compared on the left of the screen.

The image displayed on the left is that of the first test. Values represent the differences between the second and first test:

- Green indicates an increased sensitivity;
- White indicates no change;
- Red indicates a reduced sensitivity.

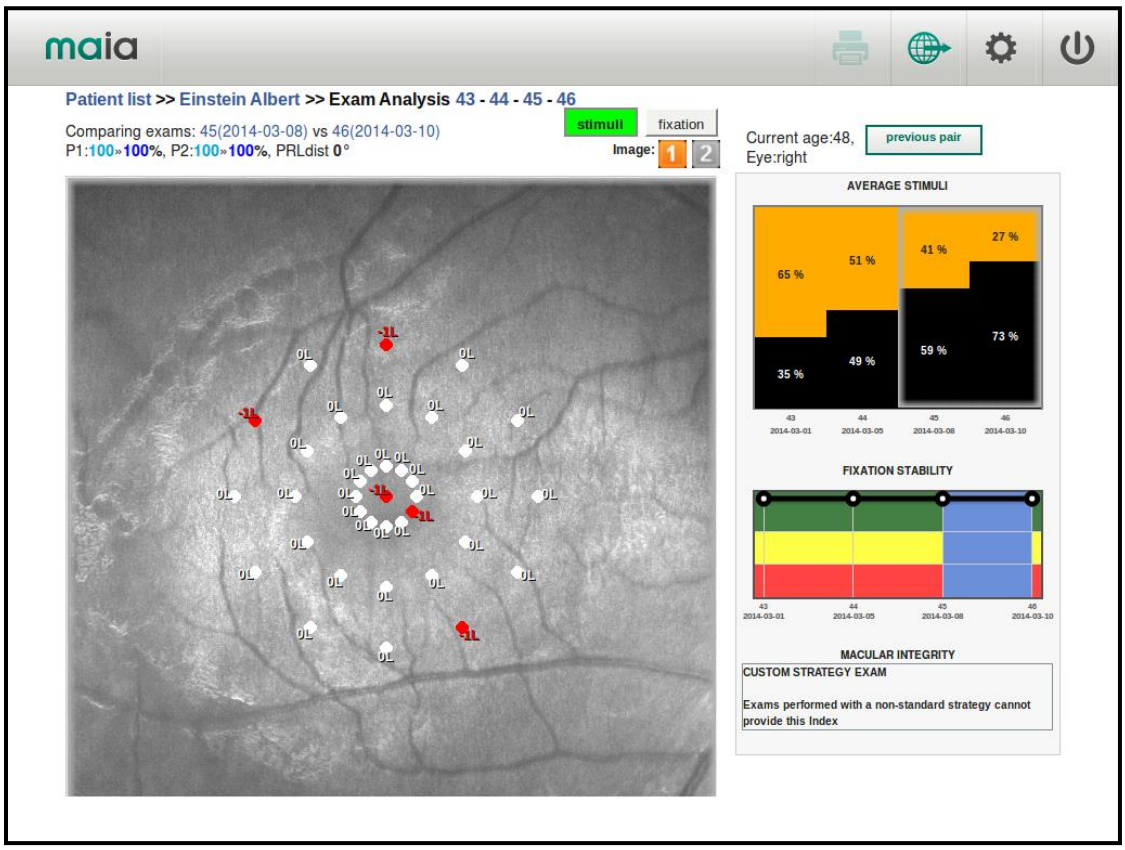


Fig. 58 - time analysis screen: Scotoma Finder strategy

In case of ***Scotoma Finder*** strategy the right section of the screen shows again two graphs:

- AVERAGE STIMULI depicts by an histogram, for each exam, the percentage distribution of the two different responses, i.e. “seen at 0 dB” (orange) and “not seen at 0 dB” (black);
- FIXATION STABILITY is a time plot of the related index, where the horizontal axis represents time and the vertical one the values of the index. The normal, suspect and abnormal areas are colored in green, yellow and red. The blue bar highlights the two consecutive exams that are compared on the left of the screen.

The image displayed on the left is that of the first test. Values represent the differences between the second and first test:

- Green indicates an increased sensitivity;
- White indicates no change;
- Red indicates a reduced sensitivity.

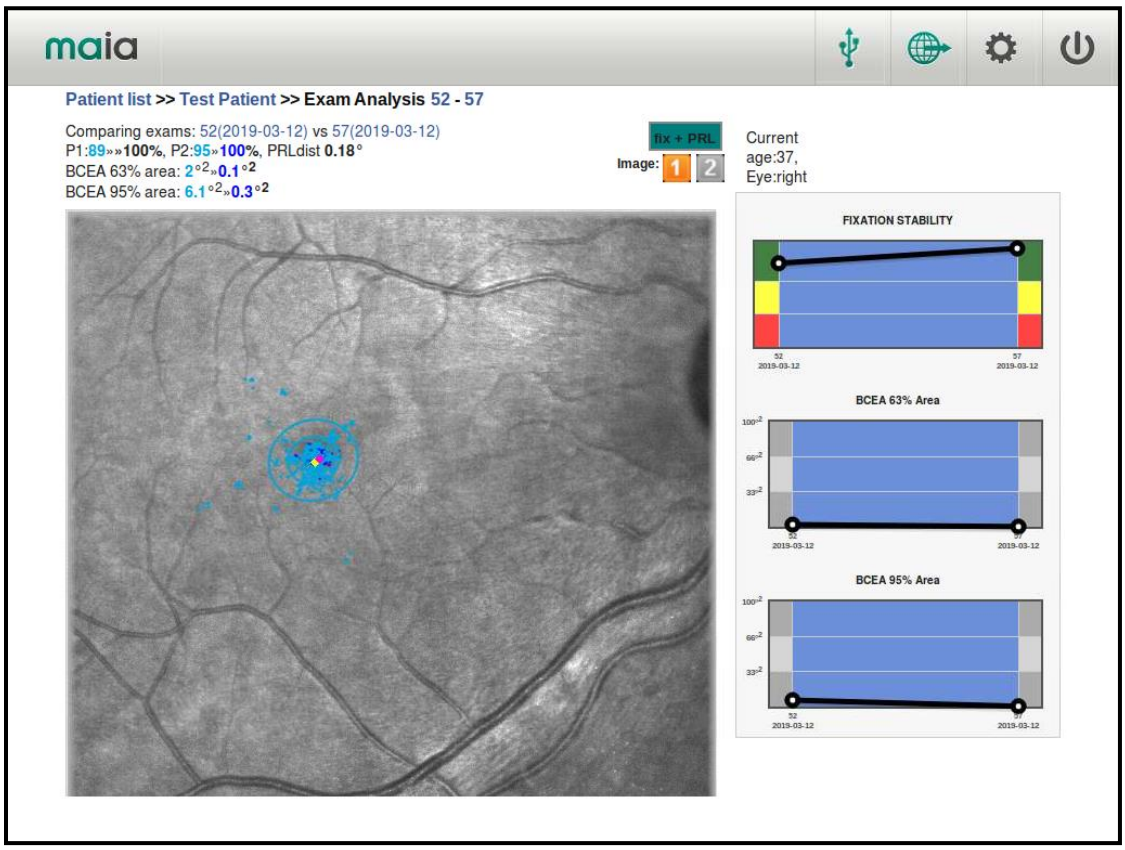


Fig. 59 - time analysis screen: Fixation Only strategy

In case of ***Fixation Only*** strategy the right section of the screen shows again three graphs:

- FIXATION STABILITY is a time plot of the related index, where the horizontal axis represents time and the vertical one the values of the index. The normal, suspect and abnormal areas are colored in green, yellow and red. The blue bar highlights the two consecutive exams that are compared on the left of the screen.
- BCEA 63% and 95% AREA are a time plot of the areas of the BCEA describing the distribution of the fixation points of each exam. The blue bar highlights the two consecutive exams that are compared on the left of the screen.

Whatever the strategy, click on "**previous pair"** or "**next pair**" to select two different tests for comparison.

Click on **stimuli** to enable/disable display of the differences.
Click on **fixation** to enable/disable display of the fixation points and PRLs of the two tests: points of the first test are in green and the PRL in yellow (points in blue and PRL in magenta for the second test).
The following information is also presented on the top:

- **avg diff** (***4-2*** strategy only): indicates the average difference in dB between the two tests;
- **P1** e **P2**: shows the change in fixation stability;
- **prl dist**: indicates the distance in degrees between the two PRLs.

9.4 Handling patient's data

In the patient's record screen it is possible to delete an exam, edit the patient data or delete permanently the entire patient record and the related exams.

To delete an exam press the trash icon displayed on the right of the exam line. A confirmation box will appear: press "**delete**" to confirm or "**cancel**" to abort and go back to the patient page.

To delete a patient and all related exams, press the trash icon on the right of the patient's name. A confirmation box will appear: press "**delete**" to confirm and "**cancel**" to go back to the patient's page.

By pressing the pencil icon on the right of the patient's name, it is possible to change a patient's data or add notes. When finished editing, click on the **Update** button to store the new data.

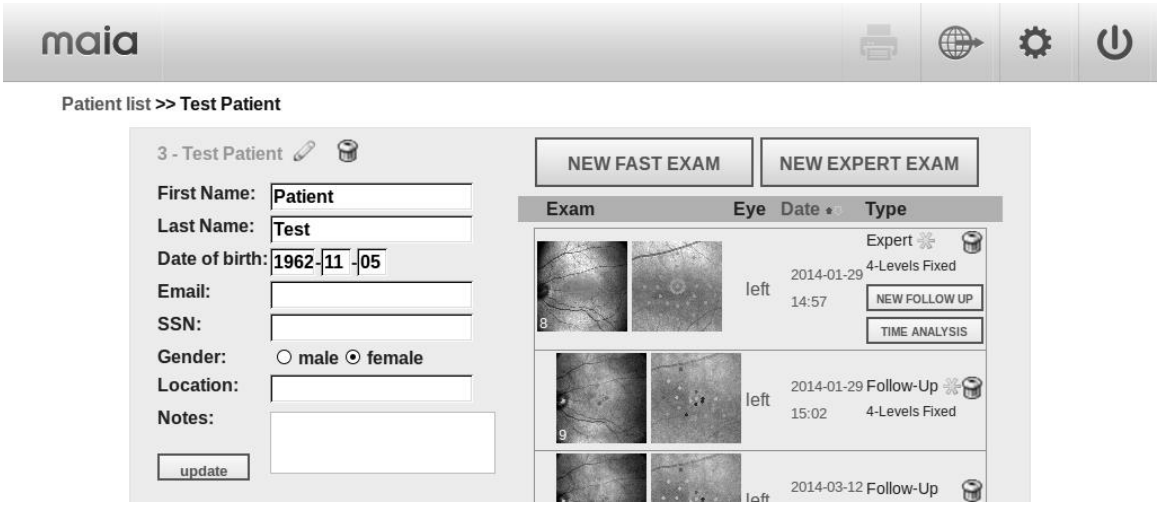


Fig. 60 – editing patient data

If a USB drive is plugged in, a USB icon appears on the top bar (indicated by the circle in Fig. 61): pressing it will allow to export all the data of the current patient in the USB drive as a partial backup: the backup can then be imported on another unit (with the "***Append***" mode, see Par.11.7) in order to perform follow-up exams of the patient: this function is useful for clinics with more than one MAIA or for multicentric clinical studies.

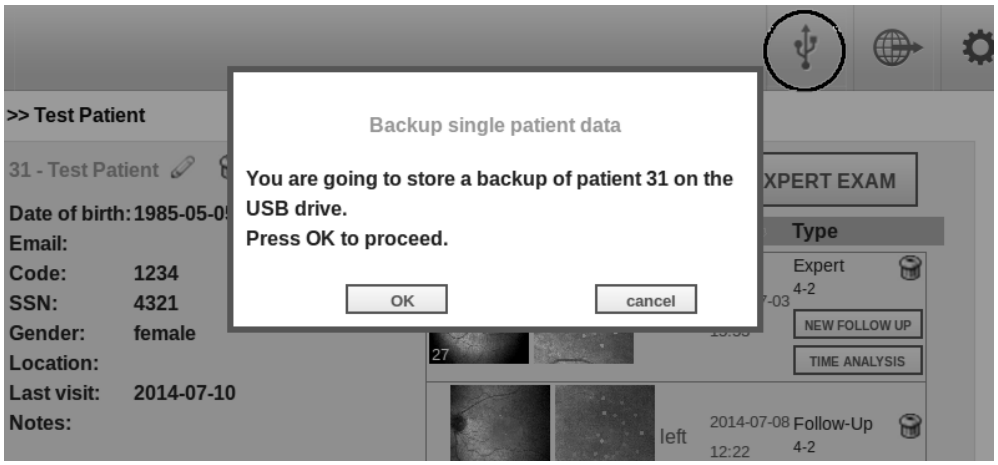


Fig. 61 – exporting patient data

	When re-importing the patient's data, if the patient is already present in the unit database it shall be deleted or renamed, otherwise the exams already present will be duplicated.

10. PRINTING

To print a test results click on **Print** In the results screen, then select **Printer** as destination (see Fig. 63). If no printer is connected the Printer option will not be enabled.
To print to pdf file click on **Print** then select **USB key** as destination.
If the shared folder is enabled and correctly configured in settings, also the option **Ext. shared folder** will be available.
The following picture shows a printout example:

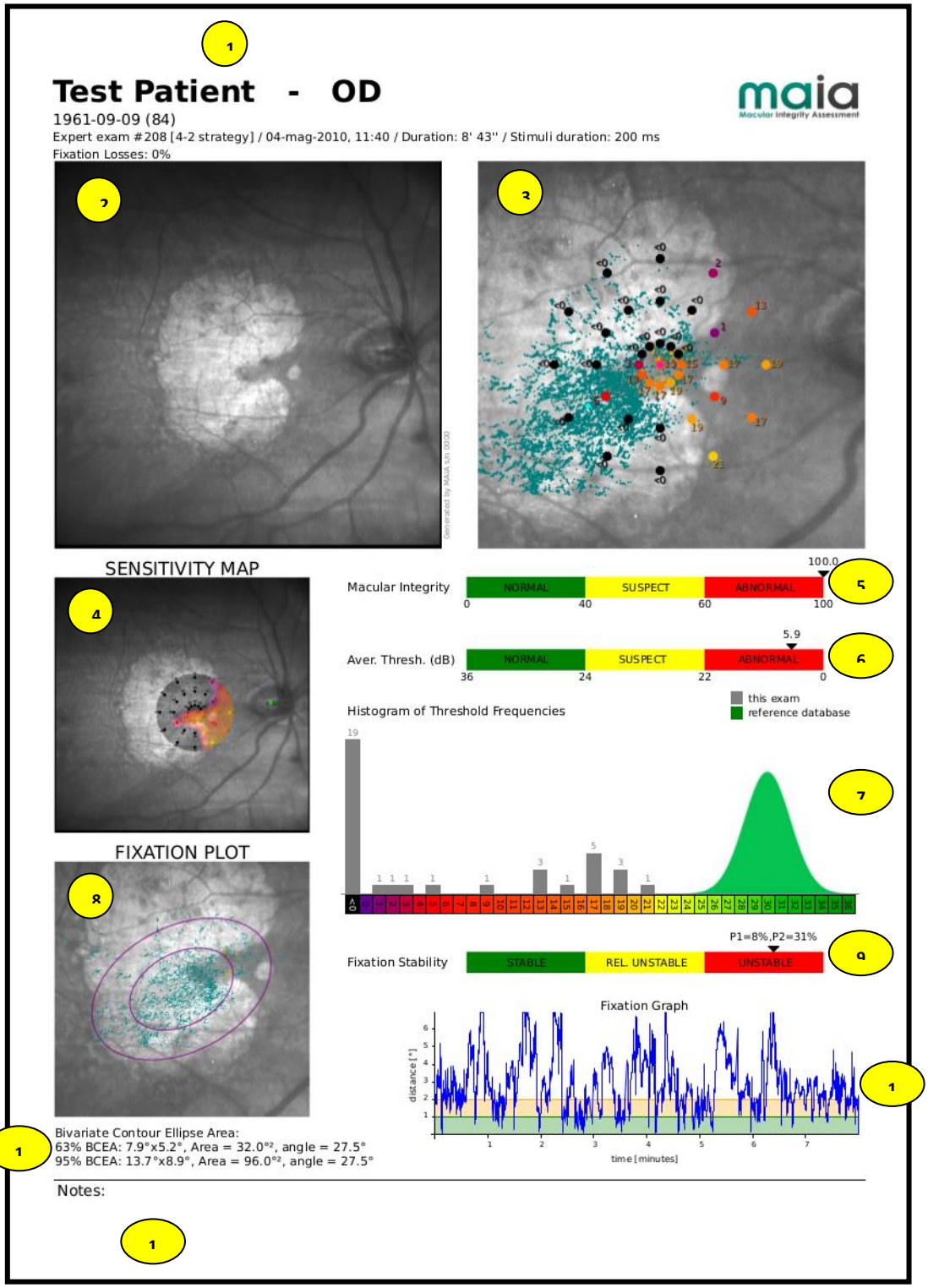


Fig. 62 – Print layout

The printout includes the following information:

1. Printout header, reporting the following information:
   - Hospital/Clinic name (if specified in the settings)
   - Patient last name / first name
   - Eye (OD/OS)
   - Patient date of birth / age
   - Type of exam (expert, fast, follow-up) and number
   - Date and time of exam
   - Duration of exam
   - Fixation Losses index
   - Patient code and Social Security Number (enabled in settings and specified for the patient)
2. Full retinal image
3. Zoom on sensitivity map (dB) with fixation points
4. Full image with interpolated threshold color map
5. *Macular integrity* index (only for ***Fast*** test and for ***Expert*** test with ***4-2*** strategy)
6. Average threshold (dB) (only for ***Expert*** test with ***4-2*** strategy)
7. Histogram of threshold frequencies vs. MAIA reference database
8. Fixation plot with ***Bivariate Contour Ellipse Area*** (BCEA) analysis.
9. Fixation stability indices
10. Fixation graph: shows a time plot of the distance (in degrees) between the fixation point at any given time and the average fixation position (i.e. the PRL-final)
11. Notes

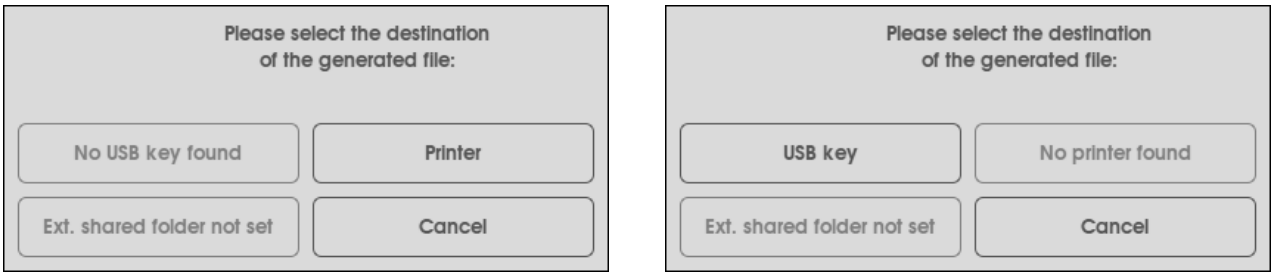


Fig. 63 – Printout destination choice (left: printer connected; right: printer not connected)

11. SETTINGS

To access the Settings page, click on the icon in the top right corner of the patient list screen. The following tabs are available:

- *Preferences*
- *Time*
- *Network*
- *Security*
- *System*
- *Share*
- *Backup*
- *About*

11.1 Settings - Preferences

This page allows to activate:

- an additional patient code, to be typed when inserting a new patient (option **Custom Patient Code);**
- a patient's **Social Security Number**;
- the name of the **Hospital / Clinic / Organization,** which will appear in the printouts.
- Enable/disable the **enhanced Fixation** option, i.e. the projection of a blinking 0dB stimulus at the center of the fixation target during the determination of the PRL-high, that will increase the patient concentration on the fixation target.
- The exam default settings for Vision Condition (applies to S-MAIA only), Strategy and Grid: the values selected will be selected by default when entering the Expert exam interface; selecting "Last used" will set the option selected when exiting the Exam interface the last time.

Click on **Save changes** to store the preferences.

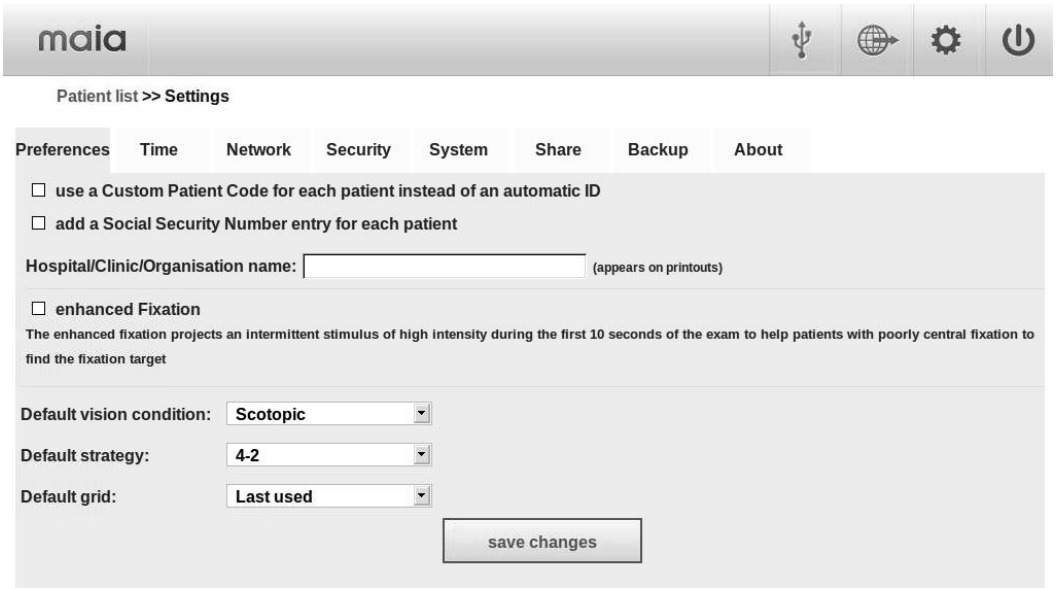


Fig. 64 – Settings / preferences

11.2 Settings - Time

This page is used to set the current date and time. Click on **Set date / time** to save the changes.

Fig. 65 – Settings / Time

11.3 Settings - Network

This page allows to enable remote data access from any computer connected through the LAN to the MAIA. The system will automatically perform a network scan to see if any LAN or Internet connection is available. MAIA needs to be connected to the LAN via Ethernet cable to enable this feature.

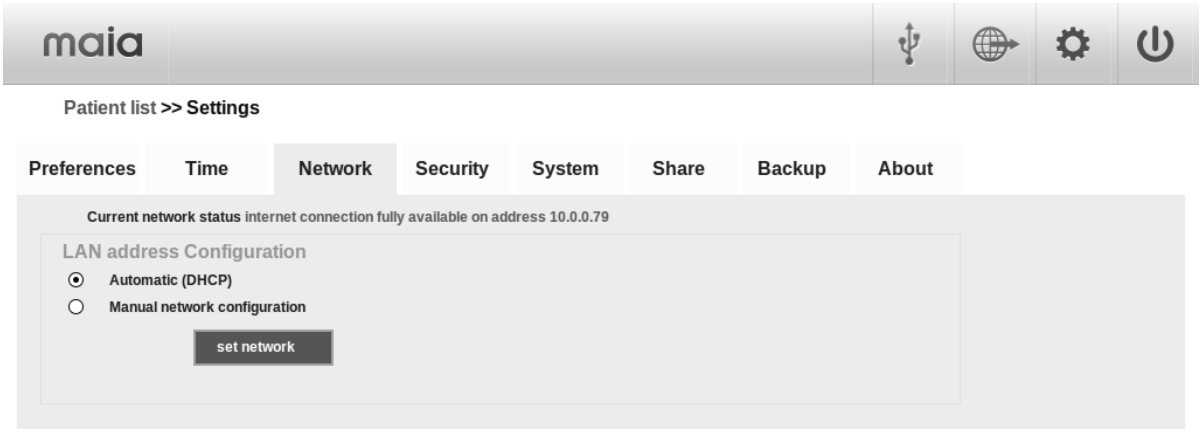


Fig. 66 – Settings / Network

Check network configuration

Once the network scan is completed, the result will be displayed on the screen next to the **Current network status** label.

The result can be any of the following:

- ***Internet connection fully available on address XXX.XXX.XXX.XXX***: MAIA is fully connected to the Internet (this option can be used for technical support purposes).
- ***LAN working on IP XXX.XXX.XXX.XXX***: a valid network is set and the local network is ready.
- ***No working connection*****:** MAIA is not connected to any network.

In the first and second case it is possible to review the MAIA exams via any PC connected to the local network, by typing the MAIA IP address on the remote PC's Internet browser. The network

status and MAIA IP address are also shown at the bottom of the startup screen: the network label says either “Internet” or “local” or “off” according to the above conditions.

Network configuration

In most of the LAN configurations it is sufficient to connect the network cable to MAIA (see Fig. 2) and keep the default configuration (**Automatic DHCP**). If no valid IP address is retrieved it will be necessary to configure the network manually.

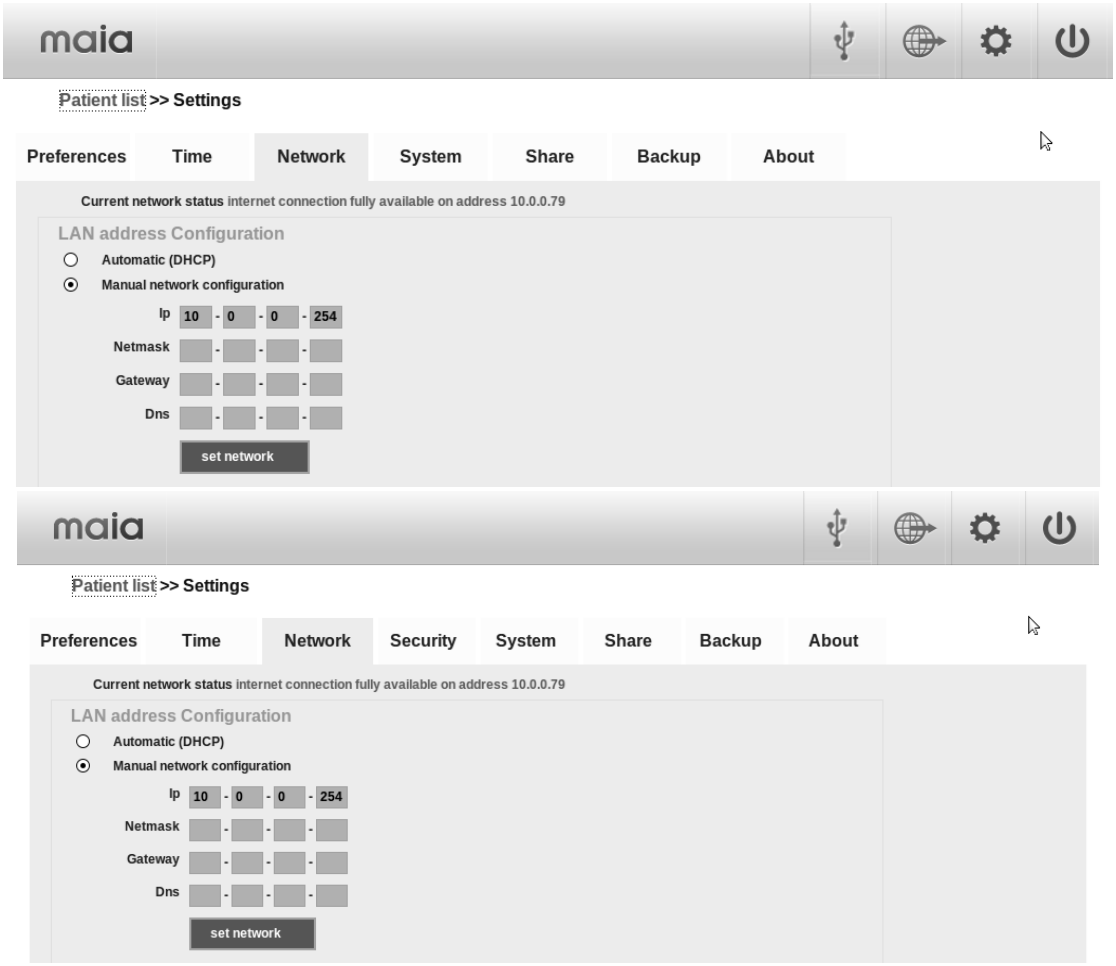


Fig. 67 – Manual configuration of the network

To do that, proceed as follows:

- ask your network administrator to provide appropriate IPV4 address (mandatory), netmask (mandatory), gateway (optional) and DNS (optional) for your network;
- select the **Manual network configuration** option;
- type the above data in the corresponding fields and click on **Set network**.

11.4 Settings - Security

MAIA allows to setup a password protection in order to prevent unauthorized access to the patients data stored in the unit. It is possible to setup two different passwords: one for local access and one for the access through the remote viewer.
The Security menu (see Fig. 68) allows to configure the password protection parameters.

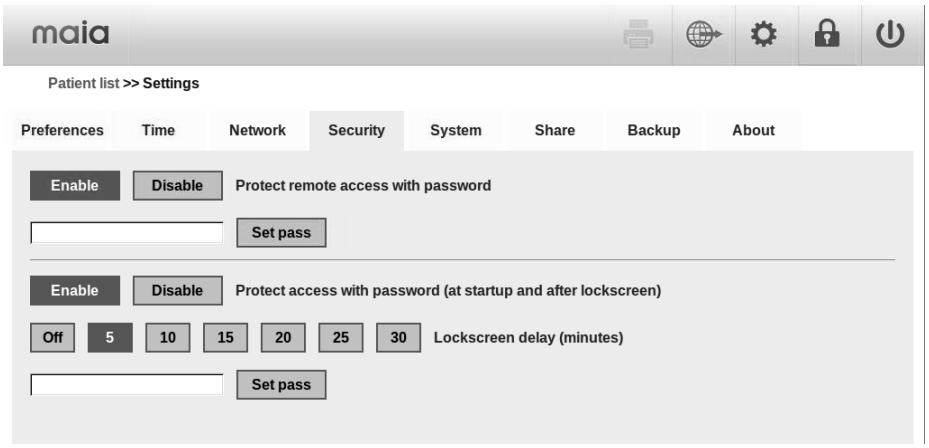


Fig. 68 – Security configuration

The top part of the page allows to enable/disable the password used to access the unit via the Remote Viewer. In order to set a new password, press the "***Enable***" button and input the desired password in the text field below, then press "***Set pass***" button to make it active.

The bottom part allows to setup the password for the local access (in the unit monitor). The password set will be prompted at the system startup. It is also possible to set the ***Lockscreen delay***: when the selected amount of time elapses without any user interaction on the unit monitor, the system will lock up prompting to input the password (see Fig. 69).

If a password has been set, it is possible to activate the lock screen immediately by pressing the Lock icon ( ) on the right of the top bar.

Fig. 69 – Lockscreen prompting for the password

When a password is set for the Remote Viewer, any previously logged-on user will be presented the Lockscreen prompting to input the remote access password.

11.5 Settings - System

This menu gives access to the following diagnostic tools:

- **Reset head**, that forces the auto-reset of the motors (the same operation that takes place also at the system startup)
- **Calibrate Touch-screen**, that allows to recalibrate the touch-screen display: the calibration consists in pressing with the finger at the center of the symbol below until it moves to the following corner of the screen.

- **System checkup**, that checks the hard-disk integrity
- **Remote assistance,** that enables the remote assistance: this will allow Service technicians to connect to the device using a remote display protocol (VNC) or a console protocol (SSH). Once clicked and accepted the disclaimer, the authorization code needed to connect will appear: this must be communicated to the technicians that need to connect to the unit. A label below the button will display the code and the connection status (Closed, Waiting for connection or Active). To close the remote assistance, click again on this button: all the currently connected clients (both VNC and SSH) will be disconnected; it will be closed automatically at the next system reboot, anyway.
- **Shipment position,** that moves the optical head in a position suitable for shipment in order for MAIA to be placed in its box, then switches off the unit.
- **Reset database,** that allows (after proper confirmation) to delete all patients data and exams stored in the system.
- **Service Access**, that allows to enter the password-protected Service Panel or Calibration Interface.
- **Raw Data Export,** that launches the Raw Data Export tool which allows to export all exams data in .txt files for advanced statistical analysis. For further details, check the par. ***APPENDIX A: MAIA grids XML*** format

Custom MAIA grids can be created, defining as many projection locations as desired. The position of each location can be expressed in Cartesian or Polar coordinates, as desired.

The grid shall be defined in XML format, which describes a tree of nested nodes. Each node can have child nodes and/or attributes). Each XML node can be expressed in two ways:
1) with opening and closing tags (i.e. **<node>** and **</node>**): mandatory if it has child nodes
2) with the "/>" closing tag, if it has no child nodes (i.e. **<node attribute="value" />**)

The same XML file can contain the description of more than one grid: when importing it, all the contained grids will be imported into the unit.

The main structure of the XML file shall be:

```
<!DOCTYPE MitPatterns>
<patterns>
    <pattern_expert>
      <Grid name="3&#176; Circle plus center">
           <Stimulus id="1" … />
           <Stimulus id="2" … />
      </Grid>
      <Grid name="4&#176; square grid">
```

```
            <Stimulus id="1" … />
            <Stimulus id="2" … />
        </Grid>
    </pattern_expert>
</patterns>
```

The first line (**MitPatterns**) is a header. The main node ("**patterns**") is the root node of the XML, and shall contain the "**pattern_expert**" node; for Scotopic test grids (used in S-MAIA), the tag **pattern_expert** shall be replaced with **pattern_scotopic**. The **pattern_expert** and **pattern_scotopic** nodes shall contain one **Grid** node for each defined grid.

The **Grid** node shall have a "name" attribute, containing the name given to the grid, that will be displayed in the Grid selection interface (see par. 8.4.4). In the example, the "**°**" tag is used to display the degrees (°) symbol. Each **Grid** node shall then contain several **Stimulus** child nodes, each one describing one stimulus location to be projected on the retina. Each **Stimulus** shall have a unique id attribute: the id must be >0 (dedicated to the stimulus on the optic disk, used to calculate the Fixation Losses index) and <1000 (dedicated to custom added stimuli, see par. 8.4.11).

As said, each location can be expressed in two ways:

```
<Stimulus id="3" x_deg="2.5" y_deg="4.33" />
<Stimulus id="3" ray="5" angle_deg="60" />
```

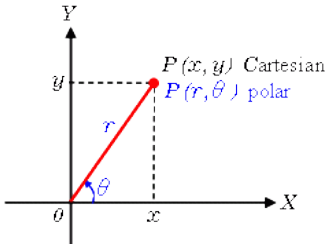


Fig. 81 – Cartesian vs Polar coordinates

The above example shows two different ways to express the same location, referred to the grid center: the first in Cartesian coordinates (***x_deg,*** y_deg), expressed in retinal degrees; the second in Polar coordinates ***(ray,*** angle_deg ***corresponding*** to **r** and θ in Fig. 81: ray is again in retinal ***degrees, while*** angle_deg is in degrees measured anti-clockwise starting from the X axis).

The coordinates (0, 0) refer to the center of the grid, which will be projected over the PRL-i, unless the "Change grid position" option is selected (see par. 8.4.10). All the coordinates refer to the RIGHT eye: when examining the LEFT eye, the grid will be flipped horizontally. Stimuli locations cannot overlap (i.e., the minimum distance between two stimuli is 0.5 degrees).

- APPENDIX B: RAW Data Export Tool .
- **Update Software,** that launches the Software Updater which allows to install software updates and packages provided by CenterVue.**Upload log files** and **Save log files on USB**, that allow to extract the system log files of the unit (mostly in encrypted format) and either upload them directly to CenterVue Service servers, or to store them on a USB drive in order to be sent via email to Service technicians.

Beware: the reset database operation cannot be cancelled or restored unless you have backed up your data!

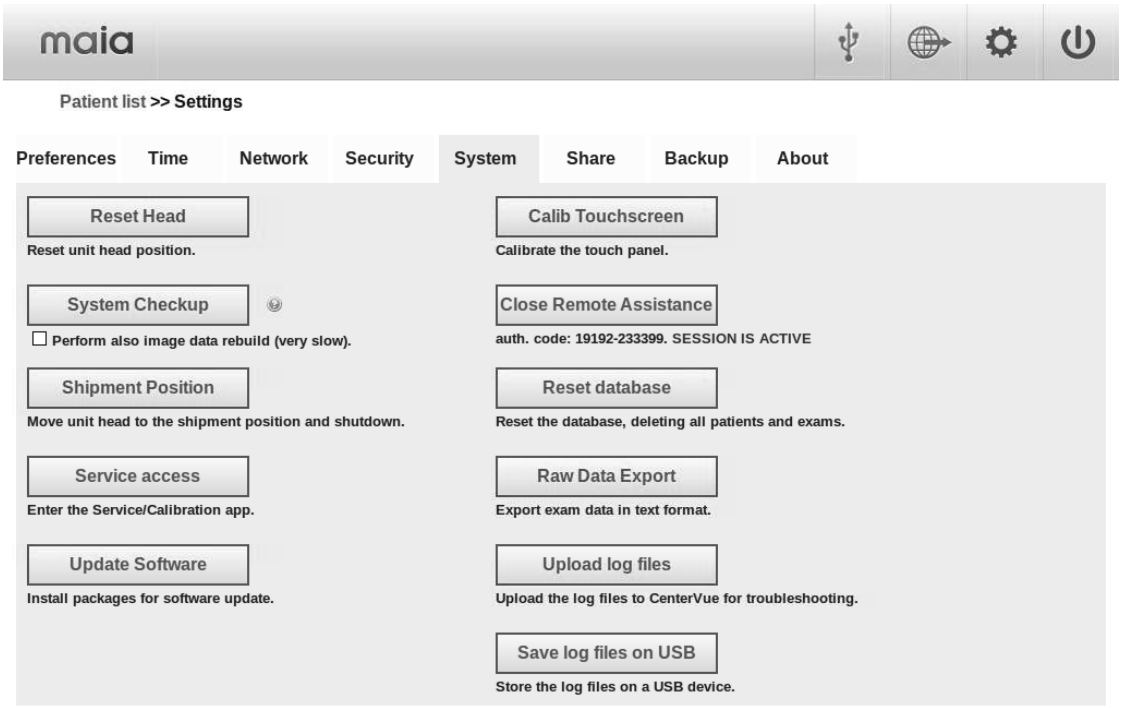


Fig. 70 – Settings / System

11.6 Settings - Share

This page allows to setup the export of images and printouts to an external windows network shared folder:

- **On/off** buttons enable/disable the shared folder.
- **JPEG/PNG/PDF** allow to select the export format for images and printouts
- **Auto/manual** determine if the export will be done automatically at the end of each exam, or manually (using the export/print button in the exam local viewer)
- It is possible to select also the template of the filename that will be generated
- **Configure** allows to reconfigure the shared folder
  In the lower left corner, you can see the network path of the currently configured shared folder

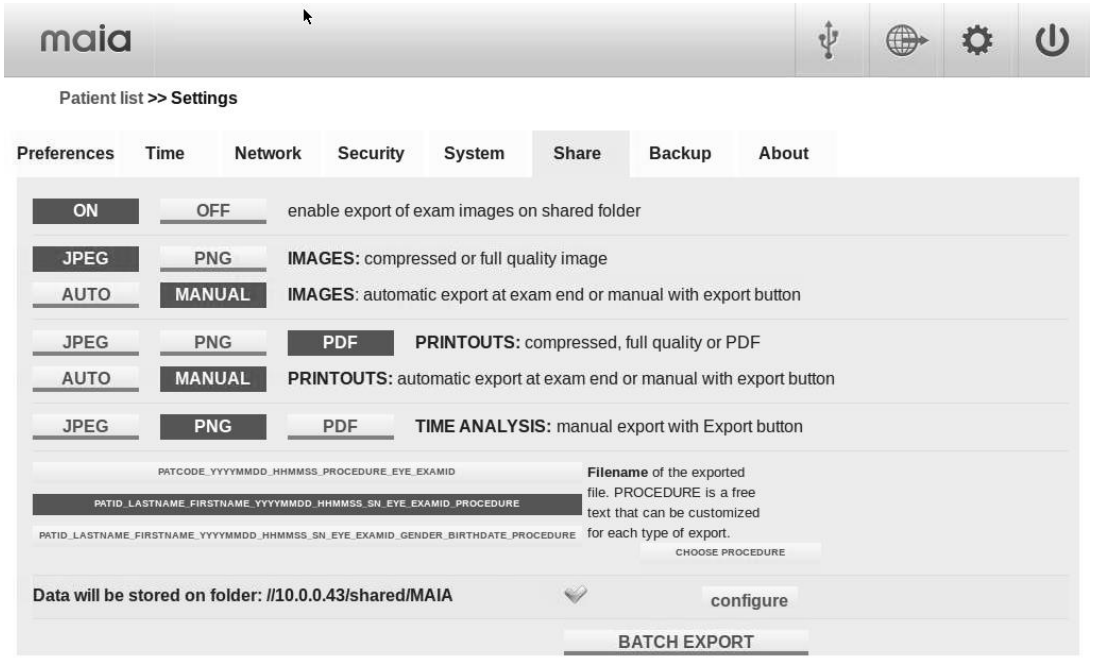


Fig. 71 – Settings / Shared folder configuration

The Shared Folder connection uses Samba (SMB) protocol. From v. 2.6.0, MAIA supports SMB protocol up to version 3 (SMBv3); earlier sw versions support SMBv1 only.

When shared folder is enabled the system checks automatically if there is a configured shared folder and if there is one it checks the connection. The status of the current configuration is always in the lower part of the screen:

- the block flashes in grey when it is checking the connection
- the block becomes light green if the current connection is working
- the block becomes red if the current connection fails to work

If shared folder is enabled the system examines if the current configuration is valid.

- if the system has no shared configuration at all, it forces to set a configuration in order to be set to "ON"
- if the system has an invalid configuration, a window displays an error in shared folder connectivity, and it is possible to press "cancel" to keep the current configuration even if it not working in that moment

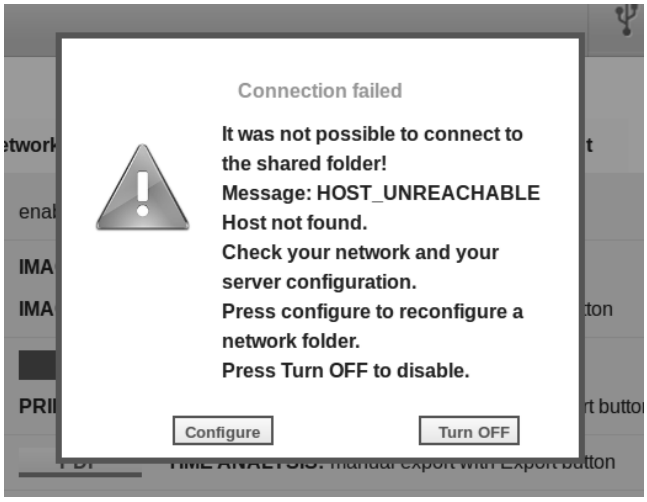
To configure the shared folder to connect press the button “configure”. A popup window appears asking for:

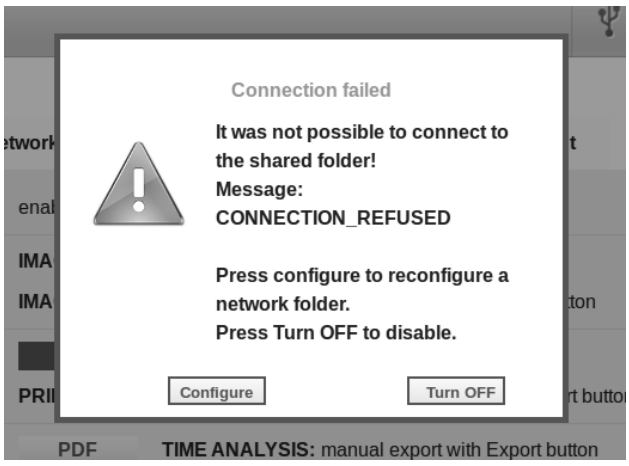
- hostname or IP address of the pc where the shared folder is configured
- the name of the network shared folder. It is possible to configure a subfolder of a network shared folder, by entering the full path with “/” (forward slashes) or “\” (backslashes) as subfolder separators
- Username, password and Windows Domain. These are optional parameters that depend on the Shared Folder configuration. Username and Password are usually needed to connect to the Shared Folder. They can be set to blank to connect to the shared folder anonymously. It is possible to insert also the windows domain, as an optional parameter. The domain is seldom needed for some Windows configurations.

The system tries to connect with the information provided.
If the connection is successful, a message informs that it is all OK and the system is ready to work with the configured shared folder:

If guest access fails, a message informs the user that the configuration doesn't work and leaving the option to the user to leave the configuration as it is or to change the connection parameters.

The exact message shown also depends on which Windows Server is being used. Most common messages, such as the three examples shown below, are accompanied with a suggestion for resolution.





Less common messages will be displayed as they are received from the Windows Server, and can be very useful to detect a problem if present.
The configuration parameters are saved on the MAIA and will remain even after shutdown.

It is possible to separately configure IMAGES, PRINTOUTS in order to get them being exported either manually or automatically. In the case of TIME ANALYSIS manual export only is allowed.

If automatic export is selected, images and/or printouts are exported automatically at the end of each exam.
If manual export is selected:

- from the exam local viewer, it is possible to export the image by selecting “Export” and then “Ext. Shared folder” button. The image will be exported with the layers that are shown in that moment
- from the exam local viewer, it is possible to export the printout by selecting “Print” and then “Ext. shared folder” button
- from the Time Analysis viewer click on the “SHARED FOLDER” button to export what is shown on the screen.

Only when shared folder is enabled, and it is correctly configured, that is when the lower part of the screen is in light green and the current connection is working, below the block a **BATCH EXPORT** button appears.

By clicking such button, a batch process is started, which exports as a whole ALL the exams saved in the unit. A dialog box with the two buttons IMAGES and PRINTOUTS allows to choose the kind of files to be exported.

The export will then start. A dialog box will show the process progress, which, depending on the total number of exams, could be very long. A STOP button allows to abort the process at any time.

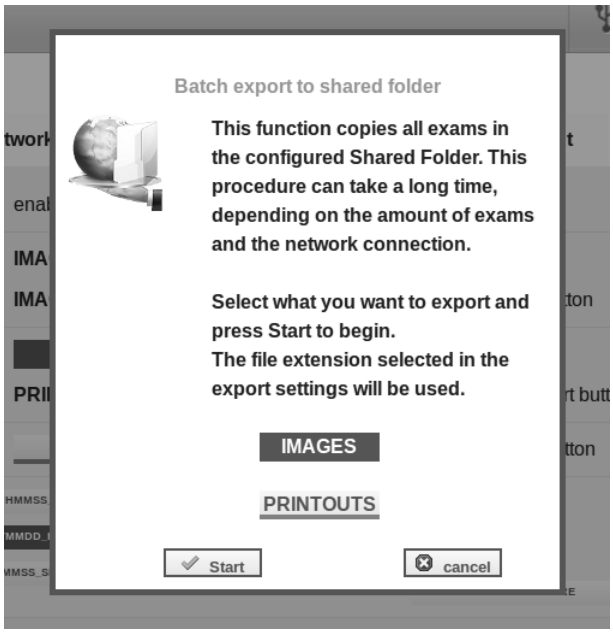


Fig. 72 – Batch export - choice

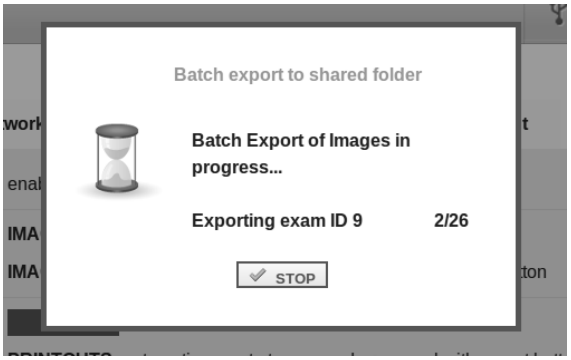


Fig. 73 – Batch export – progress window

11.7 Settings - Backup

This page allows to perform a full data backup on an external USB media (USB key or hard drive) or on a remote shared folder (the same used to export the Images and the Printouts, see par. 11.6), and is divided in two frames (see Fig. 74):

- The top frame allows to perform the backup/restore from the USB media: plug it in one of the available USB ports and press **Start Backup**.
- The bottom frame allows to perform the backup/restore from the previously configured shared folder. The frame shows the connection status of the shared folder and its network path, if connected. If the shared folder is not configured correctly, the message at Fig. 75 is displayed and the bottom frame is disabled. The **Start Backup** button in this frame allows to start a backup and store it in the remote shared folder.

This procedure will make a complete copy of all stored data.

MAIA indicates the storage system capacity required to perform the data backup: if the space available is not sufficient, it will not be possible to effectively perform the backup.
It is fundamental to frequently backup the data in order to prevent any possible data loss due to a failure of the internal hard drive.

From this page it is also possible to **restore** an existing backup archive into MAIA pressing the related button in any of the two frames (see Fig. 74).

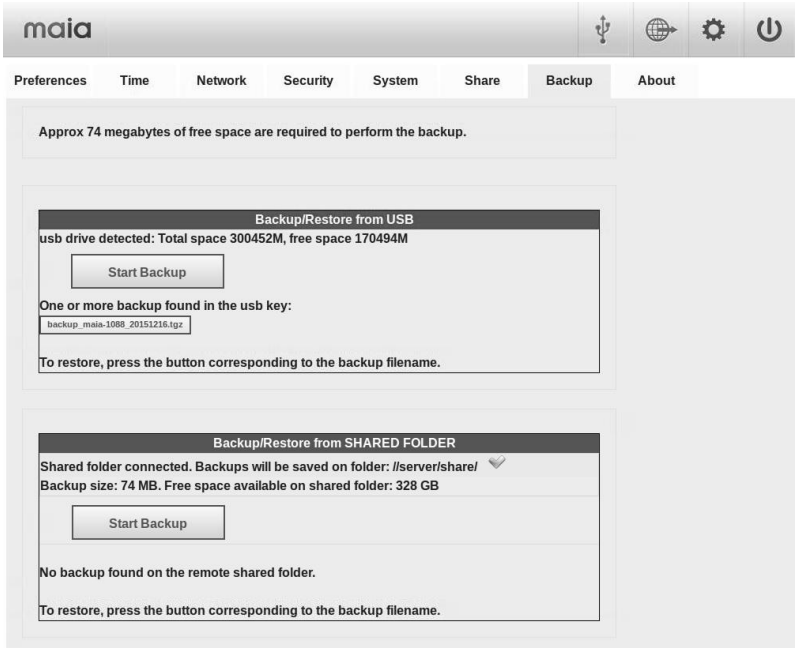


Fig. 74 – Settings / Backup

Fig. 75 – Settings / Backup: shared folder not connected

According to operator's choice (Fig. 76) this operation can either REPLACE (**Erase current**) the data currently stored in the system, or MERGE (**Append current**) data from backup with the existing data.

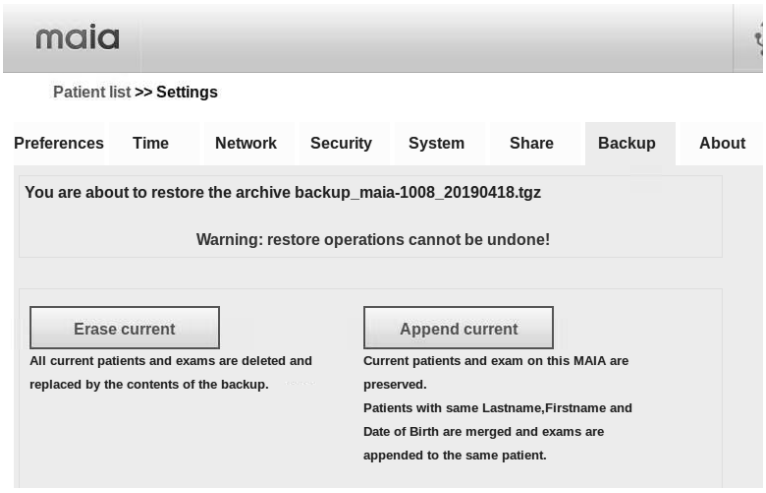


Fig. 76 - Restore method selection

	Restore operations cannot be undone. The use of "**erase current"** button will delete all data contained in the MAIA.

	Restoring a backup archive in APPEND mode will probably alter the original patient and exam IDs, both if the archive was generated by the same unit, and if it was generated by another device.

	When restoring a backup archive in APPEND mode, in case of duplicate patients found (with the same name, surname and date of birth), corresponding exams will be merged inside the same patient folder. Since sw 2.6.0, already-existing exams are not restored so no exam duplication occurs. At the end of the process, the outcome of the Restore is displayed, reporting how many patients and exams have been imported, merged or skipped because they were already present (see Fig. 77).

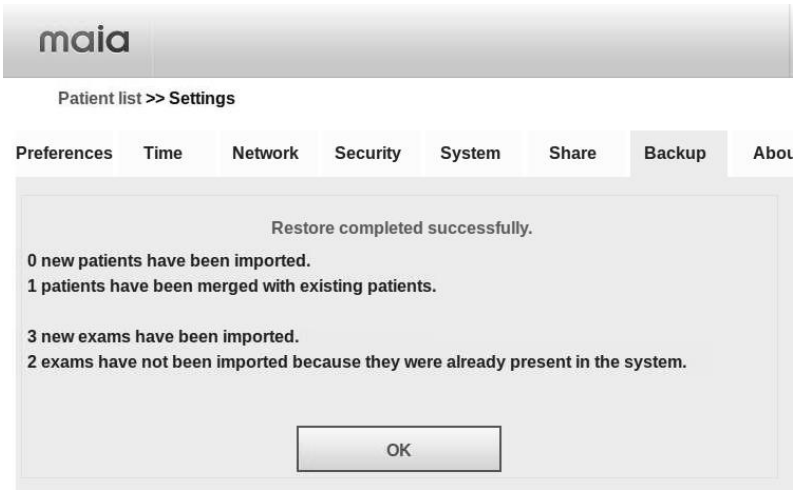


Fig. 77 - Restore procedure outcome

11.8 Settings - About

This page provides the following information:

- The unit serial number;
- The installed softwareversion;
- Optional modules installed;
- The list of **supported printers** (built-in driver).

By clicking the button **POSTSCRIPT**, the built-in postscript driver is enabled instead: in this case any available printer providing **genuine** (non-emulated) Postscript3 protocol support can be used.

	Some Postscript compatible printer require to be pre-configured, in order to be used as Postscript printer and not with proprietary driver: please refer to the printer's accompanying documentation.

By clicking the button **BUILTIN**, only the printer model listed on the page can be used.
Currently selected option is the one highlighted in dark cyan.

By clicking the button "more" the information expands including more detailed information usually needed for service intervention, such as:

- The installed Operating System version;
- The firmware and we software version
- The Production ID of the device, useful for components traceability
- The Ethernet MAC address, useful for firewalled networks
- The space left on disk. When this value is below 10GB it is advisable either to remove some patients/exams in order to free some space on disk, or to perform a Reset database, or to contact service assistance.
- The number of records (patients and exams) stored in the unit DB

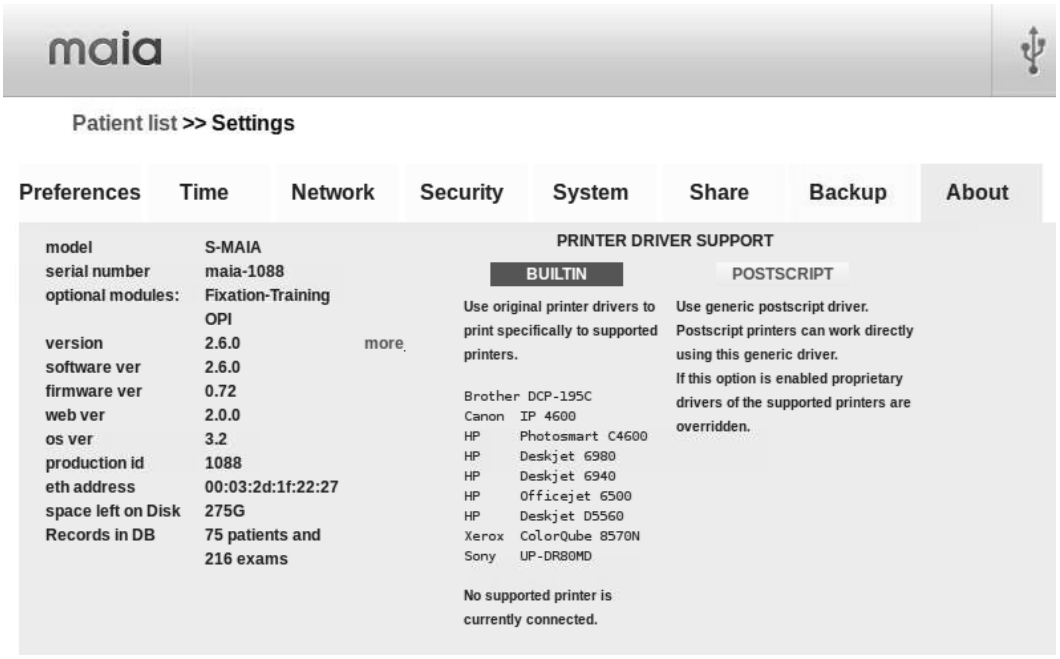


Fig. 78 – Settings / About

12. REMOTE VIEWER

It is possible to access MAIA from a remote computer to review exams, images and data stored in the device. This procedure allows one for example to analyze the images on a PC equipped with a high-resolution monitor or to make the data available on a PC located in a room far from the instrument. In order to accomplish this, it is necessary to:

- connect MAIA to the local network in order to get the MAIA IP address and follow the procedure described at par. 11.3;
- type the MAIA IP address in the URL box of the browser.

Supported browsers: Internet Explorer 7 or more recent, Firefox 3 or more recent, Apple Safari.

Once the connection is established, the startup screen will show up on the remote PC.

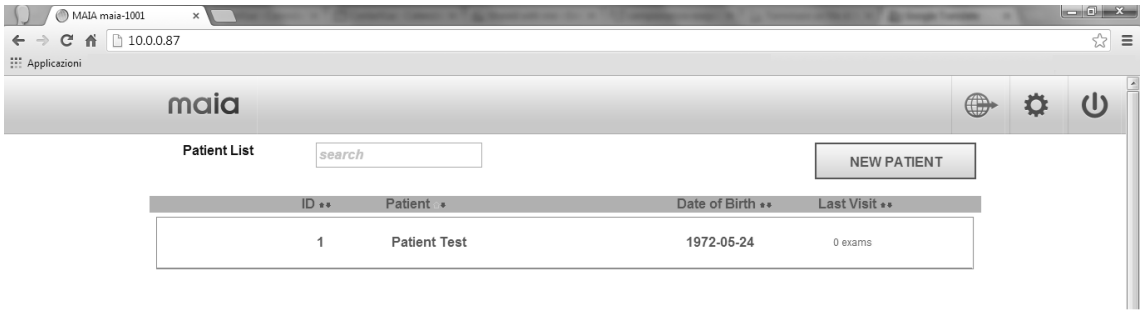


Fig. 79 – startup screen on remote PC

Available functionalities include:

- Patient list;
- Creation of a new patient;
- Access to the settings page;
- Access to the patient record and related exam list and access to individual exams.

Other functionalities are not available through remote connection, in particular:

- Execution of a new exam;
- Network configuration.

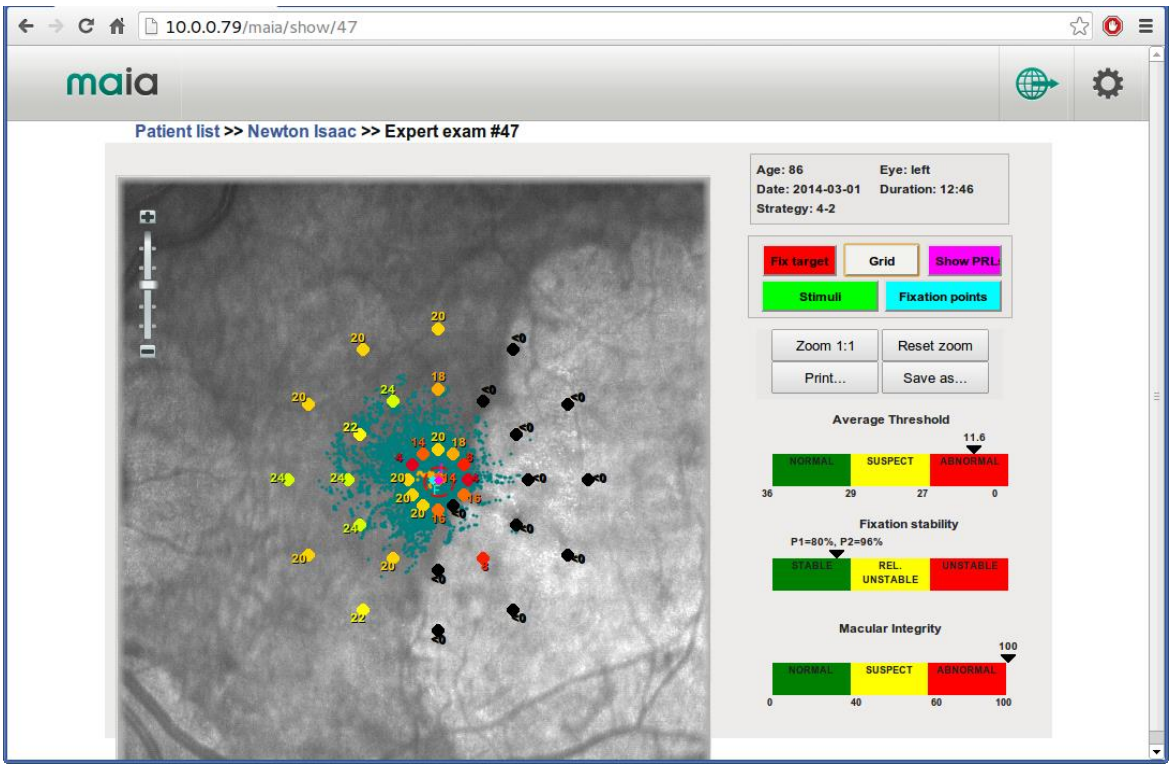


Fig. 80 – Results screen via remote access

The remote viewer behaves exactly like the local viewer of the instrument.
Available functions include:

- image zoom;
- overlay of the fixation target, PRL, stimuli and fixation points;
- **Zoom to grid**: zooms to the area covered by the perimetric grid;
- **Reset zoom**: shows the entire image;
- **Print**: generates a pdf printout of the exam, ready to be printed with the pc;
- **Save as**: downloads the retina image with all the layers (target, PRLs, fixations, stimuli) currently selected.

13. SYSTEM SHUTDOWN

To shut down the system go back to the **patient list** and click on **POWER OFF**. Wait for the progress bar to completely roll back and then turn off the **main switch**.

Turning the system off by the main switch without completing shutdown procedure could result in data loss and in damages to the internal storage system.

14. CLEANING

This paragraph explains how to clean the system.
The chin rest and the front rest shall be disinfected, between one patient and the next. The disinfecting solution should be applied using a wipe, taking care of not sprinkling parts not belonging to the patient rest. Painted parts of the chin rest, such as the twist grip, should not be cleaned by means of aggressive solutions.
The objective should be cleaned by using a small rubber blower, to blow away dust. Only if really needed, for instance due to the presence of a fingerprint, the objective can be cleaned by means of photographic cleaning paper, dampen by ethyl alcohol.
The touch screen panel should be cleaned only with a cloth damped in water.
When cleaning the rest of device, the device must be off, and the power cord shall be disconnected from mains. If needed, the external covers of the unit can be cleaned by means of a slightly damp cloth.

15. BASIC TROUBLESHOOTING

This paragraph provides very simple instructions to perform basic troubleshooting.

Symptom	Possible Cause(s)	Solution
The main switch does not light up when turned ON	The power cable is not properly connected	Connect the power cable
It is impossible or very hard to align to the subject's pupil	The system head is not positioned properly when starting the test	Start the test with the system head fully retracted (far from subject's eye) to enlarge the observed field
The LCD is blank after turning ON the main switch, even if the main switch lights up	Failure of the LCD or failure of the internal PC	**Contact service representative**
The retinal image is blurred after performing the auto-focus	Auto-focus software failure	Adjust focus manually with the **Focus+** and **Focus-** commands
When turned ON, the system makes a strange noise and does not move to the usual starting position	Failure of a motor, connector or movement limiting sensor	**Contact service representative**
At the system startup you see the message "Unable to connect to control board"	Communication problem with the main control board	**Contact service representative**
At the system startup you see the message "System date could be wrong"	BIOS battery fault	The BIOS battery responsible of updating the system date has discharged. Replace it.
Entering the exam interface you receive the message "Projection System initialization failed"	Problem with the reset of the motors responsible of deflecting the stimulus	Try to exit and re-enter the exam interface. If the problem persists, **contact service representative**
Stimulus is outside the fixation target during the "Projection System checkup" (see Par.8.1)	Projection System is unstable or out of calibration	**Contact service representative**
The head of the system does not move in one direction	Wrong use of the joystick	Check joystick operation at par. 8.3
	The head reached the position limits in that direction	Correct the position of the subject's head
	Failure of a motor or of a proximity sensor or of a cable	**Contact service representative**

16. ELECTROMAGNETIC COMPATIBILITY

This device is classified in class B according to IEC60601-1-2.
This device has been tested and found to comply with the limits for medical devices contained in IEC60601-1-2 and Medical Devices 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 these 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 by 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 is connected;
- consult the manufacturer or field service technician for help.

17. TECHNICAL SPECIFICATIONS

CE 0123

Class and type of applied part

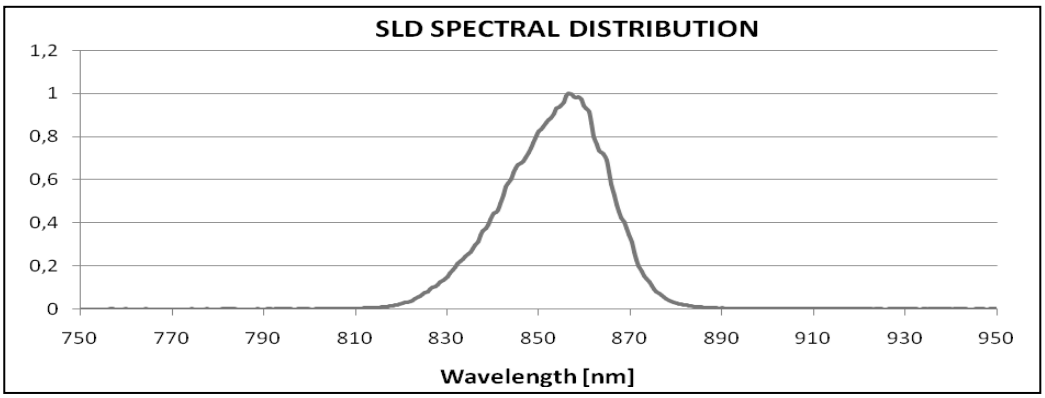
1, B (according to CEI EN 60601-1).

IP classification

IPX0 (according to the degree of protection provided by the enclosure with respect to harmful penetration of particulate matter or water).

Fundus imaging

- Line scanning laser ophthalmoscope
- Field of view: 36° x 36°
- Digital camera resolution: 1024 x 1024 pixel
- Optical resolution on the retina: 25 microns
- Optical source: infrared superluminescent diode at 850 nm



- Imaging speed: 25 fps
- Working distance: 33 mm

Fundus perimetry

- Standard macular test 10°
- Projection field: 30° x 30°
- Tracking speed: 25 Hz
- Stimuli size: Goldmann III
- Background luminance: 4 asb
- Stimuli dynamic range: 36 dB
- Maximum luminance: 1000 asb

Other features

- Minimum pupil diameter: 2.5 mm
- Focus adjustment range: from -15D to +10D (auto-focus)
- Automatic OD/OS recognition
- Pushbutton presence detection ***[2013 Edition only]***
- Multiple fixation targets ***[2013 Edition only]***

Optional accessories

- Printer
- Electrical table
- 3D joystick ***[2013 Edition only]***

Dimensions

- **MAIA - 2013 Edition:**
- Unit size (WxHxD): 348 × 580 × 600 mm (13.7 × 22.8 × 23.6 in)
- Unit weight: 23 kg (50.7 lbs)
- **MAIA - 2009 Edition:**
- Unit size (WxHxD): 522~540 × 556~560 × 482 mm (20.5~21.2 × 21.9~22.0 × 18.9 in)
- Unit weight: 28.5 kg (62.8 lbs)

Power requirement

- Voltage: 100-240 VAC, 50-60 Hz, fused 3.15 A (T type)
- Power consumption: 110 VA (2013 Edition), 300 VA (2009 Edition)

Laser classification

- Class I laser product conforming with 60825-1 IEC:20007

18. DECOMMISSIONING AND DISPOSAL

MAIA contains ePHI (electronic Personal Health Information) in its internal storage that must be erased before the device can be decommissioned. Contact your CenterVue Authorized Service Center to request information about the correct data wiping procedure.

MAIA is made of different materials, such as plastics, aluminum, electronic parts. In case of instrument disposal, please separate the various materials and follow the laws and regulations regarding disposal or recycling for each material effective in your own country.

Separate collection for electrical and electronic equipment

The European Directive 2012/19/UE 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. Users have a fundamental role in 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 (e.g. cables, connectors and plastic cases).

19. MAINTENANCE

CenterVue recommends the periodic maintenance of the components listed in the following table.
Only properly qualified CenterVue Authorized Service Technicians can perform calibration activities.
Contact your local CenterVue distributor or service center if you think your MAIA requires calibration.

TEST ITEM	TEST DESCRIPTION	ACCEPTANCE CRITERIA	TEST FREQUENCY	IN CASE OF FAILURE
Push-button	Enter the examination screen, press the push-button at least 3 times, once every 2 seconds.	The "Button" indicator turns orange anytime the button is pressed	Before performing any test	Push-button is not working and no patient response is detected. Test results are affected. Check proper insertion of the push-button connector in the MAIA unit. If connection is OK and the problem persists contact Technical Support.
Front lens	Visual check of front lens external surface.	No presence of dust or stains detected	Daily	Image quality is adversely affected. Clean the lens as explained at section 14 of this Manual.
Fixation target	Visual check of the red fixation target during the daily Stimulus Projection System check.	There should be a red target like this: 	Daily	The fixation target is not working and test results are affected. Contact Technical Support.
Perimetric stimulus	Visual check of the white stimulus during the daily Stimulus Projection System check.	The white dot center should be inside the external border of the fixation target (see Fig. 18)	Daily	The stimulus projection system is not working (damaged or not calibrated) and test results are affected. Contact Technical Support.
Patient data	Backup the patient database on an external USB media.	The backup procedure completes successfully.	Weekly	External media could be corrupted (use a different media) or USB connection is faulty. If problem persists, contact Technical Support.

TEST ITEM	TEST DESCRIPTION	ACCEPTANCE CRITERIA	TEST FREQUENCY	IN CASE OF FAILURE
Speaker	Enter the examination screen, start exam and proceed until the stimuli projection begins, then remove the patient.	The tracking alarm starts (make sure it is not muted)	Monthly	Either the speaker or the amplifier is not working. Contact Technical Support.
USB ports	Connect a USB mouse to each of the two USB ports.	Pointer on screen should move with mouse	Yearly	The USB port is not working. Contact Technical Support.
Ethernet port	Connect MAIA to a LAN cable, enter the Settings and configure the network as explained at Par. 11.3.	See Par. 11.3	Yearly	The LAN connection is not active or the internal network board is not working. Contact Technical Support.
Cooling fan	Turn ON the MAIA and verify that the cooling fan is working.	Fan noise should be heard near the LCD	Yearly	The fan is not working and may affect embedded PC operation. Contact Technical Support.
Stimulus Projection System	Request the periodic inspection, greasing and calibration of the Stimulus Projection System by a CenterVue Authorized Service Technician.	Calibration procedure completes successfully.	Once every two years	The Stimulus Projection System must be replaced and calibrated.

APPENDIX A: MAIA grids XML format

Custom MAIA grids can be created, defining as many projection locations as desired. The position of each location can be expressed in Cartesian or Polar coordinates, as desired.

The grid shall be defined in XML format, which describes a tree of nested nodes. Each node can have child nodes and/or attributes). Each XML node can be expressed in two ways:
1) with opening and closing tags (i.e. **<node>** and **</node>**): mandatory if it has child nodes
2) with the "/>" closing tag, if it has no child nodes (i.e. **<node attribute="value" />**)

The same XML file can contain the description of more than one grid: when importing it, all the contained grids will be imported into the unit.

The main structure of the XML file shall be:

```
<!DOCTYPE MitPatterns>
<patterns>
    <pattern_expert>
      <Grid name="3&#176; Circle plus center">
           <Stimulus id="1" … />
           <Stimulus id="2" … />
      </Grid>
      <Grid name="4&#176; square grid">
           <Stimulus id="1" … />
           <Stimulus id="2" … />
      </Grid>
   </pattern_expert>
</patterns>
```

The first line (**MitPatterns**) is a header. The main node ("**patterns**") is the root node of the XML, and shall contain the "**pattern_expert**" node; for Scotopic test grids (used in S-MAIA), the tag **pattern_expert** shall be replaced with **pattern_scotopic**. The **pattern_expert** and **pattern_scotopic** nodes shall contain one **Grid** node for each defined grid.

The **Grid** node shall have a "**name**" attribute, containing the name given to the grid, that will be displayed in the Grid selection interface (see par. 8.4.4). In the example, the "**°**" tag is used to display the degrees (°) symbol. Each **Grid** node shall then contain several **Stimulus** child nodes, each one describing one stimulus location to be projected on the retina. Each **Stimulus** shall have a unique id attribute: the id must be >0 (dedicated to the stimulus on the optic disk, used to calculate the Fixation Losses index) and <1000 (dedicated to custom added stimuli, see par. 8.4.11).

As said, each location can be expressed in two ways:

```
<Stimulus id="3" x_deg="2.5" y_deg="4.33" />
<Stimulus id="3" ray="5" angle_deg="60" />
```

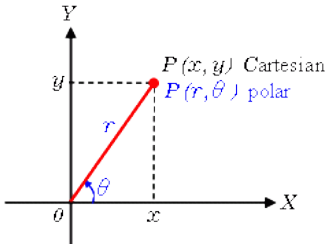


Fig. 81 – Cartesian vs Polar coordinates

The above example shows two different ways to express the same location, referred to the grid center: the first in Cartesian coordinates (***x_deg, y_deg***), expressed in retinal degrees; the second in Polar coordinates (***ray***, ***angle_deg*** corresponding to ***r*** and **θ** in Fig. 81: ***ray*** is again in retinal degrees, while ***angle_deg*** is in degrees measured anti-clockwise starting from the X axis).

The coordinates (0, 0) refer to the center of the grid, which will be projected over the PRL-i, unless the "Change grid position" option is selected (see par. 8.4.10). All the coordinates refer to the RIGHT eye: when examining the LEFT eye, the grid will be flipped horizontally. Stimuli locations cannot overlap (i.e., the minimum distance between two stimuli is 0.5 degrees).

APPENDIX B: RAW Data Export Tool

The RAW Data Export Tool allows to export the exams data on a USB drive in .txt files, using tab-separated format. This format can be easily imported in spreadsheets applications like Excel for statistical analysis. The Tool can be launched within the Settings – System menu (see par. 11.5). The tool shows a list of all the patients stored in the DB (see Fig. 82). It is possible to select individual patients or to select them all with the "***Select All***" button. A filtering field allows to filter the patient list. Once selected the desired patients, the "***Export data***" allows to export all the exams related to the selected patients. An USB drive must be plugged in the device before pressing the button. The progress bar will show the advancement of the progress; at the end, an Information dialog will display the number of exams and patients that have been exported.

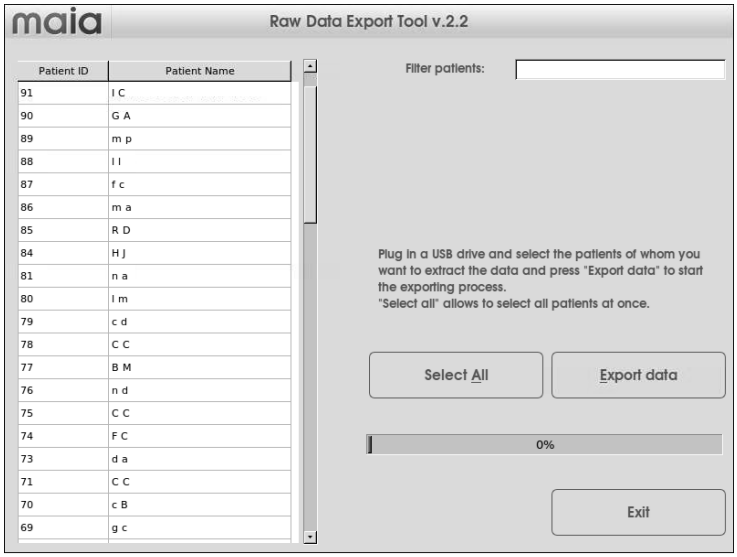


Fig. 82 – RAW Data Export Tool interface

RAW data Export format

After pressing the "***Export data***" button, the tool will generate 3 types of file (in the file names, ***#SN#*** represents the serial number of the device, ***#pID#*** the patient ID, and ***#eID#*** the examID):

a) **maia-*#SN#*_patientsTable.txt** : this is a table that contains the patient list, linking each patient name with its ID, Code and SSN numbers (if used, see par. 11.1). If the data need to be sent for statistical analysis anonymously, it is possible to just delete this file: all the other exported files refer to the patient IDs, so they are anonymous.

b) For each exam, a **maia-*#SN#_#pID#_#eID#*_threshold.txt** and a **maia-*#SN#_#pID#_#eID#*_fixation.txt** files, in the **maia-*#SN#*_data/** subfolder : these contain the export of the measured thresholds and of the fixation data, respectively.

- **maia-*#SN#_#pID#_#eID#*_*.txt** header structure :

each of these files provides a header, containing the main exam results. In case of a Scotopic test, the results values are divided in two columns, the first for the cyan exam and the second for the red exam (refer to ***S-MAIA: Scotopic Test Manual***). The header is divided in 3 parts:

1. Exam Info: provides the unit Serial Number, patient and exam IDs, strategy used, eye, exam date and age of the patient, exam duration in sec., the pix2deg ratio (that allows to relate measures in degrees with positions on the retinal image), the Fixation Losses index and the average reaction time (in millisecs).

2. PRL Info: provides
   - the average sensitivity (average of all thresholds measured);
   - position of the PRL_i and PRL_f (divided in two rows: x and y, respectively. The values are expressed in degrees, and are relative to the top-left corner of the retinal image: since MAIA field of view is 36.5°x36.5°, the point [18.25,18.25] refers to the center of the image);
   - the distance (in degrees) between the PRL initial and final;
   - the Estimated Fovea Location (EFL), if set
   - in case of a follow-up exam, the position of the PRL_i of the baseline exam in this exams, retinal image, and the rototranslation values (in three rows: x shift, y shift and rotation, in degrees) between the baseline and the follow-up: these allow to correctly position the stimuli on the retinal image.

3. Fixation Results: provides the P1 and P2 indices, the 63% amd 95% BCEA area values (in squared degrees) and their angle (in degrees)

- **maia-*#SN#_#pID#_#eID#*_threshold.txt** values :
  after the header, the threshold files provide a table containing a list of the stimuli values: the ID (each stimulus in a grid has a unique ID; the ID #0 refers to the stimulus placed in the optic disk, used to calculate the Fixation Losses index), its X and Y coordinates (in degrees, and relative to the PRL_i position), and the measured threshold at that location (this can be expressed in DBs for 4-2 strategy, and in levels for the 4LF and Scotoma Finder strategies).

- **maia-*#SN#_#pID#_#eID#*_fixation.txt** values :
  after the header, the fixation files provide the fixation data measured by the retinal tracking: only valid points are exported (i.e., those for which the tracker gave a valid results, so blinkings are removed). The X and Y coordinates are expressed in degrees and relative to the top-left corner of the retinal image. The fixation points are divided in two sections:
  1. Registration points: these are a list of the 250 fixation points acquired during the Registration phase, and are the ones used to determine the PRL_i (which is an average of these points, after removing some outliers). Each record shows X and Y coordinates and time (in milliseconds, from the beginning of the Registration phase).
  2. Fixation points: these are a list of all the other fixation points, acquired during the stimuli Projection phase, and are the ones used to determine the PRL_f (which is an average of these points, after removing some outliers). Each record shows X and Y coordinates and time (in milliseconds, from the beginning of the Projection phase). In case a stimulus projection was occurring at that time, the related stimulus ID is provided in the fourth column.