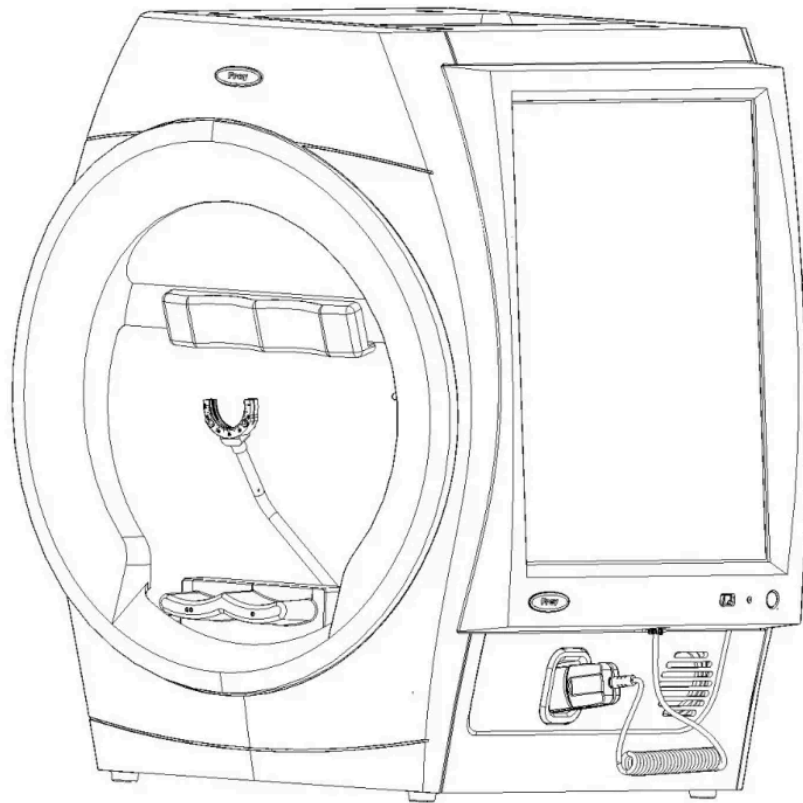




OPERATION MANUAL

AUTOMATED PERIMETER AP-600

All specifications are subject to change. January 2021

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1 INTRODUCTION

This OPERATION MANUAL describes the purpose, overall view, installation, setup and user maintenance of the AP-600 Automated Perimeter. This manual is intended for medical personnel and who will use AP-600 to examine patients. This instruction provides information concerning installation, setup, cleaning and basic user maintenance that should be very precisely presented to the cleaning and technical personnel of the clinic in order to decrease the probability to harm the device.

MEDICAL RESPONSIBILITY - The manual does not provide guidance or interpretation of clinical results. The operator must ensure that he or she has received an appropriate medical training in such interpretation. For the same reason, FREY cannot be held responsible for misdiagnosis of results..



The right to repair of the AP-600 Automated Perimeter or to carry out periodical part replacements is reserved only to the Manufacturer or to persons authorized by the Manufacturer.

AP-600 Automated Perimeter is to be used only in accordance with this Operation Manual.

If you have encountered problems when using your AP-600 Automated Perimeter which you cannot solve, or the device parameters are changed, please, in all these cases contact the Manufacturer or his authorized representative.

If you have questions about use, please contact the Manufacturer or distributor.



During the lifetime of the device, this manual should be kept in an easily accessible place for the user to at any time it is available.

In case of loss of this manual, please contact your authorized distributor

1.1 DESCRIPTION OF SYMBOLS



Manufacturer



Production date



Follow the instructions for use



The CE mark on this product indicates it has been tested to and conforms with the provisions noted within the 93/42/EEC Medical Device Directive



Symbol of selective collection of electrical waste..



Type B Applied part



Warnings – Observe these prescriptions in order to ensure safe operation of the the device and safety of Patients and Operators!



Notes and hints - Useful functions to know. Paying attention to these will prevent the noted problems.

1.2 DESCRIPTION OF THE SYSTEM

1.2.1 GENERAL DESCRIPTION OF THE DEVICE

AP-600 Automated Perimeter is a modern diagnostic device for fast and precise testing of a patient's visual field utilizing either static or kinetic perimetry one of many available test strategies. For static perimetry patient's visual field is assessed by briefly projecting a stimulus of known size, brightness, and location on the inside surface of a roughly hemispherical bowl. Bowl illumination is automatically controlled to establish a desired contrast between the stimulus and the area around it. AP-600 enables to define the sensitivity threshold of the retina in a given area, as well as to make a fast screening test. Perimeter software has built-in many internal mechanisms that increase the reliability of the test results. Testing of a patient is performed automatically, and detailed information about the test progress is continuously presented to the operator on the screen. The friendly and easy user interface allows intuitive movement over available options. The user can view and analyse test results in many different presentation methods including regression analysis.

The patient's fixation performance is monitored by one of two possible techniques: One is the Heijl-Krakau technique, with random stimulus presentation in the blind spot region. The second one is based on the built-in digital camera allowing eye-detection during examination and during adjusting the patient's position. Due to auto-detection of the pupil position, it allows a continuous automatic control of the fixation. The patient's fixation performance is continuously presented to the operator in both cases.

In addition to static perimetry, AP-600 allows you to perform kinetic perimetry that emulates manual standard Goldmann perimetry.



In order to avoid the possibility of uneven ambient lighting falling onto the bowl surface, all overhead lighting must be switched off and field testing be carried out in a dimly lit or completely darkened environment.

Conducting a test in improper lighting conditions may cause systematic errors of the test results due to a lower contrast of the stimulus over the stimulator bowl surface. This will decrease the overall sensitivity of the retina as acquired in the test result.

1.2.2 INTENDED USE

Automated Perimeter AP-600 is a device designed to measure the visual field of the human eye.

1.2.3 INDICATIONS FOR USE

The AP-600 Automated Perimeter is designed to detect visual field defects for screening, monitoring, and aiding in the diagnosis and treatment of eye diseases such as glaucoma and related neurological disorders.



The AP-600 Automated Perimeter is not intended to be used as the sole diagnostic method for disease.

1.2.3.1 Body parts in contact with equipment

The AP-600 Automated Perimeter physically interacts with the patient's forehead and chin. The patient's hand and fingers are also used to press the patient response button.

1.2.3.2 Operation mode

The AP-600 Automated Perimeter is designed for continuous use, but it is assumed that in most locations the unit is used for 10 hours a day or less, indoors, in a doctor's office or hospital. The place of use should be free of soot, adhesive fumes, grease, and volatile organic chemicals. Other requirements for the working environment are given in Section 7.2, "Working Conditions." Application warnings are given in this section and elsewhere in the manual.

1.3 WARNINGS

IMPORTANT SAFETY INFORMATION

Intended use



Do not use AP-600 Automated Perimeter for any purpose other than specified in this Operation Manual!

Installation



Do not install the device in a place exposed to water or chemicals. Any water or chemicals entering the instrument may cause electric shock or failure!

Do not install the device in a place exposed to direct sunlight, high temperature and humidity or air with high dust, salt and/or sulphur content. This may cause the device to malfunction or fail!

Do not place any objects on the perimeter.

The device shall be installed in a location sufficiently isolated from any other equipment that may interfere with the test.

Power connections

Before connecting the perimeter to a power outlet, make sure that the power supply voltage on the local grid matches the operating voltage of the perimeter!



Connect the perimeter only to a three-wire contact with a ground pin!

Use only undamaged power cords. Replace the cable if it is cracked, burned through or otherwise damaged!

Do not strain the power cord. Doing so may cause the cord to break.

Do not use extension cords or adapters for connection.

External devices



Do not connect any external devices to the perimeter other than those specified by the manufacturer.

If any external devices are connected to the instrument, the operator must ensure that the complete system still meets the requirements specified in IEC 60601-1.

Precautions during operation



In the event of smoke, odor or abnormal sound, immediately turn off the unit, unplug the power plug from the outlet and contact your local distributor or manufacturer!



If any equipment failure occurs, stop operation immediately, identify the failure and contact your local distributor for repair.

Do not modify the device under any circumstances! Doing so may result in an electric shock or equipment failure!

Storage and transportation



The device must be properly prepared for transportation to avoid damage. Use the original shipping packaging when shipping the device.

For more information on storage and transport, see section 8.3

Cleaning and servicing



Do not perform any service or maintenance on the perimeter while the patient is being examined!

Turn off the power and remove the power cord before cleaning or servicing the perimeter. Wipe all parts of the instrument dry before reconnecting power.

For more information on cleaning and servicing, see section 8.2

Interference



The AP-600 perimeter has been tested to withstand external interference such as high energy broadband emissions, magnetic fields, electrostatic discharges (large electric motors, portable radio receivers, cell phones, etc.).

The device emits a certain constant level of electromagnetic radiation, which is within the range specified by the relevant standards.

Excessive electromagnetic interference may disturb the Perimeter or cause it to stop. If this happens, remove the cause of the interference and restart the Perimeter.

The manufacturer is responsible for the safe and reliable operation of the equipment if:



- All installation, maintenance, service and repair activities are performed by personnel trained and authorized by the manufacturer.
- The electrical system complies with electrical standards.
- The device is used in accordance with these Operating Instructions.



The manufacturer is not responsible for any modifications to the AP-600 Automated Perimeter made outside of FREY.

2 INSTALLATION

2.1 PACKAGE CONTENTS



Open the package and check that the following items are present and undamaged. If an item is missing or damaged, please contact your local distributor as soon as possible.

It is recommended that you keep the original box and packing materials for use when moving or transporting the unit.

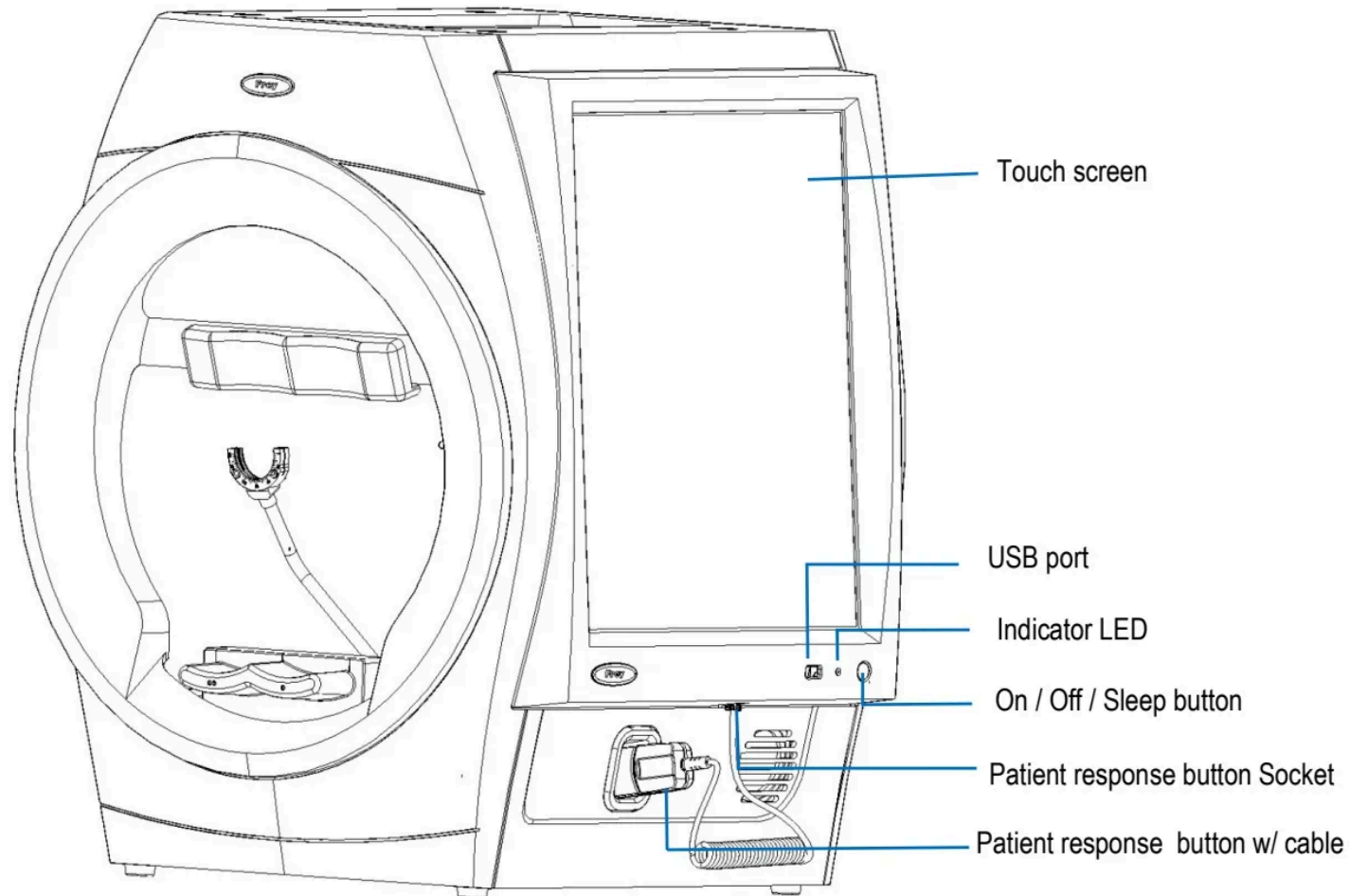
After delivery, it is recommended to leave the unit in the packaging for several hours before unpacking to reduce the risk of condensation.

Package includes:

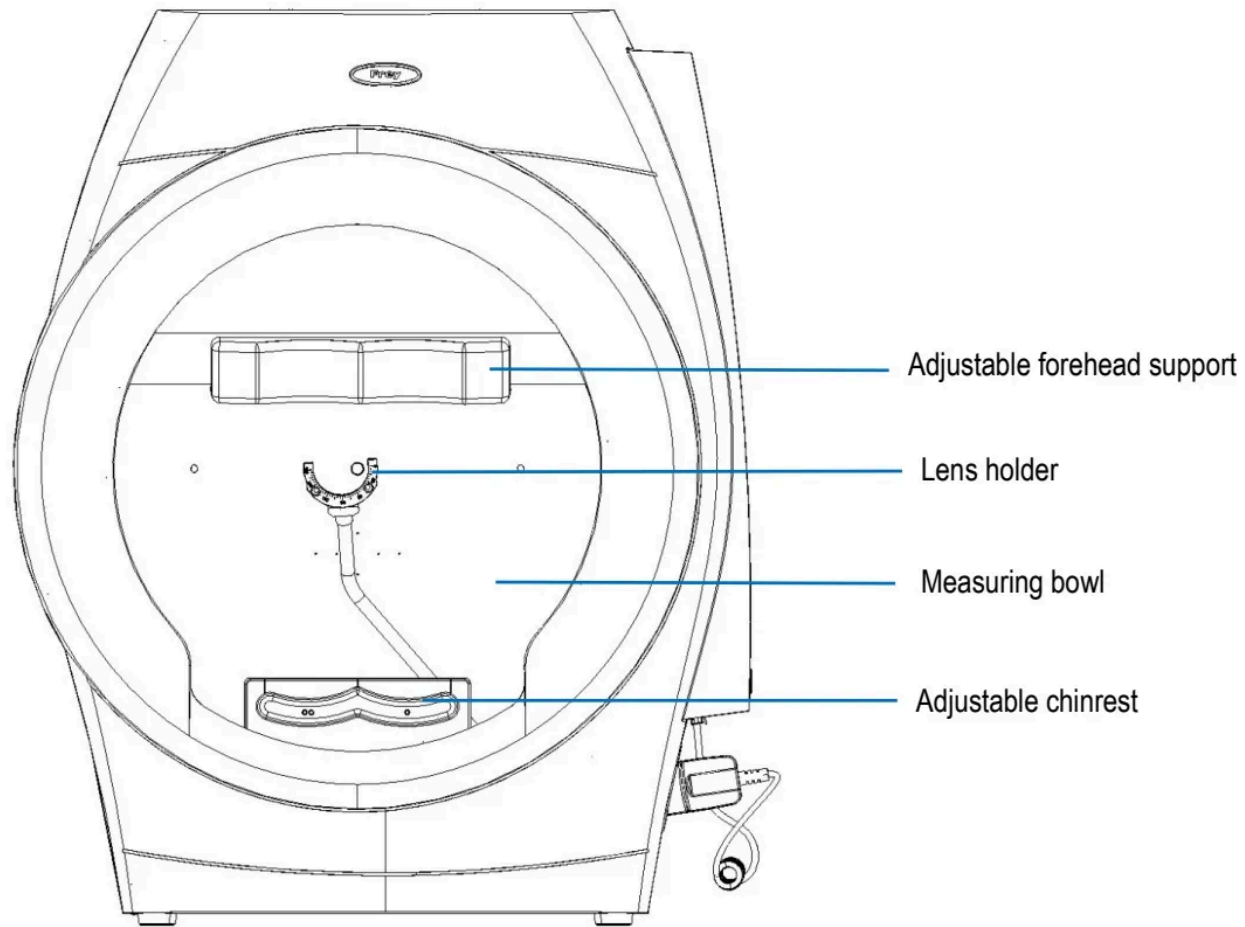
- Automated Perimeter AP-600
- Patient response button
- Power cord
- Instructions for use
- Eye cover (2 pcs)
- Dust cover

2.2 DESCRIPTION OF THE DEVICE

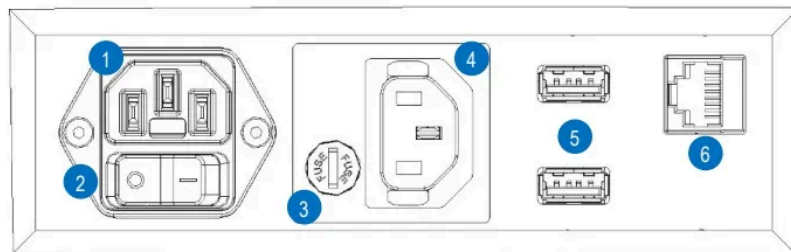
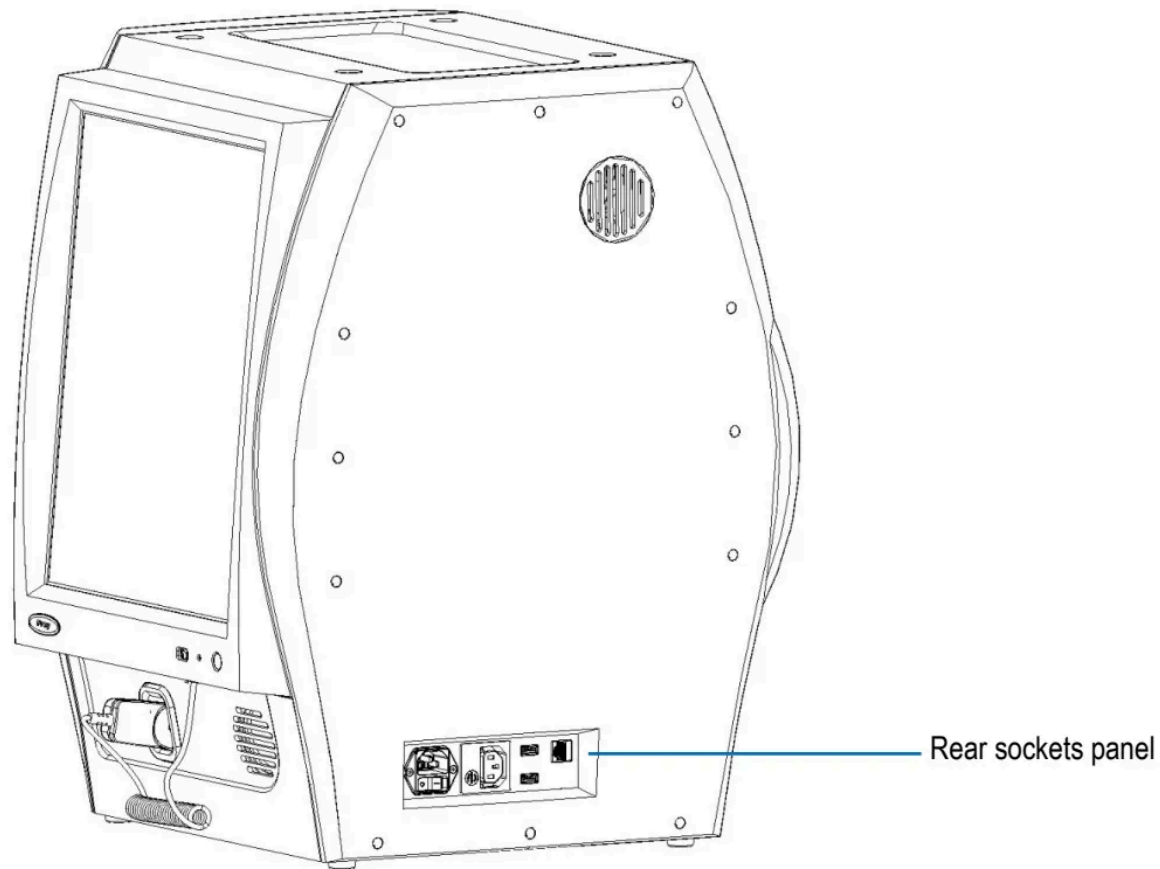
Operator's side view



View from the patient side



Rear view



Detailed view of the rear panel of slots

1. Power inlet
2. Power switch
3. Fuse socket
4. Power outlet
5. USB port x2
6. Ethernet port

2.3 INSTALLATION



When unpacking the AP-600 Automated Perimeter, be careful not to accidentally damage or discard any of the accessories included in the package.



Before unpacking, leave the AP-600 in its packaging for several hours after delivery to reduce the risk of condensation formation.

The Perimetry Test Set consists of an AP-600 Perimeter with a built-in PC along with an integrated touchscreen monitor that controls the test run and controls the operation of the device, and a patient response button.

The Automated Perimeter is designed to operate with an alternating supply voltage level of 110V - 230V and must be plugged into an outlet equipped with a grounding pin. Before turning on the perimeter, make sure that the correct voltage level is selected for operation.

To install the device, connect the power cord to the power socket (1) on the back panel and connect the patient response button to the socket under the display panel. If you want the perimeter to work in a local network, connect the network cable to the LAN (*Ethernet*) socket on the rear panel (6)

Optionally, a printer can be connected to the perimeter - via USB port or network printer via LAN. Printer is only supplied with the perimeter as an option - on request. The user can also connect their own compatible printer - local or network.

For a local printer, power the printer from the power outlet (4) on the rear panel of the perimeter.



The AC output socket is protected by a transformer.

In the case of external connection, the operator must ensure that the complete system still meets the requirements specified in IEC 60601-1

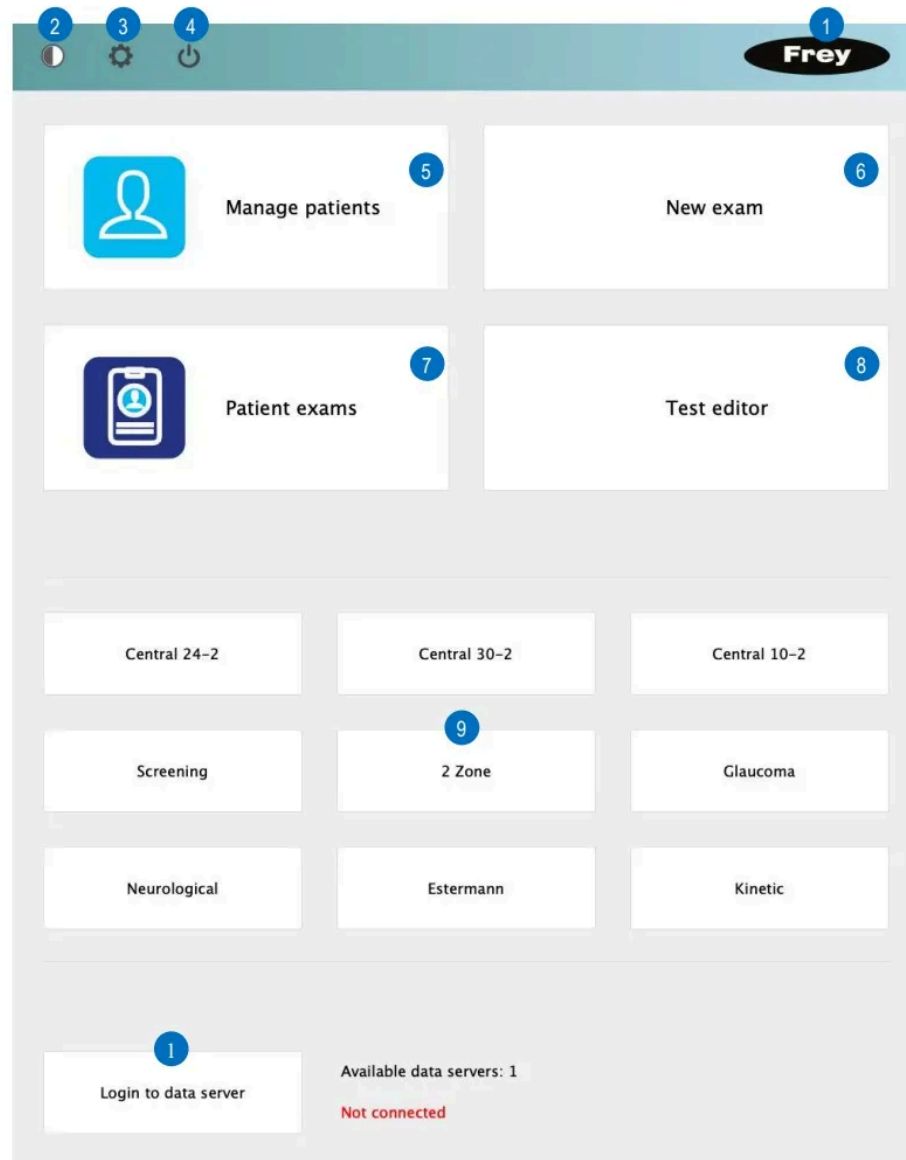
The maximum power consumption shall not exceed 250W

If required, USB pointing devices (mouse / keyboard) or any other USB device can be connected to the perimeter to one of 3 available USB ports.

3 DEVICE OPERATION

3.1 MAIN SCREEN

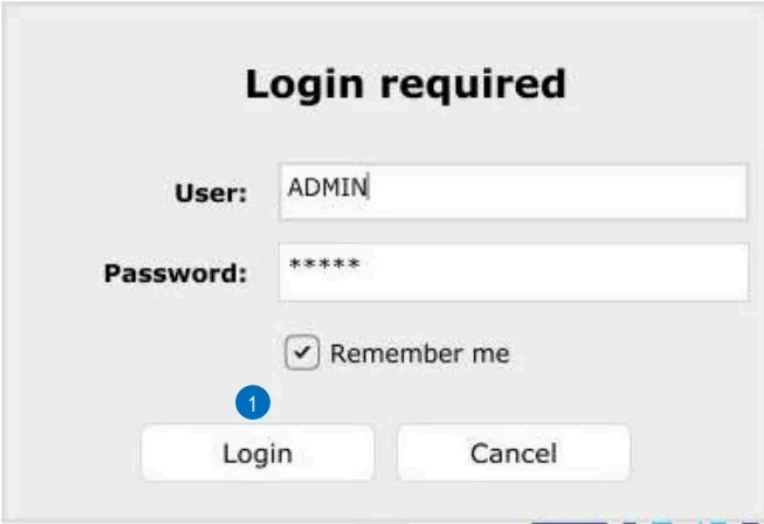
The main screen appears automatically when you turn on the device. It contains a number of buttons and icons whose meaning and functionality is described below.



- 1) Icon: **FREY logo** - displays a screen informing about the device name and software version.
- 2) Icon: **DISPLAY MODE** - toggles between light and dark graphic display mode. The setting is automatically saved and will be restored when the unit is turned on again.
- 3) Icon: **SETTINGS** - displays the screen with the service tabs described in the section "Configuration and Service Functions"
- 4) Icon: **POWER** - is used to turn the unit off. The device should always be turned off using this function and not directly using the power button. This ensures that all system data is safely saved.
- 5) Button: **MANAGE PATIENTS** - displays a screen with patient data and the functions for managing that data, which are described in the subsection "Patient Data Management"
- 6) Button: **NEW EXAM** - initiates the procedure for a new study. Refer to the subsection "Conducting the Test" for a detailed description.
- 7) Button: **PATIENT EXAMS** - Displays the screen for viewing a patient's tests, making test reports, printing and exporting them, and analyzing the results. These functions are described in the "Reviewing and Analyzing Test Results" subsection.
- 8) Button: **TEST EDITOR** - displays a screen for editing custom test fields and coupling them to the selected strategy to create a new test. The description of the editor's functions is contained in the subsection "Test Editor".
- 9) Buttons: **TESTS** - these buttons are used to quickly start a new test. Press the button with the name of the selected test to select the patient and start the test as described in the section "Performing a test". (the selected test will already be preset)
- 10) **LOG IN / LOG OUT** button and information about the status of the connection to the database server - using the login button you can connect to the database server or log out if the connection is active. In addition, information is displayed next to it about how many database servers are available in the network environment and which server is currently connected.

3.2 USER LOGIN

You can access patient data and test results by logging into the database. Logging in is not required if there is no user in the database (see the section titled "Setup and Service Features" for managing users). When multiple database servers are available in a network environment, the database server selection window will be displayed first. The last login data can be remembered by checking the "Remember me" box(1).



The image shows a 'Login required' dialog box with a light gray background. At the top, the title 'Login required' is centered in bold black text. Below the title, there are two input fields. The first is labeled 'User:' and contains the text 'ADMIN'. The second is labeled 'Password:' and contains six asterisks '*****'. Below the password field, there is a checkbox that is checked, followed by the text 'Remember me'. At the bottom of the dialog, there are two buttons: 'Login' and 'Cancel'. A blue circle with the number '1' is positioned above the 'Login' button, indicating the step described in the text.

3.3 PATIENT DATA MANAGEMENT

The patient data management screen includes a patient list, **NEW PATIENT** and **SEARCH** buttons, and a **SHOW PATIENTS IN QUEUE ONLY** switch.

1) **PATIENT LIST** displays the details of all patients stored in the database with information on date of birth, ID and number of tests performed.

Select patient record to perform an action...

FIRST JAMES No exams

Date of birth: 01-01-1966 ID: 54546

1

3 Search

2 New patient

4 Patients in queue only

←

Touching a patient record displays the available options:

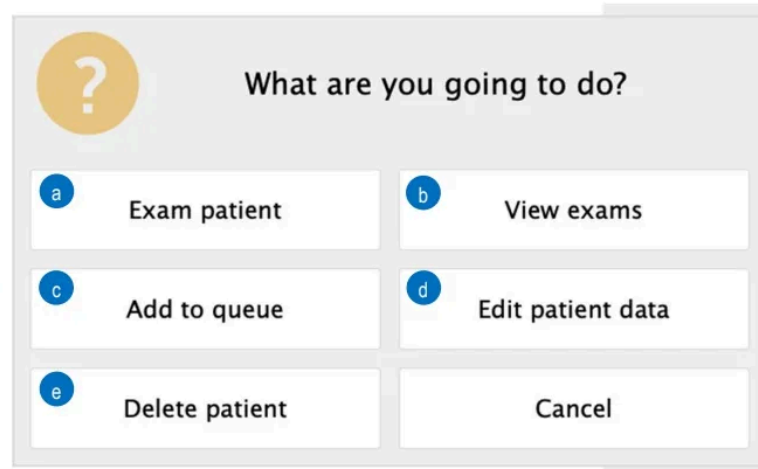
a) **EXAM PATIENT** - Starts the procedure for performing a new test as described in the "Performing a Test" section. Refer to the "Run Creation" subsection for a detailed description.

b) **VIEW EXAMS** - Displays a screen for viewing patient test results, printing and exporting test reports, and analyzing test results. These functions are described in the "Viewing and Analyzing Test Results" section.

c) **ADD TO QUEUE / REMOVE FROM QUEUE** - adds or removes a patient to a queue. By placing a patient in a queue, you can create a list of patients who, for example, are referred for examination on a given workday. The examiner does not have to search for each patient, but can easily select a patient from the list if the "Show patients from queue only" switch is on.

d) **EDIT PATIENT DATA** - Displays the Edit Patient Data window. You can change the first name, last name, date of birth, and ID. The ID field is unique within the database, so if a patient already exists with that ID, it is not possible to use that ID for another patient.

e) **DELETE PATIENT** - allows you to delete patient data and all test results from the database. The operation must be confirmed and is irreversible.



2) **NEW PATIENT** button - displays the Patient Data Editor so you can enter patient data into the database. Note: Patient ID and date of birth are required fields. The ID field is unique, meaning there cannot be multiple patients with the same ID.

3) button **SEARCH** - allows you to find a patient in the database on the basis of the entered ID or personal data (surname, first name, date of birth). If an exact match is found, it will be highlighted in green - otherwise the most similar record to the search will become active and will be highlighted in red.

4) **SHOW PATIENTS IN QUEUE ONLY** switch - a switch in the on position (highlighted green) means that only patients in the queue are displayed.

3.4 CONDUCTING THE TEST

A patient examination can be started in three ways: through the **New Exam** option on the home screen, through the quick select test option (the test buttons on the main screen), or from the patient data management screen. In the first two cases, the patient list will be displayed (the same as on the patient management screen). Selecting a patient record will display the test parameter selection screen:

The following options are available on the screen:

Test parameters

1 Test:

2 Eye: ☒ Right ☐ Left

3 Correction: ☒ No ☐ Yes

4 Fixation control: ☐ Digital ☒ Heijl-Krakau

5

Basic test parameters

- 1) **Test selection** (the corresponding test is selected if you have previously used one of the quick test selection buttons on the main screen)
- 2) **Selecting the test eye** (not active when a binocular test is selected)
- 3) **Correction**: if the patient is wearing spectacle correction, enter the near vision and farsightedness data - the value of the lens that should be placed in the lens holder for the exam will be automatically determined.
- 4) **Fixation control**: digital fixation tracking or macular monitoring method (Heijl-Krakau).
- 5) **Advanced** button: toggles to the full exam settings view with advanced settings.

- 6) Monitoring of false positives
- 7) Monitoring of false negative errors
- 8) Fluctuation testing
- 9) Testing the FOVEA field (central field viewpoint)
- 10) Use of non-standard fixation points
- 11) Change of color and size of the stimulus according to Goldmann standard
- 12) Use of a flashing stimulus (flicker perimetry)
- 13) Switch to basic settings view

Test parameters

Test:

Eye: ☐ Right ☐ Left

Correction: ☐ No ☐ Yes

Fixation control: ☐ Digital ☐ Heijl-Krakau

6 False positives: ☐ Yes ☐ No

7 False negatives: ☐ Yes ☐ No

8 Fluctuation: ☐ Yes ☐ No

9 Fovea test: ☐ Yes ☐ No

10 Wide fixation: ☐ Yes ☐ No

Stimulus colour:

11 Stimulus size:

12 Flicker:

13 < Basic

Start Cancel

Full selection of test parameters with advanced settings

Test parameters are described in detail in the "Test Fields, Strategies, and Test Parameters" section.

3.4.1 Static Tests

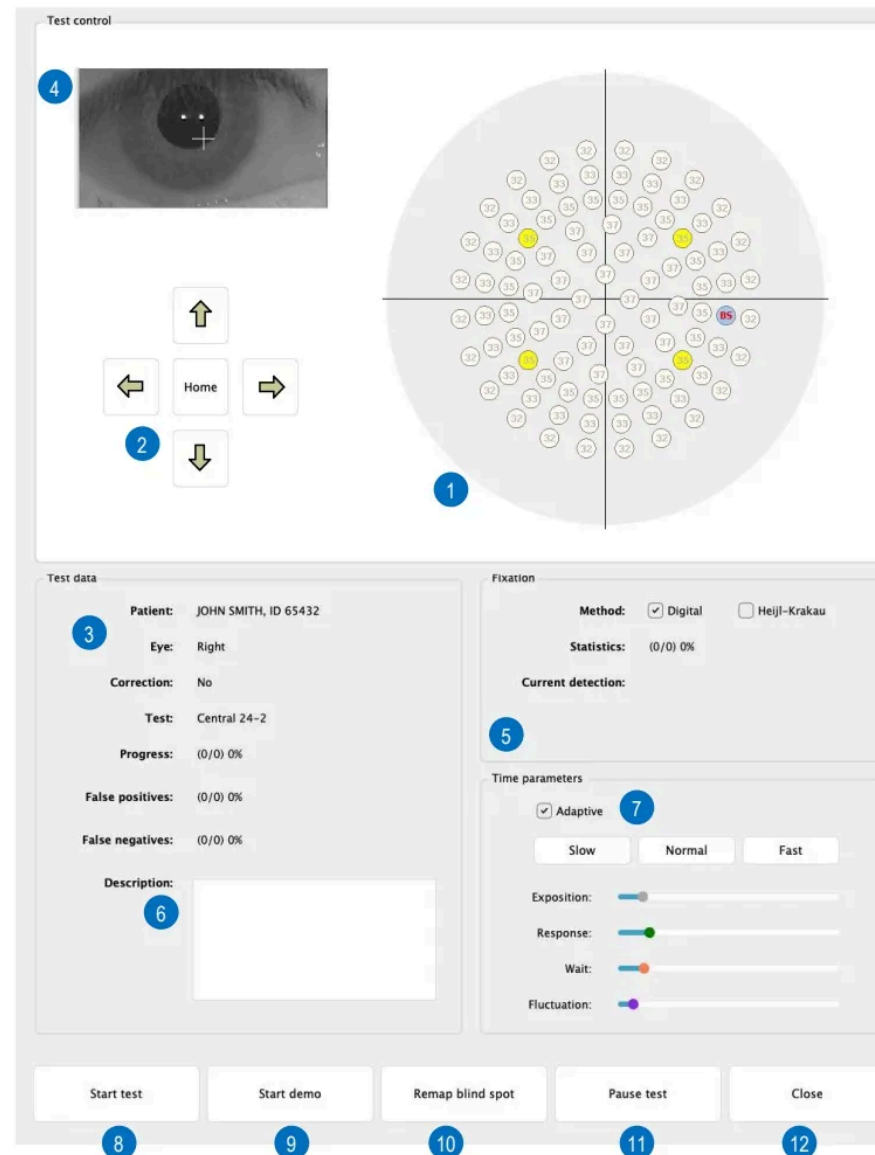
If one of the static tests is selected, the static test screen will be displayed containing:

1) **A test field** with the points to be tested marked.

In each point, a value in decibels is written indicating the brightness of the tested point at that moment of testing. Points already tested are coloured blue, points under testing green, red or black. A point whose testing has not yet begun is coloured gray. Green means that the point with the last tested brightness was seen by the patient, red means that the point was not seen. Black indicates that the patient's response was abnormal (too fast or too slow, i.e. outside the test cycle) and testing of the spot will be repeated.

2) **Buttons for chin and forehead support control.**

The buttons are used to set the correct patient position - the patient's eye should be in the center of the video preview window (but does not have to be perfectly in the center). It is possible to correct the patient position during the test, but the test is then automatically terminated and the "Continue" button must be used to continue the test.

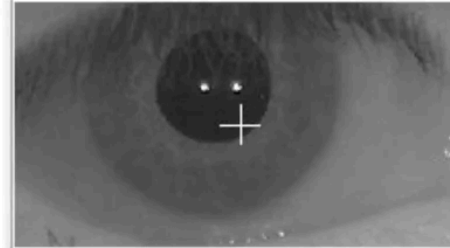


3) Panel with patient data and test parameters

The panel contains information about the test patient and the test parameters (name, false positive and negative errors, loss of fixation). The information about false positives, false negatives and loss of fixation is updated on a regular basis.

4) Panel with video camera view of patient's eye

The panel displays a video camera image of the patient's eye. For proper operation of the digital eye tracking and test run, it is important that the patient's pupil be in the center of the image (ideal center location is not required). If automatic patient fixation detection is used, the software determines the current fixation deviation (the position of the eye relative to the center of the image). It is not necessary for the eye to be perfectly centered at all times. It is much more important for the patient to focus on observing the fixation point. The software calculates the eye position based on digital analysis of an image containing infrared diode reflections on the eye (two white dots within the pupil).



5) Fixation bar

The bar represents the level of fixation over time. An instantaneous fixation indicator is placed on the left side of the bar. This bar takes on three possible colors:

- (a) BLACK, when the level of fixation cannot be determined (closed eye, etc.)
- b) RED when loss of fixation is too great
- (c) GREEN at the correct fixation level

The height of the bar shows us the current level of fixation. If the program cannot find the pupil in the image (closed eye, blinking, improper lighting) the instantaneous fixation bar reaches its maximum height. On the fixation chart this will be indicated by a black line pointing downwards from the center of the chart.

The color and height of the instantaneous bar are transferred to a horizontal fixation plot at the end of each measurement cycle. The points at which fixation was determined are drawn from the center upwards to the height resulting from the fixation level.

6) Comment field

Allows you to add a comment during the run. The comment will be visible in the study results.

7) Time parameter panel and "Adaptation" switch

The Slow, Normal, Fast keys are used to quickly change all test timing parameters.

The following times are assigned to them:

Time parameters	Slowly (1)	Normally (2)	Quickly (3)
Exposure time (b)	0.2 s	0.2 s	0.2 s
Response time (c)	1.1 s	1.1 s	0.8 s
Delay (d)	0.6 s	0.4 s	0.4 s
Fluctuation (e)	0.6 s	0.4 s	0.3 s



The time parameters can be modified manually by pulling the mouse over one of the horizontal time bars.

Adaptive (a) - Starts automatic control of timing parameters. The program estimates the patient's reaction speed times and changes the times to reduce the maximum duration of the test, taking care that the reliability of the result is not reduced.

Exposition time (b) - the duration of illumination of the stimulus.

Response time (c) - the time the perimeter waits for the patient to respond after the stimulus is extinguished.

Wait (d) - parameter specifying time between two consecutive test cycles. It is counted from the end of the Response Time. After this time the next test cycle will start, i.e. the next point will be lit.

Fluctuation (e) - a random time interval between 0 and the set value by which the Wait time is increased.

8) Start test button

It begins the test.

9) Start demo button

Button for demonstration mode. It allows demonstrating to the patient the principles and the way of examination. Additionally, the Demo mode allows for checking the proper functioning of the automatic eye fixation control. It is recommended to demonstrate the test to the patient before each examination.

10) Button Remap blind spot

Redetermination of the position of the blind spot points. Available only in Heijl-Krakau (blind spot monitoring) mode. The button should be used if the patient's fixation is unsatisfactory or has suddenly deteriorated.

11) Pause / Continue button

Press this key to temporarily stop the test. The test will continue when this key, which has its description changed to "Continue", is pressed again.

12) Close button

Allows you to end testing at any time and return to the main program window. If this button is pressed before a test is scheduled to end, you will be asked if you are sure the program should end the test

3.4.1.1 Static Test run

The test proceeds according to the strategy and the chosen parameters for controlling the reliability of the test. Points are tested in random order. The area corresponding to the test point is highlighted in green for the duration of the exposure. Points that have not yet been tested are marked in grey. The point is tested with the brightness as described on each cell. If there is no response to the stimulus, the cell description turns red. A positive response is coloured green. A point whose testing has been completed is marked with a blue label.

Between standard test point exposures, the program performs special cycles. These include control of false positives, false negatives, fluctuations, blind spot control (with Heijl-Krakau fixation). Information about the execution of special cycles is displayed in the upper left corner of the test field area.

The program allows the user to manually adjust the levels with which the points will be tested during the test. It is also possible to retest already tested points.

Retest
0 dB
3 dB
6 dB
9 dB
12 dB
15 dB
18 dB
✓ Show full field

A right mouse button pressed on any cell in the field or holding the field on the touch screen for a longer time opens a list of available options. The **Re-Test** function triggers a retest of the selected cell. Testing starts at the level assigned to the cell at the beginning of the test. Decibel values allow you to assign the selected cell a specific value with which it will be retested.

The **Show Full Field** option allows you to display a field with cells that are not part of the field being tested. By pressing the right mouse button on an inactive (gray) cell or by holding the field on the touch screen longer and then selecting Add to Field, the cell will be marked as active.



Performing changes in brightness levels in an unconsidered manner may introduce errors into the test result. It is recommended that only users proficient in perimetric measurements use this option.

A complete cycle of one measurement consists of four timing parameters. The cycle time is the sum of these parameters.

Exposition time	Response time	Wait time	Fluctuation time
Stimulus presented		Waiting for an answer	Delay between stimuli
Cycle duration			

Scheme of a single test cycle.

Exposition time - the duration of a presented stimulus. The duration range can be set from 0.1 s to 9.9 s with 0.1 s accuracy

Response time - the maximum time until the response from a patient after the stimulus is turned off. The response time range can be set from 0.1 s to 9.9 s with 0.1 s accuracy

Wait time - time between stimuli are visible. Wait time is defined as the time between the end of one cycle (when the patient's button is released or the response time is over) and the beginning of the next cycle.

Time Fluctuation - This parameter introduces a random a random delay between consecutive test cycles, i.e. a variable time from the patient's reaction to the start of the next stimulus presentation. The delay value can vary from min: Wait + 0 s to max: Wait + Fluctuation time.

This parameter reduces patient fatigue during testing by introducing a random factor.

3.4.2 Kinetic Test

If the kinetic test is selected, the test screen will appear containing:

1) Test field

2) Buttons for chinrest and forehead support control.

The buttons are used to set the correct patient position - the patient's eye should be in the center of the video image window (but does not have to be perfectly in the center). It is possible to correct the patient position during the test, but the test is then automatically terminated and the "Continue" button must be used to continue the test.

3) Panel with patient data and test parameters

The panel contains information about the test patient and the test parameters (name, false positive and negative errors, loss of fixation). The information about false positives, false negatives and loss of fixation is updated on a regular basis.

Test control

4

2

1

Test data

3

Patient: JOHN SMITH, ID 65432

Eye: Right

Correction: No

Test: Kinetic

Progress: (0/0) 0%

Description:

6

Fixation

5

Method: ☒ Digital ☐ Off

Statistics: (0/0) 0%

Current detection:

Isopters

7

Number of isopters: 8

☐ A ☒ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H

Meridian angle: 30

Size: IV

Brightness: 1 (25dB)

Modifier: A (+4dB)

Colour: White

Velocity: 4 deg./s

Start angle: 50

End angle: 5

Start test Start demo Pause test Close

4) Panel with video **camera view** of patient's eye

The panel displays a video camera image of the patient's eye. For proper operation of the digital eye tracking and test run, it is important that the patient's pupil be in the center of the image (ideal center location is not required). If automatic patient fixation detection is used, the software determines the current fixation deviation (eye position relative to the image center). It is not necessary for the eye to be perfectly centered at all times. It is much more important for the patient to focus on observing the fixation point. The software calculates the eye position based on digital analysis of an image containing infrared diode reflections on the eye (two white dots within the pupil).

5) **Fixation bar**

The bar represents the level of fixation over time. An instantaneous fixation indicator is placed on the left side of the bar. This bar takes on three possible colours:

- (a) BLACK, when the level of fixation cannot be determined (closed eye, etc.)
- b) RED when loss of fixation is too great
- (c) GREEN at the correct fixation level

The height of the bar shows us the current level of fixation. If the program cannot find the pupil in the image (closed eye, blinking, improper lighting) the instantaneous fixation bar reaches its maximum height. On the fixation chart this will be indicated by a black line pointing downwards from the center of the chart.

The color and height of the instantaneous bar are transferred to a horizontal fixation plot at the end of each measurement cycle. The points at which fixation was determined are drawn from the center upwards to the height resulting from the fixation level.

6) **The comment field** allows you to add a comment during the study. The comment will be visible in the study results.

7) Kinetic test parameter field

a) **Number of isopters** - up to 8 isopter can be selected. A different range of parameters can be set for each isopter. Isoptera are marked with letters (from A to H). By pressing a key of a given isopter you can access a set of parameters characterizing it.

Below is a check box with four available options: Custom test, Standard 45, Standard 30 and High Res 1. Standard 45, Standard 30 and High Res 15 are standard tests with fixed parameters that cannot be modified by the user. With the Custom test option active, the following test parameters can be modified:

The screenshot shows the 'Isopters' configuration window. At the top, 'Number of isopters' is set to 8. Below this, a row of checkboxes for isopters A through H is shown, with 'B' checked. Underneath, a grid of parameters is displayed for the selected isopter (B). The parameters and their values are: Meridian angle: 30; Colour: White; Size: IV; Velocity: 4 deg./s; Brightness: 1 (25dB); Start angle: 50; Modifier: A (+4dB); End angle: 5. Each parameter has a dropdown menu or a set of options.

(b) **Meridian angle** - determines the number of meridians for a given isoptera. Number of meridians = $360 / \text{Angle}$ between meridians, e.g. for angle between meridians = 10, number of meridians = 36. The isoptera in this case will consist of 36 points connected by lines. The smaller the angle between the meridians, the higher the accuracy of the survey.

(c) **Size** - Goldmann standard light stimulus size (I to V)

(d) **Brightness** - Stimulus brightness may be selected within the range provided for the specifics of the kinetic test, i.e.

1 = 25dB 2 = 20dB 3 = 15dB 4 = 10dB

(e) **Modifier** - a parameter that docks the brightness of a stimulus according to a scale:

A = +4dB B = +3dB C = +2dB D = +1dB E = +0dB

For example, if the stimulus brightness = 1 (25dB) and the brightness modifier = D (+1dB), then the actual stimulus brightness used during a given isopter test will be 25dB + 1dB = 26dB and labelled 1D.

(f) **Colour** - Four stimulus colours are available:

White Green Red Blue

(g) **Velocity** - the stimulus moves along the isopter at a specified angular velocity. The available velocities are:

2 deg/s 4 deg/s 6 deg/s 8 deg/s

(h) **Start angle** - The angle marking the origin of the meridian, or the starting point of the stimulus movement.

(i) **End angle** - The angle marking the end of the meridian, the point at which the stimulus ends its motion.

8) **Start demo** button

Button for demonstration mode. It allows demonstrating to the patient the principles and the way of examination. Additionally, the Demo mode allows for checking the proper functioning of the automatic eye fixation control. It is recommended to demonstrate the test to the patient before each examination.

9) **Start test** button

It begins the test.

10) **Pause / Continue** button

Press this key to temporarily stop the test. The test will continue when this key, which has its description changed to "Continue", is pressed again.

11) **Close** button

Allows you to end testing at any time and return to the main program window. If this button is pressed before a test is scheduled to end, you will be asked if you are sure the program should end the test

3.4.2.1 Running the Kinetic Test

During the kinetic test, a stimulus is presented to the patient near the outer edge of the canopy for 1 second. If the patient did not see the stimulus within 1 second, the stimulus begins to move toward the center of the bowl. When the stimulus is seen, the patient should press a button. The perimeter repeats the stimulus movement along consecutive, randomly selected meridians. For the operator's convenience, the stimulus is also presented on the test screen as a circle of appropriate colour and size.

The graphical representation of the test result is an isoptera, which is a line connecting points located on consecutive meridians where the patient noticed the stimulus. Within a given isoptera, multiple meridians may be tested, spaced at an angular density set by the tester. Up to 8 isopters can be tested within a kinetic test.

When the user completes the test, a selection window is displayed with the following options:

- Repeat the test for the same eye,
- Performing the second eye test (with the same test parameters as for the first eye)
- Transitioning to the test result,
- Print and/or export the survey
- Back to main screen

3.5 VIEWING TEST RESULTS

You can view the results of a test either from the main screen (**Test Results** button) or from the patient data management (described in the section titled "Managing Patient Data". In the first case, you will see a list of patients. Selecting a patient record will open a list of all available exams.

Selecting a exam opens up a window with options:

- 1) Display test results,
- 2) Delete exam.

Select exam record to perform an action...

Date of exam: 23 May 2019 7:09:55

Eye: L Notes:

Date of exam: 23 May 2019 7:09:53

Eye: L Notes:

Date of exam: 23 May 2019 7:09:50

Eye: L Notes:

Date of exam: 23 May 2019 7:09:49

Eye: L Notes:

Date of exam: 23 May 2019 7:09:48

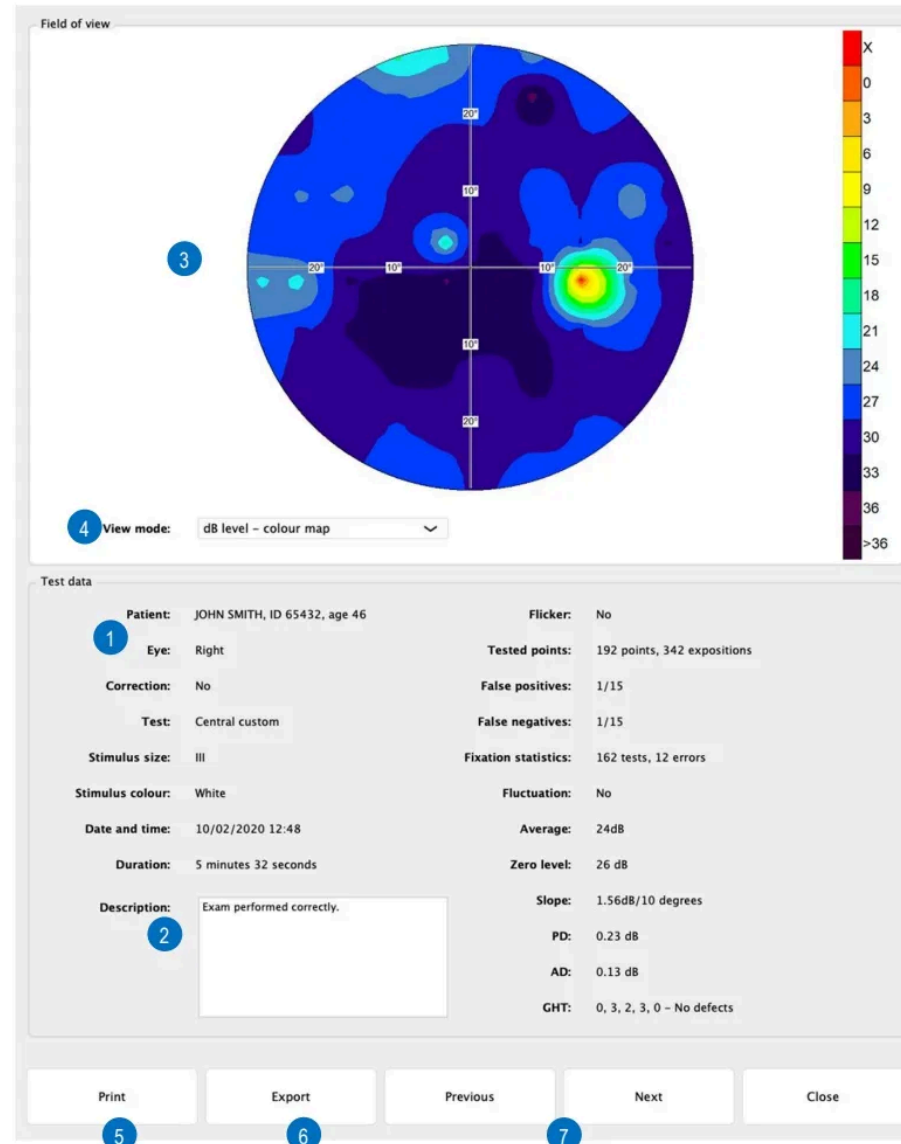
Eye: L Notes:



3.5.1 Static Test Results

The static test results screen provides the following information and functions described below:

- 1) **Test Parameters panel.** Displays the parameters of the run and the run indexes. Test indexes are described later in this section. The parameters and indexes depend on whether a static or kinetic test was performed.
- 2) **Description.** The editor allows you to enter a description. If the description was entered when the run was performed, it will be visible here.
- 3) **Results presentation panel.** The panel presents in one of many graphical or numerical forms the result of visual field examination. The different modes of result presentation are described later in this chapter.
- 4) **View mode selection box.** Allows you to select a presentation mode of the survey results. The different modes of presentation of results are described later in this chapter.
- 5) **Print button:** allows you to print the test in one of three standards for static tests:
 - (a) HFA standard
 - (b) Standard 7 on 1
 - (c) Single field



6) **Export button.** Allows you to export data in one of the selected formats:

a) PDF b) JPG/PNG c) DICOM

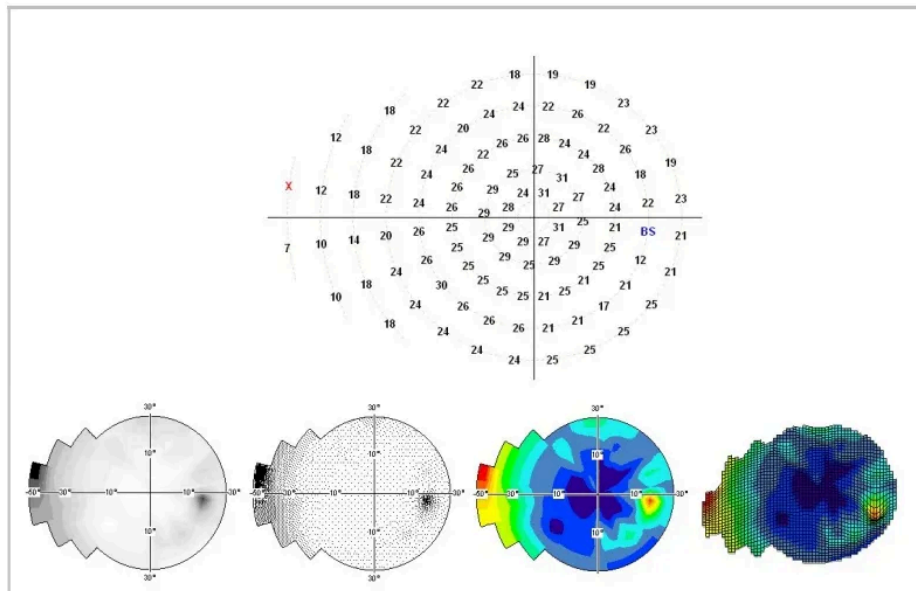
7) **Next/Previous Runs buttons.** These buttons allow you to move to the previous or next chronological study without having to close the results window and select a study from the list.

3.5.1.1 Presentation of static test results

The presentation selection box provides the following options:

A. dB map

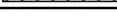
The absolute graph is the classical presentation of the determined values. The sensitivity of each cell corresponds to its decibel value measured during the test. This is a direct representation of the sensitivity of the retina to light. The higher the value presented, the better the sensitivity. The decibel map contains numbers in the range 0dB to 45dB. The map can be presented as numeric, grayscale, color scale, or 3D.



Available decibel map presentation types.

On the numerical scale, X marks the points not seen by the patient. The BS box indicates the location of the tinted macula. The other black numbers show the retinal sensitivity expressed in decibels per cell. For the Constant and Bi-Driving strategies, the value in dB that was used to test the field is displayed in green in the lower left corner.

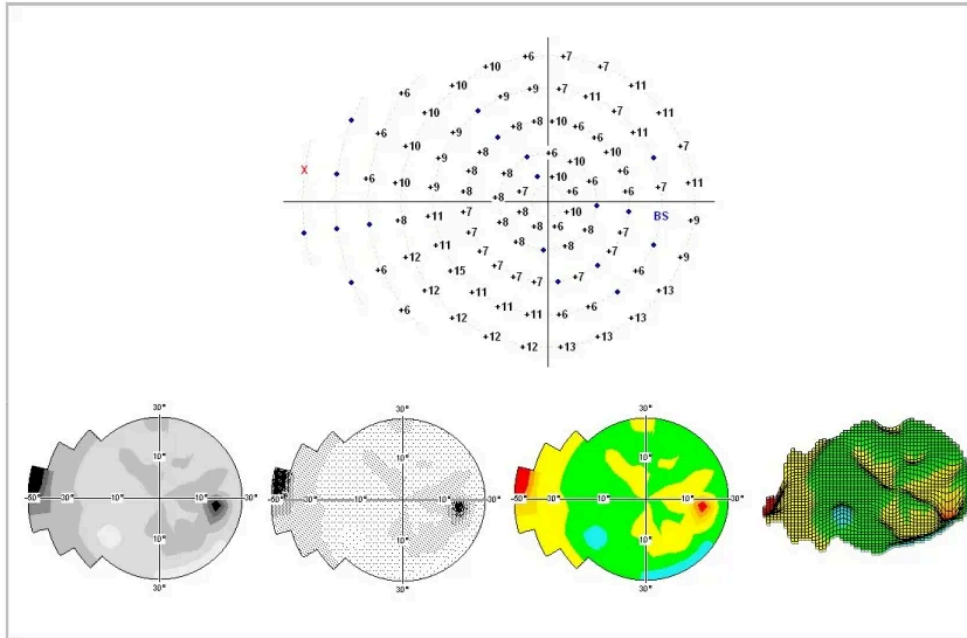
For the graphic maps, range boundaries were assumed as follows.

Range difference	Scales		
	Dot	Greys	Colorful
X			
0			
3			
6			
9			
12			
15			
18			
21			
24			
27			
> 27			

Decibel values and their corresponding graphical representation.

B. AN map (age deviation)

Relative graph. It is created by subtracting the values resulting from the age standard from the decibel levels determined during the test. The result is thus the difference in dB between the measured value and the theoretical value for a given age group. The map can be presented as numeric, grayscale, color scale, dot scale or 3D.



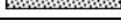
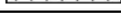
Age norm - map types.

The following designations and symbols were adopted for the numerical scale:

Symbol	Importance of
	Points whose sensitivities do not differ by more than ± 6 dB from levels derived from the age standard.
-N	Defects with a level greater than 6 dB from normal.
+N	Fields with sensitivity greater than 6 dB above the standard.
X	Points where the patient could not see the stimulus even at maximum brightness.
BS	The location of the macula.

Symbols used in an AN map for a numerical scale. AN graphical maps have a reduced dynamic range compared to a numerical chart. They consist of seven ranges. The boundaries of the ranges are assumed as follows.

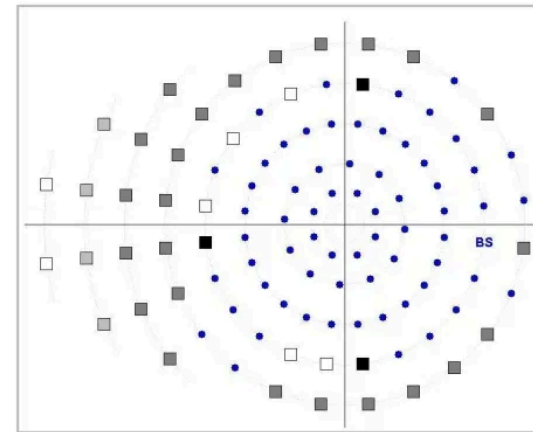
Ranges of decibel values and corresponding graphical representation of AN.

Difference	Designation		
	Dot	Greys	Colorful
≤ -18 dB			
-12 dB			
-6 dB			
0 dB			
+6 dB			
+12 dB			
$> +12$ dB			

Some of the points marked on the numerical scale with different values will be presented on the gray scale as the same level. For example, in the left part of the numerical map in Figure 45 we have values of -12 dB and -15 dB. On the graphical scales these are presented as one value in the range < -17 dB, -12 dB $>$ and are marked with the same color.

C. Map AN probability

Represents the probability of a defect at a given point. The lower the probability at a given point, the more suspicious the location of the pathology. The map is created based on the AN chart. The greater the difference between the test result and the age norm, the greater the probability of defect.



Age norm - probability

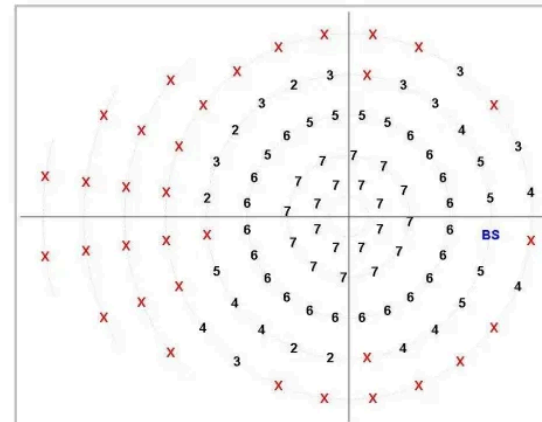
The limits of the defect probability ranges were assumed as follows:

Symbol	Range of difference between standard and test	Importance of
	$< -6, N$	Points without defect.
□ $< 5\%$	$< -9, -6$	The value obtained occurred at the location in less than 5% of the population tested. Possible small defect.
■ $< 2.5\%$	$< -12, -9$	The value obtained occurred at a given location in less than 2.5% of the population examined. Defect with average depth.
■ $< 0.5\%$	$< -15, -12$	The value obtained occurred at a given location in less than 0.5% of the population tested. High probability of deep defect.
■ $< 0.1\%$	$(-N, -15)$	The value obtained occurred at the location in less than 0.1% of the population tested. Very large defect.

Defect probability ranges and corresponding graphical representation of AN.

D. ABS map

A graph obtained by dividing the values of all cells in a decibel map by 3. It can only be presented in numerical form. By dividing the decibel values, the dynamics of the scale are reduced. Large numbers disappear, local changes (glaucomatous dark circles) are emphasized, making the graph easier to analyze.



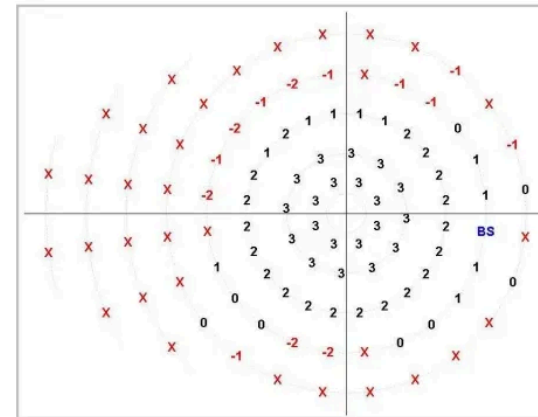
ABS Chart.

E. ABS map normalized

Graph obtained by subtracting the mean value of the field divided by 3 from the values in each cell of the ABS graph.

$$\text{ABS Norm.} = \text{ABS} - (\text{Average} / 3)$$

Representation in numeric form only. Cells can take on negative values. This usually happens at points of reduced sensitivity. The numbers representing negative values are marked in red with a - sign. This makes local changes showing reduced sensitivity even more pronounced.

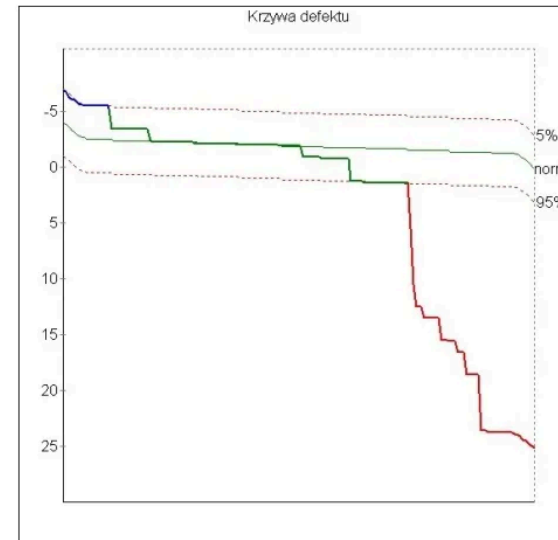


Normalized graph.

F. The defect curve (Bebi)

A cumulative graph showing the total amount of attrition. Determined by the difference of the obtained score from the norm. On the vertical axis are the values of the deviation of the brightness of individual points from the age norm. On the horizontal axis all the examined points are arranged. They are arranged in sequence starting from the points with the highest sensitivity to the lowest sensitivity.

If there is an overall decrease in sensitivity in conditions such as cataract, the entire curve will be lowered. Lesions and local cavities will cause the curve to fall in its right-hand portion. The greater the losses, the faster the curve will fall. A local increase in visual sensitivity will raise the curve in its left part.



Defect curve.

Points with sensitivity greater than normal are marked in green, equal in blue. Points with sensitivity less than normal are marked in red.

3.5.1.2 Test parameters determined from test results:

Loss of fixation

The parameter is measured in two ways: with the Heijl-Krakau method of blind spot stimulation or with a digital camera and eye position analysis. With the first method, fixation is checked randomly between standard measurement cycles. The second method checks the position continuously. Thus we have information about fixation during measurement of each point of each visual field. The parameter is presented as:

Fixation loss : 12/33 = 20% on average

The first number indicates the number of stimuli (abnormality) noticed, while the second number indicates the number of trials. In the example given, fixation was checked 33 times, of which 12 times fixation was found to be missing. The result is presented as a percentage with an additional description. The following percentage ranges were adopted:

0% to 10%	Very good
11% to 15%	Well
16% to 20%	Average
21% to 25%	Poorly
26% to 100%	Insufficiently

Error False positive

This is an error that tells you about patient responses to stimuli that were not presented. During the measurement, from time to time the program performs a dead cycle - it does not light the spot and checks if the patient presses the button. The most common cause of this error is the patient pressing the button rhythmically or not understanding the test principle. In order to "break" the patient from the rhythm of the cyclic button press, it is recommended to increase the Time Fluctuation parameter. The stimuli are then presented at more random time intervals. The parameter is presented as:

False + : 12/33 = 20% good

The first number represents the number of stimuli noticed (incorrectly), while the second number represents the number of trials (cycles without stimulus). The error should not exceed 15%. Descriptions for percentage limits were adopted analogously to those for fixation loss.

Error False negative

This error occurs when the patient fails to respond to a stimulus that should be seen. The error is tested at points whose visual threshold was determined earlier during the test. Such a point is tested with a brightness that is 6dB higher.

The most common cause of error is patient fatigue or lack of understanding of the test principle. The parameter is presented as:

False - : 12/33 = 2 % good

The first number represents the number of stimuli unnoticed, while the second number represents the number of trials. The error should not exceed 15%. Descriptions for percentage limits were adopted analogously to those for fixation loss (see Table 11).

Fluctuation

Defines the variability of designated brightness levels. It involves retesting four points whose brightness has already been determined. Four points are randomly selected for testing, one from each quart and lying no more than 22° from the center. Fluctuation testing begins after all cells lying within a field up to 22° from the center have been tested. The fluctuation value is greater the greater the difference in sensitivity between the same tested points. The parameter is represented as:

Fluctuation : - 0.75dB (+2, -2, X, 3)

The first number is the mean value of the fluctuations expressed in dB. The parameter can have a positive or negative value depending on whether the patient saw the selected points better or worse on the second test. The next four numbers in parentheses tell about the individual differences in the determined sensitivity of the points for each quart. If, for example, the fluctuation level could not be measured because of a large cavity in a quart, the program will indicate this with the symbol - in the result. If the point selected for the fluctuation test was unseen by the patient, that point will be marked with an X in the result.



Fluctuation measurement is only available with threshold strategies (Threshold, Fast Threshold).

The fluctuation for a well-performed test should not exceed ± 3 dB.

Tested - number of stimulus presentations

The parameter specifies the number of stimulus presentations relative to the number of test fields. It is converted in the form:

Tested : 420/164

The first number defines the number of stimuli presented. Cycles checking false-positive errors and controlling fixation are not included. Stimuli checking false negative errors and determining fluctuation are added to the number of presentations. The second parameter is the total number of test cells of a given field. The macular cell is not counted among them.

Sensitivity level on 1° and 3° circle - 3 deg. Level

The level determined by the sensitivity in the two circles closest to the center, i.e., the one- and three-degree circles. From the points lying on the aforementioned circles, one cell with the highest brightness is selected. Then, in both circles, the average of all points whose sensitivity does not differ by more than 6dB from the determined maximum value is calculated. This average is the sensitivity of the top of the visual hill. If it is not possible to determine the 3 deg. level, the value according to the age standard is taken. In this case the parameter is marked with an additional asterisk. If the patient cannot see in the central part of the field (all cells used to calculate the 3 deg. level have X values), the 3 deg. level is then taken as 0dB* marked with an additional asterisk.

Slope - theoretical slope of the viewing hill

Specifies the predicted slope of the viewing hill. The slope is expressed in dB per 10 degrees.

For the over-threshold strategy (Screening), a constant curve slope value of -3.0 dB per 10 degrees is assumed.

For threshold strategies (Threshold, Fast Threshold) the slope is calculated. In each ring, a point with maximum sensitivity is found. Then points with brightnesses no more than 6 dB from the maximum in that ring are selected for the calculation. These points are used to calculate the average for each circle. In this way, a set of average values is formed, through which a straight line slanted to pass as close as possible to each of them is run. Its slope corresponds to the slope of the theoretical hill of vision. This slope should be between 1.0 dB and 4.5 dB / 10°.

If a value outside the range is reached, the slope takes the value closest to the limit value of the range and the parameter is marked with an additional asterisk * indicating the slope outside the range:

Slope : 4.5 dB *

Level Zero

The most common decibel value in the test result.

Average

The mean value expressed in decibels and calculated from all points in the tested visual field. For fields that the patient could not see, marked with an X, a value of -1dB is used to determine the average.

PD pattern defect

It is determined from the projected graph of the HoV vision hill. First, the standard deviations for each circle, the so-called local deviations, are calculated. These are then multiplied by the weighting factors accordingly. The further away from the center, the smaller the weighting factor, i.e., the influence of the local deviation on the final pattern defect decreases. After multiplying the local deviations by the corresponding weights, the average value is determined from them. This average is the so-called PD pattern defect.

The pattern defect can only take positive values. Depending on the magnitude of the PD parameter, additional designations with an asterisk symbol have been introduced:

Scope of PD	Labels
< 0 dB , 3 dB > .	PD : N dB
(3 dB , 6 dB >	PD : N dB *
(6 dB , 9 dB >	PD : N dB **.
(9 dB , N dB)	PD : N dB ***

A pattern defect tells us about local changes (cavities or areas of increased sensitivity) in the visual field. An irregular field (hills, pits) will have a high level of PD. An even field without cavities - a low level. The PD parameter is not affected by an overall lowering or raising of the sensitivity level.

Medium AD Defect

It is the average of all the deviations formed by subtracting the values of the corresponding points of the test result and the age norm. To determine the average, only those points are taken into account which are considered to be within the norm on the HoV chart (marked with blue dots), i.e. points whose determined value does not differ by more than 6 dB from the level resulting from the theoretical visual hill.

The AD parameter can take on positive and negative values. Local losses have no effect on AD. However, an overall decrease or increase in visual sensitivity has a large effect. The mean defect will take on negative values when the field has reduced sensitivity and positive values when the sensitivity is above normal.

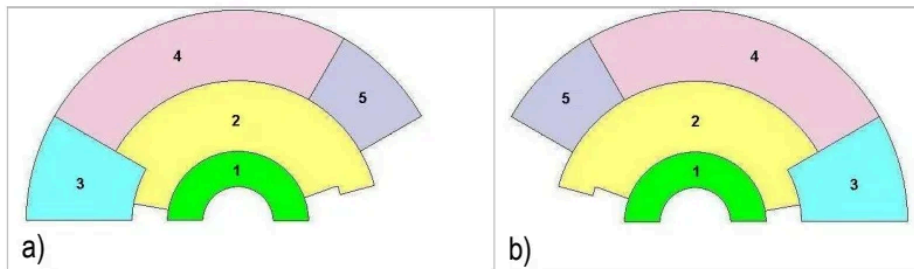
Depending on the size of the AD parameter, additional asterisk markings were introduced.

AD range	Labels
< -3 dB , 3 dB >	AD : $\pm N$ dB
< -6 dB , -3 dB) (3 dB , 6 dB >	AD : $\pm N$ dB *
< -9 dB , -6 dB) (6 dB , 9 dB >	AD : $\pm N$ dB **.
(-N dB , -9 dB) (9 dB , N dB)	AD : $\pm N$ dB ***

Additional AD designation.

GHT - Glaucomatous Zonal Comparison

A parameter whose value is the result of comparing five zones in the upper and lower half of the field. The zones were established in the places of the most frequent occurrence of glaucoma lesions. The compared zones were placed symmetrically in the upper and lower parts of the field. Each field in the upper part of the field corresponds to an analogous field in the lower part. The zones cover an area up to 30 degrees from the center. The 1° circle and points lying in the vicinity of the blind spot are excluded from the comparison areas. Figure 54 provides a schematic location of the top five zones for the left and right eyes.



GHT - sectors. Left eye - (a), right eye - (b).

In the analysis, the decibel mean value of the corresponding zones is compared. The result of the comparison is presented as follows:

GHT: +2,-3,0,+1,-3 Field collapsed

Each number shows the difference in average decibel value between the zones. The digits correspond to the result of comparing the respective zones, with the first digit corresponding to the first zone and the last digit corresponding to the fifth zone.

The following designations were used to represent the result :

0	No difference
+ N	Average sensitivity of the lower zone lower than the upper zone by N dB.
- N	Average sensitivity of the lower zone higher than the upper zone by N dB.

GHT - description of the degree of difference between zones.

If GHT cannot be determined, the parameter field is left blank.

In addition, the following descriptions were adopted according to the depth of differences in the corresponding zones.

Description	..1.1.1.1.1.1 Evaluation criterion
No defect	No differences
Suspected defect	Difference in one zone > 3 dB
Defect	Difference >= 6 dB in one zone or difference > 3 dB in two or more zones
Sunken field	Difference in three or more zones > 3 dB

Designations adopted to describe the zone defect.

3.5.1 Kinetic test results

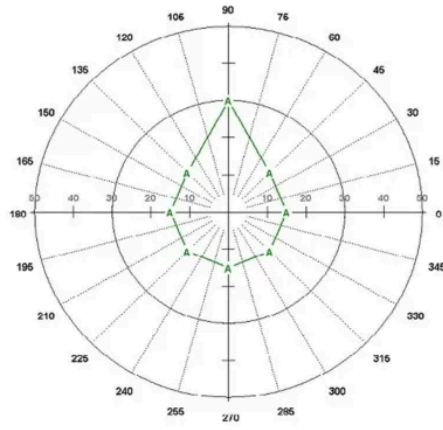
3.5.1.1 Presentation of results

For the kinetic test, the following options are available for selecting the test presentation:

1) **Isopters** - a field with drop-down lists showing all parameters of a given isopter and the patient's responses for stimuli moved along given meridians.

2) **Buttons A to H** - the buttons correspond to the isoptera being tested in turn (A - the first isoptera, B - the second, H - the eighth). Pressing a given button draws or blurs the corresponding isoptera on the screen. This option is particularly important when multiple isopteras have been tested within a single kinetic test. Drawing all isopters at once could make the graphical result of the test unreadable. Each isopter is drawn using a different, permanently assigned color.

Field of view



Show: ☒ Meridians ☒ Outlines ☒ Markers ☒ Responses

2 Isopters: ☒ A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H

Test data

Patient: JOHN SMITH, ID 65432, age 46

Eye: Right

Correction: No

Test: Kinetic

Number of isopters: 1

Fixation statistics: 54 tests, 1 error

Date and time: 10/03/2020 11:16

Duration: 2 minutes 12 seconds

Description: Exam performed correctly.

1 Current isopter: A

Stimulus size: IV

Brightness: 1 (25dB)

Modifier: A (+1dB)

Velocity: 4 degrees / s

Colour: White

Number of meridians: 5

Angle between meridians: 60

Start angle: 30 degrees

End angle: 5 degrees

3 Print 4 Export 5 Previous Next Close

	a	b	c	d
Show:	☒ Meridians	☒ Outlines	☒ Markers	☒ Responses
Isopters:	☒ A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H			

- (a) **Meridians** - traces the test result with or without the meridians marked.
- (b) **Envelopes** - Traces the test result with or without the canopy envelopes at 30 and 50 degrees.
- (c) **Markers** - traces the test result with or without the angle values marked.
- (d) **Responses** - Traces the test result with or without the patient's response items.

3) **Print button** - For a kinetic test, only a single field printout is possible. The printout will contain exactly the same graphical representation of the test results as currently displayed on the screen. This makes it possible, for example, to obtain separate printouts for each isopter within a single test.

4) **Export button**. Allows you to export data in one of the selected formats:

a) PDF b) JPG/PNG c) DICOM

5) **Next/Previous Runs buttons**. These buttons allow you to move to the previous or next chronological study without having to close the results window and select a study from the list.

4 TESTS EDITOR

A feature that allows the user to define a custom test. It is particularly useful when only a portion of the patient's visual field is of interest, for example, one where vision problems were detected during previous examinations. By limiting the field using the field editor you can shorten the examination time and reduce patient fatigue.

Start editing a test by selecting the desired eye (1) and, optionally, the test field from which you want to build a new test field (2). The following test fields are available by default:

- *Central 22°*
- *Central 30°*
- *Driving*
- *Full*
- *Glaucoma*
- *Macula*
- *Peripheral*
- *Wide*

You can also use a field from any user test.

New points can be added to the test field by left-clicking or holding down the touch screen. Points can be deleted by double-clicking. Before saving the test field, define the strategy to be used for the test.

Test field

Test data

1 Eye: ☒ Right ☐ Left

2 Basic test: Glaucoma

New test name: Glaucoma custom

Save Export Delete Close

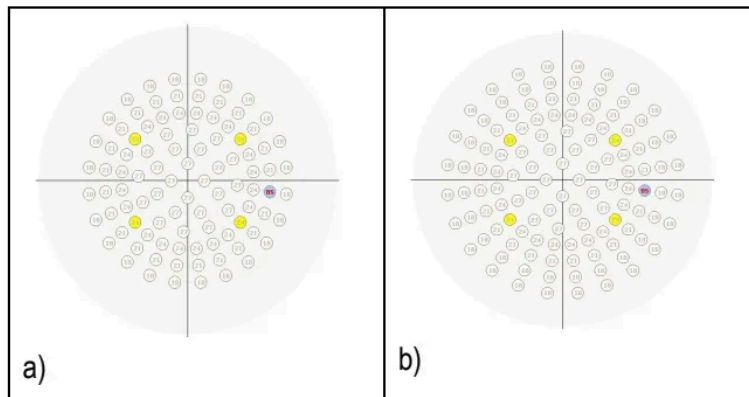
5 TEST FIELDS AND TESTING STRATEGIES

A perimetric test is a composite of a test field reflecting the extent of the visual field being tested and a strategy, or algorithm, by which points in the test field are tested.

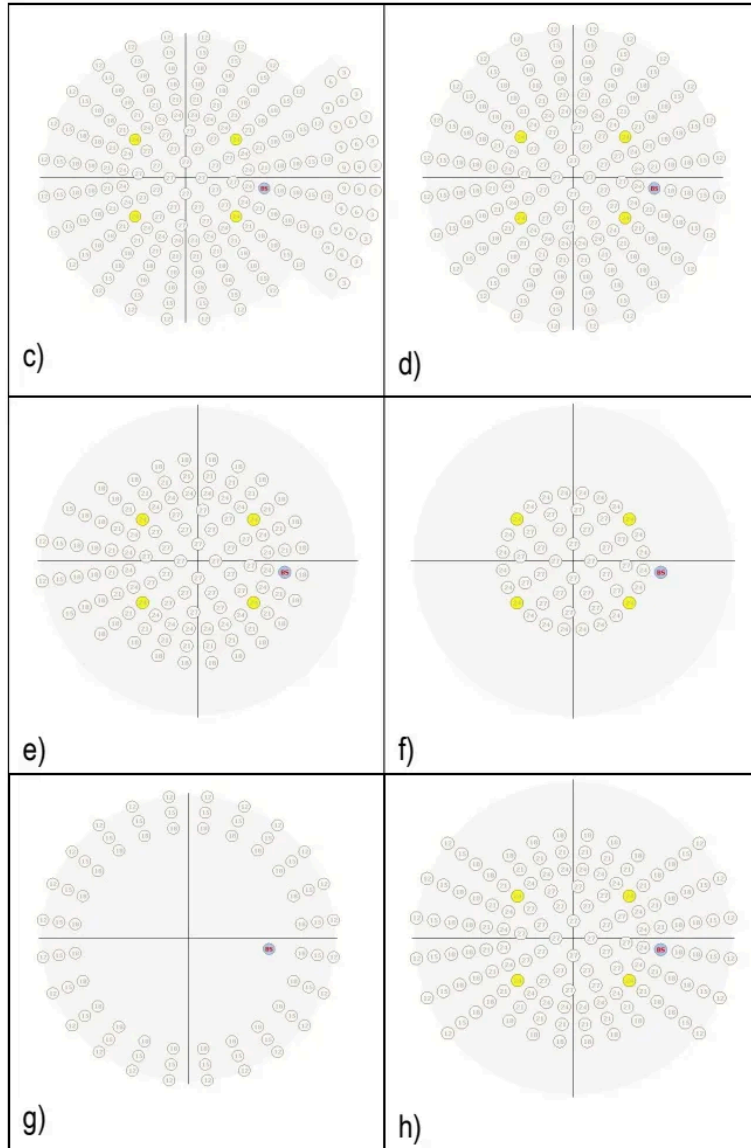
5.1 TEST BOXES

The standard available test fields are described below (you can edit your own fields, as described in the "Test Editor" section):

Test name	Angle range		Number of test points	Figure
	Nosowo	Temporarily		
Central 22°	22°	22°	93	a)
Central 30°	30°	30°	117	b)
Driving	50°	80°	189	c)
Full	50°	50°	162	d)
Glaucoma	50°	30°	102	e)
Macula	10°	10°	45	f)
Peripheral	from 30° to 50°	from 30° to 50°	72	g)
Wide	50°	30°	126	h)



- a) **Central 22°** - standard central field. The small number of fields makes the examination fast in all available strategies.
- b) **Central 30°** - A **central field** that extends up to 30 degrees. Because of the small number of points, it can be used with *Threshold* and *Fast Threshold* strategies.



(c) **Driving** field - designed for driver testing. Due to the large number of test points, it is recommended to use with the *Quantify Defect* or *Screening* strategy.

d) **Full** field - This test covers a full 50° degree field. It is recommended for use with *2 Zone*, *3 Zone*, *Quantify defect* and *Screening* strategies due to the large number of test points and the resulting long test time.

(e) **Glaucoma** field - This is a 30° degree central field extended to 50 degrees in the nasal direction. It can be used to track the development of glaucomatous defects and is a favorable alternative to central fields.

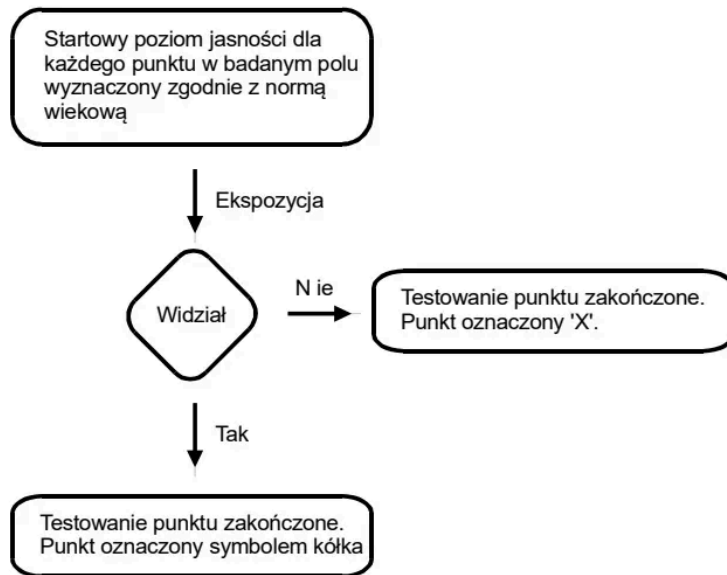
(f) **Macula** field - extends from 1 to 10 degrees from the fixation points. Provides a quick diagnosis of the macula. Recommended for use with threshold strategies.

(g) **Wide** field - central field expanded to 50 degrees in the horizontal plane. Convenient for tracking glaucomatous defects. When examining the elderly, it eliminates the drooping eyelid effect because it extends only to 30 degrees in the temporal direction.

h) **Peripheral** field - includes 73 test points lying on 30, 40 and 50 degree circles. Recommended for diagnosis of light sensitivity of the peripheral part of the retina.

5.2 STRATEGIES

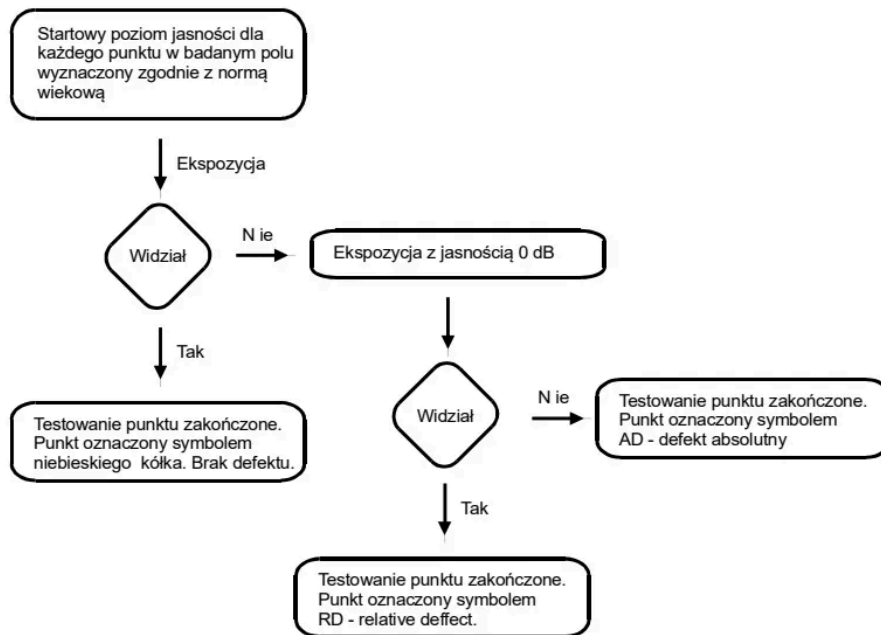
Strategy 2 Zone - This is the fastest test strategy available in the software. Before the test begins, all points in the field are assigned starting brightness levels. The levels are determined from the age standard according to the age of the patient. The program does not perform an initial calibration based on the four yellow calibration points. Each field point is tested only once. If a positive response is received, the point is marked as seen with a ○ circle symbol. If the patient does not respond, the point is marked as not seen with an X



2 Zone strategy flow chart.

Strategy 3 Zone - very similar to the strategy 2 Zone. The assignment of starting brightness levels to the points of the tested field is done in the same way as in the 2 Zone strategy. The program does not test retinal sensitivity for the four yellow calibration points. All points are tested according to the following scheme.

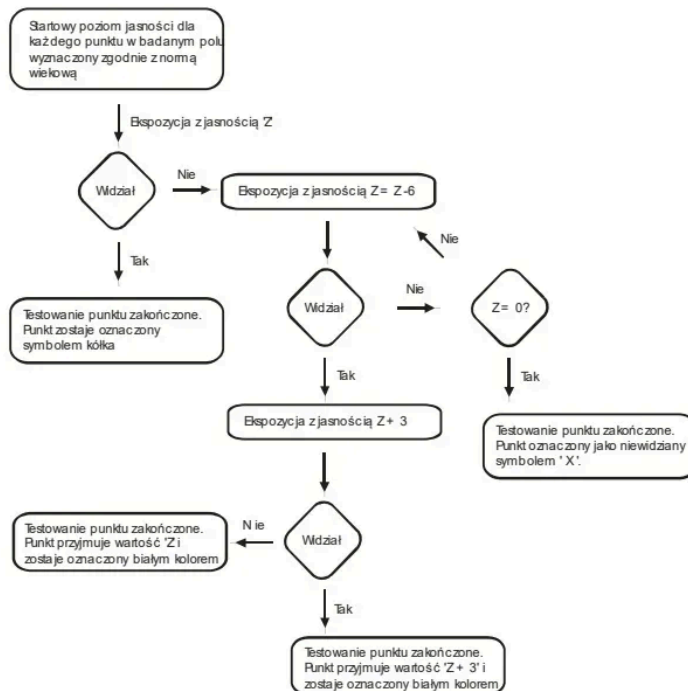
The point is lit with a starting brightness level. In the case of a positive response, point testing is terminated and the tested field is marked with a blue ○ symbol indicating no defect. In the case of a negative response, the point is tested again with a maximum brightness level of 0 dB. If the stimulus is observed, the point will take on the value **RD** - relative defect - in black. If the stimulus is again unnoticed, the field is marked in red as **AD (absolute defect)**.



3 Zone strategy flow chart.

Quantify Defect strategy is a simplified version of the *Screening strategy*. The assignment of starting brightness levels to the points of the tested field is done in the same way as in the *2 Zone strategy*. The program does not pre-calibrate the brightness levels for the four yellow calibration points. Each point is tested according to the following scheme:

The point is lit with a starting brightness level derived from the age standard. In the case of a positive response, testing of the point is terminated and a blue circle symbol $\circ$ is placed on the field under test. In the case of a negative response, the point is tested again with the brightness reduced successively by 6 dB until a positive response is obtained. In the absence of a positive response, the point will be marked with **an X**. If a positive patient response is obtained at a certain brightness level Z , the point will be further tested with a brightness of $Z + 3$ dB. In the case of a positive response, testing of the point will be completed and the value of $Z + 3$ dB will be used as the result. In the case of a negative response, the result will be the Z value.



Flow chart of the Quantify Defect strategy.

Screening Strategy - a standard suprathreshold strategy. The first step of the strategy is to determine the retinal sensitivity at four calibration points. The calibration points are marked in yellow. Calibration of the four test points is performed according to the *Threshold strategy*. The starting brightness level of the calibration points is taken according to the age standard. Calibration of the points is not performed if we use a standard of a previously performed test. After calibration is completed, only one of the four points with the highest decibel value (maximum sensitivity) is selected. On its basis, the starting brightness values for the remaining points in the field are determined according to a fixed scheme. Thus, if the point with the maximum sensitivity takes the value of N dB then the remaining points - depending on which circle they lie on - will be assigned the following brightness levels in dB :

Circle (degrees)	Assigned level (dB)
1°	N
3°	N
6°	N
10°	N
15°	$N - 3$
22°	$N - 6$
30°	$N - 9$
40°	$N - 12$
50°	$N - 15$

Each of the four calibration points whose designated sensitivity level is less than the maximum is retested, starting with the brightness resulting from the table above.

If all four calibration points have a calibration level that is 6 dB below the level derived from the age standard for those points, a message will be displayed indicating a possible calibration error.

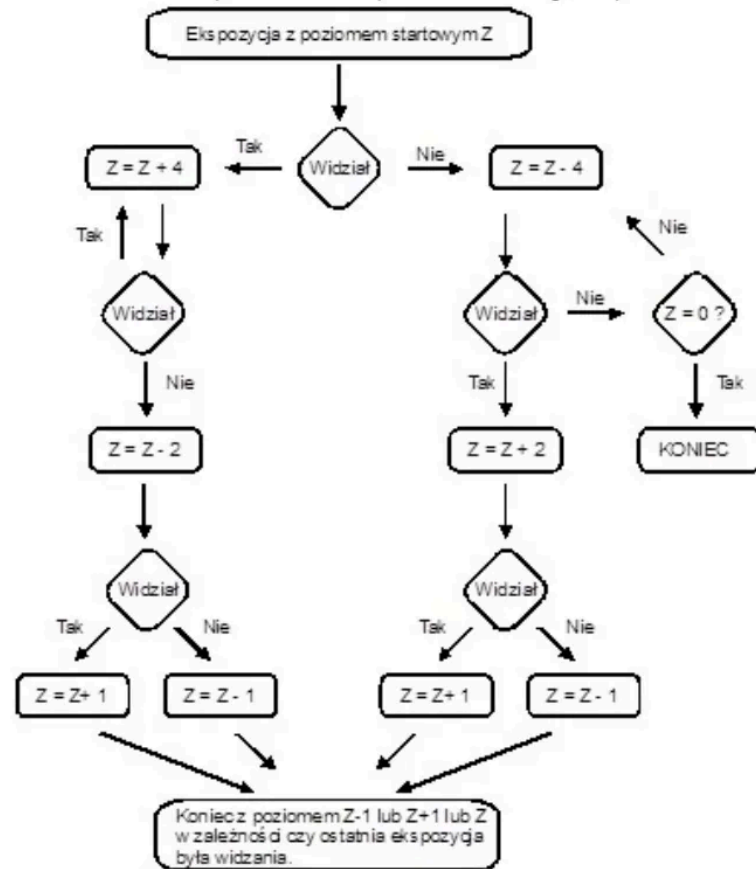
The user will have the choice to continue with the test starting at the designated level or to use an age-appropriate calibration according to the age of the patient. It is recommended that the test be continued with the sensitivity level determined during calibration.

In a further step the test will proceed by presenting the points with the corresponding intensities calculated from the calibration level. If the point is not seen then the intensity is increased by 3dB and the point will be tested again. The testing of the point will be terminated when the patient gives a positive response.

Neurological strategy - A neurological strategy based on the *Screening strategy*. The first phase of the test is identical to the *Screening strategy*. Four calibration points are tested and decibel values are assigned to the remaining points based on the rules described in Section 22.4. Four points are then randomly selected in each quarter (from circles placed to 30 degrees) to be tested. If all points in a given quarter give a negative response (including one calibration point for that quarter), that quarter is all considered unseen and filled with X values. The remainder of the test follows the *Screening strategy*. The Neurological strategy cannot use the field pattern from previous tests.

Fast Threshold strategy. It gives very similar results to the *Threshold strategy*, while at the same time the duration of the test is shortened significantly, which has a positive impact on the reliability of the results. The test begins by determining the sensitivity of four calibration points. This is done using the *threshold strategy*.

One cell is then selected in each ring of the given quart. This cell is assigned a value resulting from the sensitivity level determined at the calibration point for that quart and its angular position according to table number 17.



sensitivity within the age norm ends the cell testing process.

Circle (degrees)	Assigned level (dB)
1°	N+3
3°	N+3
6°	N+3
10°	N
15°	N -3
22°	N -6
30°	N -6
40°	N -9
50°	N -12

. Fast Threshold strategy - point calibration.

The selected cells are also tested using a threshold strategy. The determined sensitivity of the selected cells is used to predict the sensitivity of cells in fields located on the same ring of a given quadrant. In this way, the viewing threshold of the remaining approximately 80% of cells not yet tested is determined with very high probability. These cells are further tested with the threshold strategy, additionally referenced to the age norm. This means that a positive response with

Threshold Strategy - A standard threshold **strategy**, with a flow identical to *Fast Threshold*, is devoid of reference to an age norm. For this reason the testing process is prolonged. The result obtained is very precise and the sensitivity is determined to within 1 dB.

Fastscan strategy - The *Fastscan* strategy has the same flow as the standard over-threshold strategy (*Screening*). The only difference is that half of the points from the selected field are tested. This reduces the duration of the test, but decreases the spatial resolution of the result obtained.

Binocular strategy - The *Binocular* strategy is used for the so-called *Binocular single vision* test. A pair of eyes is tested simultaneously. Points are presented at maximum intensity (0dD). The patient decides whether the presented point is seen singly or doubly. If single - the patient should press the button once, if double - twice, and if the point is not visible - the button should not be pressed. All points seen as single are indicated by the letter s, as double - by the letter D. Points that are not seen are tested again and if there is no response again, they are marked with an X. In the *Binocular* strategy, exposure time = 4.0s, response time = 1.5s, wait time = 0.2s, and delay time = 0.2s. The time settings cannot be modified. When performing the *Binocular* strategy, the fixation control is disabled.

Fast Threshold BY strategy



Prior to testing with the *BY (Blue on Yellow)* strategy using a yellow background color, it is necessary for the patient to adapt to the new lighting conditions by staring at the perimeter bowl for a specified period of time. The adaptation time for *BY* tests ranges from a few minutes to several minutes and is reported in the literature.

The **Fast Threshold BY (Blue on Yellow) strategy** proceeds identically to the *Fast Threshold* strategy (Section 23.6) except that the test is performed with blue stimuli and a Goldmann V-compliant size with the yellow background illumination on.

Threshold BY strategy - The standard *Threshold BY (Blue on Yellow)* strategy, with a flow identical to *Fast Threshold BY*, lacks reference to an age norm. For this reason, the testing process is prolonged. The result obtained is very precise and the sensitivity is determined to within 1 dB.

Constant strategy - The *Constant* strategy is identical to the *2 Zone strategy*, except that the cells of the test box are not filled with values derived from the age norm, but with a constant value. This value - assumed to be 5 dB by default - can be changed

in the test parameter selection window (Chapter 10). When *Constant* is selected in the *Strategy* field, a box is displayed next to it for changing the value. The *Constant* strategy omits the calibration of the 4 calibration points on the grounds that all cells are tested at the same brightness level. This value is displayed in green in the lower left corner on the numerical presentation of the test result.

Bi-Driving strategy - The *Bi-Driving* strategy is used to perform a two-eye test using both extended fields (up to 80° right and left). In this strategy the test field is automatically generated by the program and the user has no influence on its selection. The principle of filling in the test fields is identical to the *Constant* strategy, that is, all cells are tested at the same brightness level (default 10 dB for the white stimulus and 3dB for the green stimulus). The exposure time is 0.4s and cannot be changed. The video preview covers two eyes. The patient (in his/her own spectacle correction) is instructed to gaze with two eyes at the fixation point. The entire test should be performed in the patient's own correction.

Smart Threshold strategy - the *Smart Threshold* strategy consists in testing particular cells of the field in the same way as the *Fast Threshold* strategy, with the difference that initially half of the cells in the field are selected for testing. Then, as the test proceeds, a condition is checked if a cell not selected by the algorithm for the test has as neighbors (in the same circle) cells whose test has already finished. If the difference in levels of the two cells is equal to or greater than 4dB, the cell lying between them will be included in the test. If the difference is less, the cell is considered to be tested with a brightness level that is the average of the levels of both neighboring cells. The *Smart Threshold* strategy allows for a significant (on average about 50%) acceleration of the test run compared to the *Fast Threshold* strategy.

Smart Threshold BY - The *Smart Threshold BY* (*Blue on Yellow*) strategy is identical to the *Smart Threshold* strategy except that the test is performed with blue stimuli and Goldmann V-compliant size with the yellow background illumination on.

6 CONFIGURATION AND SERVICE FUNCTIONS

The Service Options screen contains a number of tabs whose functions are noted below.

6.1 DATABASE TAB

Device (server) name: SLI-200

1 Data port: 7779

2 File port: 7778

3 Advertiser port: 7774

4 Remote server IP: 145.239.94.249

Available storage space: 3.44 GB

Backup / repair 5

Users management 9

Work as database server 6

Advertise data on network 7

Default connection 8

- 1) Data Port - the system port number used for network communication with the data server (default value 7779)
- 2) File Port - the system port number used for network communication with the data server for file transfer (default value 7778)
- 3) Broadcast port - the port number used by the notification system to allow external devices to automatically recognize the presence of a database server perimeter on the network
- 4) Remote server address - if the database server is hosted on a remote server, you can use the IP address of that server to define the default connection to the database server
- 5) Copy / repair - provides options to copy the database to an external carrier (USB flash drive or externally powered USB drive). The repair option should be used only if a connection error occurs regularly while connecting to the database and does not disappear after restarting the device. It is possible that recently performed operations on the database are lost.

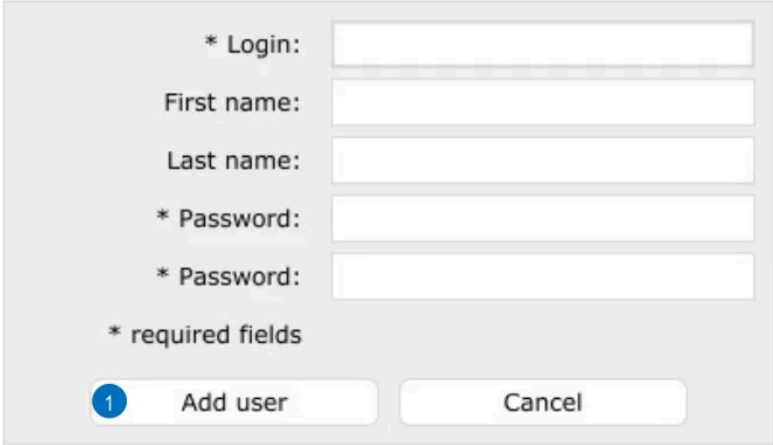
- 6) "operation in data server mode" switch - if the database is to be located on the internal disk in the AP-600 perimeter, the switch should be in the on position
- 7) "Broadcast to Network" switch - switch in the on position causes information about the presence of a running data server to be broadcast on the network so that external devices (other perimeters and devices compatible with the Frey Eyemager technology infrastructure) can connect to the server running on the perimeter
- 8) "default connection" switch - switch in the on position causes the perimeter program to automatically connect to the database server whose IP address was entered in the "Remote Server Address" field
- 9) User Management - allows you to add, delete and edit database server user data (name, surname, login, password). After pressing the button a screen with a list of users will appear:

6.2 USER MANAGEMENT

You can add any number of users to protect the database from unauthorized access. It is recommended that you enter at least one user to secure access.

Add User button (1) - creates a new user record. The password is case sensitive. The new password must be entered twice, into separate fields. User's login must be unique - there cannot be several users with the same login. Required fields are marked with an asterisk.

Selecting a user displays the available options to edit or delete the user. In the case of editing, it is not possible to change the login.



* Login:

First name:

Last name:

* Password:

* Password:

* required fields

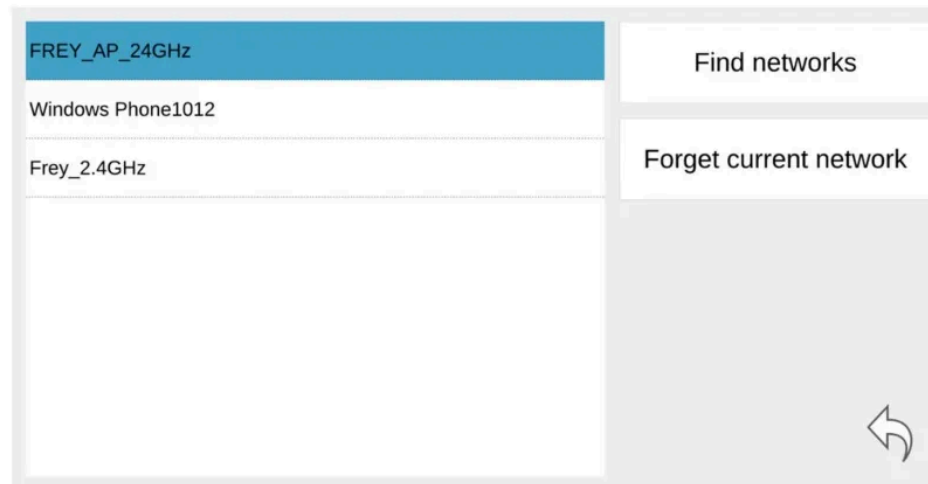
1 Add user

6.3 LANGUAGE AND KEYBOARD TABS

They allow you to select the used language and keyboard (containing e.g. national characters in a specific layout). It is possible to upload language and keyboard files to the perimeter using the "Add language" and "Add keyboard" options

6.4 WiFi TAB

Perimeter Ap-600 provides network connectivity using wireless network (WI-FI). Wi-Fi tab provides a list of available wireless networks and enables connection to a selected network (network access password must be entered). If the network connection was successful, the active network is highlighted in blue and the local IP address assigned to the AP-600 perimeter is given.



6.5 SERVICE MODE TAB

Allows access to service functions of the device and software. An unlocking password must be entered. Service functions are not the subject of this manual - their detailed description is available for qualified service personnel in a separate technical document.

7 TECHNICAL SPECIFICATION

7.1 TECHNICAL DATA

Functional characteristics				
Stimulator Bowl Type	Approximately hemispherical ('Bullet shape'), 30cm radius. Integrated diffusion coating			
Visual Field Extent	100°			
Standard Test Fields	Field name	Scope of the test		Number of measurement points
		Nosowo	Temporal	
	Central 22°	22°	22°	165
	Central 30°	30°	30°	101
	Driving	50°	80°	117
	Full	50°	50°	93
	Glaucoma	50°	30°	128
	Macula	10°	10°	72
	Peripheral	from 30° to 50°	from 30° to 50°	45
	Wide	50°	30°	189
Kinetic test	Test fields: 30°, 40°, 50°, 50°/80°			
	Meridian angles: 0° to 360° in 1° steps			
	Number of isopters: 1 to 8			
	Stimulus speed: 2°/s, 4°/s, 6°/s, 8°/s			

Stimulus source	Front projection LED	
Stimulus color	White, Green, Blue, Red	
Stimulus size	Goldmann size I to V	
Stimulus brightness	0.03 asb to 10000 asb in 15 3dB or 45 1dB steps	
Exposure Time	Adjustable: 0.1 to 9.9s	
Response Time	Adjustable : 0.1 to 9.9s	
Inter Test Delay	Adjustable : 0.1 to 9.9s	
Background illumination	White 10asb (3.2 cd/m2) for green and red stimulus White 31.5asb (10 cd/m2) for white stimulus Yellow 100 cd/m2 for blue stimulus Automatic brightness adjustment	
Fixation control method	Heijl-Krakau - blind spot method Digital Eye-tracking with CCD camera	
Fixation point	Central - Green 565nm FOVEA - Red 700nm	
Test lens diameter	38 mm	
Chinrest	Electrically adjustable	
Forehead support	Electrically adjustable	
Physical characteristics		
Dimensions and weight	Dimensions S/W/D	566 x 633 x 396 mm
	Weight	24 kg
Supply voltage	110-230 VAC 50-60 Hz	
Power consumption	Max 575 VA	

Fuses	1x T 2.5 A
Power outlet	Insulating Transformer 2.0A Pmax: 500VA
Class of protection against electric shock for electromedical equipment	I B
Application part	Chinrest & Forehead support, Patient response button
Compliance	CE EC/93/42
Expected lifetime	10 years

7.2 OPERATING ENVIRONMENT

Environmental conditions	
Place of installation	Inside
Temperature	+10°C to +40°C
Humidity	30 to 75%
Atmospheric pressure	700 to 1060 hPa
Power fluctuations in the network	Less than $\pm 10\%$ of rated voltage
Environmental conditions for storage and transport	
Humidity	< 95%
Temperature	+5°C - +50°C

7.3 RADIO EMISSION

Wi-Fi	
Frequency range	2400-2483.5 MHz, 5150-5250 MHz, 5250-5350 MHz, 5500-5700 MHz
Output power	2.4 GHz- 802.11(b) +16 dBm- 802. 11(g) +13 dBm- 802 .11(n) +11 dBm
	5 GHz- 802.11(a) +15 dBm - 802.11(n/ac) +13 dBm - 802.11(ac) +9.5 dBm

7.4 DEVICE CONFORMING STANDARDS

EN 60601-1:2006 +A11:2011 +A1:2013 (PN-EN 60601-1:2011 +A11:2011 +A1:2014))

EN 60601-1-2:2015 (PN-EN 60601-1-2:2015)

EN 62304:2006/A1:2015 (PN-EN 62304:2010/A12015)

EN ISO 14971:2012 (PN-EN ISO 14971:2012)

EN ISO 12866:1999 (PN-EN ISO 12866:2002)

EN ISO 12866:1999/A1:2008 (PN-EN ISO 12866:2002/A1)

8 MAINTENANCE

8.1 EXPECTED LIFE TIME

The Manufacturer has determined the expected lifetime of the AP-600 Automated Perimeter to be 10 years.

8.2 CLEANING AND MAINTENANCE ACTIVITIES



Disconnect the unit from the power source before cleaning!

8.3 STORAGE AND TRANSPORTATION



Do not store the unit in an area exposed to water or chemicals. Water or chemicals entering the unit may cause electric shock or malfunction!

Store the unit in a place not exposed to direct sunlight, high temperature and humidity or air with high dust, salt and/or sulfur content. This may cause the unit to malfunction or fail.

Automated Perimeter AP-600 should be properly prepared for transport to avoid damage. For transport it is recommended to keep the original packaging of the device from the manufacturer.

8.4 DISPOSAL

Dispose of the device or its parts in accordance with local environmental protection and waste disposal and recycling regulations.



This symbol applies to EU member states only.

To prevent potential damage to the environment and possibly human health, this device should be disposed of **in EU member states in accordance with the WEEE directive (2002/96/EC on Waste Electrical and Electronic Equipment)**, or in all other countries in accordance with local regulations for disposal and recycling.

9 NOTES

Manufacturer:



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