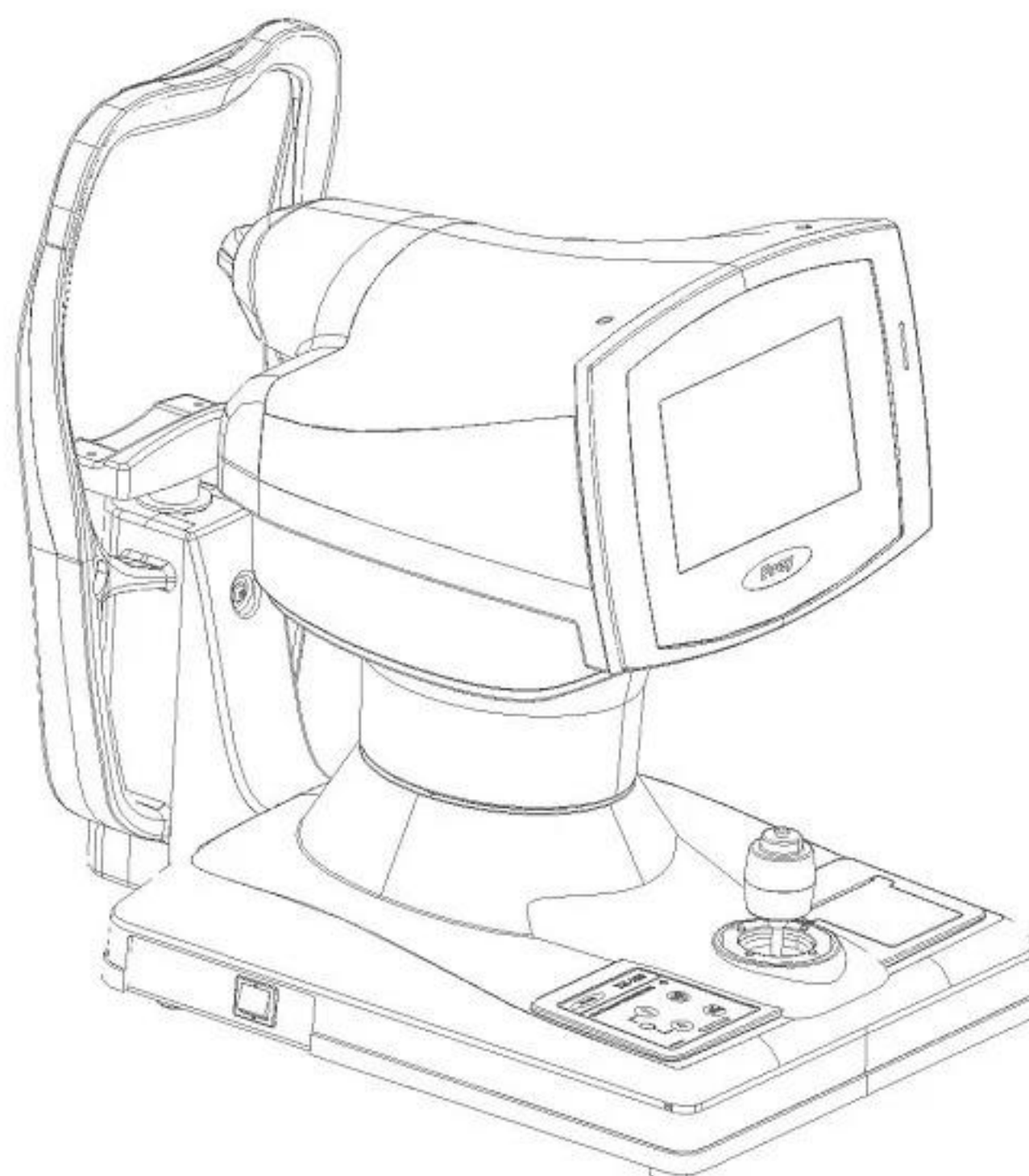

TN-100

NON-CONTACT TONOMETER

OPERATION MANUAL



All specifications are subject to changes without notice.
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1 INTRODUCTION

This OPERATION MANUAL describes the purpose, overall view and user maintenance of the TN-100 Non-contact Tonometer. This manual is intended for medical personnel and who will perform measurements on patients using TN-100 device. This instruction provides information concerning 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 equipment.

If you have encountered problems when using your TN-100 Tonometer which you cannot solve, or the Tonometer parameters are changed, please, in all these cases contact the Manufacturer or his authorized representative.



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

The right to repair or set up the TN-100 Tonmeter or to carry out periodical part replacements is reserved only to the Manufacturer or to persons authorized by the Manufacturer.

TN-100 Non-contact Tonometer is to be used only in accordance with this Operation Manual.



If you have questions regarding the use, please contact the manufacturer or distributor.

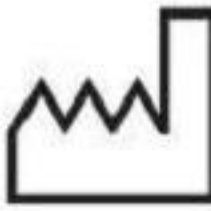
During the lifetime of the device, this manual should be kept in an easily accessible place for the user to at any time it is available.

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

2 SYMBOLS



Manufacturer



Date manufacture



Follow Instructions for Use



The CE mark - indicates conformity with the provisions of 93/42/EEC Medical Device Directive



Separate collection of Waste Electrical and Electronic Equipment - Indicates that this device should be disposed of for EU member countries in accordance with Directive 2002/96/EC (WEEE).



Type B Applied Part



Temperature limit during transportation and storage.



Humidity limitation during transportation and storage.



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..

SYSTEM DESCRIPTION

TN-100 Non-contact Tonometer is a modern diagnostic device for fast and precise measuring of the intraocular pressure of patient's eye.

The measurement is carried out without coming into contact with the patient's eye.

TN-100 allows to conduct measurement both in automatic or manual mode. The device has an option to make an automatic correction of the intraocular pressure value obtained by the thickness of the patient's cornea.

TN-100 is equipped with a color 7" touch screen display, with which can be controlled all the operations. The friendly and easy user interface allows intuitive navigation through available options. Additionally, the device has the control panel with keys, located on the unit housing.

TN-100 has a built-in printer, which allows to print out of the results of intraocular pressure measurements.

The position of the measuring head of the device is electrically adjustable in three dimensions, using the multi-function joystick.

General outline of operation of TN-100:

- The patient places their chin on the chinrest and looks into the sight-fixing LED in the measurement head.
- The physician observes the patient's eye on the screen and roughly aligns the measuring position. After the onscreen indicators confirm that correct initial position has been reached, he presses the 'Auto' button, which initializes an automatic fine alignment of measuring position, and then the conduct of the measurement.
- When measurement has started, air blows from the nozzle in the outlet of the measurement head. When the cornea becomes flat due to blown air, corneal reflected light from the light source is received by the light receiving element. Then the instrument calculates the intraocular pressure by analyzing changes in air pressure in the device's measurement circuit, and shows the result on the screen.

3 SAFETY PRECAUTIONS

Intended use



TN-100 Non-contact Tonometer is medical device designed to calculate intraocular pressure of patient's eye. Do not use tonometer for any other purpose!

Installation



Do not lift device by holding the measuring head, chin rest, or joystick. These elements can disconnect from the device, causing it to fall, and as a result cause injury!

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 where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the device and ignite!

Install the device in a location not subject to direct sunlight, high temperature and humid, or air with significant dust, salt and/or sulfur content. This may cause failure or malfunction of the device!

Install the device in a location that is sufficiently clear of any other equipment that may interfere with the examination when using the device.

Power connections



To power the Tonometer may be used ONLY the power supply supplied with the unit!

Power connections



Check the frequency, voltage and allowable current (or power consumption) of the power source before connecting the power supply. Connecting to inappropriate power source may cause fire or an electric shock!

Connect the power plug only to a grounded 3P-outlet. Otherwise a short circuit due to failure of the device may result in electric shock.

Use an intact power cord. Replace the cord if it is cracked, frayed, broken or otherwise damaged.

Do not apply tension to the power cord., do not place any heavy object on the power cord or squash the cord,. This may cause fire or electric shock!

Do not use extension cords or adapters of any type.



Device is designed for continuous use.

External connections:



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

Precautions during operation



When moving the measurement head and/or chinrest of the device, pay attention to the position of the patient's face, hands and fingers. The patient may be injured by the moving section of the device.

Do not allow any person to place their hands or fingers in the clearance under the measuring head or the section under the chinrest. Their hands or finger may be injured!

Never touch the cutter in the printer, it may cause the injury!

If any smoke, offensive odor, or abnormal sound occurs, turn off the device immediately, disconnect the power plug from the outlet, and contact local distributor or the manufacturer!



If any device failure occurs, stop operation immediately, indicate the failure, and contact local distributor to request repair.

Do not attempt to repair device yourself!

Never modify the device! Doing so may cause electric shock or failure of the device!

Storing and transportation



The device must be properly prepared for transport to prevent



damage. To do this, press button on the control panel for 3 seconds to lower the measuring head to the lowest position. Not lowering the measuring head may cause damage of the device during transport!

For more information on storage and transport of the device refer to the chapter 9.5.

Cleaning and maintenance



Do not perform any service or maintenance activities on the device during examination of the patient!

Turn of the device and disconnect the power cord from the outlet before attempting any maintenance or cleaning activities on the device. Before reconnecting the power, wipe dry all parts of the device

Do not use ammonia-, phenol-, or acetone-based cleaners. Get rid of moisture completely before reconnecting to the mains outlet.

Do not immerse the device in any liquid. Do not allow liquid to enter the device.

Do not sterilize the device.

For more information on storage and transport of the Tonometer refer to the chapter 9.3.

Interferences



This device emits a certain level of electromagnetic radiation that is within the levels specified by applicable standards.

This instrument has been tested against the effects of external interference including high energy frequency emission, magnetic fields and electrostatic discharge (for example large motors, portable radios, cellular phones, etc.). It has been tested according to the requirements of applicable standards.

Excessive interference may affect the device operation. If it occurs the failure cause shall be removed.



The Manufacturer is responsible for the safety, reliability and performance of the TN-100 Tonometer only if:

- All operations of assembly extensions, adjustment, modification or repairs have been carried out by people authorized by manufacturer.
 - The electric setting of the room complies with the electric standards.
 - The instrument is used in compliance with Operation Manual.
-



The Manufacturer accepts no responsibility for any modifications made to the TN-100 Non-contact Tonometer outside the factory.

4 PACKAGE CONTENT



Open the package and check that the specified amount of the following items are included in the package and are not damaged. If any item is missing or damaged, contact local distributor as soon as possible.

It is recommended to keep the box and packaging materials for use when moving or transporting the device.

When taking the device out of the box, be careful not to lift the device up by directly holding the measuring head, chinrest, forehead support, or joystick. The device may be damaged!

Package contents: :

- Main unit
- External Power Supply
- Operation Manual
- Power cord
- Built-in printer paper - 2 pcs.
- Dust cover
- SD card

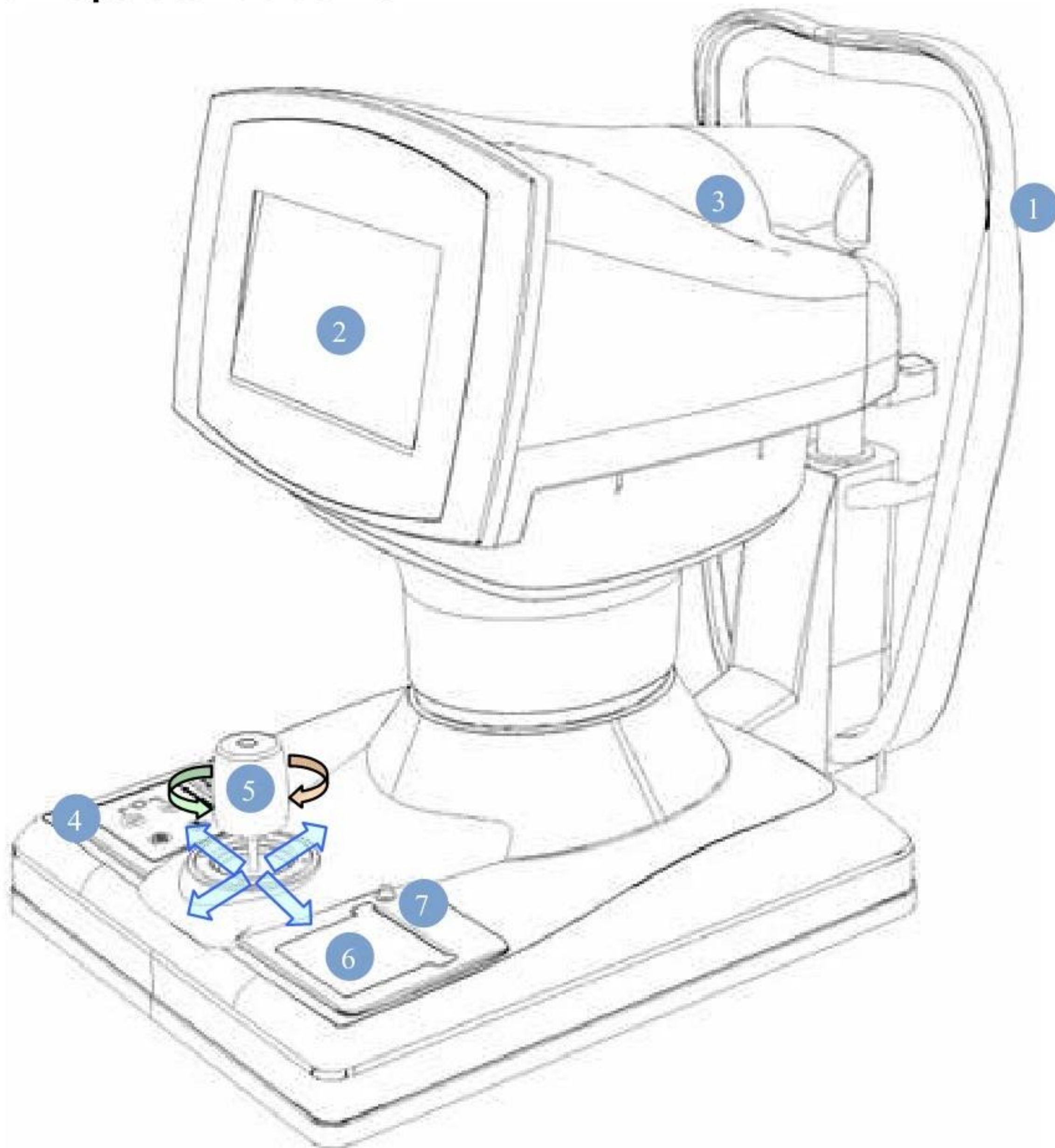
5 GLOSSARY

[CCT]: Central cornea thickness

[IOP]: Intraocular pressure

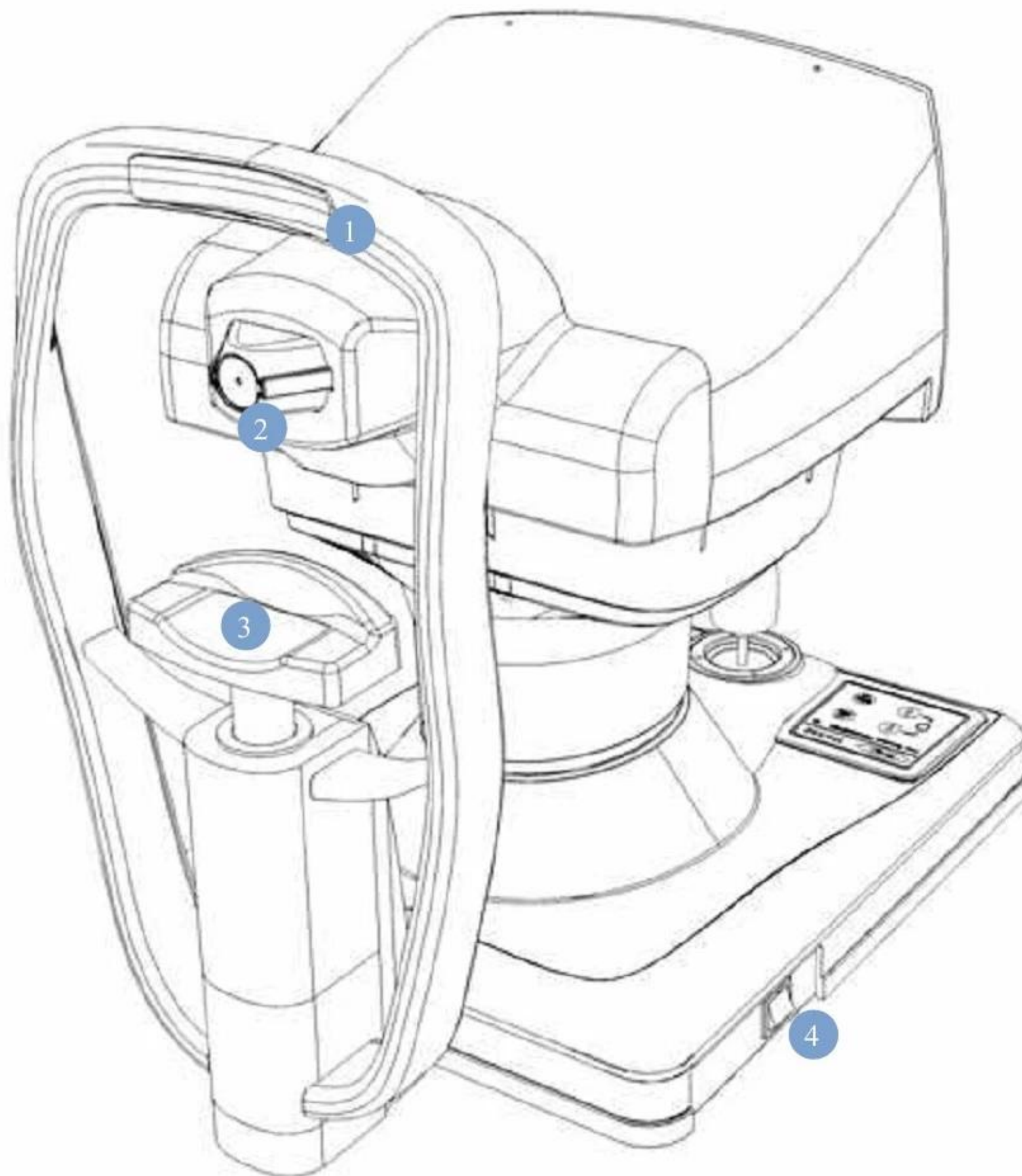
6 DEVICE DESCRIPTION

6.1 Operator's side view



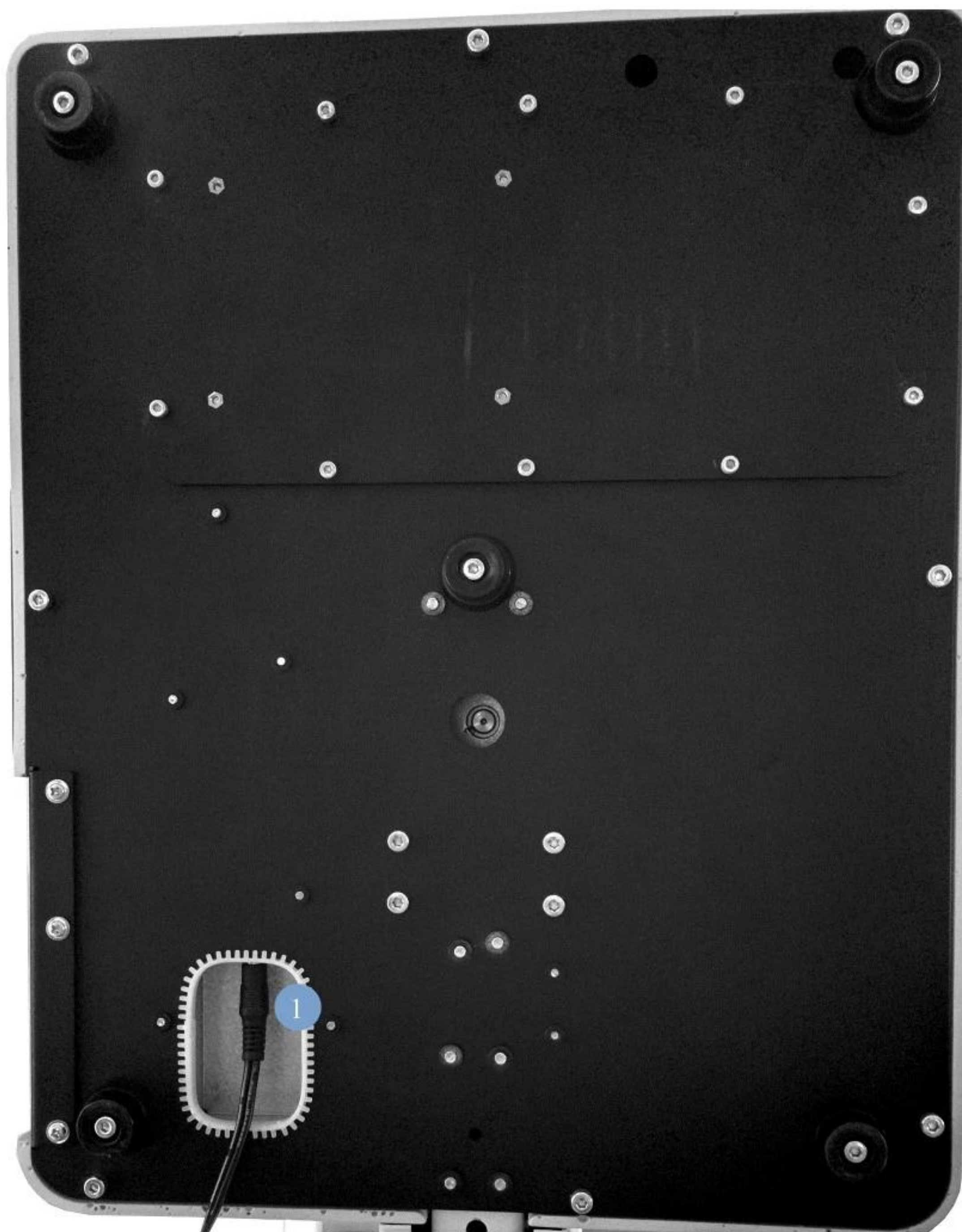
1. Eye level mark - a reference mark when aligning the patient's eye.
2. LCD Touch screen - displays the measurement screen and various settings screens. Touch the touch panel buttons shown on the screen to make various settings and operate the device.
3. Measuring head.
4. Control Panel - refer to chapter 6.4
5. Three-axis joystick with a button. Joystick movement in the horizontal plane causes the corresponding movement of the measuring head (in axis X or Z). Height control of measuring head position (movement in the Y-axis) is done by turning the knob of the joystick clockwise or counterclockwise.
6. Built-in printer flap.
7. Button for opening the printer flap.

6.2 Patient's side view



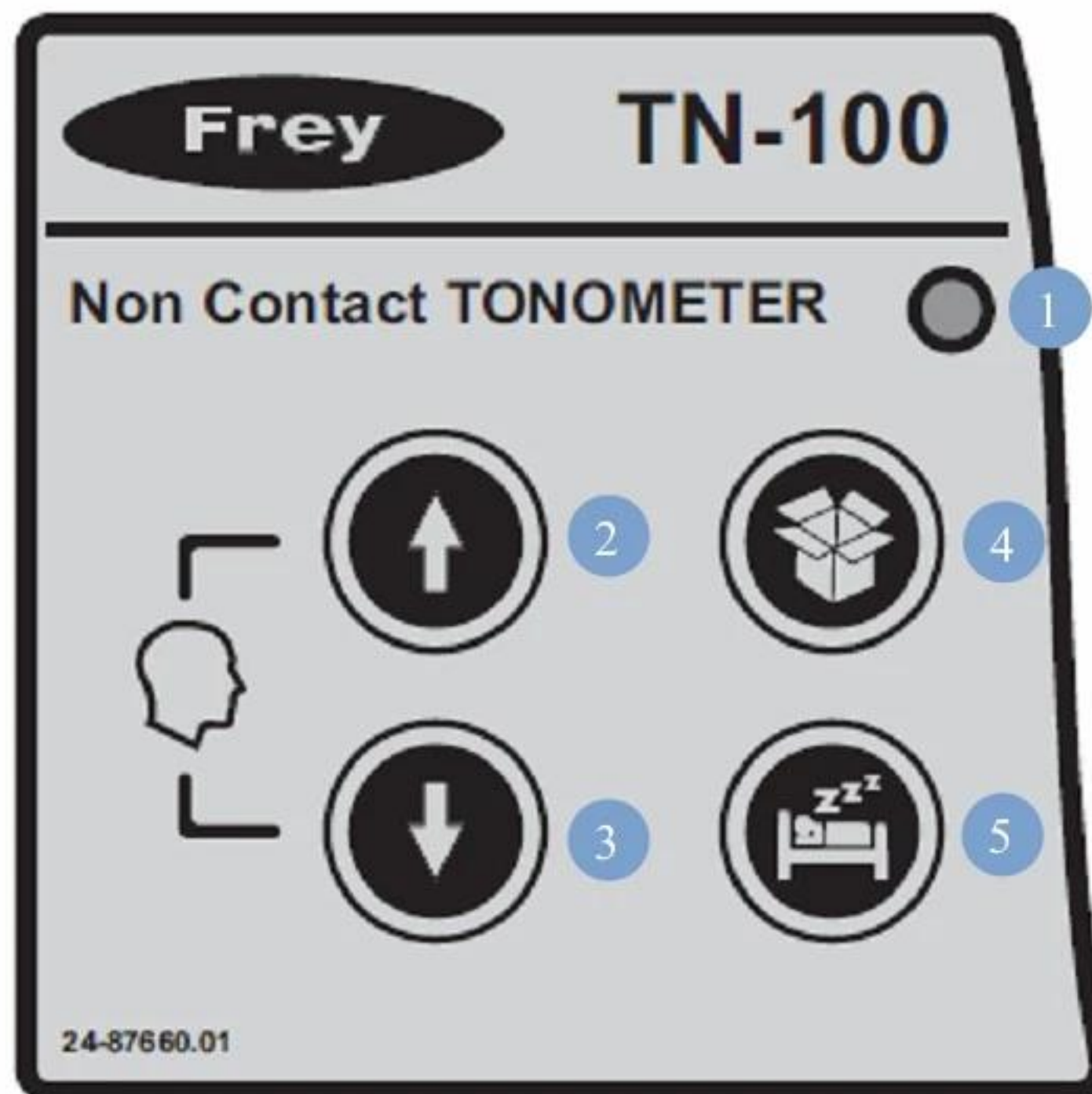
1. Forehead support.
2. The outlet of the measuring head.
3. Chin rest.
4. Power switch.

6.3 Bottom side view



1. DC Input.

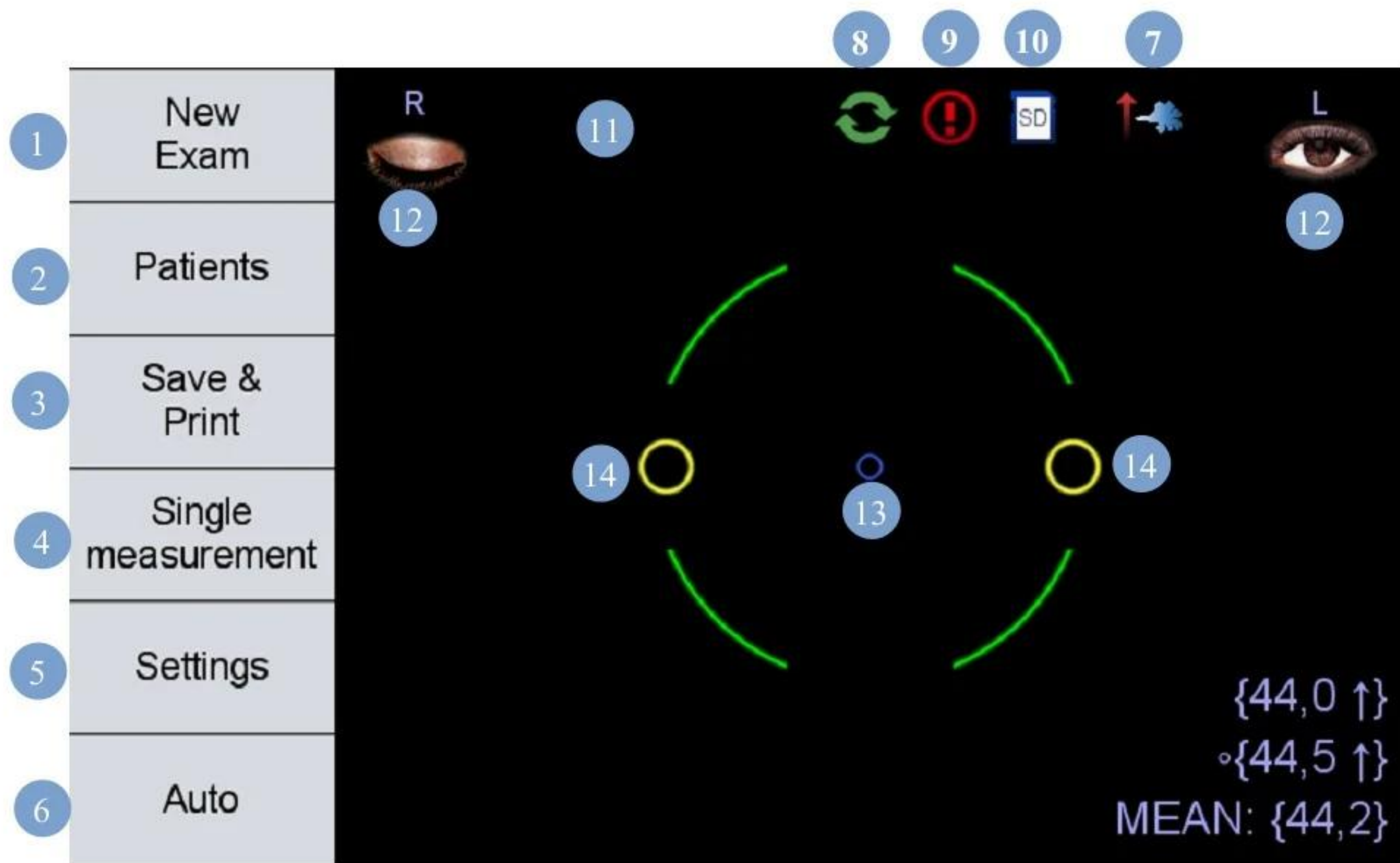
6.4 Control panel



1. LED Power indicator.
2. Chin rest 'Up' button.
3. Chin rest 'Down' button.
4. 'Sleep' button - to switch the device in the sleep mode - it turns off the display.
5. 'Packing' button - pressing this button for 3 seconds moves the measuring head to the lowest position for packing.

6.5 Display

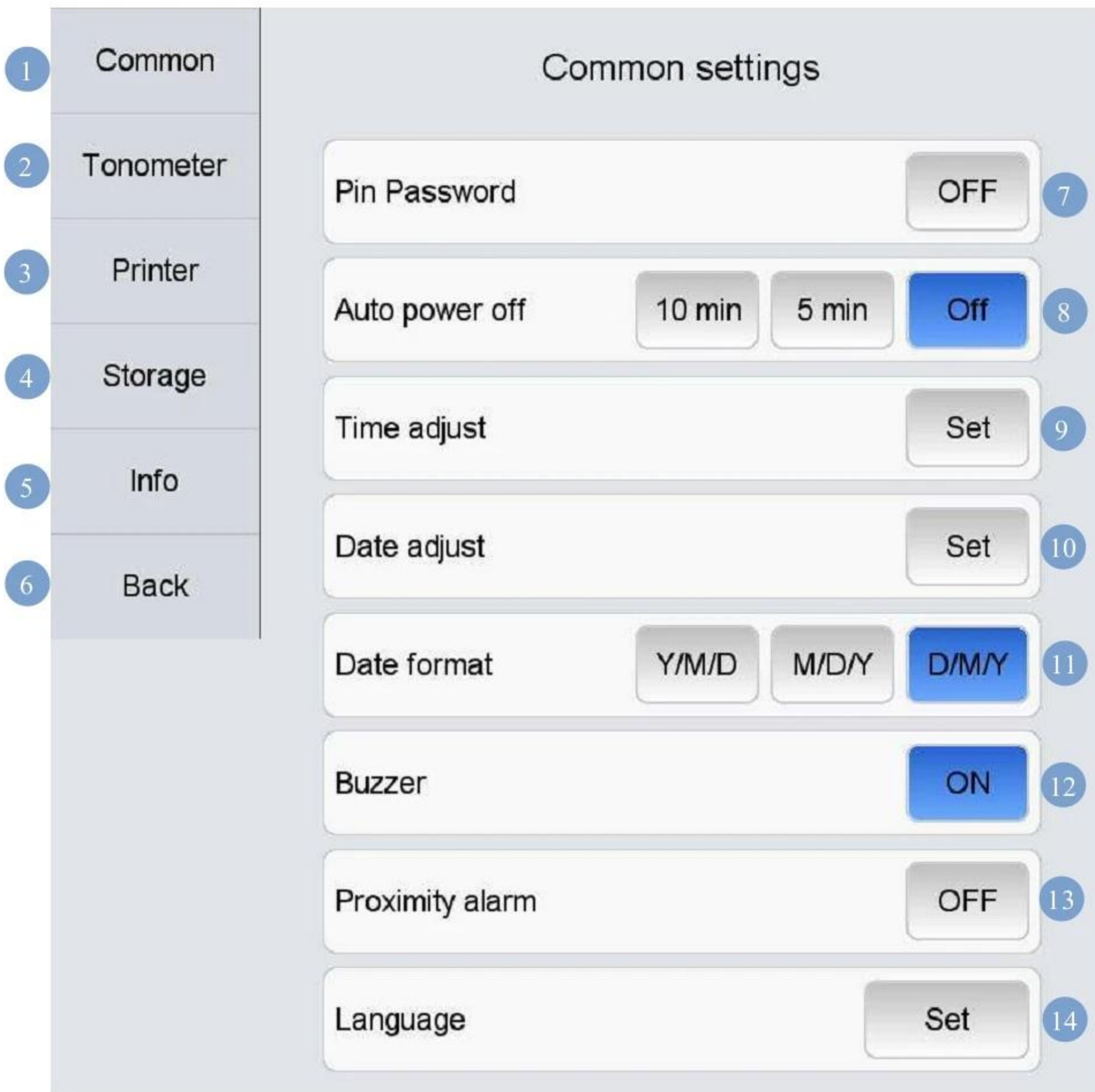
6.5.1 Main screen



1. 'New Exam' - prepares the device for examination by clearing the previous results.
2. 'Patients' - go to the list of patients (7.5.7).
3. 'Print' - allows to save and/or print the results.
4. 'Single measurement'/'Triple measurement' - toggles between two available measurement modes: triple and single measurement.
5. 'Settings' - go to the device setup screen.
6. 'Auto' - triggers the automatic measurement.
7. Intraocular pressure mode Indicator / Switch -
Shows in which mode: High Intraocular Pressure (HIOP) mode (icon with red arrow) or normal mode (grey icon) device is currently working. By touching this button you can also toggle between these two modes manually.
8. This icon indicates that WiFi card is in use. If the icon is silver and keeps turning - database synchronization is being in progress. The green icon indicates that internal database synchronization is completed.
9. This icon indicates that the 'Eye to close!' warning is disabled by the user.
10. This icon indicates that the SD card is inserted into the device.

-
11. In this place on the screen patient's name is displayed, if he was selected from the database.
 12. These buttons allow to choose the eye which will be examined.
 13. Inside this circle, during the examination in a manual mode, the reflection of the fixation LED on the eye should be placed.
 14. These circles are used to set the correct initial position of the measuring head relating to patient's eye, to start examination in an auto mode. Before triggering the auto mode measurement, the operator should reach the eye in such a way that the two white reflection markers were inside the yellow circles.

6.5.2 Common settings



1. 'Common' - go to the common settings screen.
2. 'Tonometer' - go to the tonometer settings (7.5.3).
3. 'Printer' - go to the printer settings (7.5.4).
4. 'Storage' - go to the storage settings (7.5.5).
5. 'Info' - go to the info screen (7.5.6).
6. 'Back' - return to the main screen.
7. Pin Password - enable / disable access to the database with a PIN code.
To enable / disable code protection, press the key (7), the window for entering the code will appear:



You need to enter 4 digit PIN code and confirm with OK.

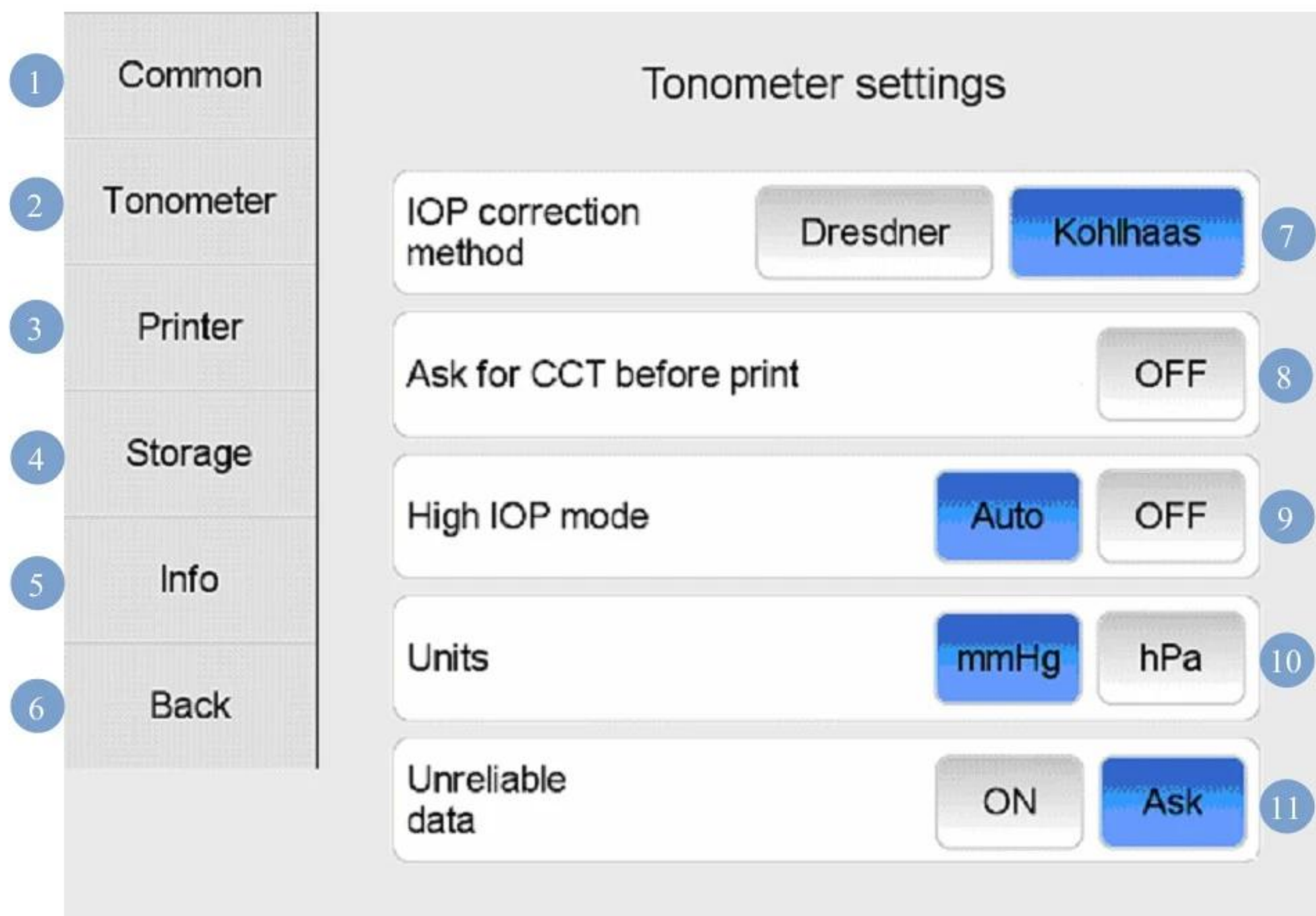
When PIN protection is enabled, you must enter the code:

- when trying to enter the list of patients;
- when trying to export / import a database to / from a SD memory card;
- when trying to delete the entire database.

Once PIN code was entered correctly in any of cases mentioned above, it will be remembered until restart the device or use of logout button, available in the patient list screen. (6.5.7).

8. Auto power off - setting the time after which the display will automatically go off. There are 3 options available:
 - a) 10 min – display automatically goes off after 10 minutes of inactivity.
 - b) 5 min – display automatically goes off after 5 minutes of inactivity.
 - c) Off – display won't go off automatically.
9. Time adjust - a time setup.
10. Date adjust - a date setup.
11. Date format - select preferred time and date format:
 - a) Y/M/D – date is presented in Year/Month/Day format.
 - b) M/D/Y – date is presented in Month/Day/Year format.
 - c) D/M/Y – date is presented in Day/Month/Year format.
12. Buzzer - turn off/on of the sound signal, which informs about important events.
13. Proximity alarm - turn off/on the option of the automatic warning in case the measuring head went too close to patient's eye. When the alarm is disabled, on the main screen red warning indicator is visible. Disabling the proximity alarm allows to move the measuring head to the patient's eye as long, as the touch emergency protection will react.
14. Language - select the language of the device.

6.5.3 Tonometer settings



1. Common - go to the common settings screen (7.5.2).
2. Tonometer - go to the tonometer settings.
3. Printer - go to the printer settings (7.5.4).
4. Storage - go to the memory settings (7.5.5).
5. Info - go to the info screen (7.5.6).
6. Back - return to the main screen.
7. IOP correction method - allows to choose the method of correction of the intraocular pressure, taking into account central corneal thickness (CCT) of patient's eye.
8. Ask for CCT before print - allows you to enable automatic request for the thickness of the patient's cornea before printing. This feature only works when printing the results from the main screen.
9. High IOP mode - allows to enable the high intraocular pressure mode:
 - a) Auto – when the measured pressure is above 30mmHg, operator will be asked, whether to switch to the high pressure mode. If the next measurement shows the intraocular pressure below 30mmHg, operator will be asked whether to return to the normal pressure mode. Switching back to the normal

pressure mode occurs also when pressing the 'New exam' button on the main screen.

b) Off – device always operating in the normal pressure mode.

10. Units - is used to choose the pressure units:

a) mmHg – results are shown in mmHg.

b) hPa – results are shown in hPa.

11. Unreliable data - allows to choice of how to proceed with the results considered to be unreliable:

a) On – unreliable data are always saved.

b) Ask – operator is asked whether to save the unreliable result.

6.5.4 Printer settings

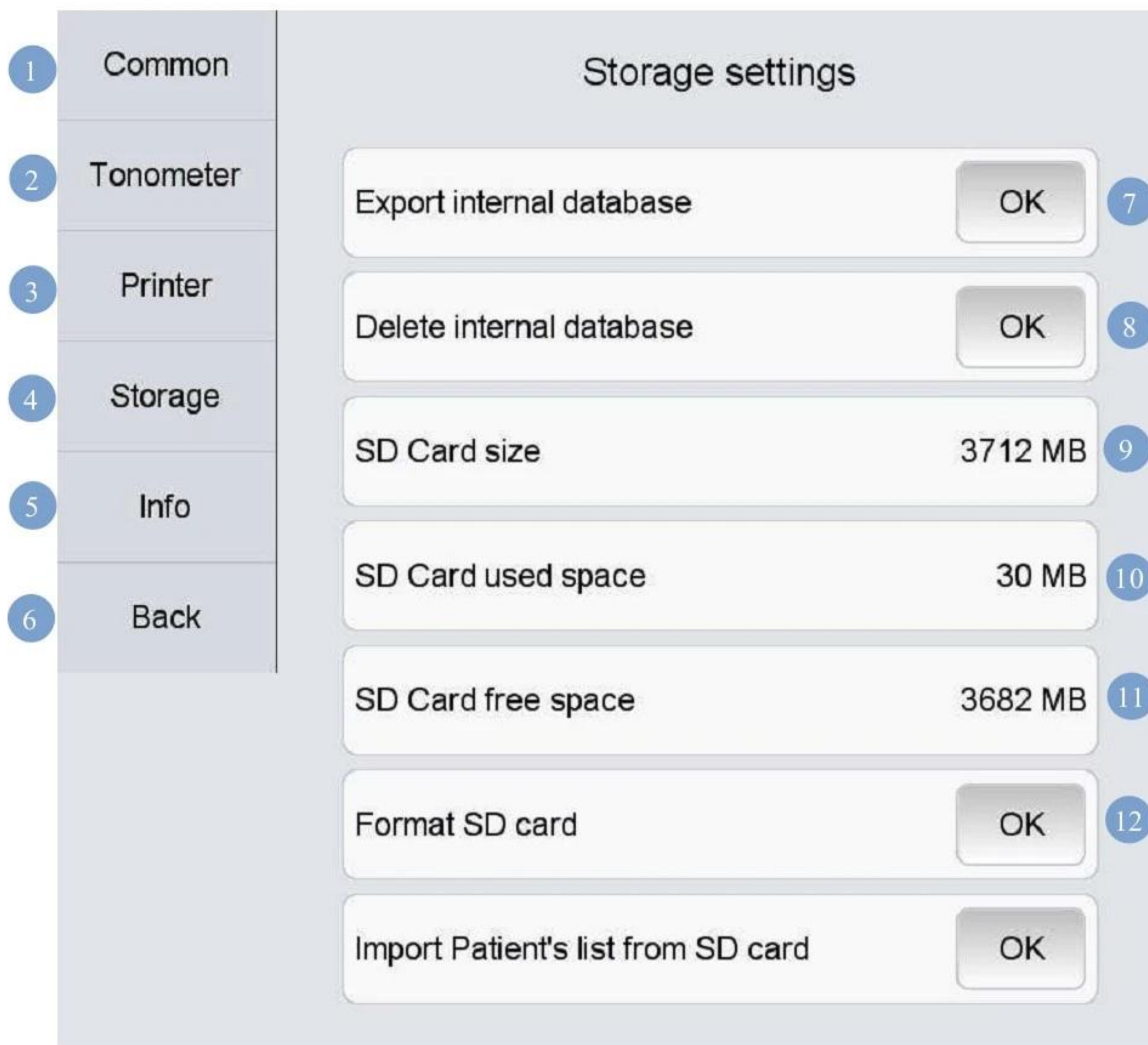
The screenshot shows the 'Printer settings' screen. On the left is a vertical menu with six items: 'Common', 'Tonometer', 'Printer', 'Storage', 'Info', and 'Back'. The 'Printer' item is highlighted. The main area of the screen contains various settings, each with a callout number in a blue circle:

- 1: Common (menu item)
- 2: Tonometer (menu item)
- 3: Printer (menu item)
- 4: Storage (menu item)
- 5: Info (menu item)
- 6: Back (menu item)
- 7: Print date and time (ON)
- 8: Print ID (ON)
- 9: Print name (ON)
- 10: Print surname (ON)
- 11: Print results (Mean, Results)
- 12: Print measured or corrected results (Measured, Corrected)
- 13: Print central corneal thickness (ON)
- 14: Print device name (ON)
- 15: Print serial number (ON)

1. Common - go to the basic settings screen (7.5.2).
2. Tonometer - go to the tonometer settings (7.5.3).
3. Printer - go to the printer settings.
4. Storage - go to the storage settings (7.5.5).
5. Info - go to the info screen (7.5.6).
6. Back - return to the main screen.

-
7. Print time and date - enables/disables adding time and date of measurement to the printout.
 8. Print ID - enables/disables adding patient's ID to the printout.
 9. Print name - enables/disables adding patient's name to the printout.
 10. PRINT SURNAME - enables/disables adding patient's surname to the printout.
 11. Print results - allows to choose how to present the results of measurement on the printout:
 - a) Mean – the averaged pressure value is printed.
 - b) Measured – results of individual measurements are printed.
 - c) Mean + Measured - values of the individual measurements and the averaged value are printed.
 12. Print measured or corrected results - enables/disables adding on the printout the result corrected by the patient's corneal thickness.
 13. Print central corneal thickness - enables/disables adding patient's central corneal thickness (CCT) to the printout.
 14. Print device name - enables/disables adding the name of the device to the printout.
 15. Print device serial number - enables/disables adding the serial number of the device to the printout.

6.5.5 Storage settings



1. Common - go to the basic settings screen (7.5.2).
2. Tonometer - go to the tonometer settings (7.5.3).
3. Printer - go to the printer settings (7.5.4).
4. Storage - go to the storage settings.
5. Info - go to the info screen (7.5.6).
6. Back - return to the main screen.
7. Export internal database - allows to export internal database to SD Card.
8. Delete internal database - allows to completely delete the internal database.
9. SD Card size - the size of the SD Card (in Megabytes).
10. SD Card used space- the amount of used space on the card.
11. SD Card free space - the amount of free space on the card.
12. Format SD card - allows to format the SD Card, to FAT32 file system.

-
13. IMPORT PATIENTS LIST FROM SD CARD – with this option you can import list of the patients from another FT-800 Tonometer or from 'Perimeter' application on a PC.

Only patients that have unique ID number assigned are subject to import. In case in the list which is to be imported there are any patients already present in tonometer's database, their data will not be changed at all; only patients who have an unique ID will be added to database.

To import patients list follow the steps below:

- a) Export the database from another FT-800 or „perimeter application to SD card;
- b) Insert SD card into a card slot;
- c) Go to 'Settings' -> 'Storage'
- d) Press 'OK' button at 'Import Patients list from SD card' entry;
- e) Actual progress of the import is shown on the progress bar displayed on the screen.

Immediately after importing a new list of patients can be used at normal operation.

6.5.6 Device info

Menu Item	Field	Value
1. Common		
2. Tonometer		
3. Printer		
4. Storage		
5. Info	Device name	Frey tono
	Serial number	12345678
	Firmware version	1.1.1
	Hardware version	1.1.1
6. Back		
	Service mode	

1. Common - go to the basic settings screen (7.5.2).
2. Tonometer - go to the tonometer settings (7.5.3).
3. Printer - go to the printer settings (7.5.4).
4. Storage - go to the storage settings (7.5.5).
5. Info - go to the info screen.
6. Back - return to the main screen.
7. This field contains the name of the device.
8. This field contains the serial number of the device.
9. This field contains info about the software version.
10. This field contains info about the hardware version of the device.
11. Service mode - this button allows to enter the service mode; to launch this mode password is required.

6.5.7 Patients list



1. Add patient - go to the screen for adding patient (7.5.8).
2. Search by surname - when you touch this button, the onscreen keyboard appears, allowing you to enter a surname to search (8.4.2).
3. Logout - allows you to log out, if the PIN Password database protection is enabled (6.5.2).
4. Back - return to the previous screen.
5. In this area of the screen, the list of all patients from the internal database is displayed.
6. Touching the field with patient's ID/Name opens detailed patient view (7.5.9).

6.5.8 Adding a patient

The screenshot shows a user interface for adding a new patient. On the left is a vertical sidebar with two buttons: 'Create' (top) and 'Back' (bottom). The main area contains several input fields for patient information. Each input field has a blue play button icon on its right side. The fields are labeled as follows: 'ID' (containing '12345678'), 'First name' (containing 'John'), 'Surname' (containing 'Doe'), 'Birth date' (containing '12/12/1912'), 'CCT Left' (containing '540 um'), and 'CCT Right' (containing 'Blank'). Numbered callouts are placed around the interface: 1 points to the 'Create' button, 2 points to the 'Back' button, 3 points to the 'ID' field, 4 points to the 'First name' field, 5 points to the 'Surname' field, 6 points to the 'Birth date' field, 7 points to the 'CCT Left' field, and 8 points to the 'CCT Right' field.

1. Create - adding the new patient.
2. Back - return to the previous screen.
3. Field for entering patient's ID.
4. Field for entering patient's forename.
5. Field for entering patient's surname.
6. Field for entering the patient's date of birth.
7. Field for entering the CCT of the left patient's eye.
8. Field for entering the CCT of the right patient's eye.

6.5.9 Detailed view of patient

1	Append results	ID	5432	7
2	Print last exam	First name	JOHN	8
3	Print all results	Surname	SMITH	9
4	Select patient	Birth date	22/12/1963	10
5	Delete patient	CCT Left	538 um	11
6	Back	CCT Right	584 um	12
		Exam 01/01/2014 00:04	13	
		31,0 [31,5] mmHg	22,0 [20,5] mmHg	
		36,5 [37,0] mmHg	22,0 [20,5] mmHg	15
		30,5 [31,0] mmHg	22,0 [20,5] mmHg	

1. Append results - appends results located on the main screen to the currently displayed patient.
2. Print last exam - allows to print the last exam of the patient.
3. Print all - allows to print all exams of the patient.
4. Select patient - selects given patient from database for examination.
5. Delete patient - allows to delete currently displayed patient.
6. Back - return to the previous screen.
7. Field for displaying ID of the current patient.
8. Field for displaying first name of the current patient.
9. Field for displaying surname of the current patient.
10. Field for displaying date of birth of the current patient.
11. Field for displaying, and to modify the CCT of the left eye of the current patient.
12. Field for displaying, and to modify the CCT of the right eye of the current patient.

-
13. Header of the exam, containing time and date of performing the exam.
 14. Results for the left eye. Color of pressure value displayed indicates reliability of that result, from most to least reliable: black (reliable), yellow, red. The arrow next to the result indicates that the exam has been conducted in the high IOP mode.
 15. Results for the right eye. Color of pressure value displayed indicates reliability of that result, from most to least reliable: black (reliable), yellow, red. The arrow next to the result indicates that the exam has been conducted in the high pressure mode.

6.5.10 On screen keyboard



1. Field in which the entered content is displayed.
2. Button to confirm the entered content.
3. SHIFT button to toggle between lower and upper case letters.
4. BACKSPACE button that removes last entered sign. Holding this button removes subsequent signs continuously.
5. To enter the national character, you have to long hold the corresponding key, until the window with available national characters appears.

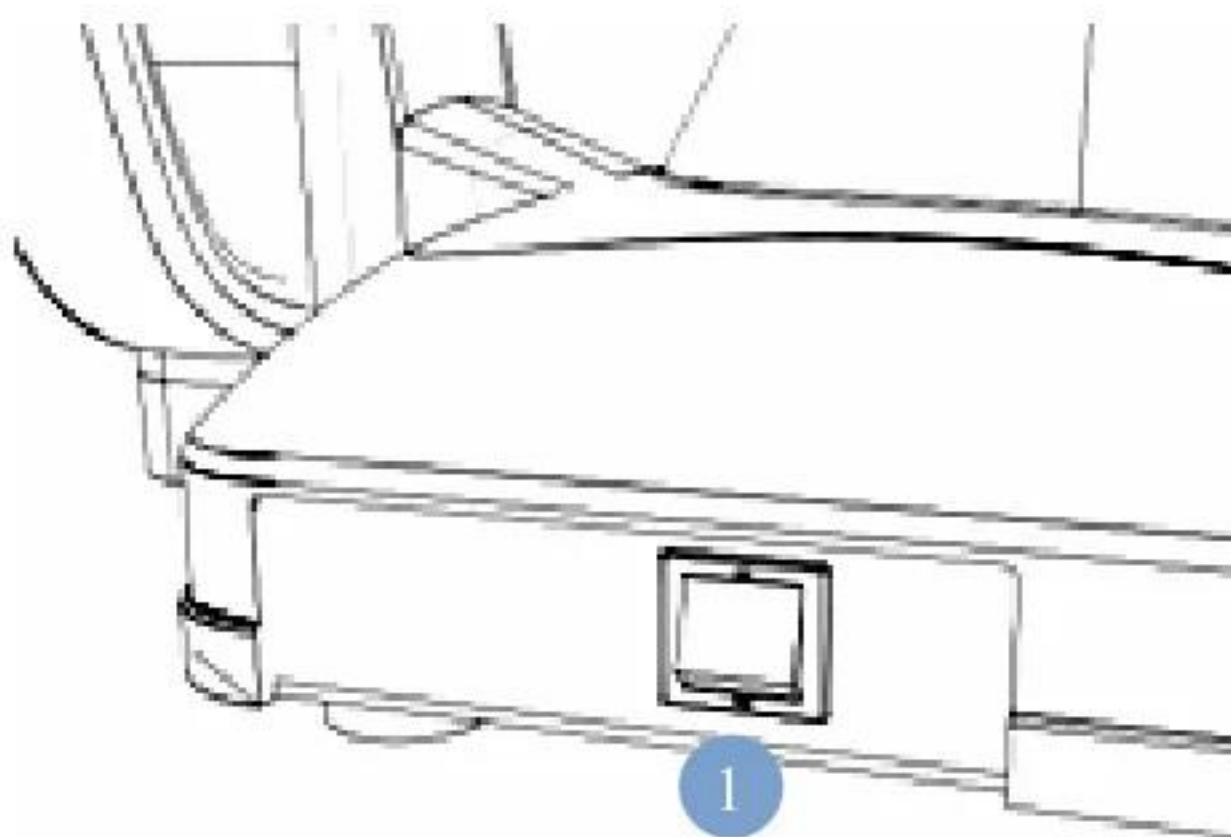
7 OPERATING THE DEVICE

7.1 Preparation for the measurement

7.1.1 Starting tonometer



Immediately after starting the device, the measuring head moves and an air blow test is performed. Do not allow the patient to place their face on the chin rest until the air blow test is complete. Otherwise the patient may be injured.



Turn on the power switch (1).

The power LED on the control panel lights.

The measuring head starts to move to its initial position, also air blow test starts automatically.

If no problem is found during the tests, the main screen appears on the display.

7.1.2 Settings

For detailed description of available settings please refer to chapter 7.5.3.

7.1.3 Checking the paper in printer



Never touch the cutter in the printer, it may cause the injury!

Lift the flap at the printer and check if the paper roll is inside. Check also that the paper is loaded properly. For details please refer to chapter 10.4.1.

7.2 Measurement



This device is designed to calculate the intraocular pressure based on the Goldmann applanation tonometry. If more accurate measurement is required, it is recommended to use the Goldman applanation tonometer.



Do not use this device for eyes with weak corneas due to disease or surgery. Doing so may result in complications or damage to the cornea.



Explain the measurement procedure to the patient to avoid surprise when air is suddenly blown onto their air.

Measured value of pressure is considered unreliable in one of the following cases:

- Measurement result is displayed in yellow or red, in the main screen.
- The difference between two measured values for the same eye is too large.

When the measured value is unreliable as described above, review the examination result by re-measurement with this device or using the Goldmann applanation tonometer.

7.2.1 Setting the patient's position



When moving the measurement head and/or chinrest of the device, pay attention to the position of the patient's face, hands and fingers. The patient may be injured by the moving section of the device.

If the tip of the measuring head is contaminated with tears, etc., clean it off, referring to the chapter 9.3.1.

Have the patient take a sit in a comfortable position and place their face on the chin rest. Using the UP /DOWN buttons on the control panel (1) adjust the chin rest height so that the height of the corner of the eye is aligned with eye level mark. After reaching the proper height, the patient should press the forehead against the forehead support, in order to stabilize the position during the examination.



7.2.2 Conducting the measurement



Do not allow any person to place their hands or fingers in the clearance under the measuring head or the section under the chinrest. Their hands or finger may be injured!



The eye lid and/or eyelash covering the automatic alignment ring during measurement may affect measurement results. Ask the patient to open their eyes wide or have the physician lightly hold the patients upper eyelid with their fingers.



Ask the patient to look into the fixation LED located in the measurement head tip. If the patient looks in a different direction or moves, the measurement may not be correctly conducted.



Auto Alignment may not be effective when the patient blinks frequently during measurement. Ask the patient to stop blinking during measurement.



This device is designed to perform measurement in Auto mode to ensure higher accuracy thorough standard operation. However, auto alignment may not be particularly effective when insufficient light is reflected due to deformation or inflammation of the cornea. In such case, conduct a measurement manually.



The reflection of the center of the cornea may not be clearly viewed when deformation and/or inflammation of the cornea is severe. In this case, an error may occur in manual mode.

8.2.2.1 Automatic mode measurement



In order to conduct measurement in automatic mode, follow the steps below:

1. Using the button (1) select the measurement mode: single or triple.
2. Using joystick, roughly get close with the measuring head to the patient's eye, so that the white markers reflected off the cornea, were near the yellow circles on the screen (2).
3. Touch the Auto button (3) - at this point a green circle on the screen starts to blink alternately in blue and yellow, and the 'auto' button stays highlighted in blue, until the end of measurement.
[Note] Touching any other button during auto alignment/measurement will cancel the measurement.
4. The device automatically fine aligns position of the measuring head, to reach to the eye, and then conducts measurement.
5. If the auto alignment procedure does not start (measuring head stands still, the circle blinks yellow/blue), you must manually adjust the position of the measuring head, using the joystick, so that white markers were accurately within the circles. As soon as the correct position is reached, tonometer will automatically complete the procedure of auto alignment, and conduct the measurement.
6. After completion of the measurement result is displayed on the main screen (4). The last made measurement is marked with "°" symbol on the left. The colors of displayed results reflect reliability of the measurement, from the most to the least reliable: grey (reliable), yellow and red, respectively. The arrow

next to the result indicates that the exam has been conducted in the high pressure mode.

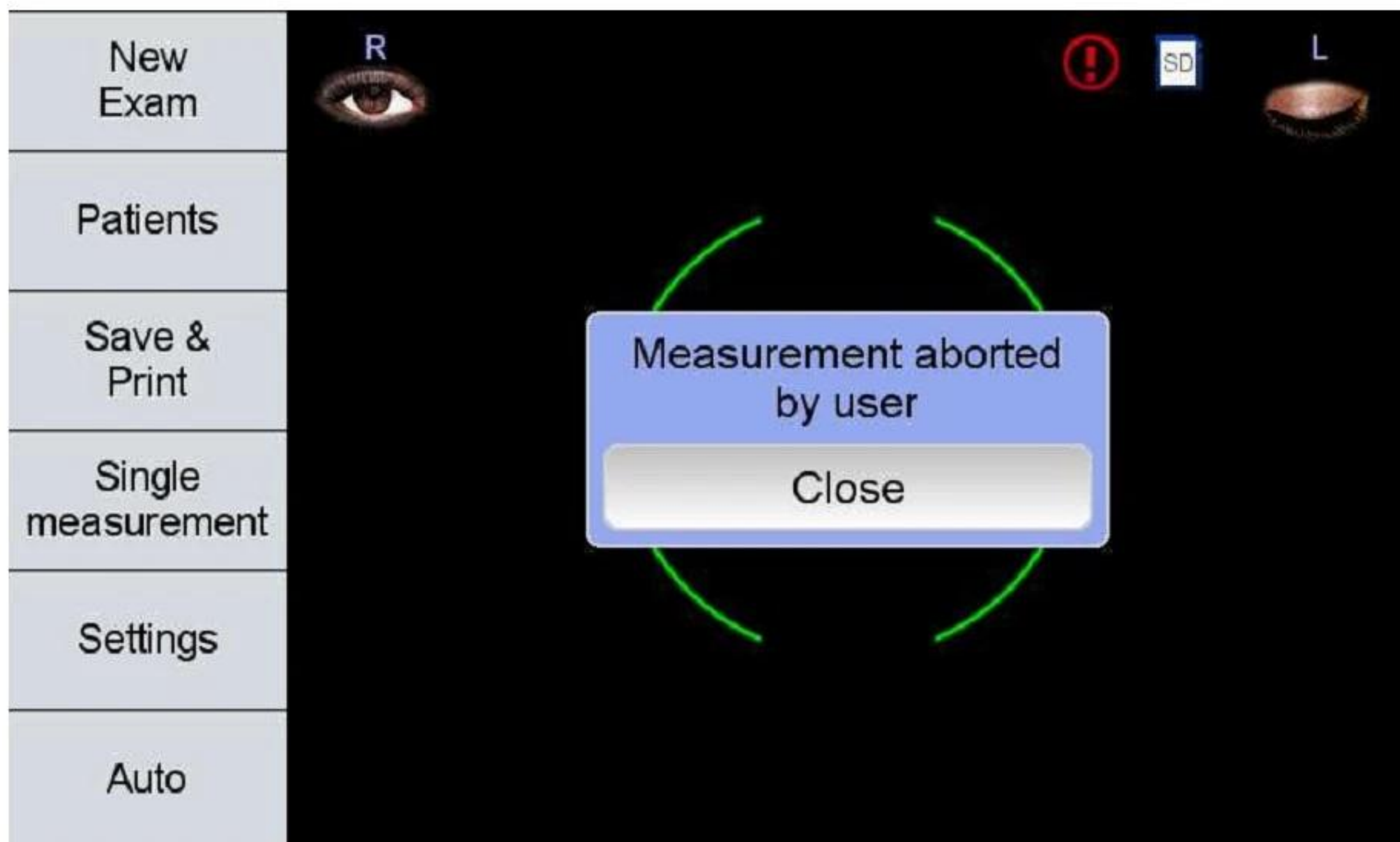
8.2.2.2 Manual mode measurement



In order to conduct measurement in manual mode, follow the steps below:

1. Using joystick, roughly get close with the measuring head to the patient's eye, so that the white markers reflected off the cornea, so that white markers were accurately within the yellow circles (1).
2. As soon as the markers are placed in within the circles, in the center of the screen appears a third, blue marker.
3. Manually adjust the position of the measuring head, using the joystick, so that the blue marker is accurately within the blue circle (2).
4. When the blue marker is in the center of the blue circle, the operator can trigger a measurement by pressing a button on the joystick.
5. After completion of the measurement, result is displayed on the main screen (3). The last made measurement is marked with "°" symbol on the left. The colors of displayed results reflect reliability of the measurement, from the most to the least reliable: grey (reliable), yellow and red, respectively. The arrow next to the result indicates that the exam has been conducted in the high pressure mode.

8.2.2.3 Aborting measurement

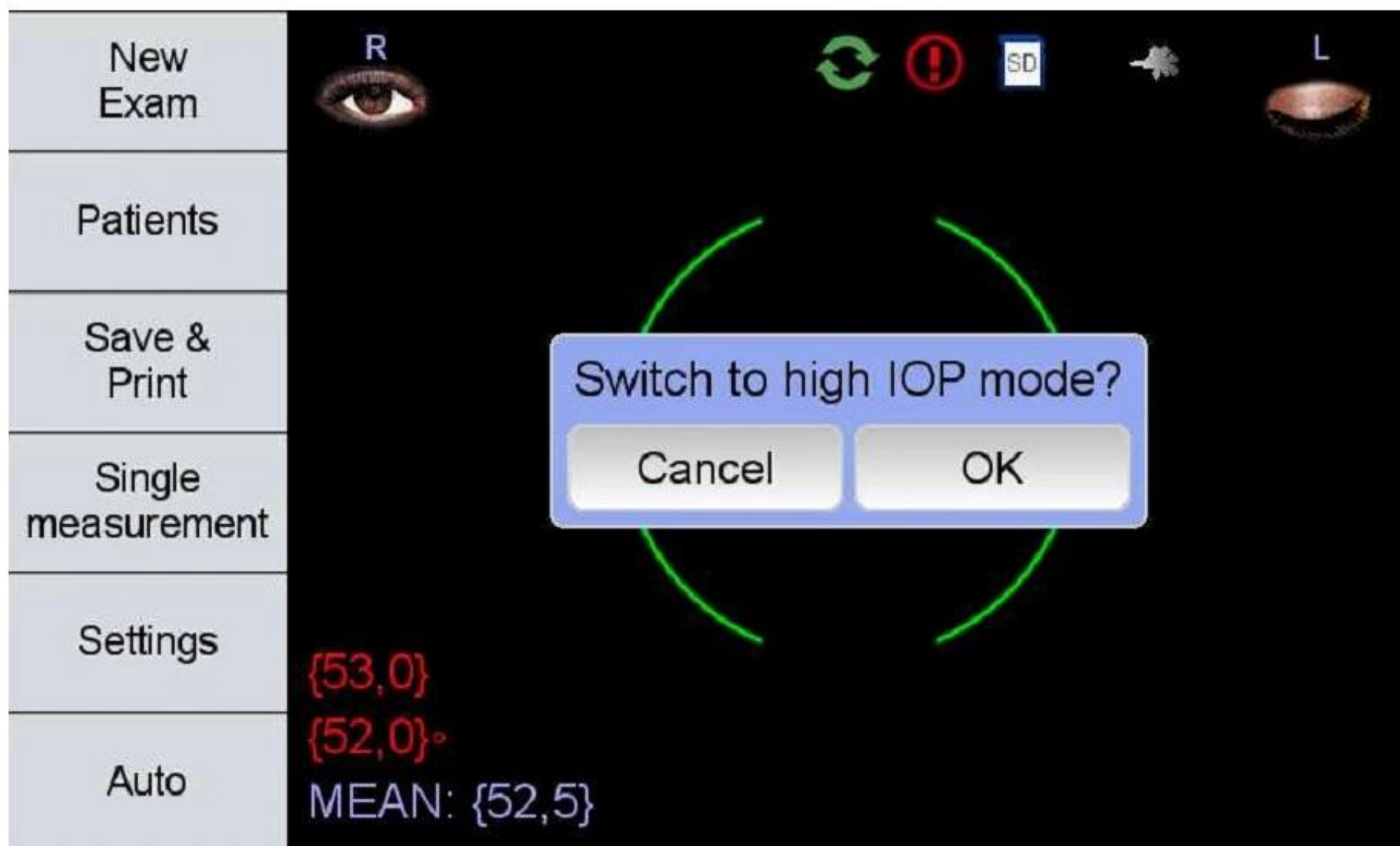


To abort the auto measurement operator needs to pull the joystick maximally towards oneself.

Alternatively, touching any button on the main screen while the auto alignment/measurement is ongoing, also canceling the measurement.

Aborting the measurement is always confirmed with the on screen message.

7.2.3 High / Normal IOP selection dialog



1. When the measurement is conducted in normal IOP mode.

When the measurement result exceeds the range of a normal pressure, and in settings of the tonometer the high IOP mode is enabled, the on-screen dialog appears, asking whether to switch to the high pressure mode (HIOP). If the operator accepts, the next measurement is conducted in the high pressure mode, and if rejects, subsequent measurement will be conducted still in the normal pressure mode.

2. When the measurement is conducted in high IOP mode.

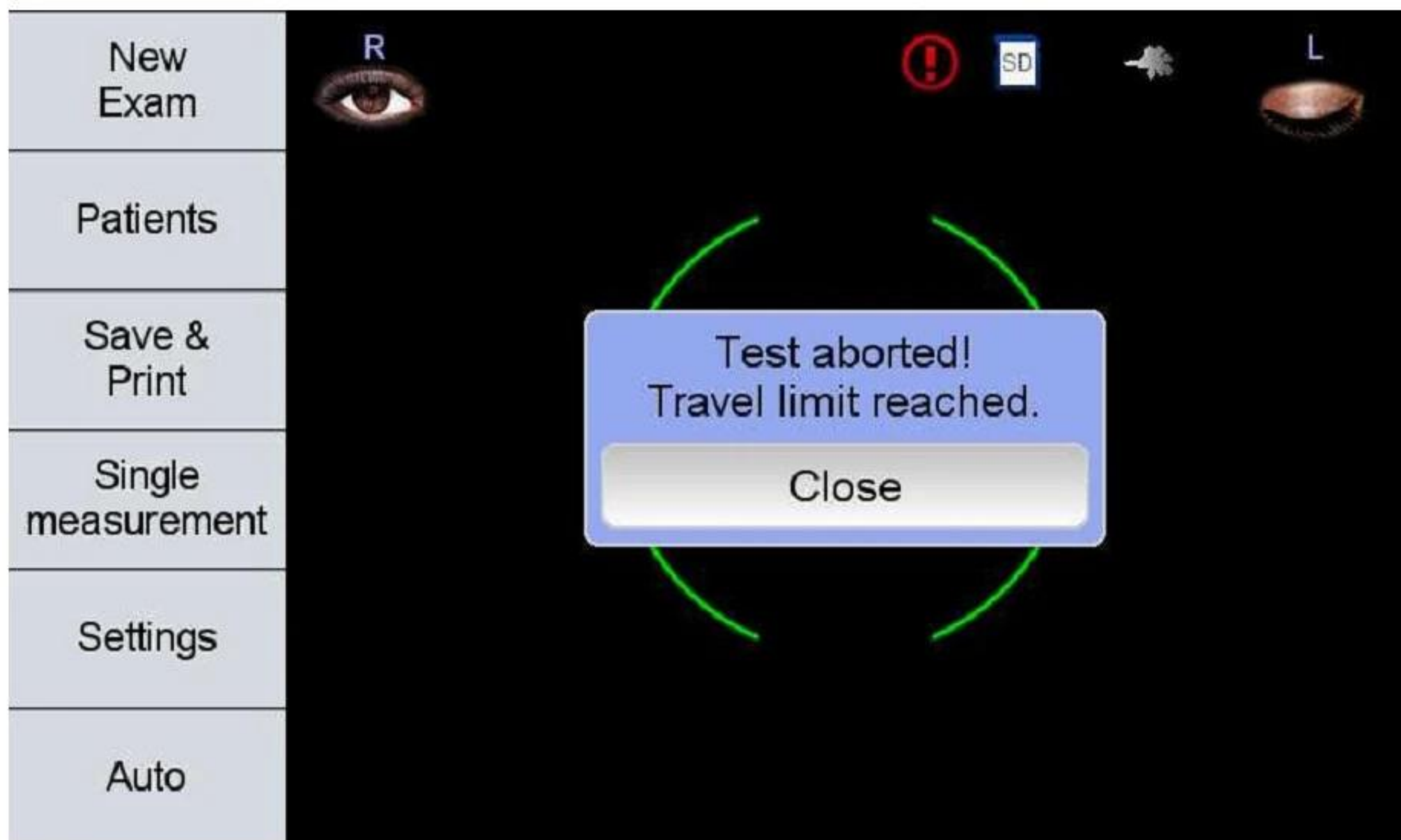
When the measured result is below the threshold of a high pressure, the on-screen dialog appears, asking whether to switch to the normal pressure mode. If the operator accepts, the next measurement is conducted in the normal pressure mode, and if rejects, subsequent measurement will be conducted still in the high pressure mode.

7.2.4 Saving unreliable results dialog

When the measurement result is qualified as unreliable, the machine informs the operator, by asking whether to save the result. In case of rejection of the result by the operator, the measurement shall be deemed null and void. However, in the case of approval, the unreliable measurement is appended to the results in yellow or red, depending level of its reliability (yellow is more reliable).

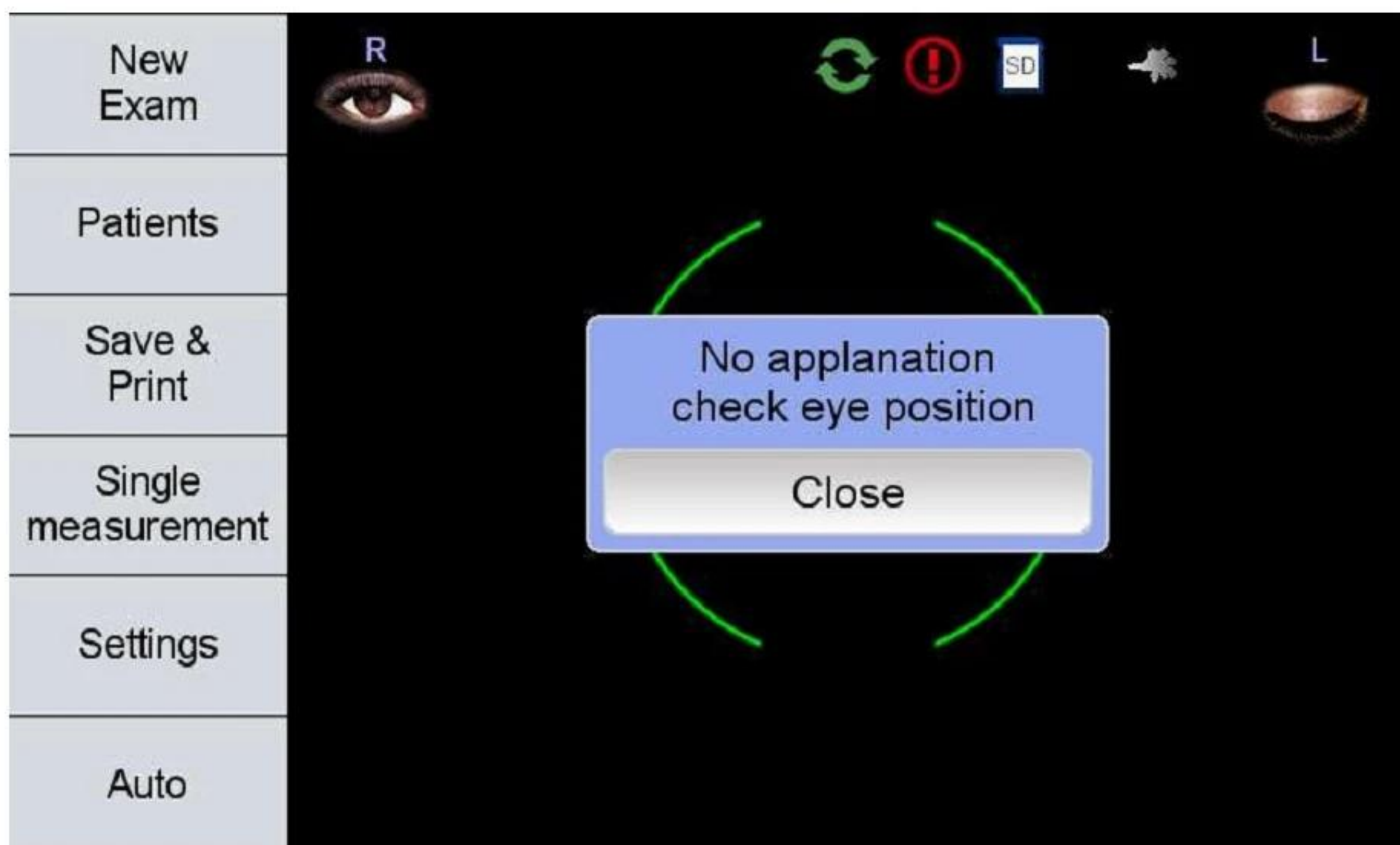
7.2.5 Error messages during measurement

In case any error message appears during the examination, the measurement is automatically halted.



This message indicates that the measurement head has reached one of travel limits on one of axis.

You need to use joystick to move out of the limit, check the patient's position and correct if needed, then start the measurement procedure again.



You need to verify and correct if needed patient's head position, then start measurement procedure again.

7.3 Printing



Before printing, make sure the printer has enough paper.

The built-in printer is a thermal printer. Therefore, the printout fades over time, so if printouts are to be stored for a long time, you need to make a copy.

7.3.1 Printing the results from the main screen.

In case of printing the results currently displayed on the main screen, the procedure differs depending on whether the moment of printing there is selected a patient, or not. For detailed information regarding selecting the patient, refer to chapter 7.4.7.

1. Printing the results when a patient is selected.

Proceed as follows:

- a) Touch the 'Save/Print' button.
- b) In the window that appears, select whether the test result is to be saved or printed. In case you want to save the measurement result to the database, proceed as described in chapter 7.4.9.
- c) The printer starts printing.

2. Printing the results when no patient is selected.

The printing procedure is similar to that described above in point 1.

Additionally, in this case, if the setting of inquiry about CCT is enabled in tonometer settings, when you select Print, before printing starts, a window will appear where you can enter CCT, and confirm or cancel an addition of CCT to the printout.



In case of any error during printing, the user will be informed by an appropriate on-screen message.

7.3.2 Printing from the database.

In order to perform printing from the database:

1. On the main screen touch the 'Patients' button.
2. Then select a patient from the patient list, by touching the field with their ID or the name.
3. After displaying the patient data, in the menu on left side there are two options for printing::
 - a. Print last exam – printout will include only the last examination of the patient.
 - b. Print all results – printout will include all the examination results of the patient.

7.3.3 Printout format

```

*****
NAME : JOHN
SUR. : SMITH
ID : 5432

[CCT LEFT]  [CCT RIGHT]
  538        584

  {Measured}[Corrected]
  <{Mean}[Mean corrected]>
.....
DATE : 01.01.2014 00:14:14
IOP [mmHg]
    LEFT      RIGHT
  {32,0↑}[32,5]  {41,0}[39,5]
  {31,0↑}[31,5]  {42,0U}[40,5]
  {31,5↑}[32,0]  {41,0u}[39,5]
  <{31,5}[32,0]> <{41,3}[39,9]>
.....
FT-800
WCDB001H

```

"↑" next to measurement result indicates that exam has been conducted in the high IOP mode (HIOP)

"u" or "U" next to result indicates reliability of the measurement ("u" corresponds to the yellow, and "U" to the red color in displayed results)

The content of a printout can be customized in the 'Print' menu (section 7.5.4). The following is a list of all possible settings:

Menu item		Description
Print date and time	ON*	Include date and time in the printout.
	OFF	No date and time on the printout.
Print ID	ON*	Include patient's ID in the printout.
	OFF	No patient's ID on the printout.
Print name	ON*	Include patient's first name in the printout.
	OFF	No patient's first name on the printout
Print surname	ON*	Include patient's surname in the printout.
	OFF	No patient's surname on the printout
Print results	Mean*	Print averaged measurement.
	Measured*	Print single measurements.
Print measured or corrected results	Measured	Print measured results without correction.
	Corrected*	Print CCT-adjusted results.
Print central corneal thickness	ON*	Include patient's CCT in the printout.
	OFF	No patient's CCT on the printout
Print device name	ON*	Include device name in the printout.
	OFF	No device name on the printout
Print device serial number	ON*	Include device serial number in the printout.
	OFF	No device serial number on the printout

*options enabled by default

7.4 Database operations

7.4.1 Browsing the patient list

To browse the list of patients:

1. Touch 'Patients' button on the main screen.
2. Now list of all patients appears.
3. To browse the patients, scroll the list up and down.

7.4.2 Searching for patient

To search the patients list:

1. Go to the patient list (refer to chapter 8.4.1).
2. Touch the 'Search by name' button.
3. After an on-screen keyboard appears, enter searched patient's surname, and confirm with OK.
4. Patient list will scroll so that on the screen was visible the desired surname, or the one which most closely resembles it.

7.4.3 Detailed view of patient

To view details of patient and their results:

1. Enter the patients list (refer to chapter 8.4.1).
2. Search the patient (refer to chapter 8.4.1).
3. Choose the patient touching either the ID field or Surname field.
4. To browse patient's results scroll the screen up and down.

7.4.4 Adding patient to database

To add a new patient to the database:

1. Go to the Patient list (refer to chapter 8.4.1).
2. Touch 'Add Patient' button.
3. Complete the fields 'ID', 'Name' and 'Surname' (mandatory fields).
To start typing just touch the corresponding field - then an on-screen keyboard appears automatically.
4. Optionally complete fields 'Date of birth', 'CCT Left' and 'CCT Right'.
5. Having completed entering the data, touch 'Create' button, detailed view of the patient will be displayed.

7.4.5 Removing patient from database

To remove patient from database:

1. Go to the detailed view of patient (refer to chapter 7.4.3).
2. Touch 'Delete' patient' button.
3. A popup dialog appears where you'll be asked to confirm, choosing 'Yes' permanently deletes the patient.

7.4.6 Setting patient's central corneal thickness (CCT)

To add a central corneal thickness (CCT) for the patient:

1. Go to the detailed view of patient (refer to chapter 7.4.3).
2. Touch the 'CCT Left' field.
3. On the screen a dialog box appears, for entering CCT value
4. Using the '+' and '-' buttons set the correct value of patient's CCT for the left eye, and confirm with the corresponding button.
5. Similarly, carry out the procedure for the right eye, by clicking the field 'CCT Right'.

7.4.7 Selecting a patient

To select a patient from database:

1. Go to the detailed view of patient (refer to chapter 7.4.3).
2. Touch the 'Select patient' button.
3. This takes you to the main screen, the currently selected patient will be displayed at the top of the screen.

7.4.8 Deselecting current patient

Touching the 'New exam' button on the main screen will cause no patient will be selected.

7.4.9 Saving the results for currently selected patient

To append the results for currently selected patient:

1. On the main screen, touch the 'Save/Print' button.
2. On the screen appears the dialog asking you to select the action.
3. Select 'Save'.
4. The results will be append to the currently selected patient.

7.4.10 Appending the results, when no patient selected

To append the results currently displayed on the main screen to the patient that was not selected during the exam:

1. Go to the detailed view of patient (refer to chapter 7.4.3).
2. Touch the 'Append results' button.

7.5 Database export

7.5.1 Export to SD card

To export the internal database to the SD card:

1. On the main screen, touch the 'Settings' button.
2. In the 'Settings' menu, on the right side of the screen, touch the 'Storage' button.
3. In the 'Storage' menu touch the 'Export internal database' button.
4. Now the progress bar appears - when the bar reaches the end, a message appears, telling the name of the file to which the database has been exported..
5. After touching the 'Close' button, export is completed.

7.5.2 Export using a Wi-Fi card

To export internal database using the WiFi card:

1. Insert the WiFi card into the slot.
2. At this point the sync icon on the screen changes its color to silver, and starts to rotate.
3. Once synchronization completes, the icon stops and changes color to green.

8 TECHNICAL DATA

Device type	TN-100 Non-contact tonometer	
Intraocular pressure measurement range	0 - 60 mmHg (0 – 80 hPa)	
Measurement resolution	0.5 mmHg	
Main unit.	Dimensions H/W/L	460 x 300 x 480 mm
	Weight	18 kg
Power source	100-240VAC 50/60 Hz	
Power consumption	max 45VA	
Power Supply unit	External, medical power supply adapter INPUT: 100-240V ~1,5A OUTPUT: 12V $\overline{=}$ 5A	
Printer	Built-in, thermal	
Display	7" colour LCD with touch screen	
Chin rest travel distance	69 mm (up/down)	
Measuring unit travel distance	85 mm (X axis); 40 mm (Y axis); 50 mm (Z axis)	
Chin rest	Electrically regulated (up/down)	
Storage devices	Internal flash SD Card	
Database	Capacity: up to 4000 patients x 100 exams x 3 measurements (for each eye) Data format: XML	

8.1 Energy of visible light and infrared light

Light for measuring intraocular pressure	
Ligh source	LED
Wavelength	940nm
Output	Measurement < 100 μ W (limit ¹ : 3200 μ W, t = 0.02 s)

Fixation LED	
Ligh source	LED, blue
Wavelength	435nm
Output	< 0.1 μ W (Limit 1: 3.7 μ W)

Light for anterior eye segment	
Ligh source	LED
Wavelength	875 nm
Output	< 100 μ W (Limit 1: 450 μ W)

¹AEL class 1 conforming IEC 60825-1:2001

8.2 Operating environment

Operating environment conditions:	
Installation	Indoors, not in direct sunlight
Temperature	+10°C - +40°C
Humidity	30 - 75%
Atmospheric pressure	700 - 1060 hPa
Power fluctuation	Less than $\pm 10\%$ of nominal voltage
Storing and transport environment conditions:	
Humidity	< 95%
Temperature	+5°C - +50°C

8.3 Conforming standards

EN 60601-1:2006 (PN-EN 60601-1:2011)

EN 60601-1-2:2007 (PN-EN 60601-1-2:2007)

EN 62304:2006/AC:2008 (PN-EN 62304:2010)

EN ISO 10993-1:2009 (PN-EN ISO 10993-1:2010)

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

EN ISO 8612:2009

9 MAINTENANCE AND SERVICE

9.1 Durable years

This device has been designed so that its life cycle was 10 years for use, under the appropriate environment and adequately inspected and serviced.

9.2 Control of the accuracy of the measurement



Immediately after starting the device, the measuring head moves and an air blow test is performed. Do not allow the patient to place their face on the chin rest until the air blow test is complete. Otherwise patient may be injured.

Every time you run the device performs the test measurements, the result of which is subsequently used to verify the correctness of measurements performed on patients. If the device detects any deviation from the assumed value, the error will be reported to the operator.

9.3 Maintenance



Before cleaning the unit, disconnect the unit from the power source.

9.3.1 Outlet of the measuring head



During cleaning, pay particular attention to not push the contamination into the outlet nozzle of the measuring head.

Do not wipe the outlet of the measuring head with too much force. Glass sheet which is located at the tip may be scratched or broken.

The outlet of the measuring head is a part protruding from the head, closest to the eye of the patient during the test. Therefore, it is part of the device exposed for contamination by dust and tears of the patient.

Method for cleaning:

- dust and dirt located at the outlet of the head to blow away with compressed air;
- the glass cover at the outlet of the measuring head to gently wipe out with a dry cloth.

9.3.2 Chin rest and forehead support

To clean the chin rest and forehead support wipe them with a cloth with an non-invasive alcohol-based cleaner. In case you are not using protective paper pads, the action should be performed every time before starting a new patient.

9.3.3 The surface of the housing

When the outer surface of the unit is soiled, wipe it out with a dry, clean cloth. In the case of very strong surface dirt can be cleaned with a diluted neutral detergent. After this, wipe the surface dry..

9.3.4 LCD Display

The LCD panel should be cleaned with a soft cloth, with small amount of a glass cleaner if necessary.

9.4 Replacing consumables

9.4.1 Printer paper



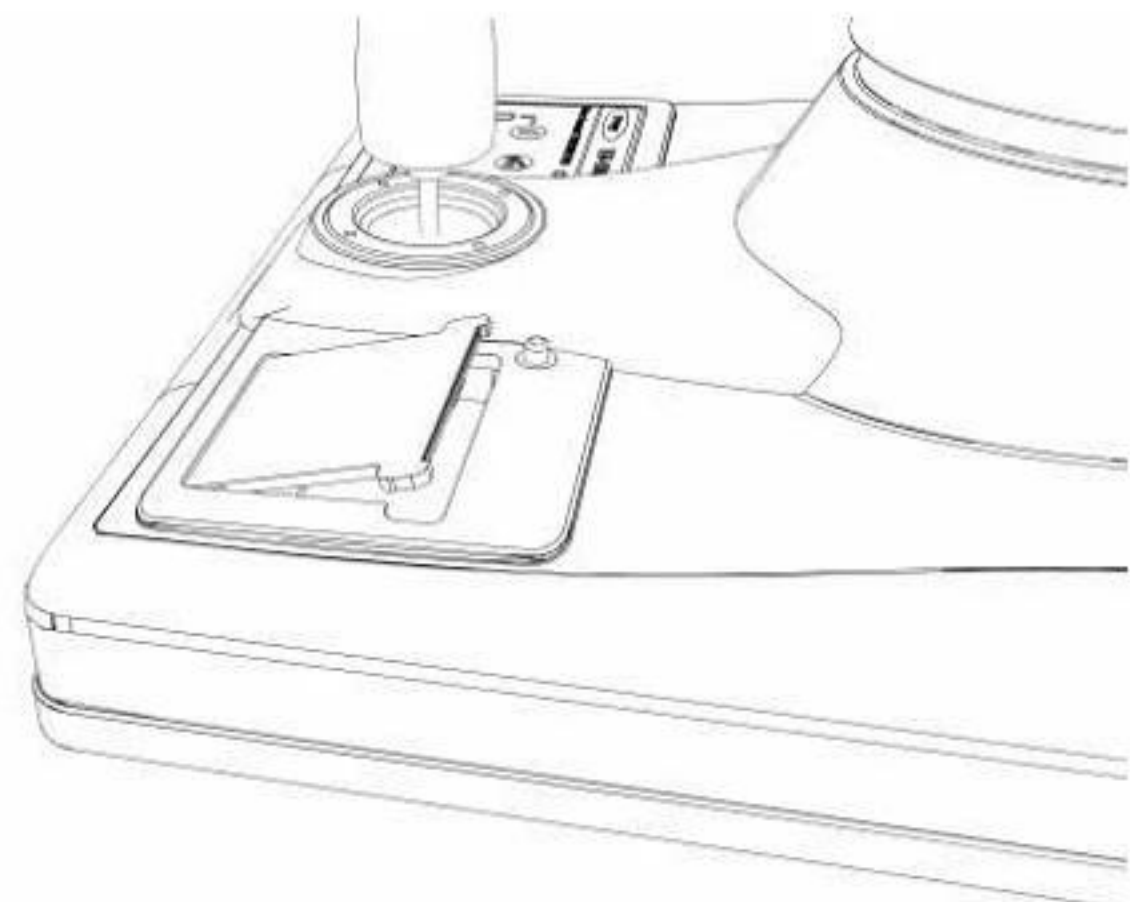
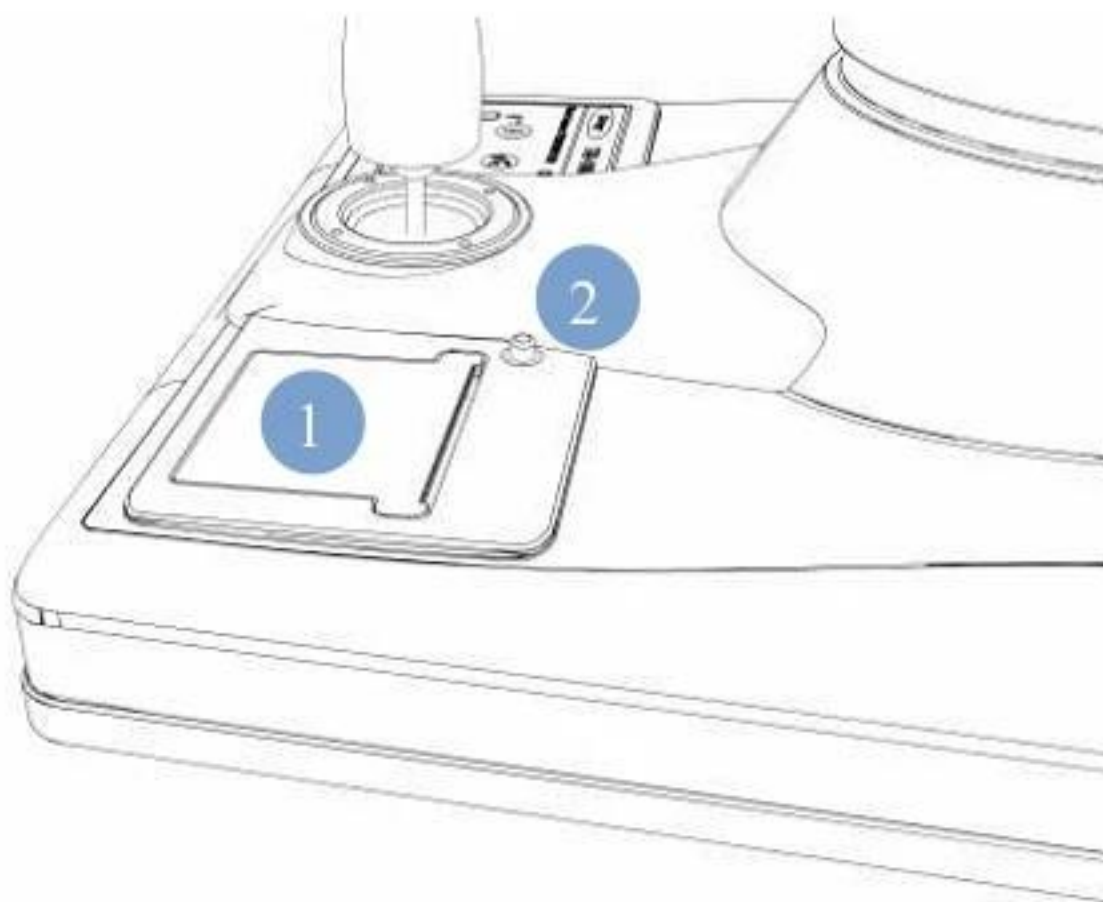
Never touch the cutter in the printer, it may cause the injury.

Use only a special paper designed for the printer. Using a different paper may damage the printer.

Do not start printing if there's no paper in the printer.

To remove the paper from the printer:

1. Press the button on the housing (2).
2. The printer flap opens up, and you can lift it (1).
3. Remove the used roll of paper and insert a new.
4. After replacing the roll, close the flap.
5. Cut off the outwardly projecting portion of the of paper.



9.5 Storing and transportation



The device should be properly prepared for transportation, moving or long-term inactivity. For details, refer to chapter 10.5.1.

- Do not store 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 store the device in a place where chemicals are stored or gases may occur. Spilt chemicals or vapor may enter the device and ignite!
- Do not lift the device up by directly holding the measuring head, chinrest, forehead support, or joystick. The device may be damaged!
- If the tonometer is not operated for a longer period of time, for safety purposes, disconnect the power cord from the outlet.
- Store the device in a location not subject to direct sunlight, high temperature and humid, or air with significant dust, salt and/or sulfur content. This may cause failure or malfunction of the device.
- If the device is not in use, put the dust cover on it. Dust and/or dirt in the optical part of the device may have a seriously negative impact on the quality of measurements.

9.5.1 Packaging

In order to prepare the device for transport:

1. Press and hold for 3 seconds the 'Pack' button on the control panel.
2. Wait until the machine completes the procedure for packaging, and turns off the display..
3. Disconnect the power supply from the unit, and power adapter from the mains outlet.



Failure to perform above procedure may result in permanent damage to the unit during transport.

9.5.2 Disposal

Disposal of the device, or parts of it, should be done according to local environmental and waste disposal and recycling regulations.



This symbol is applicable for EU member countries only.



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

NOTES