OCULUS | Corvis® STL

INSTRUCTION MANUAL

Tonometer - Pachymeter

OCULUS®

Notes on this instruction manual

Thank you for your purchase and the trust you have placed in this OCULUS product. The Corvis® STL has been manufactured and tested according to strict quality criteria. You have selected a modern and well-engineered product.

To ensure safe operation, it is essential that you use the device correctly. For this reason you should familiarise yourself thoroughly with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

- This instruction manual describes the measuring procedure of the Corvis® STL.

Due to ongoing development, the diagrams shown may depict minor changes to the actual device delivered.

If you have any queries or would like to obtain additional information about your device, do not hesitate to call or send us an e-mail or a fax. Our service team will gladly assist you.

OCULUS Optikgeräte GmbH

OCULUS is certified according to DIN EN ISO 13485, setting high standards of quality where development, manufacture, quality assurance and service regarding the entire range of products are concerned.

Table of Contents

1 Scope of Delivery

Component	Order number
■ Corvis® STL	72300
Corvis® STL pack	72210
■ Eye patch	44560
■ Dust protection cover	6010005001
■ Paper for chin rest	65313
■ Paper roll (3 rolls)	65311
■ Power supply	05150285
■ Instruction Manual	G/72300....en

We reserve the right to change the scope of delivery in line with ongoing technical development.

➔ When checking the delivery, if you discover transport damages, immediately make your claim with the transport company.

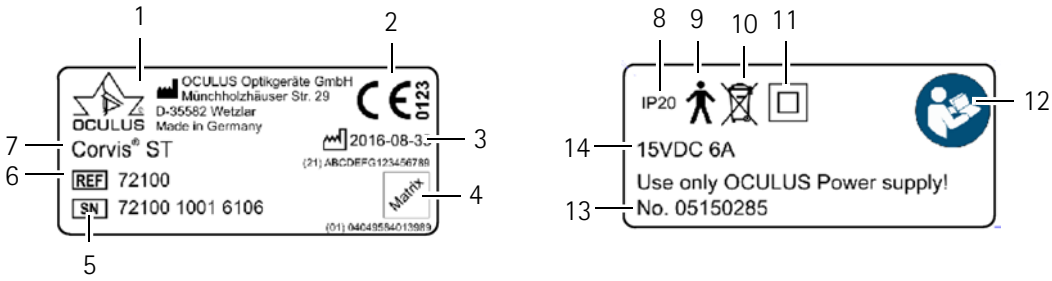
➔ Have the damage confirmed on the waybill, so that a proper claim settlement is possible.

➔ Keep the packing material.

Note

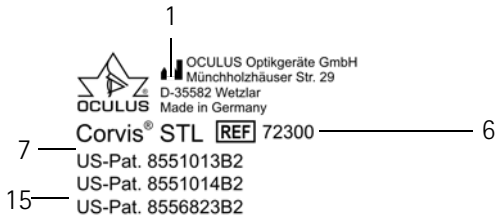
We reserve the right to change the scope of delivery in line with ongoing technical development.

2 Type Plates



1 Company logo and address
2 CE Conformité Européenne
3 Date of manufacturing
4 Matrix to identify the device
5 Serial number of the device
6 Device number
7 Device name
8 Degree of protection
9 Type B unit
10 Disposal with household waste is prohibited
11 Class of protection
12 Heed Instructions Manual
13 Power supply number
14 Power supply voltage, fuses

Abb. 2-1: Type plate: base



15 US patent number

Abb. 2-2: Type plate: measure head

3 Safety Instructions

3.1 About this Manual

➔ Read the instruction manual carefully.
➔ Carefully store the instruction manuals near the device.
➔ Observe the legal regulations with regard to accident prevention.

The instruction manuals describe the following versions:

- Control Pad: Version 1.00648
- Gauge head: Version 1.00.651

The following software versions are used:

- Corvis® STL program: Version 1.00xx
- Patient Data Management: Version 6.08xx

3.1.1 Graphic Symbols used

Warning

Describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Note

Instructions for use and useful or important information.

Precaution

Identifies important information about the product or its operation, which requires special attention.

3.2 Safety Instructions for Use

Warning

Personal or property damage due to false operation

➔ Comply with the following safety instructions.

Personal or property damage due to unsafe equipment modifications

➔ No modifications may be made to this device without the permission of the manufacturer.

Information for operators

➔ Make sure that the Corvis® STL is used only by people
- who can guarantee proper handling due to their knowledge, training and practical experience.
- who have been instructed by OCULUS staff or an authorized dealer before the initial operation.

Information for set-up and connection

➔ Do not use the Corvis® STL outdoors or in damp rooms, and do not store the device there.

➔ Keep the Corvis® STL away from water that may drip, splash or spray on the device, and make sure that no liquids enter the Corvis® STL. Do not place any containers holding liquids in the vicinity of the Corvis® STL.

➔ Do not operate the devices included in the delivery in areas where explosions may occur, or in proximity to flammable anesthetics or volatile substances such as alcohol, benzine or similar products.

➔ Do not force any electrical connections. If you are unable to connect a plug, check whether the plug fits the socket.

➔ If you detect any damage to the connection, have the defect repaired by our service personnel.

Information on operation

➔ Never put a damaged Corvis® STL into operation.

➔ Only operate the Corvis® STL using original accessory parts supplied by us, and only when the device is in technically correct working order.

➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the Corvis® STL.

➔ Only operate the device if you have understood the instruction manuals.

Information on maintenance

➔ Germany: The operating company must ensure that the device undergoes technical measurement testing every two years according to MPBtreibV, Appendix 2 Tonometer.

To ensure that it functions correctly and safely we recommend the following:

➔ Have the Corvis® STL checked every two years by our service department or an authorized dealer. If an error occurs which you are unable to correct, label the Corvis® STL as "out of order" and contact our service department or an authorized dealer.

Information on removal and disposal

➔ When you disconnect electrical connections, pull the respective connectors, not the cord.

➔ Dispose of the device according to legal regulations.

Notes on Electrical Safety

Warning

Personal or property damage due to false auxiliary equipment

Any auxiliary equipment that is to be connected to either analogue or digital interfaces of the Corvis® STL must be verified to fulfill appropriate EN or IC specifications. Furthermore, all configurations must comply with the IEC 60601-1 system norm.

➔ Make sure that only correct auxiliary equipment will be connected.

Personal or property damage due to an incorrect level of safety

Connection of the Corvis® STL with non-medical electrical equipment (e.g. data processing equipment) to a medical electrical system must not cause patient-relevant safety levels to fall below IEC 60601-1 levels. If such connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

➔ Ensure that connections with non-medical devices are made correctly.

➔ Only use the AC adapter stated in the packing list.

➔ If you use a power strip to connect the Corvis® STL: Make sure that the ground wire in the power strip is not interrupted in order to avoid excessive leakage. The power strip must meet the requirements of IEC 60601-1.

Electromagnetic Compatibility (EMC) / Cables

Warning

Personal or property damage caused by electromagnetic interference

Portable and mobile RF communications equipment can affect medical electrical equipment *sec. , page 59*.

➔ Make sure that portable and mobile RF communications equipment do not cause interference.

4 Indications for Use

The Corvis® STL is intended to measure intra-ocular pressure of the eye in patients with less than 3 diopters of corneal astigmatism. In addition, the Corvis ST is designed to photograph the eye and take Scheimpflug images of the anterior segment of the eye to evaluate the thickness of the cornea.

5 Contraindications

None known.

6 Warnings

The Corvis® STL is an automatic non-contact tonometer with the additional function of our PACHYCAM which is a non-contact pachymeter.

The automatic non-contact tonometer function is the main application while the additional Pachymetry function gives the examiner first hints of any unusual values which were unknown before the examination.

If some unusual corneal thickness values are present, further examinations with devices like our Pentacam® might be necessary. Furthermore if some unusual intraocular pressure values are preset, further examinations with devices like the Goldman Tonometer might be necessary.

Note

The Corvis® STL complies with ANSI Z80.10-2009 (in according with FDA´s extent of recognition) if eyes with astigmatism >3D are excluded. Currently there is no sufficient database according to ANSI Z80.10-2009 for eyes with corneal astigmatism >3D. OCULUS Optikgeraete GmbH therefore does not recommend using the Corvis® STL for IOP measurements for those eyes.

7 Transport to Installation Location

The transport and storage conditions according to IEC 60601-1 with the appropriate packaging are valid for a period of up to 15 weeks, see *"Transport and storage requirements (according to IEC 601 - 1)" page 54*.

➔ Wait approx. 3-4 hours after transport before operating the Corvis® STL. Extreme temperature changes from cold areas to warm rooms can cause condensation on the optical components.

Note

Equipment damage due to incorrect transport and improper storage

➔ Avoid shocks and vibration.

➔ Avoid contamination, high temperatures and humidity.

➔ Transport the Corvis® STL professionally.

➔ Store the Corvis® STL according to the storage conditions.

➔ Avoid placing near radiators and moisture.

Note

➔ Keep the packing material. You can then ship or transport the unit in the proper manner for any servicing or repairs that may arise. You can thus avoid unnecessary damage and costs.

8 Device Description

8.1 Overview of Device Components

Side – view

1 *Gauge head*
2 *Chin rest*
3 *XYZ-base*
4 *Control knob*
5 *Joystick*
6 *Function keys*
7 *Display*
8 *Printout slot*

Abb. 8-1: Corvis® STL: Side view

Front - view

1	*Forehead rest*	*6*	*On/Off switch*
2	*Air nozzle / slit lamp window*	*7*	*Control LED*
3	*Lens protection glass*	*8*	*Mains connection*
4	*LED to illuminate the eye*	*9*	*USB port*
5	*Eye height marking*	*10*	*Safety stop*

Abb. 8-2: Corvis® STL: Front view and connections

8.2 Mode of Operation of the Corvis® STL

The Corvis® STL is a non-contact tonometer equipped with an optical pachymetry function.

The Corvis® STL measures intraocular pressure without contact with the eye by applying an air puff to the eye. During the air puff the eye gets illuminated through a 9 mm slit through the apex; and a built-in high-speed camera records the movement of the eye with more than 4000 images per second.

The high-speed camera uses a sequence of 140 Scheimpflug images of the cornea which are analyzed by a built-in computer.

Intraocular pressure is determined by the detection of the applanation moments of the cornea.

Based on the Imbert-Fick principle the intraocular pressure is calculated by dividing the amount of air pressure by the area of applanated surface.

The device increases the air pressure puffed onto the applanated cornea in proportion to time. The shape of the cornea changes from the normal convex surface to a concave surface.

This change is optically detected within 140 Scheimpflug images. The device calculates the time required to applanate (plane shape) the cornea with the air puff.

The slit lamp illuminates a sectional plane from the front surface of the cornea to the back surface during the air puff. The transparent cells of the cornea scatter in such a way that the sectional plane appears as if it were self-luminous.

This is captured by a camera at an angle of 45° to the pupil, whereby the image plane of the camera is also tilted 45° to the optical axis of the camera lens, in order to sharply focus the light-scattering of the cornea plane onto the image plane of the camera (Scheimpflug image).

Due to this arrangement, sharp sectional images of the cornea can be obtained.

The pachymetry principle uses also the sectional images of the cornea.

Corneal thickness and shape are measured using the images before the cornea was influenced by the air puff.

Tonometry and pachymetry are measured during the same measurement process.

9 Start-up

Before you can operate the Corvis® STL for the first time, you must follow the instructions as per *sec. 9.1, page 11*.

If you want to put the Corvis® STL into operation after an in-house transport, follow the instructions as per *sec. 9.3, page 12*.

9.1 Initial Start-up

Before you can operate the Corvis® STL for the first time, you must

- set it up and install it
- get trained

Warning

Incorrect measurements / equipment damage due of a lack training

➔ Before first use: Let OCULUS or an authorized dealer train you how to operate the Corvis® STL.

Incorrect measurements / equipment damage due to the incorrect set-up

➔ Before the first use, make sure that the installation and connection of the "Corvis® STL" examination area is completed by someone from our service department or by a professional authorized by OCULUS.

9.2 Set-up Jobs for Initial Start-Up

➔ Wait approx. 3-4 hours after transport before operating the Corvis® STL. If the Corvis® STL was stored in a cold room or vehicle during the cold time of the year, a significant change in temperature may cause condensation to appear on optical parts of the Corvis® STL.

➔ Check if the transportation safety device is unlocked, *sec. 9.3.2, page 12*.

9.3 Adjustments after an In-house Transport

Note

Equipment damage due to incorrect lifting

If the Corvis® STL is lifted by the forehead rest, it can break off.

➔ Grab the Corvis® STL from below to lift it.

9.3.1 Device Set-up

➔ Place the Corvis® STL on a plane surface.

➔ Place the Corvis® STL so that no direct light can affect the measurement.

➔ Avoid shocks and vibration.

➔ Avoid contamination, high temperatures and humidity.

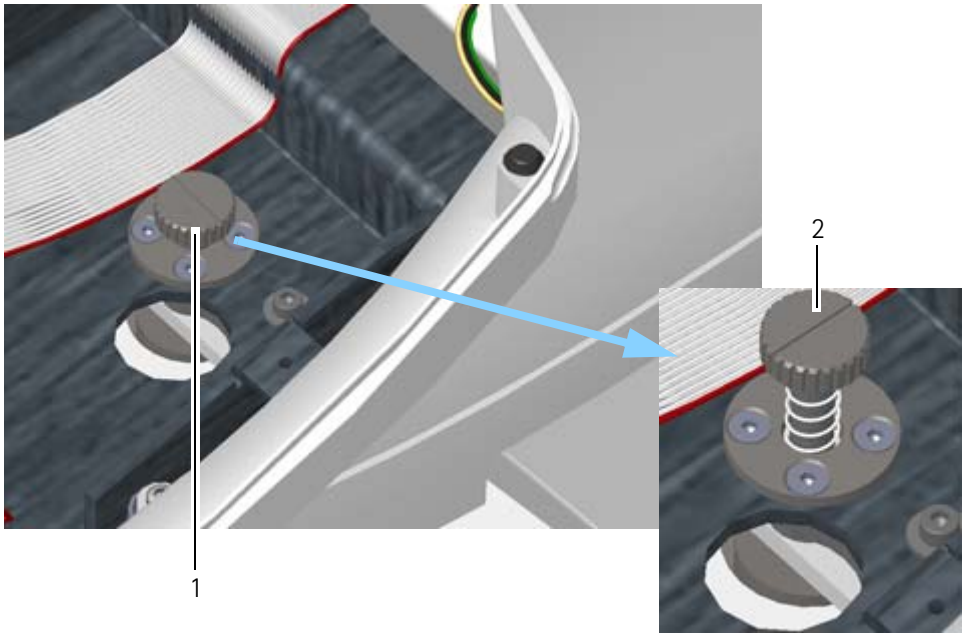
9.3.2 Unlock Transport Safety Sevice

During transport the Corvis® STL is secured with a transport safety device. This must be unlocked before use.

➔ Open the cover including the display.

Abb. 9-1: Open the cover including the display

➔ Unlock the transport safety device if it is locked (1).



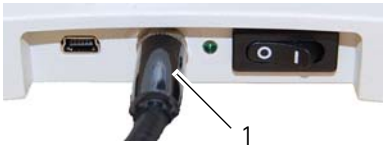
1 "Locked" position *2 "Unlocked" position*

Abb. 9-2: Unlock transport safety device

➔ Press down gently the transportation safety device and turn it counter-clockwise to the "unlocked" position (2). The spring will push the transport safety device up.

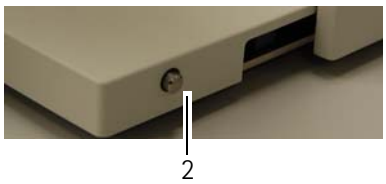
➔ Close the cover including the display, *fig. 9-1, page 12*.

9.3.3 Device Connection



➔ Connect the device to the power supply using the power cable provided (1).

Setting the safety stop



The safety stop (2) is a lock that prevents the air nozzle from touching the patient's eye.

You can individually determine the position of the stop.

➔ Press the safety stop (2) and hold it.

➔ Move the Corvis® STL into the desired position.

➔ Release the safety stop (2).

The safety stop is set. You can only move the Corvis® STL as far as this position. You can move the Corvis® STL towards the rear at any time.

Warning

Risk of contact of the patient's eye with the air nozzle

➔ Before starting a measurement, make sure the safety stop is set correctly. This prevents the air nozzle from touching the patient's eye.

Adjusting the brake

The brake (1) prevents the Corvis® STL from moving fast and jerkily on the XYZ-base. This enables you to better control the position of the device.

➔ Turn the brake to the desired position.
To the right: Corvis® STL is hard to move
To the left: Corvis® STL is easier to move

Switching off the Corvis® STL

➔ End the current session.

➔ Switch off the Corvis® STL with the On/Off Switch (1).

10 Using the Control Panel

You enter and manage patient data with the control panel. In addition, you start the measurements and can view the results with it.

1 *Display*
2 *Control knob*
3 *Joystick*
4 *Joystick button*
5 *Screen-dependent buttons*

Abb. 10-1: Functions of the Control Pad

Component	Function	Operation
Display (1)	Shows program screens Serves as a touch screen	➔ Lightly press the desired button
Control knob (2) 	Changes the corresponding parameters Enables the selected parameters	➔ Turn the control knob to the left or right. The selected parameter is highlighted in blue. ➔ Press the control knob downwards. The selected parameter is enabled or disabled.
Joystick (3)	Sets the height, distance and direction to the left and right	➔ Move the joystick forward, back and sideways, turn it, *"Fine Adjustment" page 31*.
Joystick button (4)	Starts the measurement manually (if the eye-tracking function is turned off)	➔ Press the button.

Component	Function	Operation
Buttons (5)	Enables the adjacent keyboard, depending on the associated screen	➔ Press the desired button.

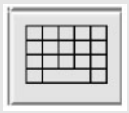
10.1 Display with Touch Screen

In addition to the screen-dependent buttons, you can also use the buttons on the touch screen. The buttons change depending on the function of the display.

➔ Lightly press the corresponding buttons on the touch screen to enable the function.

Buttons on the touch screen

You can use the following buttons in Patient Data Management.

Button	Function
	Change keyboard
	Delete character
	Escape
	Enter
	Return to upper line

11 Using Patient Data Management

When you turn on the Corvis® STL, Patient Data Management is shown first.

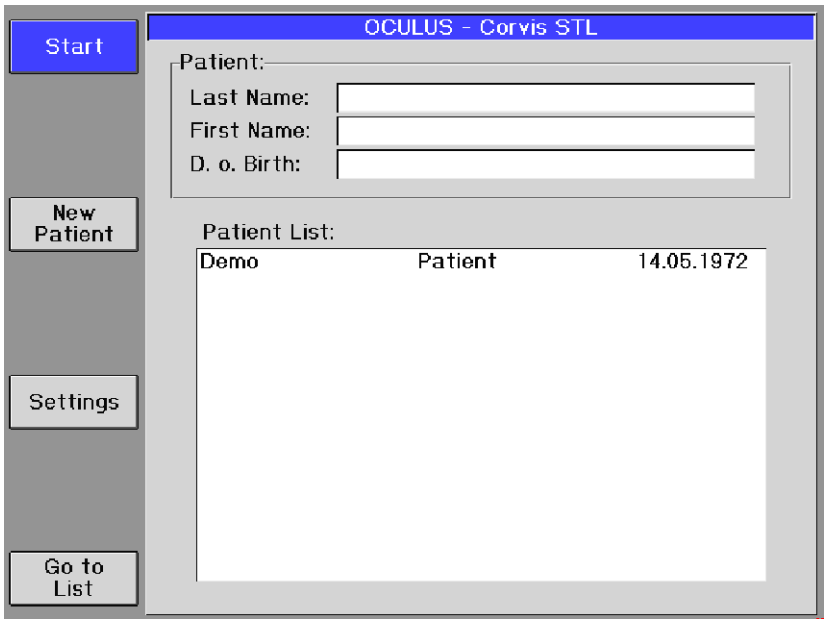


Abb. 11-1: Switching on the Corvis® STL

Use Patient Data Management to assign examinations to a patient or when you want to save them l for a long time.

Precaution

➔ In these cases, it is best to enter the patient's name and date of birth before you perform the measurement.

11.1 Entering new Patient Data

➔ To enter new patient data, press the button [New Patient] in the patient data menu.

The following screen is displayed:

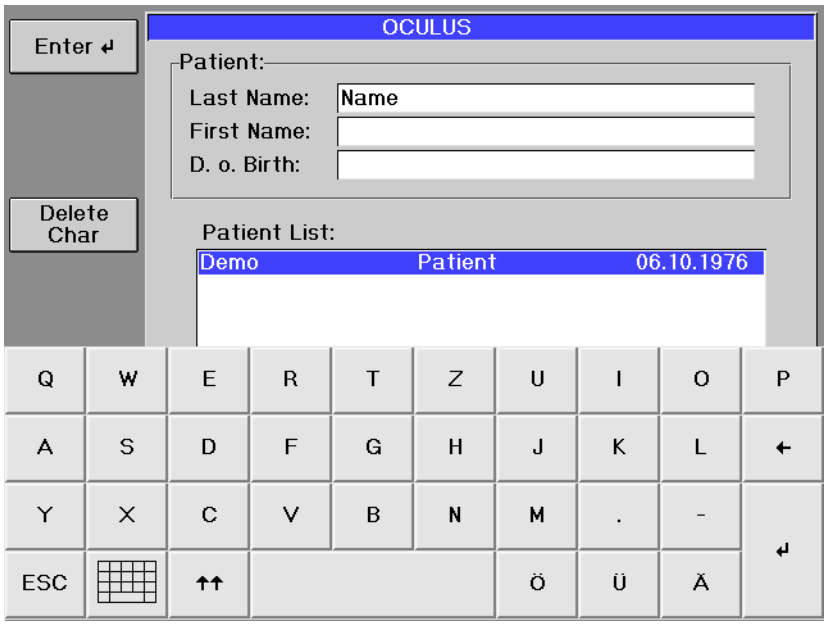


Abb. 11-2: Touch-screen keyboard, enter patient data

➔ Use the touchscreen as described in *(sec. 10.1, page 16)*.

Use the [Delete Char] button to delete the last character or number.

➔ Enter the patient's last name and confirm with [Enter].

➔ Enter the first name. Confirm with pressing [Enter].

In the "D. o. Birth" field, the touch-screen keyboard changes to a numeric keypad:

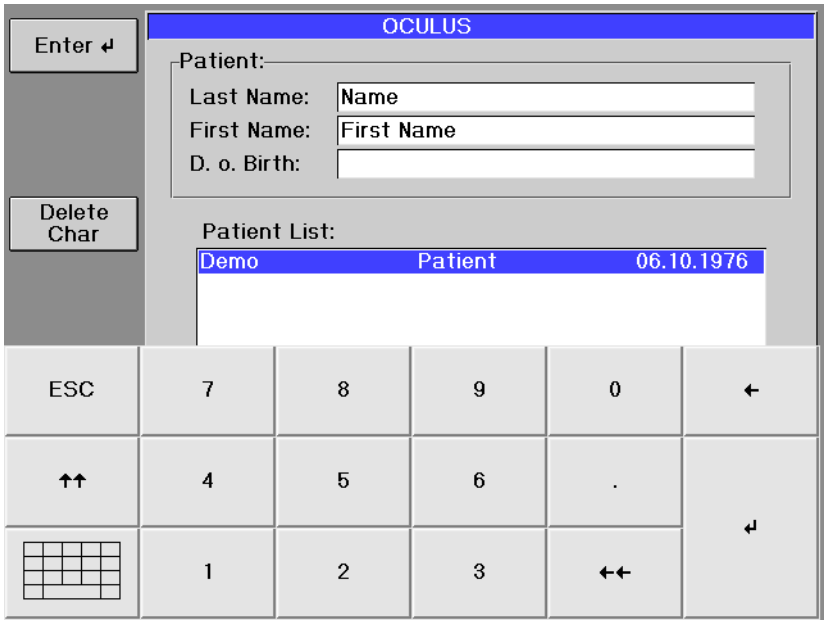


Abb. 11-3: Touch screen keyboard, numeric keypad

➔ Enter the date of birth and confirm with [Enter].

Precaution

Note for the calculation by „Spoerl: The patient´s date of birth is necessarily required for the calculation.

You will be asked if you want to save the new patient data.

➔ Select "Yes".

The patient's name appears in the list.

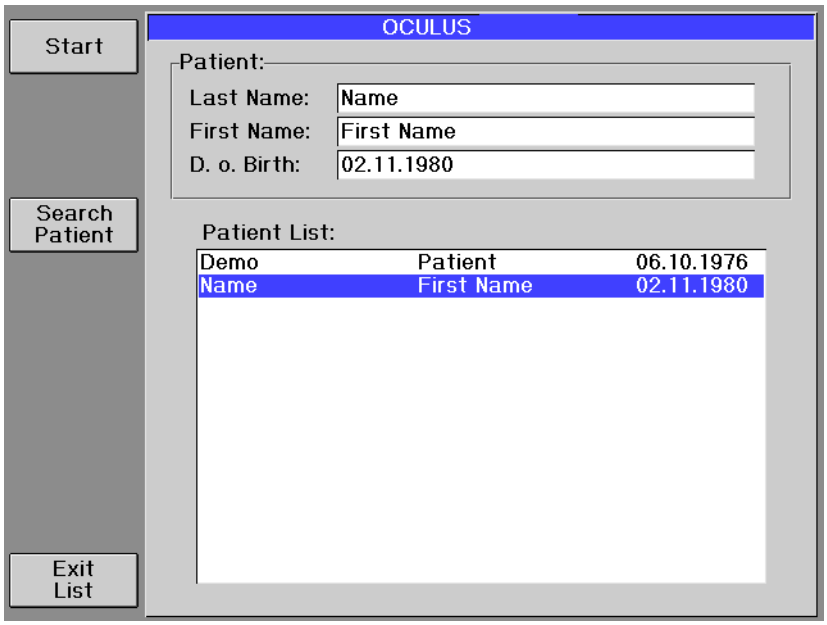


Abb. 11-4: Patient list

➔ Press the [Start] button to switch to measurement mode.

11.2 Selecting existing Patient Data

Choose a patient whose data is already stored, and whom you wish to examine again.

➔ In the Patient Data Management *(fig. 11-1, page 17)* menu, press the [Patient List] button.

➔ Turn the control knob to the desired list entry.

➔ Press the control knob to select the desired patient.

➔ Press the [New Exam/Back] button to switch to measurement mode.

11.3 Deleting a Patient or an Examination

If you want to delete a patient or an examination:

➔ Select the patient in question.

➔ Press the [Pat./Exam Delete] button.

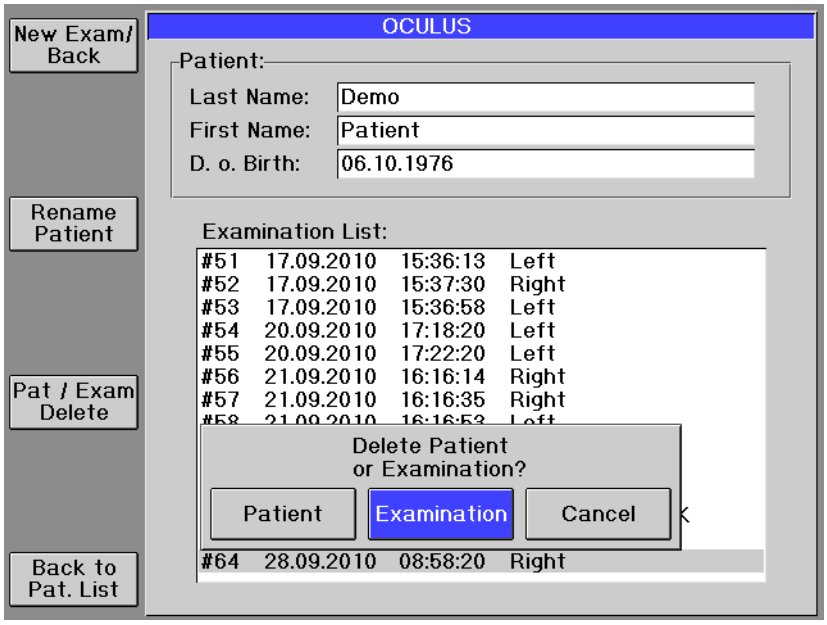


Abb. 11-5: Deleting a Patient or an Examination

To delete a patient:

➔ Press the [Patient] button.

The patient will be deleted.

To delete an examination:

➔ Select the examination to be deleted.

The line of the selected examination is highlighted in blue.

➔ Press the [Examination] button.

The examination will be deleted.

12 Changing the Settings

Here you can adjust the default settings for your individualized measurement mode.

If you do not wish to change the settings, start the measurement directly *sec. 13, page 27*.

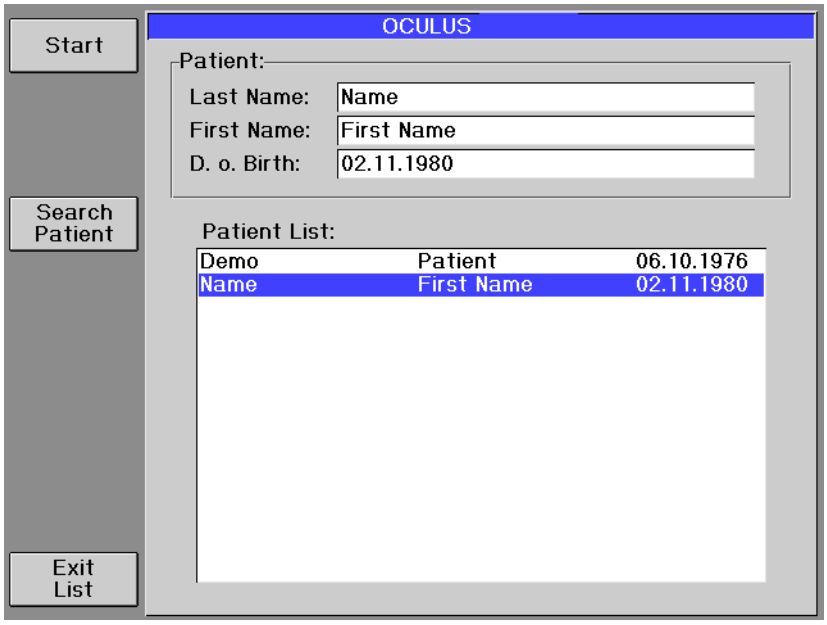
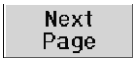


Abb. 12-1: Switching to [Settings] screen

➔ Press this button to display the "Settings 1" screen.

On each screen you can set the values as follows:



➔ Press this button to get to the next settings page.

➔ Press this button to save your settings.

➔ Press this button to cancel the settings.

➔ Turn the control knob to the left or right. The selected group box is highlighted in blue.

➔ Press the control knob downwards. You can set the parameters in the group box.

The selected parameter is highlighted in blue.

If you want to enter a value, such as "Clock" time:
Press the control knob. The parameter is highlighted in blue.

➔ Turn the knob to the desired value.

➔ Press the control knob to confirm the value.

If you want to enable/disable a radio button, such as "Startscreen":

➔ Press the control knob.

12.1 Settings 1

You can configure the measurement start and the display settings on the "Settings 1" screen.

➔ Press this button to get to the "Settings 1" screen.

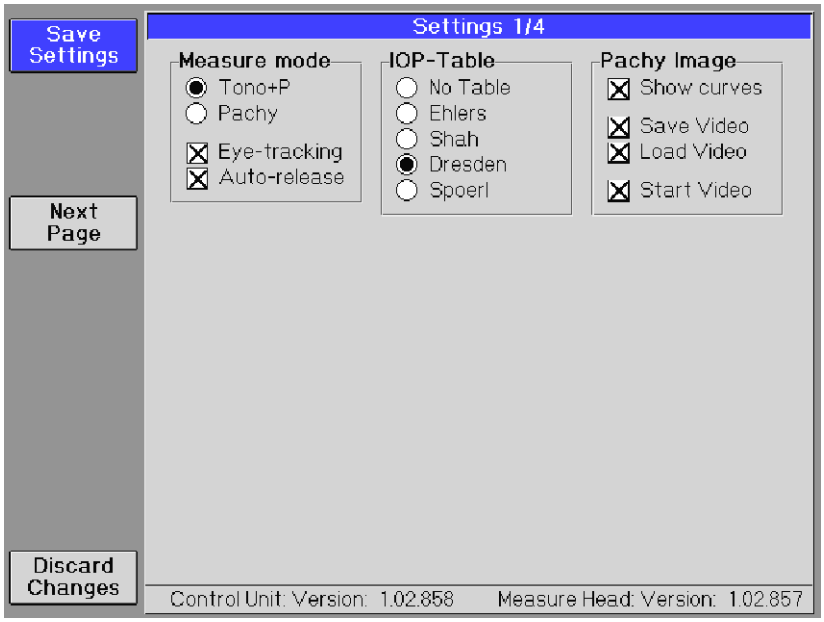
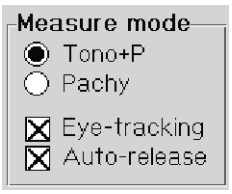


Abb. 12-2: Display: Settings 1



Measurement mode

Group Box: measurement mode

Here you can view the combinations of the measuring functions:
Tono+P: Tonometry + pachymetry.

Pachy: Pachymetry

You can set the "Eye-tracking" and "Auto-Release" functions:

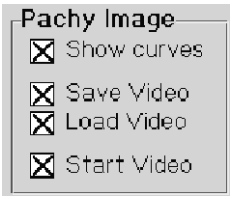
- Eye-tracking: Automatic adjustment of the measuring head in y-direction (height).
- Auto-release: Automatic triggering of the measuring process. If this feature is disabled, you must manually trigger each measurement, *"Manual measurement:" page 32*.

➔ Rotate and press the control knob to enable or disable the functionality "Eye-tracking" and "Auto-release".

Settings for IOP-Table

Group Box: IOP-Table

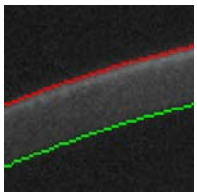
- Enabled checkbox: measured pressure values are shown, corrected by the according correction program.
  Note for the calculation by „Spoerl: The patient´s date of birth is required for this calculation.



Settings for pachymetric curves

Group Box: Pachy Image

- Enabled checkbox "Show curves": front and back are shown in red and green colors:



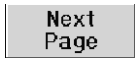
➔ Enable the checkbox "Save Video": The video of the cornea deformation process is saved in the examination data.

➔ Enable the "Load Video" checkbox: The video is also loaded when loading an examination.

➔ Enable the "Start Video" checkbox: The video will continue to play while an examination is loading.

12.2 Settings 2

You can set various display parameters with the "Settings 2" display.



➔ Press this button on the "Settings 1" screen.

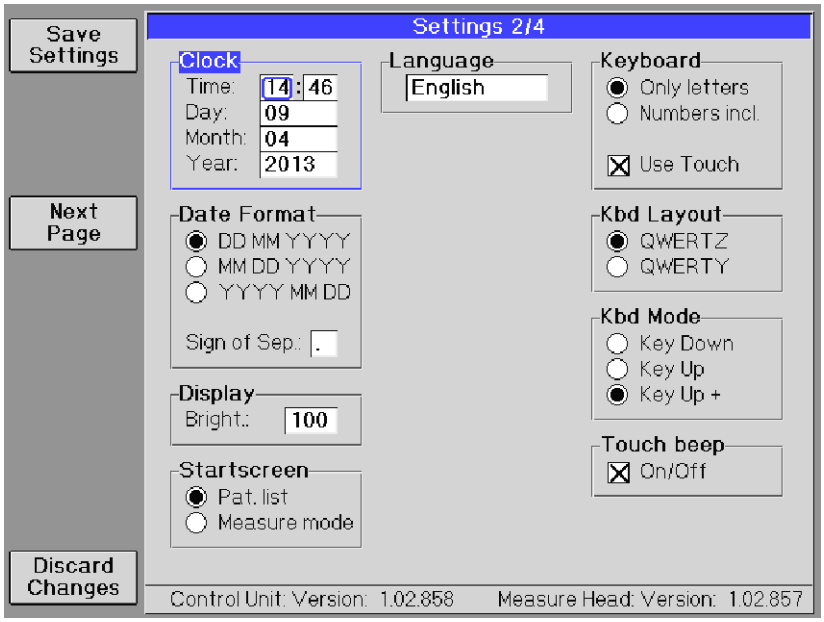
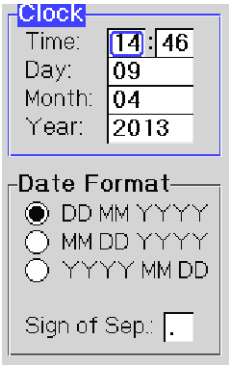


Abb. 12-3: Display: Settings 2



Setting date and time

Group box: Time / date format

➔ In these two fields, you set the time and the date by turning and pressing the control knob.

Setting the brightness of the display

Group Box: Display

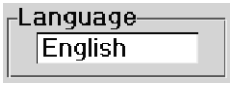
➔ Adjust the brightness of the display here.

Setting parameters for the start-up screen

Group Box: Start-up screen

➔ Enable the radio button "Pat.List" to start the Patient Data Management on start-up.

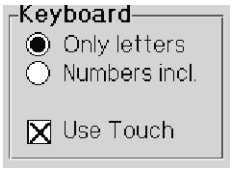
➔ Enable the radio button "Measure Mode" to start a measurement right after start-up.



Language

Group Box: Language

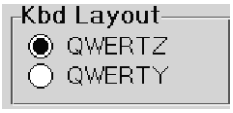
➔ Select the display language.



Setting keyboard interface

Group Box: Input

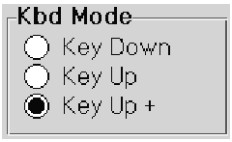
➔ In the "Keyboard" field, select the keyboard interface for the touch screen, for example, to input patient data.
Only letters: The touch-screen keyboard displays letters
Numbers incl.: The touch-screen keyboard shows letters and a series of numbers and letters
Use Touch: Touch screen is enabled/disabled



Setting the keyboard layout

Group Box: Kbd layout

➔ Select the keyboard layout:
QWERTZ: German keyboard layout
QWERTY: U.S. keyboard layout



Selecting contact control of the touch screen

Group Box: Kbd Mode

➔ Select the contact control of the touch screen:
"Key Down": Character input through direct contact with the touch screen
"Key Up": Character input by releasing the touch Screen
"Key Up+": Character input by releasing the touch Screen In addition, the entered character is also shown on the display:

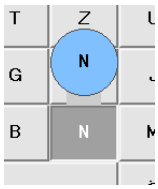


Abb. 12-4: Kbd Mode "Key Up+", Example: The letter N

Enabling and disabling Confirmation Tone (Touch beep

Group Box: Touch beep

➔ Enable/disable the confirmation tone of the touch screen with the radio button "On/Off".

12.3 Settings 3

On the "Settings 3" screen you can individually configure the printouts.

Next Page

➔ Press this button on the "Settings 2" screen.

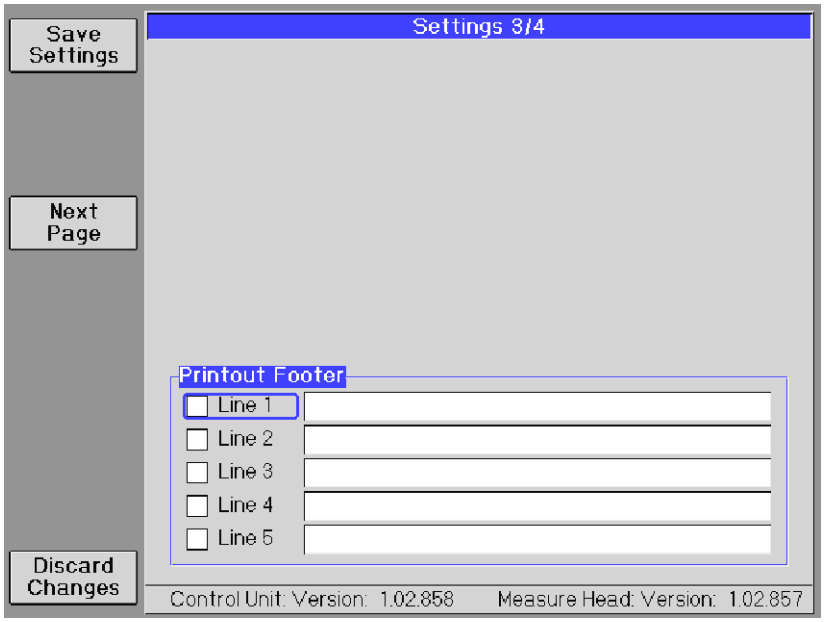


Abb. 12-5: Display: Settings 3

Printing out footer

If you want to include your business or office name on the printout:

➔ Enter the appropriate information in the lines provided for this purpose and enable the checkboxes in front of each line.

Precaution

Settings 4/4 is only used for service purposes. These settings can only be made by the OCULUS service department or authorized distributors.

13 Performing a Measurement

Warning

Risk of contact of the patient's eye with the air nozzle

➔ Before starting a measurement, make sure the safety stop is set correctly, *"Setting the safety stop" page 13*. This prevents the air nozzle from touching the patient's eye.

Danger of pinching hands or body parts

➔ During a measurement: Make sure that the patient does not put either his/her hand or any other body part between the gauge head and adjusting base.

Note

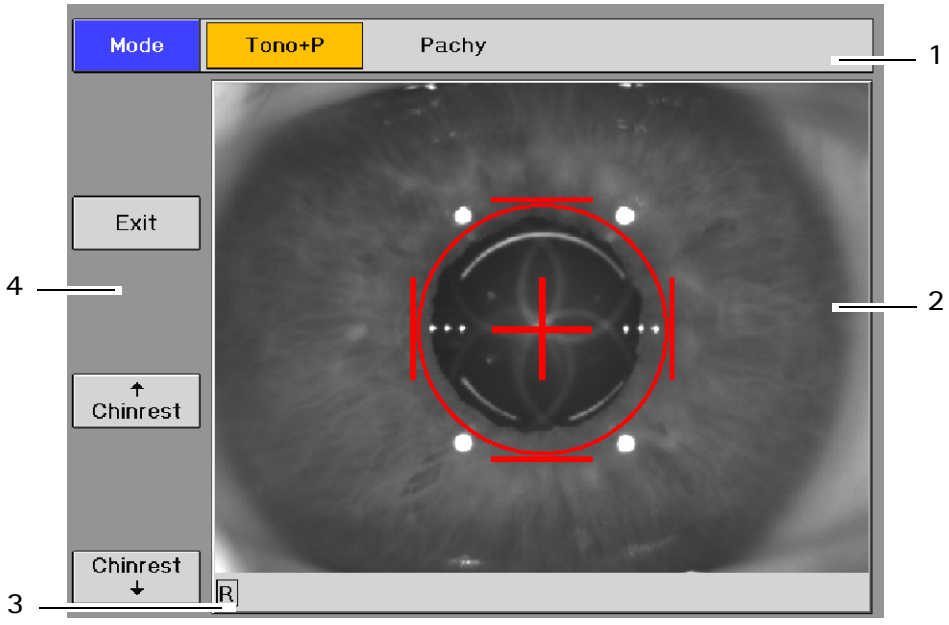
Incorrect measurements due to a dirty air nozzle

➔ Before each measurement, check the glass part of the air nozzle for dust, dirt, etc. from a diagonal angle.

➔ If necessary, clean the air nozzle *"Cleaning the air nozzle (2)" page 41*.

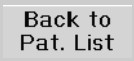
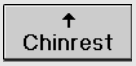
➔ Press the [Start] button to start the measurement process.

During the measurement process, you will work with the following display:



1 Measurement mode
2 Camera image
3 Examinated eye
4 Buttons

Abb. 13-1: Measurement process

Measure mode(1)	Information about the measurement mode, automatically enabled
Camera image (2)	Camera image of the patient's eye
Examinated eye (3)	The examinated eye is displayed: left (L) or right (R)
Buttons (4)	
	Measurement mode, automatically enabled
	Back to Patient Data Management
 	Adjusting height

13.1 Selecting a Measurement Mode

Depending on the version you can select the measurement mode.

➔ Press this button.

Tono + P version

➔ Press this button to display „Tono + P.“.
Tonometry and pachymetry are measured simultaneously.

Pachy version

➔ Press this button to display „Pachy“.
The corneal thickness along the horizontal sectional plane is measured but without the IOP.

13.2 Corvis® STL Adjustment

Before you initiate a measurement, you must adjust the Corvis® STL.

13.2.1 Rough Adjustment

➔ Make sure that there is new paper on the chin rest.

➔ Ask the patient to place his or her head on the chin and forehead rest.

1 Eye height marking

Abb. 13-2: Position patient according to the markings

The eye height marking (1) between the chin rest and the headrest should be located roughly at the centerline of the patient's eye.

Warning

Risk of contact of the patient's eye with the air nozzle

Fast and/or uncontrolled movements may cause the air nozzle to touch the patient's eye.

➔ When operating the Corvis® STL, move it carefully toward the patient's eye.

➔ If necessary, adjust the height of the chin rest with the buttons ↑ Chinrest and Chinrest ↓.

You can also adjust the height of the gauge head by turning the joystick:

Turn it clockwise to move the gauge head upwards.
Turn it counter-clockwise to move it downwards, see *"Fine Adjustment" page 31*.

➔ To prepare the patient prior to the measurement:

Explain to the patient what will happen next to help him/her relax:

"A little air will be blown into your eye. Don't let it scare you. Please be patient and relax for a moment".

Precaution

➔ Ask the patient to not blink during the measurement, otherwise the measurement results will be falsified.

➔ Move the adjusting base until the patient's eye is focused on the display.

➔ If necessary: Adjust the height with the buttons ↑ Chinrest and Chinrest ↓.

13.2.2 Fine Adjustment

➔ Use the information on the display and the joystick to make any fine adjustments. Move the joystick in the direction indicated.

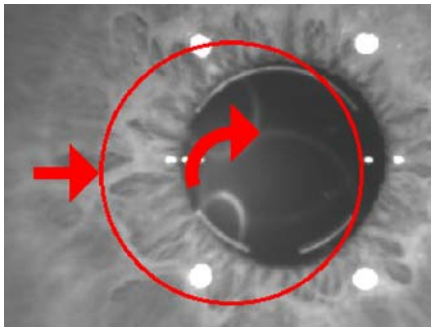


Abb. 13-3: Fine adjustment

Example ➔ Move the joystick to the right.
➔ Turn the joystick clockwise.

Arrow	Camera movement	Joystick movement[a]
→	right	Move the joystick to the right
←	left	Move the joystick to the left
↑	forward	Move the joystick toward the patient
↓	back	Move the joystick away from the patient
↷	up	Rotate the joystick clockwise
↶	down	Rotate the joystick counter-clockwise

a. If you turn the joystick to its limit, the measuring head and the chin rest move in the opposite direction.

When the position has been reached accurately enough, a cross appears in the center of the ring that is bordered by four bars.

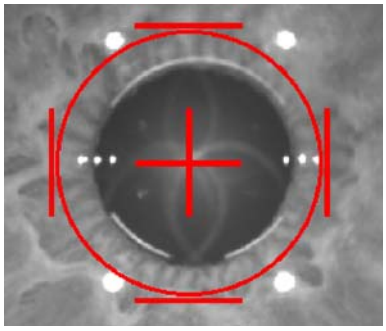


Abb. 13-4: Final position reached

13.3 Start Measurement

Depending on the setting the Corvis® STL will automatically begin measuring, alternately you can start the measurement procedure manually.

Automatic measurement

When the position has been reached accurately enough the Corvis® STL will automatically begin measuring *fig. 13-4, page 32*.

Manual measurement:

➔ To start the measurement manually, press the joystick button *(fig. 10-1, page 15, Item 4)*.

The measurement is now calculated. You have to wait for this process to be completed before you can view the results *(sec. 13.6, page 34)* or save *(sec. 14, page 39)* them.

13.4 Saving Data

Depending on the installation, your data is saved on an internal memory.

Save to Patient

➔ Press this button to save the data.

Note

Loss of data due to interrupted saving

If you turn off the Corvis® STL while the progress bar is still displayed, data will be lost.

➔ Do not turn off the power until saving is completed, e.g. when the progress bar is complete.

You can now view the examination results, *sec. 13.6, page 34*.

13.5 Completing the Measurement

➔ After each patient, remove one of the paper sheets from the chin rest. See also *sec. 14.4, page 44*.

➔ Disinfect the forehead rest after each patient, *sec. 14.2, page 43*.

Warning

Risk of infection after examining a sick patient

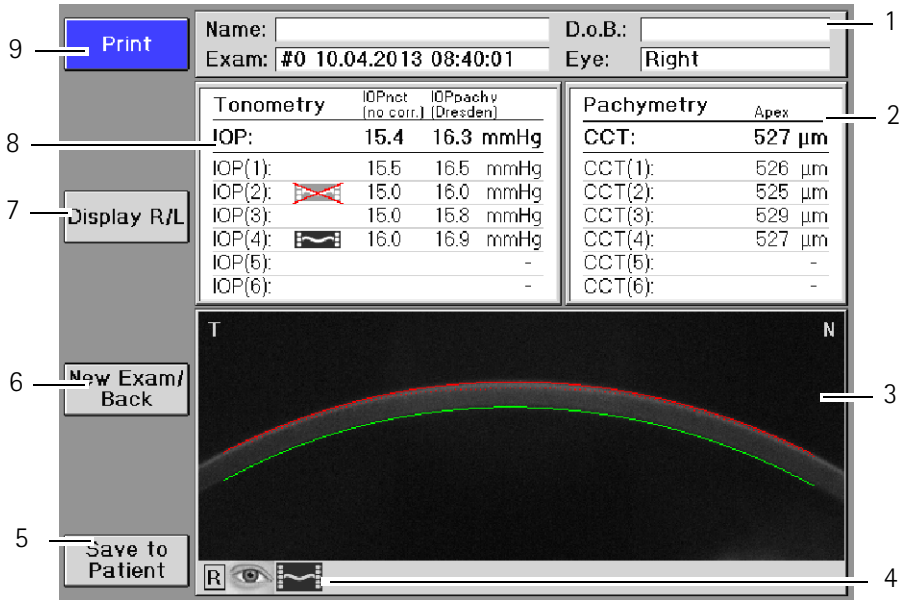
If you perform a measurement on a sick patient, the air nozzle and the front cover can be contaminated.

➔ Clean the air nozzle when you have examined a sick patient, see *"Cleaning the air nozzle (2)" page 41*.

➔ Disinfect the front cover *sec. 14.2, page 43*.

13.6 Showing the Tonometry + Pachymetry Display

The measurement results are shown as follows when using the Tonometry + Pachymetry display:



1 *Patient data*
2 *Pachymetry values*
3 *Deformation video/image*
4 *Icons*
5 *[Save to Patient] button*
6 *[New Exam/Back] button*
7 *[Display R/L] button*
8 *Tonometry values*
9 *[Print] button*

Abb. 13-5: Measurement results in the Tono + P-display

Buttons and Icons

Button	Function
Save to Patient	This button is displayed after the measurement to save examination data of the patient
New Exam Back	Switching back
Display R/L	Switching between eyes/displays
Print	Printing measurement results ➔ Press this button to start printing
	Measurement is available, displaying the measurement ➔ Press this button to display further measurements
R or L	Display of the examined eye

Patient data (1)

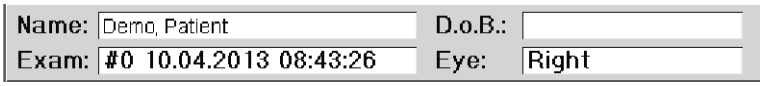


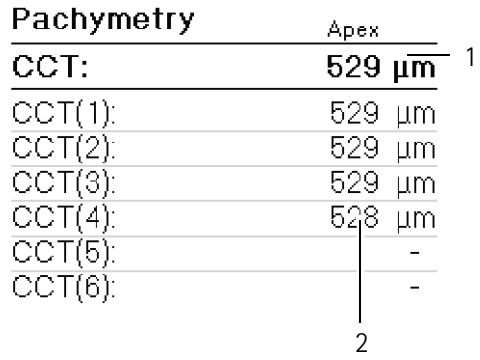
Abb. 13-6: Patient data

The most important patient and examination data is displayed in this individual display.

- Last name and first name
- Examination data and time
- Date of birth and age on examination date
- Examined eye
- Quality factor QS
  - OK: measurement is correct
  - Yellow: deviation from normal measurement
  - Red: measurement has to be repeated

Pachymetry Values (2)

Pachymetry values at the apex, individual values and mean value are displayed in the following table.



1 Mean value *2 Individual values*

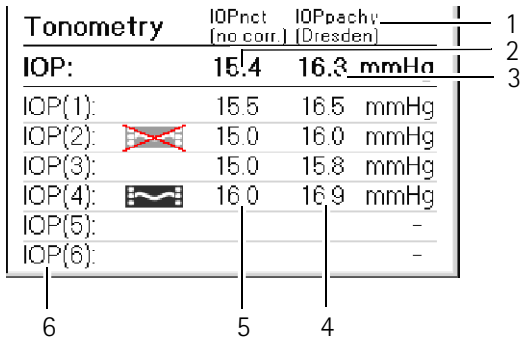
Abb. 13-7: Pachymetry values

Apex	Measuring point for central corneal thickness
CCT	Central corneal thickness

Tonometry Values (8)

Tonometry values are displayed in this table:

- Individual values (measured values and corrected values)
- Mean value (not corrected and corrected)



1 Calculation formula
2 Not corrected mean value
3 Corrected mean value
4 Corrected individual values
5 Not corrected individual values
6 IOP

Abb. 13-8: Tonometry values

You can perform up to six measurements consecutively. Based on these measurements, the tonometric mean value is calculated.

If more than six measurements are performed, the oldest one is deleted.

IOP	Intraocular pressure
	Video loaded
	Previous video deleted

The column including the corrected IOP value is not displayed if you have activated the radio button "Not able" in the "IOP" group box in "Settings 1" *("Settings for IOP-Table" page 22)*.

Precaution

The patient's date of birth is required for the calculation according to "Spoerl". If it has not been entered, "Enter D.o.B" is displayed.

1 Column for corrected IOP values

Abb. 13-9: Corrected IOP values are not displayed

If not done so beforehand, enter the patient's date of birth as follows.

➔ Touch the "D.o.B." input field in the patient data, *fig. 13-5, page 34 , Pos. 1*.

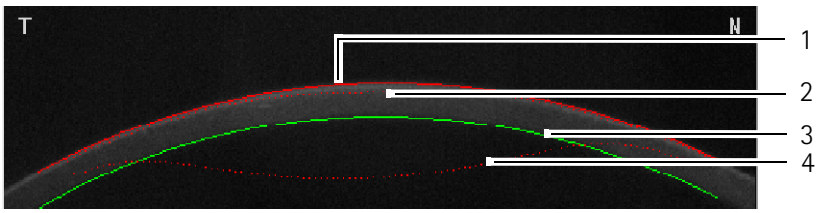
A numeric keypad opens, *fig. 11-3, page 18*.

➔ Insert the patient's date of birth and confirm with [Enter].

The IOP values corrected according to "Spoerl" are displayed.

Deformation Video/Image (3)

A Scheimpflug image with different lines is shown if no video is running. Depending on the settings, lines are shown in this display. These lines show the deformation of the cornea at different times.



1 Anterior surface of the cornea
2 Applanation 1 of the cornea
3 Posterior surface of the cornea
4 Highest curvature of the cornea

Abb. 13-10: Meaning of the lines on the Scheimpflug image

➔ Press this button to get to the image selection.

➔ Press this button to display individual images.

Video function

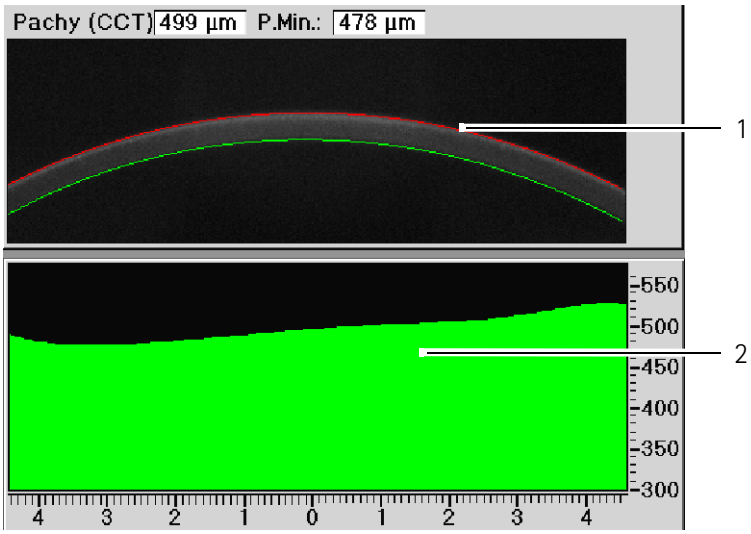
The video shows the total deformation of the cornea.

Video

➔ Press this button or the video image on the display to start the video.
➔ Touch the video image twice to stop the video.
➔ Turn the control knob to fast-forward or rewind the video.

Display R/L (8)

If the measurement mode "Pachy" is selected, this screen is displayed.



1 Scheimpflug image *2 Corneal thickness progression*
Abb. 13-11: Display "Corneal thickness"

➔ Press in the "Corneal thickness progression" field on the touch screen.
The device shows you the exact location of the cornea at the selected spot.
You can move the pointer to the left or to the right on the touch screen with the control knob.

Printing measurement results (9)

Print

➔ Press this button to print measurement results.

Note

The printer uses thermal paper. The readability of the thermal paper is reduced by ageing.

➔ Copy the prints to keep the measurement results safely.

14 Cleaning, Disinfection and Maintenance

This chapter describes how to clean, disinfect, and maintain the Corvis® STL.

Warning

Electrical Shock Hazard

➔ Unplug the power cord before cleaning the cabinet, disinfecting the device, or performing maintenance.

Note

Equipment damage due to moisture

➔ Make sure that no liquid can get into the Corvis® STL.

➔ Always pay attention to the product descriptions and instruction manuals of any materials or products that you use to care for, clean, and disinfect the device and/or its accessories.

14.1 Cleaning

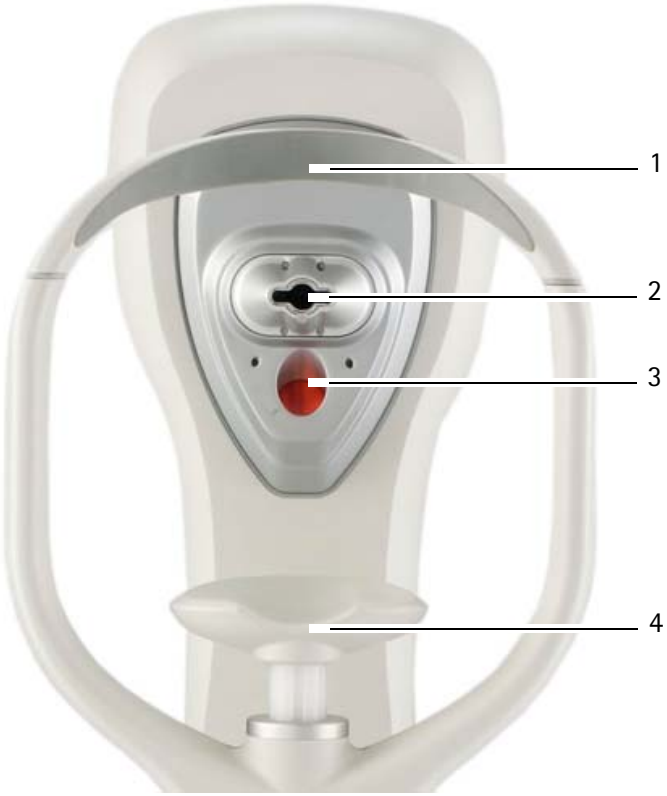
Precaution

➔ Do not clean the Corvis® STL with aggressive, chlorinated, abrasive or harsh cleansers.

Required materials:

- Cleaner for plastic surfaces with anti-static effect
- Cleaner for painted surfaces: Mixture of equal parts of alcohol and distilled water, possibly with a few drops of commercial detergent
- Soft cloth or lens brush
- Methanol or pure alcohol or lens cleaner
- Gauze moistened with rubbing alcohol
- Cotton swab
- Lens blower

14.1.1 Cleaning the Front Panel



1 Forehead rest
2 Air nozzle
3 Lens protection glass
4 Chin rest

Abb. 14-1: Cleaning lens protection glass and air nozzle

Cleaning forehead (1) and chin (4) rests

During the measuring process, sweat, cosmetics, etc. from the patient can get on the forehead and chin rest.

➔ Clean these parts before examining the next patient.

Before and after each measurement wipe off the forehead and chin rest with a clean cloth, for example, with gauze moistened with rubbing alcohol.

Precaution

Do not wipe more difficult spots repeatedly with a dry cloth. Instead moisten it with rubbing alcohol.

Cleaning lens protection glass (3)

The openings in the housing for the optics are covered by protective glass covers which must be kept dust and dirt-free.

➔ Clean the lens protection glass with a lint-free cloth moistened with alcohol.

Cleaning the air nozzle (2)

Warning

Risk of infection after examining a sick patient

If you perform a measurement on a sick patient, the air nozzle can be contaminated.

➔ Moisten a cotton swab with rubbing alcohol.

➔ Clean the nozzle with the cotton swab.

➔ Disinfect the device as needed, see *sec. 14.2, page 43*.

➔ Check the glass part of the air nozzle for dust, dirt, etc. from a diagonal angle.

➔ Blow off dust, foreign particles, etc. with a lens blower.

➔ Afterwards, carefully wipe the glass with a cotton swab which you have previously moistened with methanol or pure alcohol.

Note

Damage due to improper cleaning

➔ Carefully wipe the air nozzle and do not rub the surface.

➔ Make sure there are no foreign particles on the air nozzle when wiping it. Otherwise the glass could get scratched.

➔ Check the glass afterwards.

14.1.2 Cleaning the Housing

Wipe the forehead rest after each examination, and the housing as required.

- ➔ Turn the Corvis® STL off, *"Switching off the Corvis® STL" page 14*.
- ➔ Unplug the power cord.
- ➔ When cleaning, use a damp cloth and make sure that no liquid enters the Corvis® STL.
- ➔ Clean the lens in front of the camera using a dry, lint-free cloth.
- ➔ Clean the plastic surfaces and painted surfaces with the appropriate cleaning agents.

14.2 Disinfection

Required materials:

- Disinfection and Cleaning Kit (included),
  Alternatively: Pursept®-A Xpress disinfectant wipes,
  Merz+Co company
  D-60318 Frankfurt:
  Tel: +49 69 1503 1
  Fax: +49 (69) 596 21-50
  E-mail: merzpr@merz.de

➔ Turn the Corvis® STL off, *"Switching off the Corvis® STL" page 14*.

➔ Unplug the power cord.

1 Forehead rest *2 Front cover*

Abb. 14-2: Disinfect

➔ Disinfect the forehead rest (1) after each examination.

Warning

Risk of infection after examining a sick patient

If you perform a measurement on a sick patient, the forehead rest and the front cover can be contaminated.

➔ Disinfect the front cover (2) and the housing as required.

Note

Equipment damage due to disinfectant solution

The disinfectant solution may damage the finish if it is sprayed directly on the device.

➔ Only spray the disinfectant solution onto a cleaning cloth, not directly on the device

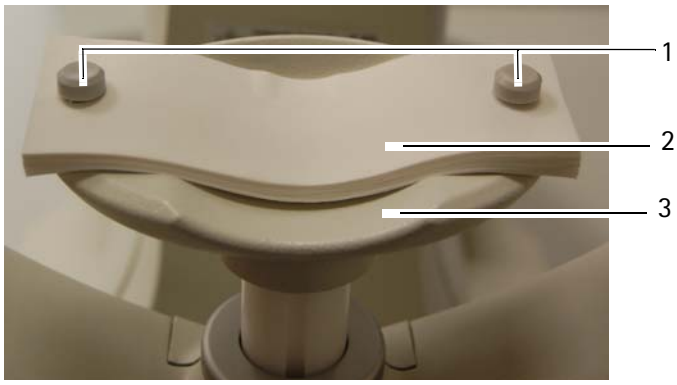
14.3 Maintenance

➔ You, as the operating company, must ensure that the device undergoes technical measurement testing every 2 years according to MPBtreibV, Appendix 2 Tonometer.

➔ To ensure that it functions correctly and safely we recommend the following: Have the Corvis® STL checked every two years by our service department or an authorized dealer.

14.4 Attaching Paper to the Chin Rest

If you want to attach new chin rest paper, follow these instructions:



1 Pins
2 Chin rest paper
3 Chin rest

Abb. 14-3: Attaching chin rest paper

➔ Pull the two pins (1) out of the chin rest.

➔ Put the chin rest paper (2) in such a way that the holes of the paper and the chin rest (3) are aligned.

➔ Insert the two pins (1) in the chin rest.

14.5 Inserting new Printing Paper Roll

➔ Open the cover including the display.

Abb. 14-4: Open the cover including the display

The following screen appears:

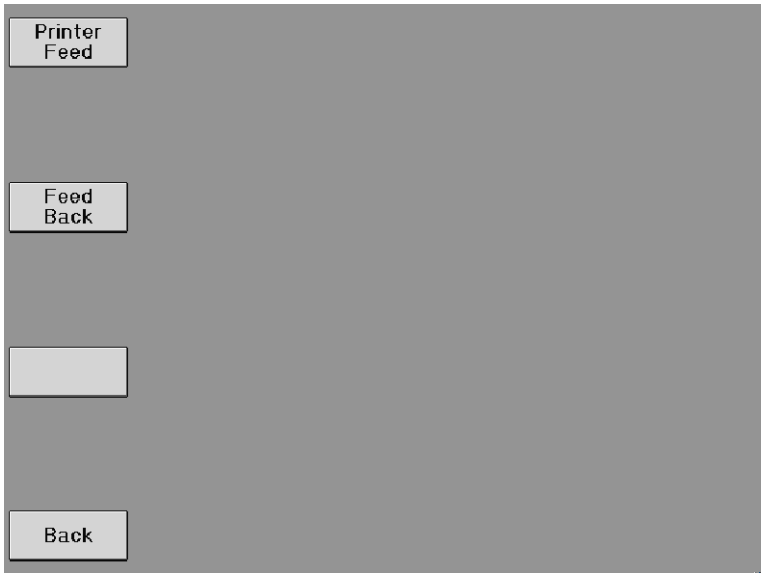


Abb. 14-5: Changing printer paper

You can advance and reverse the printer paper by pressing the buttons "Printer Feed" and "Feed Back" accordingly.

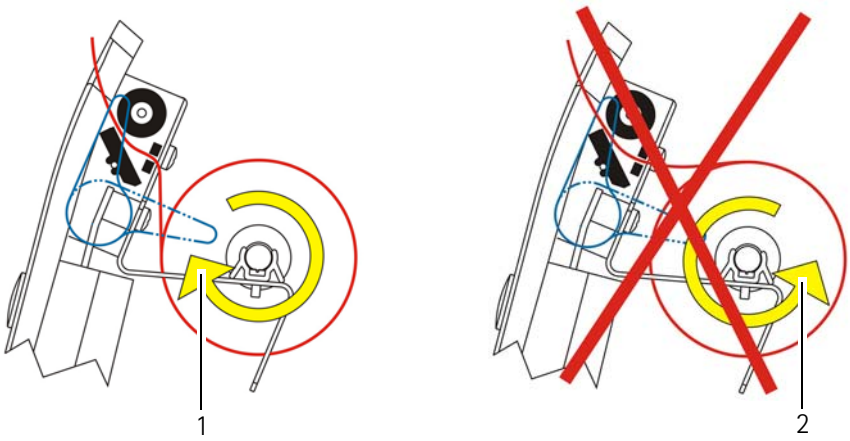
➔ Press "Feed Back" to reverse, or roll back the printer paper.

➔ Remove the feed roller from the holder and pull the metal pin out.

➔ Push the metal pin into a new printer roller and insert the printer roller into the holder.

➔ Slide the white paper through the slot from below.

➔ Make sure the paper (1) is correctly aligned.



1 Proper paper guide *2 Wrong paper guide*

Abb. 14-6: Inserting the paper

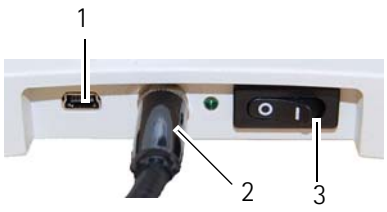
➔ Press the button "Printer Feed" so that the printer paper is pulled through the opening.

➔ Close the cover including the display, see *fig. 14-4, page 45*.

15 Dismantling, Transport and Storage

Before you transport or store the Corvis® STL you may have to dismantle it properly.

15.1 Removal



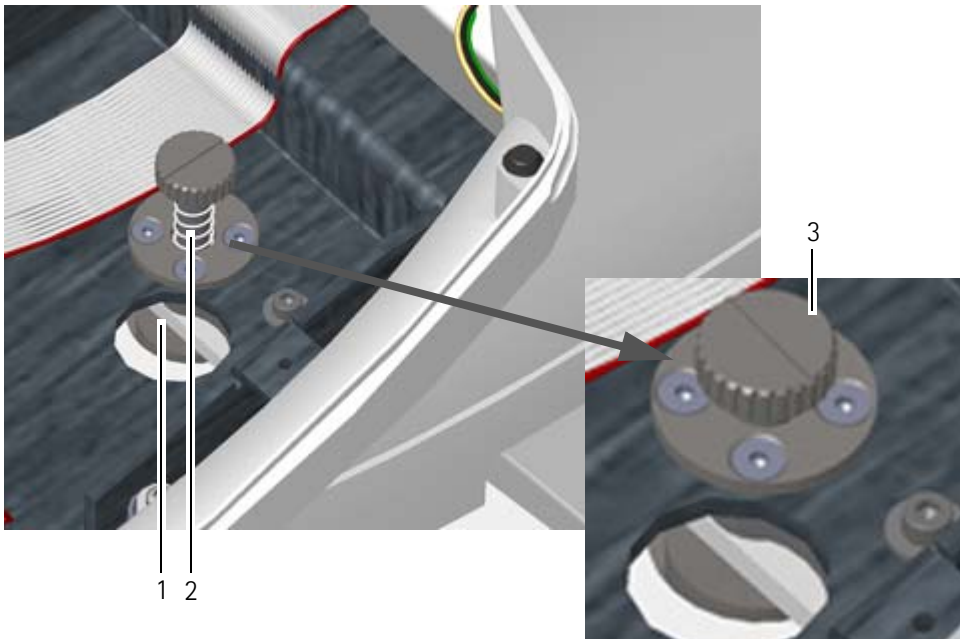
- ➔ Switch off the Corvis® STL with the On/Off Switch (3).
- ➔ Unplug the power cord.
- ➔ Unplug the power cord (2) of the device.
- ➔ If necessary, disconnect the USB cable from the USB port of the PC/ Laptop (1).
- ➔ Open the cover including the display.

Abb. 15-1: Opening the cover including the display

- ➔ Move the Corvis® STL over the opening (1) of the transport safety device in the adjusting base.

➔ Lock the transport safety device (2).

Press down gently the transport safety device and turn it counter-clockwise to the "unlocked" position (3). The transport safety device must be engaged.



1 Opening of the transport safety device
2 Spring
3 "Locked" position
Abb. 15-2: Transport safety device

➔ Close the cover including the display, see *fig. 15-1, page 47*.

15.2 Transport and Storage

The transport and storage conditions according to IEC 60601-1 with the appropriate packaging are valid for a period of up to 15 weeks, see *54*.

Note

Equipment damage due to incorrect lifting

If the Corvis® STL is lifted by the forehead rest, it can break off.

➔ Grab the Corvis® STL from below to lift it.

Equipment damage due to incorrect transport and improper storage

➔ Avoid bumps, shocks and contamination.

➔ Avoid high temperatures and humidity.

➔ Transport the Corvis® STL professionally.

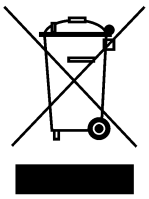
➔ Store the Corvis® STL according to the storage conditions, see *sec. 19, page 53*.

➔ Avoid placing near radiators and moisture.

➔ Check the Corvis® STL for damage every time it has been transported.

➔ Wait approx. 3-4 hours after transport before operating the Corvis® STL. Extreme temperature changes from cold areas to warm rooms can cause condensation on the optical components.

16 Disposal of Used Devices



In accordance with Directive 2002/96/EC of the European Parliament and the Council of 27 January 2003, and in accordance with German law governing the circulation, return and environmentally friendly disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste.

17 Troubleshooting

Warning

Dmage to persons or equipment due to incorrect troubleshooting

- ➔ Do not plug in or unplug any cables while the Corvis® STL is switched on.
- ➔ If an error occurs which you are unable to correct by following the instructions below, label the device as "out of order" and contact our service department or an authorized dealer.

Fault	Possible Cause	Help
No function when the On/Off switch is pressed	Corvis® STL not connected to the power supply.	➔ Plug power cord into the outlet or into the connector on the Corvis® STL.
	Power failure or power outlet is not active.	➔ Inform the in-house electrician. ➔ Check that the connector is plugged in properly.

18 Terms of Warranty and Servicing

Any software included in the delivery was tested by us and complies with technical standards. Note the following warranty provisions:

- Prior to and while operating the device it is important that you observe the instruction manual and safety instructions.
- The Corvis® STL carries a warranty to which you are entitled in accordance with the legal provisions.
- If any unauthorized persons interfere with the Corvis® STL, all warranty entitlements shall be void. Any inappropriate modifications or repairs can cause grave danger to the user and patient.
- Any entitlement to a warranty shall also be void if unauthorized persons interfere with the PC hardware and supplied software.
- Make transport damage claims to the shipping company during or immediately after delivery. Have the damage confirmed on the waybill, so that a proper claim settlement is possible.
- In general, the general terms and conditions of business and delivery apply as per the date of purchase.

18.1 Liability for Proper Function or Damages

OCULUS will only accept responsibility for the safety, reliability and serviceability of the Corvis® STL if the device is used in compliance with the following terms:

- Use the device in accordance with these instructions and the accompanying user manual.
- There are no user-serviceable parts either on or inside the Corvis® STL. OCULUS shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorized personnel; if the Corvis® STL is maintained improperly; or if it is handled incorrectly.

- If the work described above is carried out by persons authorized to do so, they must be required to supply a certification detailing the nature and scope of repairs, and, if applicable, to specify modifications to the rated data and area of work. The certificate must bear a date, a signature, specify who carried out the work, and contain company information.
- On request, and for this purpose, OCULUS will supply authorized persons with spare parts lists and additional descriptions.
- Make sure that only original OCULUS parts are used for service and maintenance.

18.2 Address of the Manufacturer and Service Department

Our service department or authorized representatives will furnish you with additional information. Address of the manufacturer and service department:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar, Germany
Tel.: 06412005-0
Fax: 06412005-255
E-mail: sales@oculus.de
www.oculus.de

USA:

OCULUS, Inc.
17721 59th Avenue NE
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WA 98223-1337
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Fax +1 425-670-0742
e-mail: sales@oculususa.com

http://www.oculususa.com

19 Technical Data

Measurement mode

IOP + pachymetry	
Tonometry	

Tonometer

Measuring range	6 to 60 mmHg
Working distance	11 mm

Scheimpflug camera

Frame Rate	4330 frames/s
Measuring range	8.5 mm/0.33 inch horizontal coverage
Pachymeter measuring range	200 to 1200µm
Measuring points	576 per image
Display resolution	576 x 480 pixels
Light source	blue LED (455 nm, UV-free)

Classification according to IEC 60601 – 1

Type of protection against electrical shock	Protection class 2
Level of protection against electrical shock	Type B
Protection level of the housing against intrusion of foreign objects and liquids	IP20

Operating conditions

Temperature	+10 °C to +40 °C
Humidity	30 % to 70 %
Air pressure	700 hPa to 1060 hPa

Transport and storage requirements (according to IEC 601 - 1)

Ambient temperature	-10 °C to +70 °C
Relative humidity, including condensation	10% to 70%
Air pressure	500 hPa to 1060 hPa

Electrical Specifications

Power supply	15 V DC; 6 A
Max. power consumption	26 W

Power adapter

Mean Well (05150285)	
AC input	80 - 264 V ~ 2.0 A 50 - 60 Hz
DC output	15 V 6 A max. 90 W

Other information

Dimensions H x W x D	19.5 - 20.5 x 10.7 x 20.5 inch (495 - 520 x 270 x 520 mm)
Weight	approx. 13.22 lbs (6 kg)
Printer	Thermal printer
Display	TFT - LCD approx. 150 mm
CE marking	CE 0123
Contraindications	none noted
Lifecycle expectancy	up to 10 years

20 Appendix

20.1 Electromagnetic Compatibility

Medical electrical equipment is subject to special precautionary requirements with respect to EMC, and must be installed and operated according to the EMC-Instructions contained in the accompanying paperwork.

No special measures need be observed in respect of OCULUS devices and systems.

Portable and mobile RF-communications devices can interfere with electrically operated medical devices.

Minimal performance quality and essential performance criteria

- A slightly disturbance of the analog camera of the Corvis® STL (slightly image noise on screen) during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short flicker of the illumination of the Corvis® STL during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short interruption of the USB connection during the examination is permissible because it will not affect the diagnosis, treatment and observation.

Warning

The use of accessories, transducers and cables not specified by OCULUS (for example as replacement parts) may result in increased emissions or decreased immunity of the Corvis® STL.

➔ Use only the original accessories, transducers and cables specified by OCULUS.

The use of accessories, transducers and cables specified by OCULUS with devices other then the Corvis® STL may result in increased emissions or decreased immunity of the other device.

➔ Do not use the accessories, transducers and cables specified by OCULUS with devices other then the Corvis® STL.

To be in compliance with the requirements of the IEC 60601-1-2 the following types of equipment, accessories, power adapters and cables must be used.

Order number	Description	
72300	Corvis® STL	
05200905	Cable with plug, EU standard	1.8 m
05200910	Cable with plug, US standard	1.8 m
05200915	Cable with plug, GB standard	1.8 m
05200920	Cable with plug, AU standard	1.8 m
05150285	Power Supply MeanWell	Input 80-264 VAC Output 15 V / 6 A

20.2 Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions and Immunity for the Corvis® STL

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2, 5.2.2.1, table 1		
The OCULUS Corvis® STL is intended for operation in the electromagnetic environment specified below. The user of the Corvis® STL should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Corvis® STL uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF-emissions CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer´s declaration electromagentic immunity, IEC 60601-1-2, 5.2.2.1, table 2

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV kine(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40 % U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 s	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40 % U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Corvis® STL requires continued operation during power mains interruptions, it is recommended that the Corvis® STL be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration electromagentic immunity,
IEC 60601-1-2, 5.2.2.2, table 4

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of Corvis® STL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 Mhz	V_{rms}= 3 V	$d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E = 3 V/m	$d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interface may occur in the vicinity of equipment marked with the following symbol: 

Note 1:	At 80 Hz and 800 MHz, the higher frequency range applies.
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Corvis® STL is used exceeds the applicable RF compliance level above, the Corvis® STL should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Corvis® STL.

b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Corvis® STL, IEC 60601-1-2, 5.2.2.2, table 6

The Corvis® STL in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Corvis® STL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Corvis® STL as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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