OCULUS Corvis® ST

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® ST 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® ST.

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

If you have any questions or wish to obtain further information on your device, please contact us by phone, email or fax. Our service team is pleased to 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.

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1 Scope of Delivery

Component	Order number
■ Corvis® ST	72100
Corvis® ST package with laptop en	72200
■ Dust protection cover	026010005001
■ Paper for chin rest	65313
■ Paper roll (3 rolls)	65311
■ USB cable	05200601
■ USB FS MED Isolator	015692000010
■ Power supply GSM90B15-P1M	05150285
■ Instruction Manual	G/72100/XXXX/EN 1019 Rev01
■ User Guide	BH/72100/EN...
■ Software Installation	SI/50000...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 bill of lading, 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 Symbols

Symbols on device				Symbols packaging	
	Manufacturer		Protection class		Keep dry
CE 0123	Conformité européenne	IP XX	Type of protection		This way up
	Follow instruction for use	REF	Article number		Fragile
	Disposal in household trash is prohibited	SN	Serial number	Transport	Limit of temperature for transport
	Applied part Type B		Caution	Lagerung	Limit of temperature for storage
		US-Pat	US patent number		Limit of humidity
(21) ABCDEFG123456789 Matrix (01) 04049584000040	Example: UDI number, consisting UDI-DI (Device-Identification) UDI-PI (Product Identifier) machine-readable matrix code				Limit of air pressure

Fig. 2-1: Type plate (example)

Fig. 2-2: Type plate: measure head

Symbols power supply					
	Indoor use only		Conform to US and Canadian standards		Meets German safety requirements
	Notified body		Nemkos symbol		
	Recycling Code		Polarity of DC connector		

There are no temporarily fixed markings on the device.

3 Structure of the Documentation

A folder containing documentation is supplied with your Corvis® ST:

- **Instruction Manual:** The design of the unit is described in detail in this document. The instruction manual also gives you general information about working with the Patient Data Management system and all safety-related instructions for use of the Corvis® ST.

Attention

All safety-related instructions for use of the Corvis® ST are given in the Instruction Manual for the unit. It is imperative that you read and understand the whole Instruction Manual before you use the Corvis® ST.

- **User Guide:** All features of the examination and analysis software are described in the User Guide, along with detailed information about the Patient Data Management system.
- **Software Installation:** The introduction to the Software Installation describes how to install the Corvis® ST software and the associated drivers.

4 Safety Instructions

4.1 About this Manual

➔ Read the instruction manuals 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 unit: from version 2.0.2007
- measure head: from ersion 2.0.2013

The following software versions are used:

- Corvis® ST program: from version 1.6r2015
- Patient Data Management: from version 6.09

4.1.1 Graphic symbols used

Warning

Identifies a potentially dangerous situation which may cause serious bodily injuries.

Attention

Identifies a potentially dangerous situation which may cause minor injury or damage to property.

Note

Instructions for use, and useful or important information.

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

4.2 Safety Instructions for Use

Attention

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 the operators

➔ Make sure that the Corvis® ST is used only by clinical persons or eye spacialists

- 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.

Transport and Storage Instructions

Refer to the notes in *sec. 16, page 62*.

Information for set-up and connection

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

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

➔ Germany: Only operate the Corvis® ST in rooms used for medical purposes if VDE 0107 installation procedures have been observed.

➔ 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.

➔ Only use a power cord which meets the requirements of the standards IEC 60227-1, Type H03VVH2-F, min. 0,75 m² and IEC 60320-1, Type C7.

➔ Set up the Corvis® ST so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

- ➔ 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, let our service personnel repair the defect.
- ➔ Establish an USB connection only with the OCULUS USB FS MEDIsolator (Nr. 01 56920 00 010).
- ➔ Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.
- ➔ Do not use the Corvis® ST with wireless technology, for example with wireless USB.
- ➔ **Data responsibility:** The device itself is not designed to connect with the internet, but only with a PC. It does not require the internet to function.

  Do not connect with the internet while using the device. It is considered misuse.

  If you elect to connect the PC to the internet for other purposes you are responsible for ensuring data security.

Patient environment information

Patient environment is the area where patients can come into contact with any part of a medical electrical equipment (ME equipment) or with another person being in contact with the ME equipment.

In the patient environment, use devices that conform to IEC 60601-1. If a multiple power socket is to be used, or if a device is to be used that does not meet the IEC 60601-1 standard, use an isolating transformer.

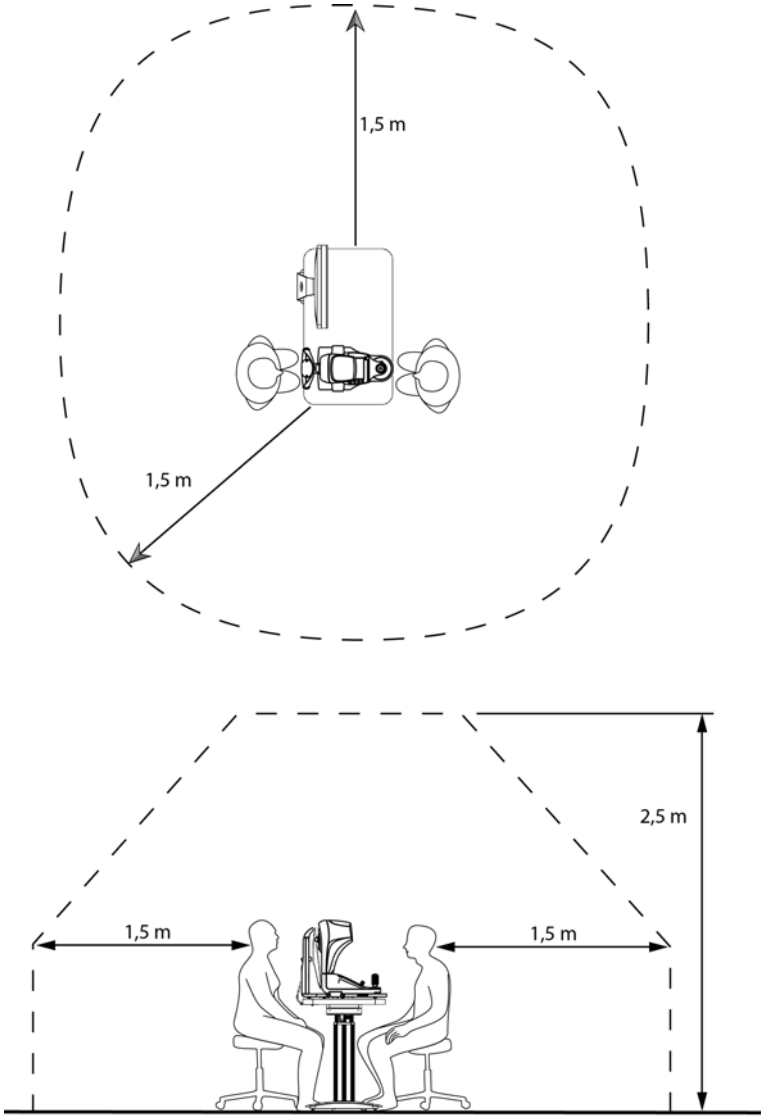


Abb. 4-1: Patient environment

Information about the operation of an ME system

The Corvis® ST and a connected computer form a medical electrical system (ME system) according to DIN EN 60601-1. If you connect additional devices, such as, for example a printer, those devices become part of the ME system.

➔ Make sure that all devices of the ME system meet the requirements of IEC 60601-1 or IEC 60950-1.

➔ Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.

Information about operation

- ➔ Never put a damaged Corvis® ST into operation.
- ➔ Only operate the Corvis® ST 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® ST.
- ➔ Only operate the device if you have understood the instruction manuals.
- ➔ Do not put the Corvis® ST, including the rechargeable battery or cable, down onto devices that produce heat, heaters (e.g. radiators) microwaves or similar.
- ➔ Do not put any heavy objects onto the unit or the cables.

Information for Maintenance

- ➔ Germany: The operating company must ensure that the device undergoes technical measurement testing every 2 years according to MPBtreibV, Appendix 2 Tonometer.
- ➔ Only authorized persons are allowed to perform the software updates.

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

- ➔ Have the Corvis® ST 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® ST as "out of order" and contact our service department or an authorized dealer.

Information for removal and disposal

- ➔ When you disconnect electrical connections, pull on the respective connectors, not the cord.
- ➔ Dispose of the device according to legal regulations.

Instructions on Electrical Safety

Attention

Risk of personal injury or damage to property due to an incorrect level of safety

Connecting the Corvis® ST with its non-medical electrical equipment (e.g. data processing equipment) to a medical electrical system must not result in a patient safety level below that prescribed by DIN EN ISO 60601-1. If making this 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 power adapter listed in the packing list.
- ➔ Establish an USB connection only with the OCULUS USB FS MEDIsolator (Nr. 01 56920 00 010).
- ➔ Use only a computer that meets the specifications given in this instruction manual, *sec. 20, page 67*.
- ➔ Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.

Attention

Use of a multiple socket extension cord

Risk of personal injury or material damage caused by unsafe multiple socket extension cord

If you use a multiple socket extension cord to connect the Corvis® ST to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of DIN EN ISO 60601-1: 20005, section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Corvis® ST and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

If you are using a multiple socket extension chord it has to be supplied with a isolation transformer.

If you are using a new computer for the Corvis® ST, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Electromagnetic Compatibility (EMC) / Cables

Risk of personal injury or damage to property due to electromagnetic interference

Portable and mobile RF communications equipment can affect medical electrical equipment *sec. 21, page 69*.

- ➔ Make sure that portable and mobile RF communications equipment do not cause interference.
- ➔ Recommendation: Maintain a minimum distance of 4 m. If the distance is shorter, you must ensure that the Corvis® ST functions correctly.

Cybersecurity

Precaution

Do not use the Corvis® ST with wireless technology, for example with wireless USB

To ensure cyber security in order to the usage of the device, the following security measures should be considered. Contact your computer administrator:

Precautions for access control of the computer

- ➔ Secure the computer with a password (for example at Windows start up).
- ➔ Choose a complex password: A good password should be at least eight characters long and are not in the dictionary. In addition to letters, it should also include numbers and special characters.
- ➔ Do not choose a name or device name for a password (for example "Corvis").
- ➔ Change the password regularly.
- ➔ Do not note the password in an accessible location.
- ➔ Use different passwords for different users.
- ➔ Enable the screen saver and use the option for the necessity of re-entering the password when exit the screen saver.
- ➔ Choose an adequate time setting for starting the screen saver if software session is inactive (e.g. 10 minutes). Adequate time setting should consider duration of examination, number of patients, time between examinations, use of other devices in the examination room, several user, etc.
- ➔ Lock the computer if you are leaving the workstation (shortcut: 'windows logo key' + 'L').

Precautions if the computer is connected to a LAN or internet network

- ➔ Prefer wired connections of the computer to the network.
- ➔ If you are using Wi-Fi connections nevertheless, please ensure the usage of adequate security methods (for example WPA2/AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- ➔ The usage of a firewall (software or hardware) is recommended.

Recommendation: Use anti-malware tools with up to date malware definitions.

Note

Also observe the regulations, notes and recommendations of the *Bundesamt für Sicherheit in der Informationstechnik* for the protection of critical infrastructures.

5 Indications for Use

The Corvis® ST is intended to measure intraocular pressure of the eye and to photograph the eye and take Scheimpflug images of the anterior segment of the eye to evaluate the thickness of the cornea.

The Corvis® ST is designed for hospitals and eye care professionals. The device may only be used in environments that are intended for eye examinations.

6 Contraindications

None known.

7 Warnings

The Corvis® ST is an automatic non-contact Tonometer with the additional function of pachymetry which is a non-contact pachymeter.

The automatic non-contact tonometer function is the center of application while the additional Pachymetry function give 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.

Furthermore if some unusual intraocular pressure values are preset, further examinations with devices like the Goldman Tonometer might be necessary.

8 Transport to Installation Location

The transport and storage conditions see *sec. 16, page 62*.

➔ Wait approx. 3-4 hours after transport before operating the Corvis® ST. 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® ST professionally.

➔ Store the Corvis® ST 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.

9 Device Description

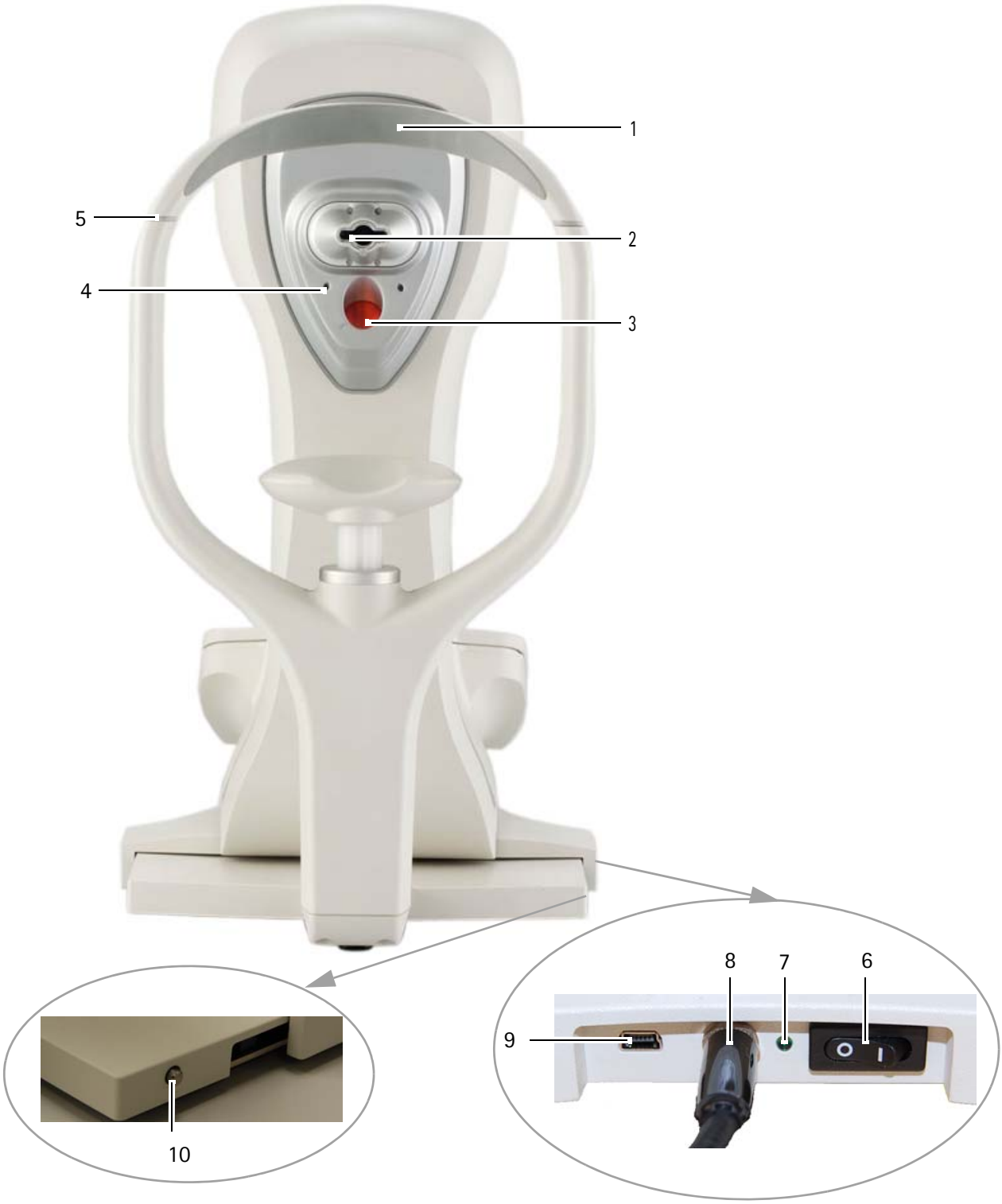
9.1 Overview of Device Components

Side – view

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

Abb. 9-1: Corvis® ST: Side view

Front - view



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

Abb. 9-2: Corvis® ST: Front view and connections

9.2 Mode of Operation of the Corvis® ST

The Corvis® ST is a non-contact tonometer equipped with an optical Pachymetry function.

The Corvis® ST measures intraocular pressure without contact with the eye by applying an air puff to the eye. During the air puff the eye gets illuminated by 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.

Intra ocular 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 into the area of applanated surface.

The device increases the air pressure puffed onto the 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 light 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 the slit light such that the sectional plane appears as if it were self-luminous.

This is captured at an angle of 45° through the pupil by a camera, 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 cornea plane onto the image plane of the camera (Scheimpflug image).

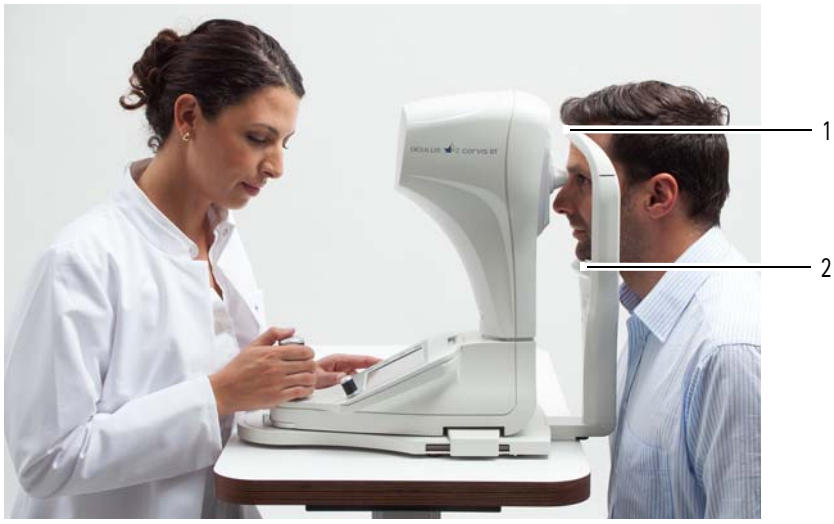
Due to this arrangement, sharp sectional images of the cornea can be obtained.

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

Corneal thickness and shape are obtained from images when the Cornea is not influenced by the air puff.

Tonometry and Pachymetry are measured at the same measurement process.

Applied parts



1 Head rest
2 Chin rest
Abb. 9-3: Applied parts

10 Start-up

Before you can operate the Corvis® ST for the first time, you must follow the instructions as per *sec. 10.1, page 17*.

If you want to put the Corvis® ST into operation after an in-house transport, follow the instructions as per *sec. 10.3, page 18*.

10.1 Initial Start-up

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

- set it up and adjust it
- get trained

Attention

Incorrect measurements / equipment damage due to a lack training

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

Incorrect measurements / equipment damage due to incorrect set-up

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

Note

➔ Do not expose the Corvis® ST to any vibrations, shocks, contaminants, moisture, or high temperatures.

➔ Handle the optical device with care.

10.2 Set-up Jobs for Initial Start-Up

➔ Wait approx. 3-4 hours after transport before operating the Corvis® ST. If the Corvis® ST 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® ST.

➔ Check if the transportation safety device is unlocked, *sec. 10.3.2, page 18*.

10.3 Adjustments after an in-house transport

Note

Equipment damage due to incorrect lifting

If the Corvis® ST is lifted only by the measure head, it can break off.

➔ Grab the Corvis® ST from below and the head rest to lift it.

10.3.1 Device set-up

➔ Place the Corvis® ST on a level surface.

➔ Place the Corvis® ST so that no direct light can effect the measurement.

➔ Avoid shocks and vibration.

➔ Avoid contamination, high temperatures and humidity.

10.3.2 Unlock transport safety device

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

➔ Open the cover with the display.

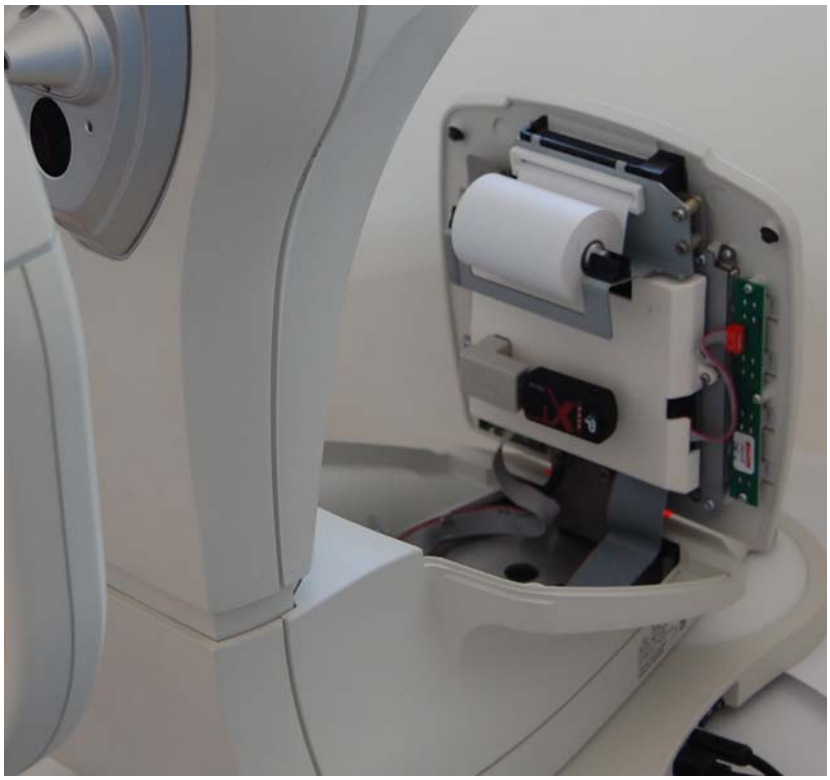
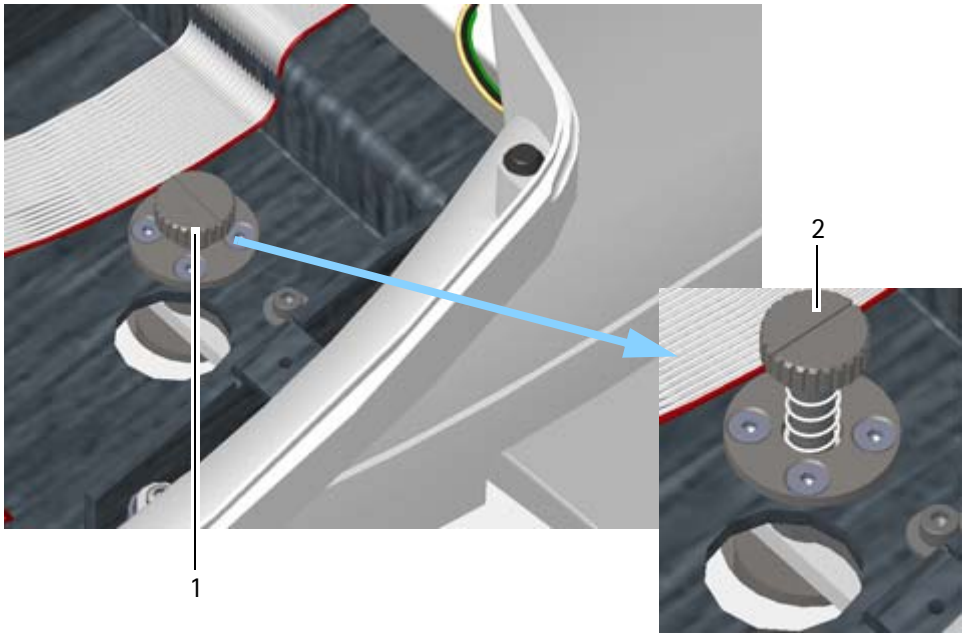


Abb. 10-1: Open the cover with the display

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



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

Abb. 10-2: Unlock transport safety device

➔ Press down gently on 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 with the display, *fig. 10-1, page 18*.

10.4 Electrical Connection

Warning

Electrical safety hazard

➔ Do not use the Corvis® ST adjacent to or stacked with other equipment.

➔ If you have to use the Corvis® ST adjacent to or stacked with other equipment, verify the correct operation of the Corvis® ST.

➔ Only use the power adapter listed in the list.

➔ Only use a power cord which meets the requirements of IEC 60227-1, type H03V VH2-F, minimum 0,75 m² and IEC 60320-1, type C7.

➔ If you use a power strip to connect the Corvis® ST: Use a power strip that complies with the requirements of DIN EN 60601-1.

➔ Do not place the multiple socket extension cord on the floor.

➔ Do not use more than one multiple socket extension cord.

➔ Plug only the Corvis® ST and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

Note

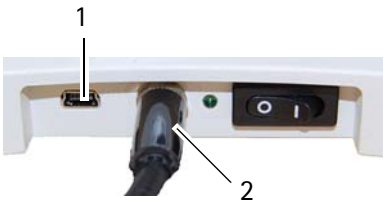
Risk of equipment damage due to incorrect connection

If you do not connect the Corvis® ST properly, and the connection is live, the unit can be damaged within a short period of time.

➔ Do not use excessive force when connecting the electrical plug.

➔ Pay attention to the specifications on the nameplate.

If the electrical plug is damaged, contact our service department or an authorized dealer to repair the damage.



➔ Connect the unit to the power supply with the power cable provided (2).

➔ If desired, connect the device to your computer/laptop using the USB port (1), with a USB cable with an USB FS MED Isolator.

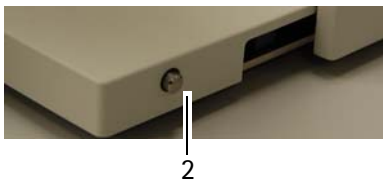
10.5 Daily operation

10.5.1 Switching on the Corvis® ST

➔ Make sure that the mains voltage is the same as the voltage specified on the rating plate.

➔ Switch on the Corvis® ST with the On/Off Switch (1).

10.5.2 Setting the Safety Stop



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

You can independently determine the position of the stop.

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

➔ Move the Corvis® ST into the desired position.

➔ Release the safety stop (2).

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

Attention

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.

10.5.3 Adjust the break

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

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

10.5.4 Switching off the Corvis® ST

➔ End the current session.

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

Attention

Risk of electric shock if the Corvis® ST is not completely disconnected from the mains for transport, cleaning, maintenance, disinfection and repair.

➔ Turn the Corvis® ST off, *sec. 10.5, page 21*.

➔ Pull the power plug before cleaning. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

11 Preparing a measurement

In order to transfer data from the device to your computer/laptop you have to install the following software on your computer:

- the Corvis® ST program
- the USB connection must be enabled in the „Settings 2: USB Transfer" of the Corvis® ST device.
- the Patient Data Management software

For more information see the *User Guide*.

11.1 Using the control unit

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. 11-1: Functions of the control unit

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 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 35*.
Joystick button (4)	Starts the measurement manually (if the eye-tracking function is turned off)	➔ Press the button.
Buttons (5)	Enables the adjacent button field, depending on the associated screen	➔ Press the desired button.

If you do not work with a PC/laptop/netbook, enter the patient data via the control panel and manage the data there. You can also initiate the measurements and view the measuring results there, see *sec. 14, page 48*.

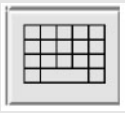
11.2 Display with Touch Screen

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

You can start the measurement and edit the patient and examination data via the computer's patient data management. This constellation is described below.

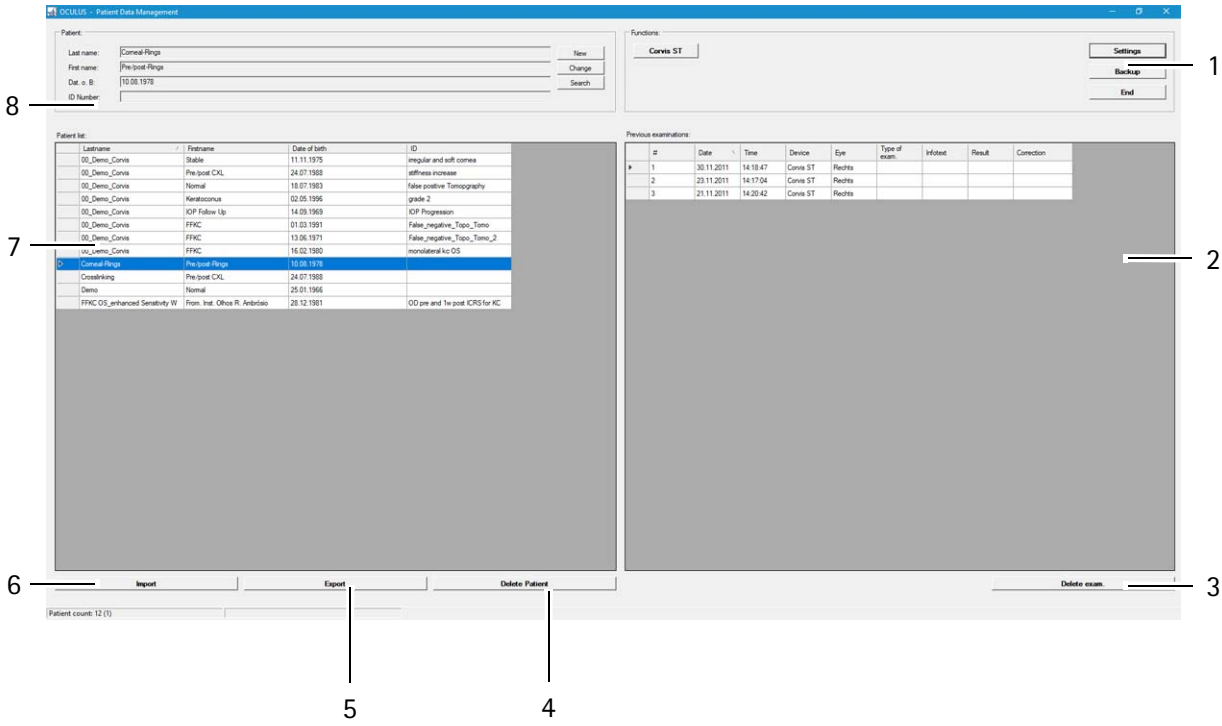
If you work without a computer/laptop, you can perform the measurement at the Corvis® ST unit itself and can save the patient and examination data; see *sec. 14, page 48*.

11.3 Start Patient Data Management

After you have switched on the computer, it first loads the operating system. Depending on the setting, the Patient Data Management opens automatically.

➔ If necessary, press the Corvis® ST icon:  .

The Patient Data Management user interface appears



1 *"Functions" group box*
2 *Previous examinations*
3 *[Delete exam.] button*
4 *[Delete Patient] button*
5 *[Export] button*
6 *[Import] button*
7 *Patient list*
8 *"Patient" group box*

Abb. 11-2: Patient Data Management User Interface

If the Windows desktop appears, you have to start the Patient Data Management from there.

11.4 Importing patient data

You can import patient data from a USB flash drive, see *sec. 14.5.2, page 53*.

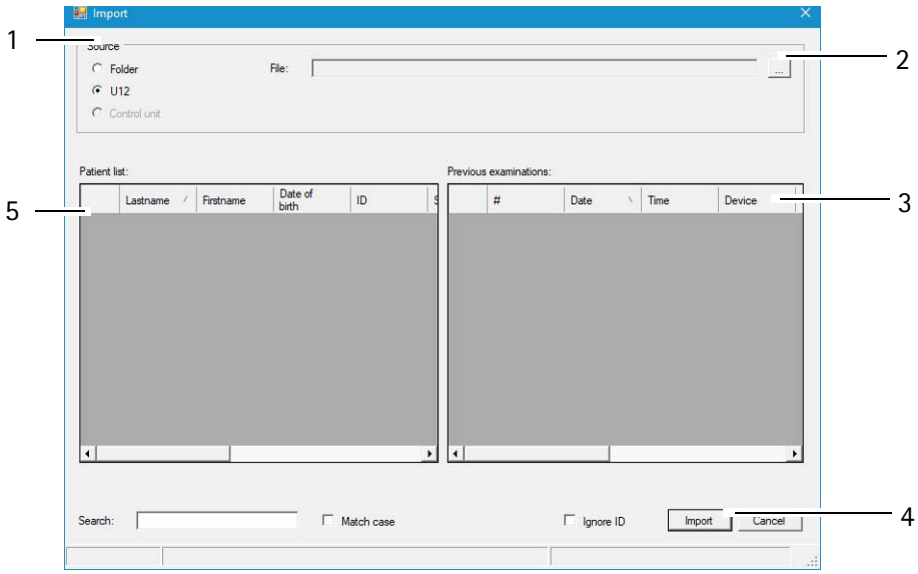
Note

Loss of data due to computer viruses

Computer viruses can cause loss of data.

➔ Run a virus check before importing data from the USB flash drive.

➔ Press the button [Import]. The following dialog appears:



1 Select the source of the data
2 [...] button
3 Previous examinations
4 [Import] button
5 Patient list

Abb. 11-3: "Import" dialog

The options for import and export of data are set as defaults in the "settings" field, see *User guide*.

➔ Depending on the settings you may not have to perform all of the following steps (e.g. selection of the directory).

➔ Select the option (1) which contains the source data ("Folder" or "Single file (U12)").

Recommendation: Import the patient data with the option "Folder".

➔ Press the [...] button. (2)

➔ In the dialog box, select the directory or the file where the patient data is located: .DAT and .BMP.

➔ Confirm your selection with [OK] or [Save].

The patients that are located and the associated examinations are displayed in the lower part of the dialog.

➔ To import the data, press the [Import] button (4).

The data will then be available in the Patient Data Management software.

11.4.1 Enter a new patient

You can only start a measurement from the computer/laptop if you have entered a patient in the patient data management.

If you start the measurement from the computer software, the patient data are transmitted (via USB cable) to the Corvis® ST and are saved there.

After the measurement with the Corvis® ST has been completed, the examination data for the patient in question are automatically saved to the computer/laptop.

Manually enter a new patient

You can also manually enter a new patient.

➔ Press the [New] button to enter a new patient in the Patient Data Management software.

➔ Enter the patient's full last name, first name and date of birth in the patient window.

Abb. 11-4: Entering patients

Optionally you can enter an ID number for the patient.

➔ To save the data you entered, click [Save].

The patient you have just entered now appears in the patient list.

11.4.2 Select an existing patient

The patient list on the left-hand side of the screen displays all previously examined patients in alphabetical order.

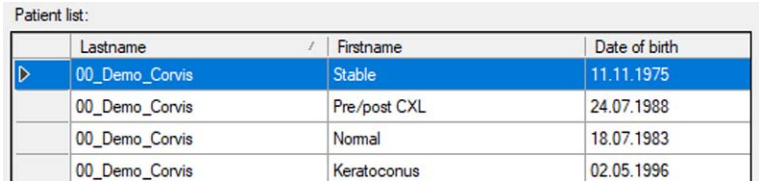


Abb. 11-5: Patient list

➔ Press the [Search] button to quickly find the patient you require in the list.

➔ Enter the patient's name or the first letter of the name in the "Last name" field.

Optionally, you can search through the patient's ID number, first name or date of birth, if it was assigned when you first entered the patient.

➔ Click the appropriate entry in the list to transfer that patient's name to the patient window. This also brings up a list of any previous examinations for that patient in the examination window (bottom right side).

Extended patient search: [Extended] checkbox

➔ Click on the Checkbox [Extended].

The screen displays additional search parameters which, for example, reference previous examinations. Proceed as you did when entering the patient name.

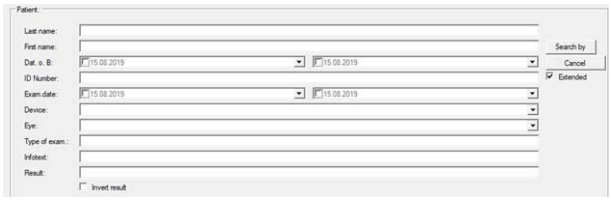


Abb. 11-6: Advanced search

12 Perform a Measurement

Perform a measurement for each eye before you save the data. To perform a measurement, you must

- Start the Corvis® ST program at the computer, *sec. 12.1, page 31*
- Adjust the Corvis® ST, *sec. 12.2, page 32*
- Start the measurement, *sec. 12.3, page 37*
- Perform a second measurement,*sec. 14.3, page 52*
- Save the data, *sec. 12.5, page 38*
- Complete the measurement, *sec. 12.6, page 39*

You can use the patient data management, *sec. 12.7, page 40*

12.1 Start the Corvis® ST Program at the Computer

➔ Select a patient´s name.

➔ Press the [Corvis® ST] button to start the Corvis® ST program.

Abb. 12-1: Start Corvis® ST program

Condition: Autostart must be activated in the Corvis® ST software settings. See *User Guide*.

12.2 Adjusting the Corvis® ST

Before starting a measurement, adjust the Corvis® ST.

Attention

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

➔ Before starting a measurement, make sure the safety stop is set correctly, *sec. 10.5.2, page 21*. This prevents the air nozzle from touching the patient's eye.

Danger of pinching to hands or body parts

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

Note

Incorrect measurements from a dirty air nozzle

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

➔ If necessary, clean the air nozzle *"Clean the air nozzle (2)" page 57*.

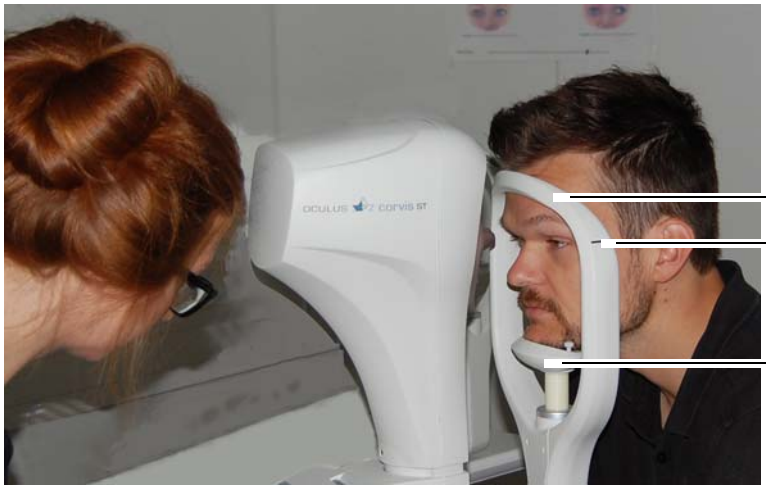
12.2.1 Rough Adjustment

➔ Check that

- fresh paper has been put onto the chin rest or that the chin rest has been cleaned.
- that the head rest has been cleaned and disinfect the head rest after each examination, *sec. 15, page 55*.

➔ Do not touch the Corvis® ST (including accessories) and the patient simultaneously.

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



1 Head rest
2 Mark eye height
3 Chinrest

Abb. 12-2: Position patient according to the markings

The eye height marking (2) between the chin rest and the headrest should be located roughly at the centerline of the patient's eye.

Attention

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® ST, move it carefully toward the patient's eye.

➔ If necessary, set the safety stop again, see *sec. 10.5.2, page 21*.

➔ If necessary, adjust the height of the chin rest with the buttons.
In addition, you can also adjust the height of the measure head by turning the joystick:
Turn it clockwise to move the measure head upwards.
Turn it counter-clockwise to move it downwards, see *sec. 12.2.2, page 35*.

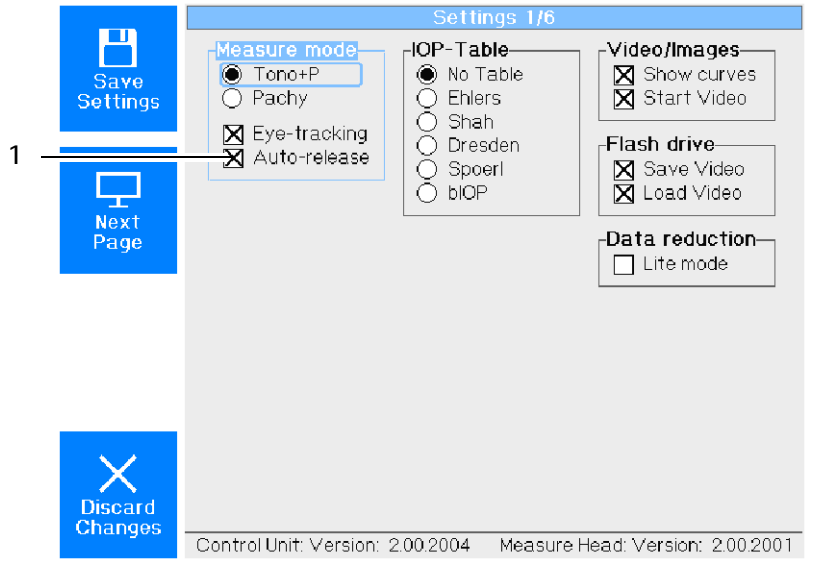
➔ To prepare the patient prior to the measurement:
Explain to the patient what will happen next to help him/her relax:
"A little air will be blown into your eye. Don't let it scare you. Please be patient and relax for a moment."

➔ 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.

The auto-tracking function automatically looks for the trigger position.



1 Auto-tracking is activated

Abb. 12-3: Settings 1

➔ Proceed as described in *sec. 12.3, page 37*.

If the auto-tracking function is deactivated, you must make a fine adjustment, *sec. 12.2.2, page 35*.

12.2.2 Fine Adjustment

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

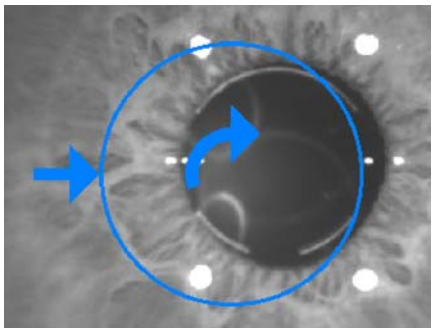


Abb. 12-4: Fine Adjustment

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

Arrow	Camera movement	Joystick movement[aa]
→	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.

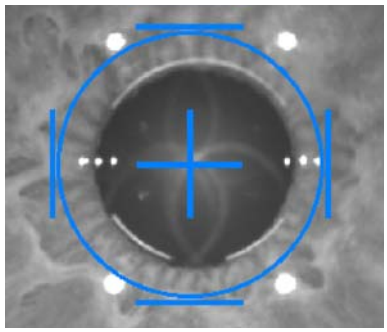
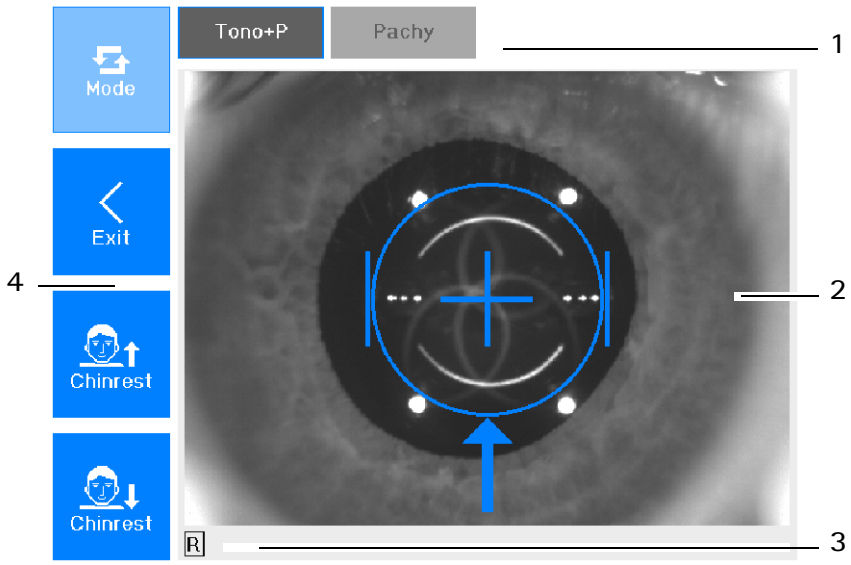


Abb. 12-5: Final position reached

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



1 Display measuringmode
2 Camera image
3 Examinated eye
4 Buttons

Abb. 12-6: Measurement procedure

Element	Function
Displaying mode(1)	Information about the displaying mode, automatically active
Camera image (2)	Camera image of the patient´s eye
Examinated eye (3)	The examinated eye is displayed: left (L) or right (R)
Button (4)	
	Measure mode, automatically enabled
	Back to Patient Data Management
 	Adjust height

12.3 Triggering the measurement

A measurement is performed for each eye. The measurement results are then transmitted to the computer/laptop.

Depending on what has been preset *(see User Guide)*, the measurement is now either triggered automatically or you must trigger the measurement manually.

Automatic measurement

When the triggering position has been reached *(fig. 12-5, page 35)*, the Corvis® ST automatically triggers the measurement.

Manual measurement

➔ Trigger the measurement manually by pressing the joystick button *(fig. 11-1, page 23, Item 4)*.

12.4 Perform a second measurement

➔ Position the patient so that his other eye is in front of the Corvis® ST.

Depending on what has been preset, the measurement is now either triggered automatically or you must trigger the measurement manually.

After the Measurements

➔ Press the „Finish" button.

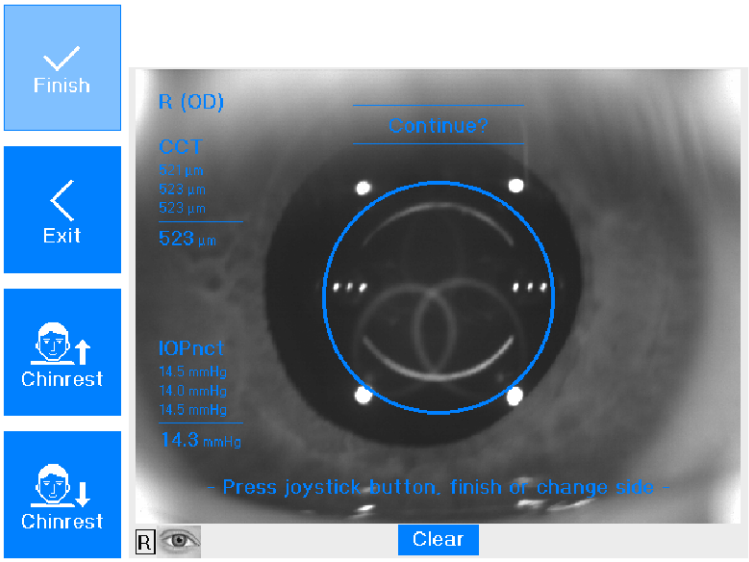


Fig. 12-7: End examination

The measurements are calculated.

You must wait for this process to end before you can save the measurement results *(3sec. 12.5, page 38)* or display the measurement results on the computer *(sec. 13, page 44)*. The IOD and pachymetry values are displayed in advance on the device.

12.5 Saving data

Depending on the installation, your data is transferred to a computer or laptop. You can use the patient data management for your data, *sec. 14, page 48*.

Note

Loss of data due to interrupted save

If you turn off the Corvis® ST 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.

If you have entered the patient data at the Corvis® ST unit itself, the measurement is not automatically saved to a file. You can use a USB stick for this purpose, *sec. 14.5.2, page 53*.

You can set the data transfer speed from the Corvis® ST to the computer/ laptop in the device settings *(see User Guide)*.

12.6 Complete measurement

With the Corvis® ST program

With this menu item, you can select other patients, or can exit the Corvis® ST program. You then return to the patient data management..

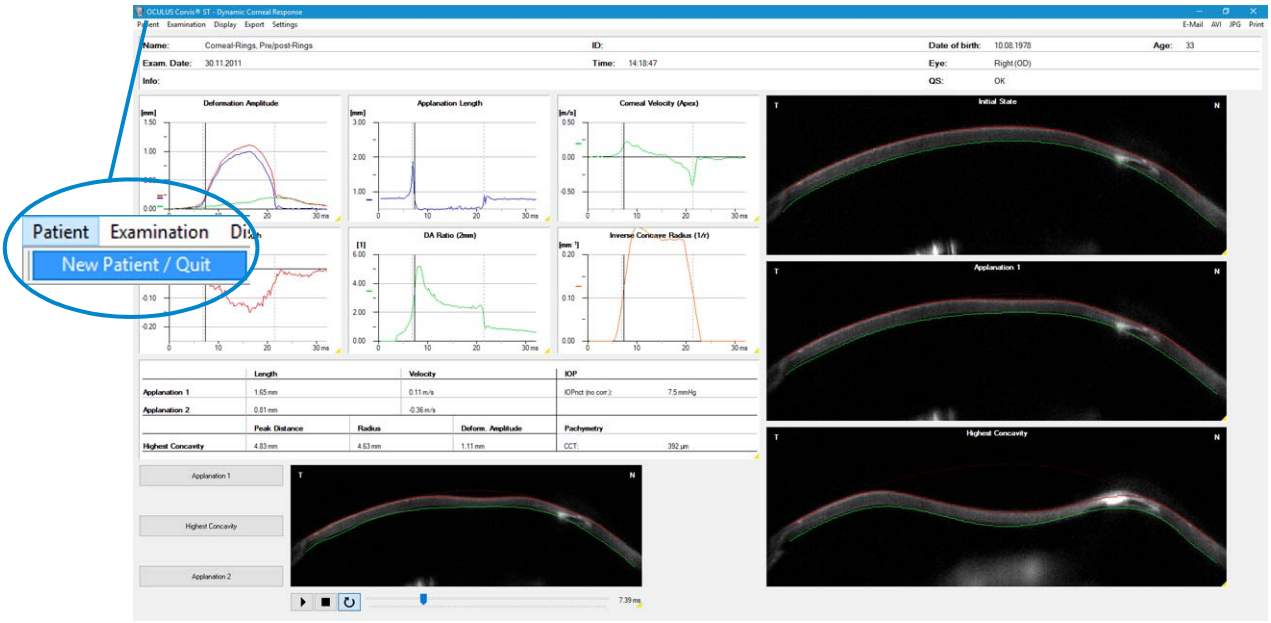


Fig. 12-8: Completing a measurment

➔ Press the [New Patient / Quit] button.

At the Corvis® ST device

➔ After each patient remove one of the paper sheets from the chin rest. See also *sec. 15.4, page 59*.

➔ Disinfect the head rest and, if neccessary, the chin rest after each patient, *sec. 15.2, page 58*.

Attention

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 *"Clean the air nozzle (2)" page 57*.

➔ Disinfect the front cover *sec. 15.2, page 58*.

12.7 Using Patient Data Management

When you have completed an examination, you can continue processing the patient data in Patient Data Management

You can do the following to the patient data

- rename, *sec. 12.7.1, page 40*
- export, *sec. 12.7.2, page 40*
- save, *sec. 12.7.3, page 41*

You can also change the Patient Data Management settings, *User guide*.

12.7.1 Rename Patient Data

Patient data can be changed retroactively after it has been added.

➔ Press the [Change] button.
The input boxes for patient data are now enabled, and the cursor jumps to the "Last name" field.

➔ Change the entries in the individual boxes.

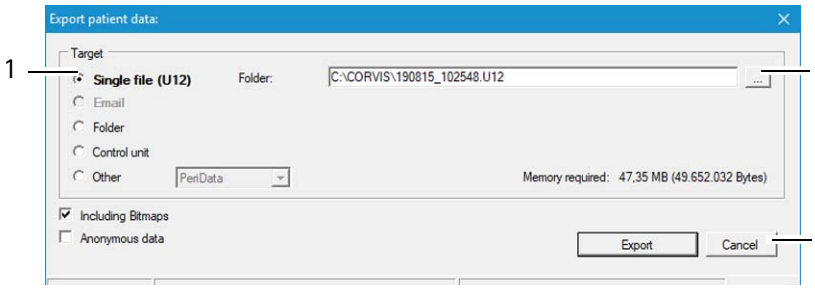
➔ Press the [Save] button.

12.7.2 Exporting Patient Data

For example, patient and examination data can be exported for forwarding to another clinic.

➔ Select the patient and also one of the examinations in the respective list.

➔ Press the [Export] button below the patient list. The following dialog appears:



1 Select destination
2 [...] button
3 [Cancel] and [Export] buttons
Abb. 12-9: "Export patient data" dialog

The options for import and export of data are set as defaults in the "settings" field, see *User guide*.

Depending on the settings you may not have to perform all of the following steps (for example selection of the directory).

➔ Select the "Target" (1) where you would like to export the data.

Recommendation: Export the patient data using the "Individual file (U12)" option.

➔ Press the [...] button. (2)
➔ In the dialog that appears, select the folder or the file to which the patient data should be exported.
➔ Confirm your selection with [OK] or [Save].
➔ To export the data, press the [Export] button (3).

12.7.3 Data backup

You should carry out a backup of patient and examination data at regular intervals. In case of a loss of data, you can reconstruct the data from a previously created backup with the help of this function. Since data backup takes several minutes depending on the scope of the database and the data to be backed up, a backup should be carried out when the computer and the device will not be needed.

Note

Loss of data due to computer viruses

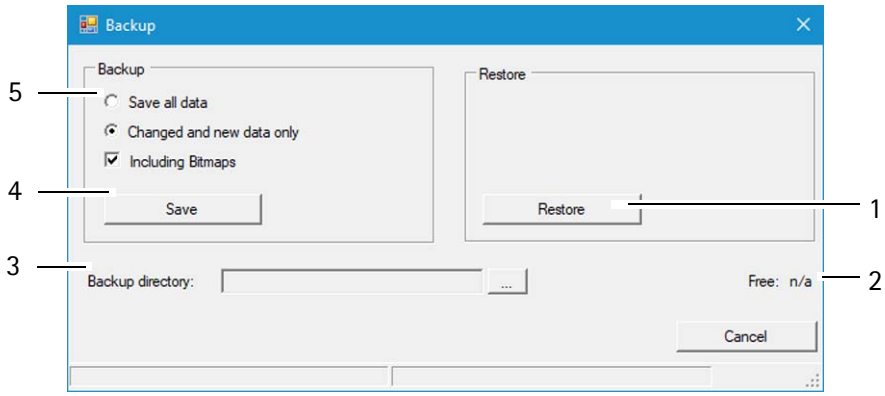
Computer viruses can cause loss of data.

➔ Run a virus check before importing data from the USB flash drive.

The general rules for security backups apply to backup copies created with the help of the Patient Data Management user interface. Storage of backup files should always be done on a separate system (for example on a USB flash drive with adequate capacity).

12.7.4 Backup data

➔ Press the [Backup] button on the upper right part in the Patient Data Management user interface. The following dialog appears:



1 [Restore] button
2 Display free storage space.
3 Backup folder and button [...]
4 [Save] button
5 Backup data selection

Abb. 12-10: "Backup" dialog

➔ Select whether all of the data or only changed data should be backed up.

The Patient Data Management function internally tags all saved data records.

If you selecting the option "Changed and new data only", only the data records that were not saved during a previous backup will be backed up.

➔ Press the [...] button to the right of the "Backup directory" box (3).
➔ In the dialog that appears, select the folder to which the data should be backed up.
➔ Confirm your selection with [OK].
➔ To back up the data, press the [Save] button (4). The previously selected data will then be backed up to the corresponding folder.

12.7.5 Reconstruct data

If a loss of data occurs, the data from a previous backup can be re-imported into the Patient Data Management user interface.

➔ Press the [...] button to the right of the "Backup directory" box (3).
➔ In the dialog that appears, select the folder which contains the backup data.

➔ Confirm your selection with [OK].

➔ To import the data, press the [Restore] button (1). All data in the appropriate directory are copied to the Patient Data Management software.

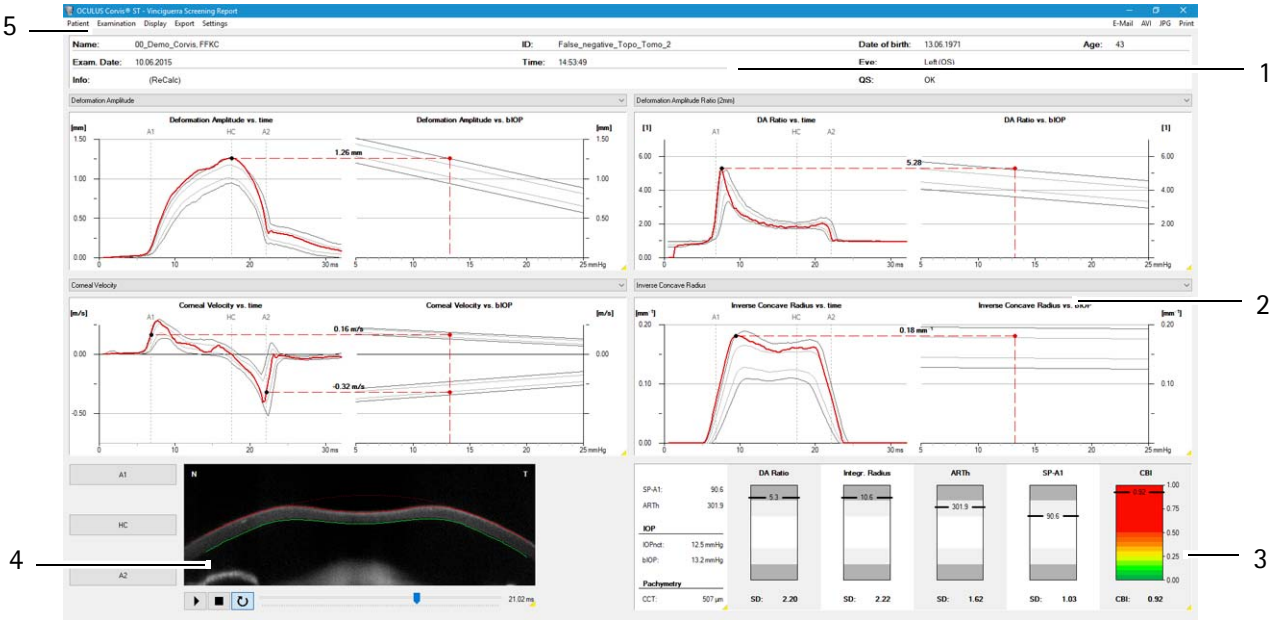
12.7.6 Automatic backup

In addition to the manually performed backup, it is also possible to automatically run a backup when exiting the Patient Data Management system. The settings required for this can be made in the "Settings" area, see *User Guide*.

13 Working with the Corvis® ST program

If you started the Corvis® ST program by selecting an examination in the Patient Data Management program, the selected examination is loaded in the Corvis® ST program.

If not, you may need to load an examination first, see *sec. 11.3, page 26*.



1 *Patient and examination data*
2 *Curv chart*
3 *Bar chart*
4 *Video function*
5 *Menu bar*

Fig. 13-1: Overview Screen; example "Vinciguerra Screening Report"

The most important controls of the Corvis® ST program are described in this section.

You will find a detailed description in the *User Guide*.

13.1 View patient and examination data (1)

The patient and examination data are displayed on every screen of the Corvis® ST program.

13.2 Working with the Menu Bar (7)

You can access the menu bar from any screen of the Corvis® ST.

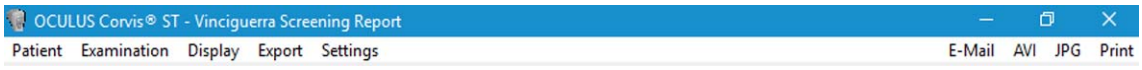
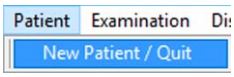


Abb. 13-2: Menu bar Corvis® ST Program

13.2.1 Menu item "Patient"

End Corvis® ST program, load new patient/examination

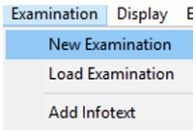


The Corvis® ST program ends and switches to Patient Data Management. There you can download a new patient/examination

➔ Click [New Patient / Quit].

13.2.2 Menu item "Examination"

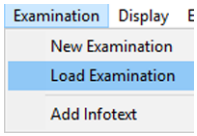
Starting a new examination



If an examination is not automatically initiated, you can initiate a new examination here.

➔ Click [New Examination].

Load an existing examanition

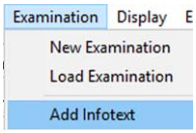


You can load an existing examanition.

➔ Click [Load Examination].

For more information, refer to the *User Guide*.

Add a comment



You can add or change information and comments.

➔ Click [Add Infotext].

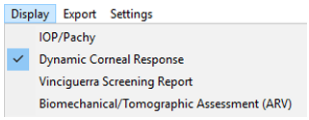
The dialog box "Load Examination" appears.

➔ Enter your text and confirm with [OK].

Abb. 13-3: Enter info text

The new text appears in the Patient Data Management in the list of previous examinations.

13.2.3 Menu item "Display"



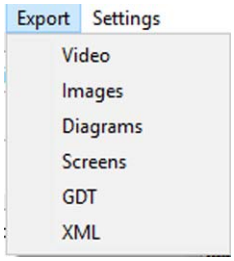
Display different presentations

You can display different presentations of an examination.

➔ Press the appropriate button.

For more information about the menu item „Display“, refer to the *User Guide*

13.2.4 Menu item "Export“

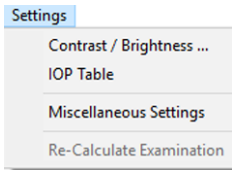


You can export different data relating to the examinations, e.g. individual videos, images, or screenshots.

➔ Press the appropriate button.

For more information, refer to the *User Guide*.

13.2.5 Menu item "Settings“



Change settings

You can change some of the settings, e.g. contrast and brightness, to get a better image quality.

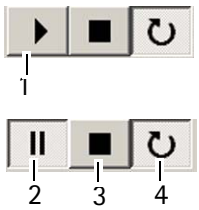
➔ Press the appropriate button.

For more information, refer to the *User Guide*.

➔ Select the menu item [Miscellaneous Settings] and then click on the desired item.

13.3 Use video function (4)

The video shows the entire deformation of the cornea.



➔ Press this button (1) to start the video.

➔ Press this button (2) to stop the video.

➔ Press this button (3) to return to the start of the video.

➔ Press this button (4) to repeat the video.

13.4 View specific images of the cornea (4)

You can view the images of the cornea at specific times; A1 (Applanation 1), HC (Highest Concavity) and A2 (Applanation 2).

➔ Press the appropriate button.

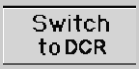
14 Perform a measurement with the Corvis® ST unit

You can perform an examination with the Corvis® ST unit alone and can directly save the patient and examination data there.

The procedure for this is as follows:

- ➔ Switch on the Corvis® ST, *sec. 10.5.1, page 21*.
- ➔ Enter the patient data, *sec. 14.2, page 49*
- ➔ Prepare and execute the measurement, *sec. 14.2.2, page 51*
- ➔ End the measurement, *sec. 14.4, page 52*
- ➔ Re-use the patient and examination data, *sec. 14.5, page 53*

Buttons and Icons

Button	Function
	This button appears after the measurement to save examination data of the patient
	Switching to the “Dynamic Corneal Response“ (DCR) screen
	Switching between eyes/displays
	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

14.1 Change Settings

You can change the default settings for your own individual measuring mode. For detailed information, refer to the *User Guide*.

14.2 Entering Patient Data

If the Corvis® ST program is started with the computer, you don not have to enter patient data.

When you turn on the Corvis® ST, you see the Patient Data Management first.

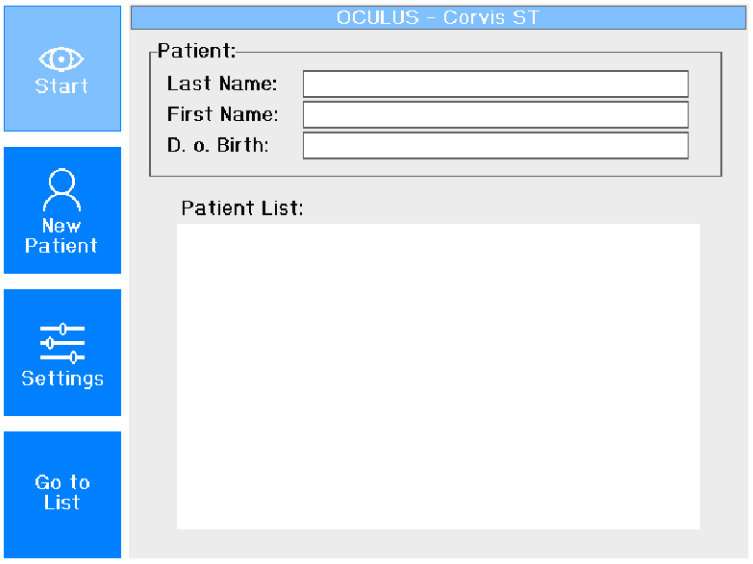


Abb. 14-1: Corvis® ST switch on

Use Patient Data Management to associate examinations with a patient or when you want to save them long-term.

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

14.2.1 Entering new Patient

➔ Press the [New Patient] button in the patient data menu to enter a new patient.

The following screen appears:

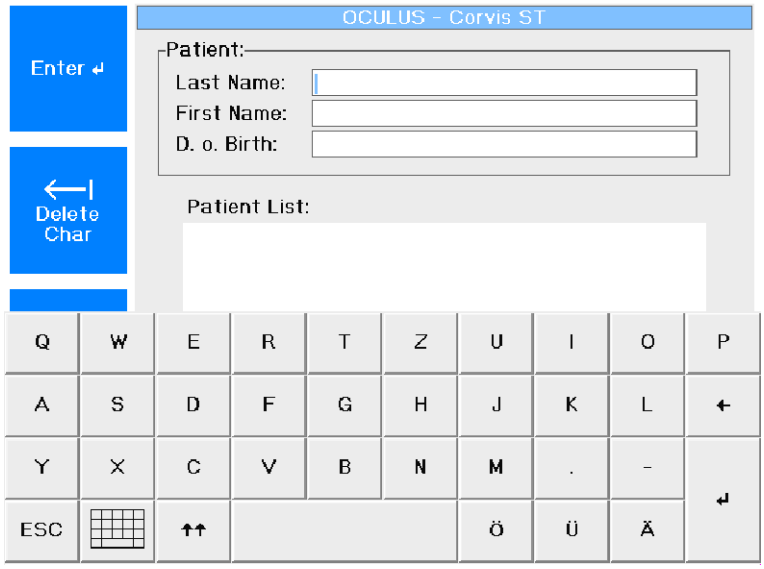


Abb. 14-2: Touch-screen keyboard, enter patient data

➔ Use the touch-screen as described in *(sec. 11.2, page 25)*.

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

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

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

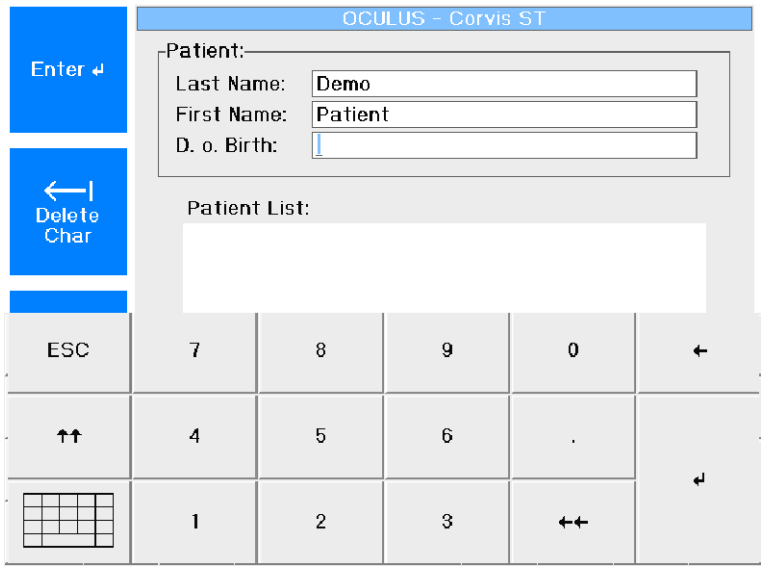


Abb. 14-3: Touch screen keyboard, numeric keypad

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

If you have entered the correction calculation per „Spoerl" you must enter the patient's date of birth so that the correction is calculated correctly.

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

➔ Select "Yes".

The patient's name appears in the list.

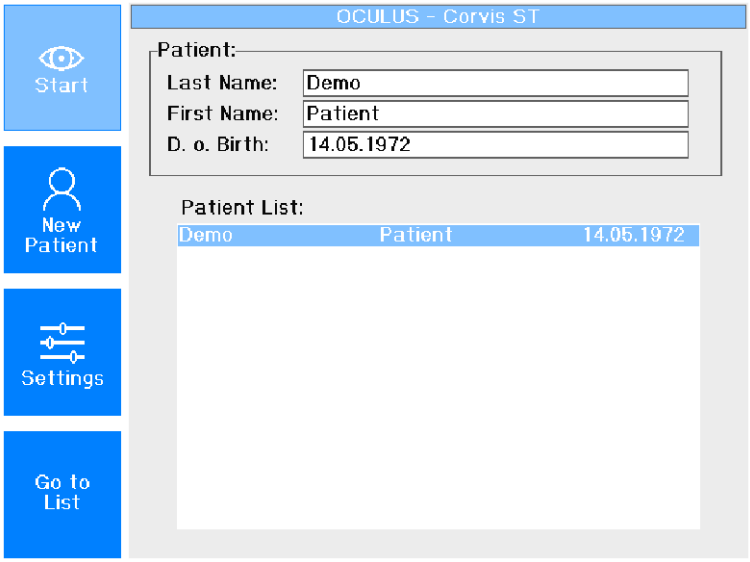


Abb. 14-4: Patient list

➔ Press the [Start] button to switch to measure mode, *sec. 12.1, page 31*.

14.2.2 Select an existing patient

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

➔ In the Patient Data Management *(fig. 14-1, page 49)* menu, press the [Patient List] button.

➔ Turn the control knob to the desired entry in the list.

➔ Press the control knob to select the desired patient.

➔ Press the [New Exam/Back] button to switch to measure mode, *sec. 12.1, page 31*.

14.3 Perform a Measurement

To prepare the measurement, proceed as described in *sec. 11.1, page 23* and *sec. 11.2, page 25* .

Perform the measurement as follows:

- Select the measuring mode, *sec. 14.3.1, page 52*
- Adjust the Corvis® ST, *sec. 12.2, page 32*
- Start the measurement, *sec. 12.3, page 37*

14.3.1 Selecting a Measurement Mode

Depending on the version you can select the measurement mode.

➔ Press this button.

Tono + P version

➔ Press the [Tono/Pachy] button.
Tonometry and pachymetry are measured simultaneously.

Pachy version

➔ Press the [Pachy] button.

➔ The corneal thickness along the horizontal sectional plane is measured but without the IOP.

14.4 Complete measurement

This button is displayed after a measurement has been conducted.

➔ Press this button to save the examination data to the patient's record.

➔ After each patient remove one of the paper sheets from the chin rest. See also *sec. 15.4, page 59*.

➔ Disinfect the head rest and, if neccessary, the chin rest after each patient, *sec. 15.2, page 58*.

Attention

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 *"Clean the air nozzle (2)" page 57*.

➔ Disinfect the front cover *sec. 15.2, page 58*.

14.5 Re-use examination data

14.5.1 Delete 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.

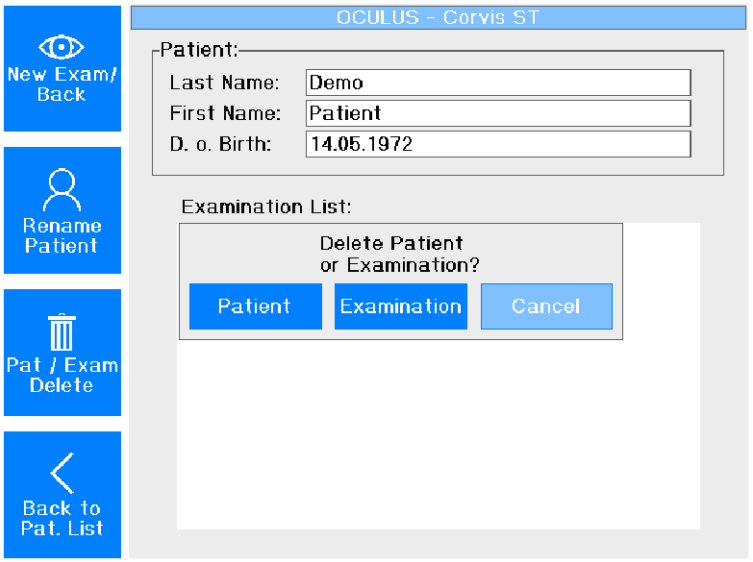


Abb. 14-5: Delete a Patient or an Examination

To delete a patient:

➔ Press the [Patient] button.

The patient will be deleted.

To delete an examination:

➔ Select the examination that is to be deleted.

The line for the selected examination appears highlighted in blue.

➔ Press the [Examination] button.

The examination will be deleted.

14.5.2 Re-using data with the USB flash drive (optional)

If your Corvis® ST is not connected to a computer, your data is stored on a USB flash drive that is connected on the inside of the unit.

➔ Press this button. The measurement results are saved with the appropriate patient's data.

You can re-use this data on a computer.

Prerequisite: You must have the Corvis® ST program, and Patient Data Management software installed on your computer/laptop.

There are .DAT and .BMP data records on the USB flash drive. You can import this data with the Patient Data Management program.

➔ Open the cover with the display.

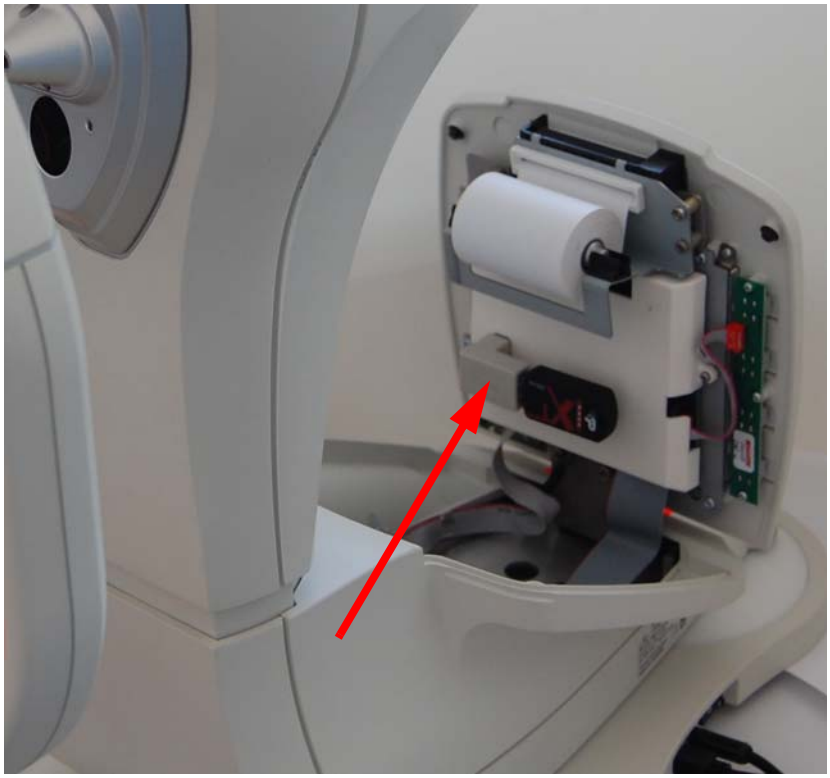


Abb. 14-6: Open the cover with the display

➔ Pull out the USB flash drive.

➔ Plug the USB flash drive into your computer.

Now you can import the data into the Patient Data Management program, *sec. 11.4, page 27*.

15 Cleaning, Disinfection and Maintenance

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

Sterilization is not required.

➔ Heed the product descriptions and instruction manuals of products and equipment you use to care for, clean, and disinfect the unit and/or its accessories.

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

Note

Equipment damage due to moisture

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

15.1 Cleaning

Attention

Risk of electric shock if the Corvis® ST is not completely disconnected from the mains for these jobs.

➔ Turn the Corvis® ST off, *sec. 10.5.4, page 22*.

➔ Unplug the power cord before cleaning. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

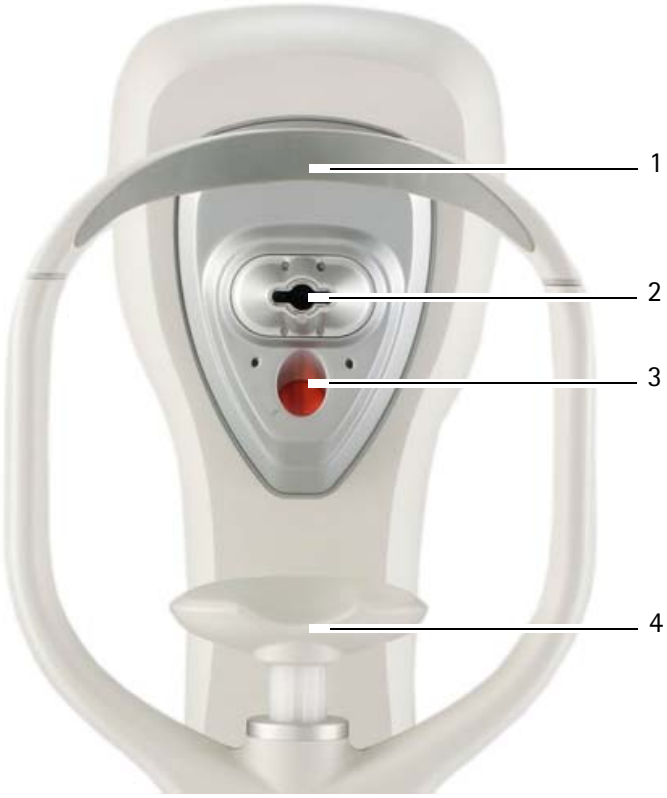
Required materials

- 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, lint-free cloth (for example gauze or microfibre)
- Cleaning alcohol
- Commercial clean agent for the glass
- Cotton swab
- if necessary: bellows

Cleaning inervalls

➔ Clean the components of the Corvis® ST once a month or if necessary.

15.1.1 Clean the front panel



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

Abb. 15-1: Clean lens protection glass and air nozzle

Clean head (1) and chin (4) rests

The Corvis® ST can remain switched on for this cleaning step.

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

➔ Clean these parts before examining the next patient.

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

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

Clean 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.

Clean the air nozzle (2)

Attention

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. 15.2, page 58*.

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

➔ 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.

Cleaning the housing

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

➔ Turn the Corvis® ST off, *sec. 10.5.4, page 22*.

➔ Unplug the power cord. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

➔ When cleaning, use a damp cloth and make sure that no liquid enters the Corvis® ST.

➔ 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.

Cleaning the display

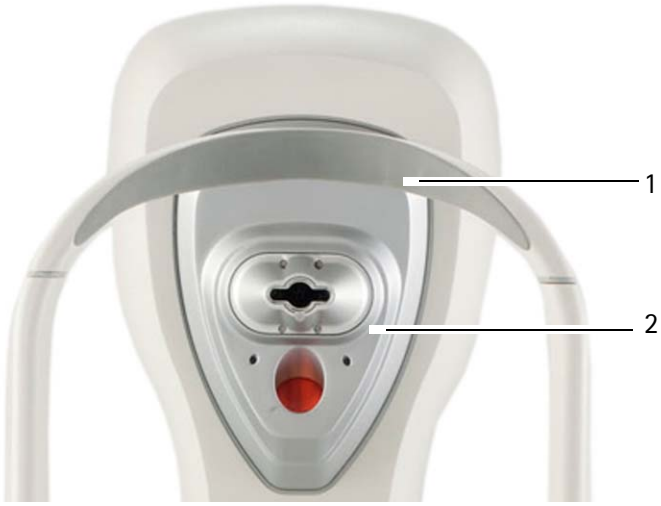
➔ Clean the display using a dry, lint-free cloth.

15.2 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® ST off, *sec. 10.5.4, page 22*.



1 Head rest *2 Front cover*

Abb. 15-2: Disinfect

➔ Disinfect the head rest and, if neccessary, the chin rest after each examination.

Attention

Risk of infection after examining a sick patient

If you perform a measurement on a sick patient, the head 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 it.

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

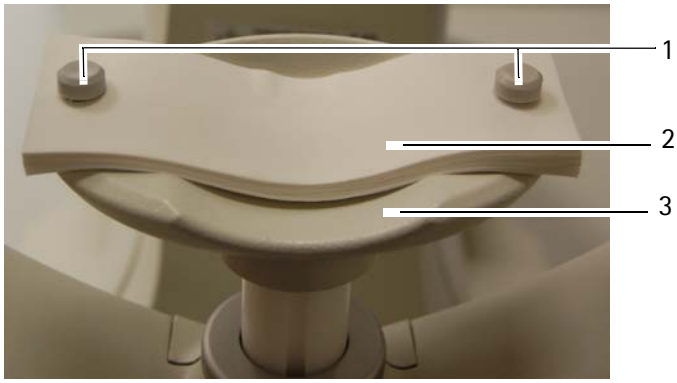
15.3 Maintenance

➔ Germany: 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® ST checked every two years by our service department or an authorized dealer.

15.4 Attach 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. 15-3: Attach 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.

15.5 Insert new printing paper roll

➔ Open the cover with the display.

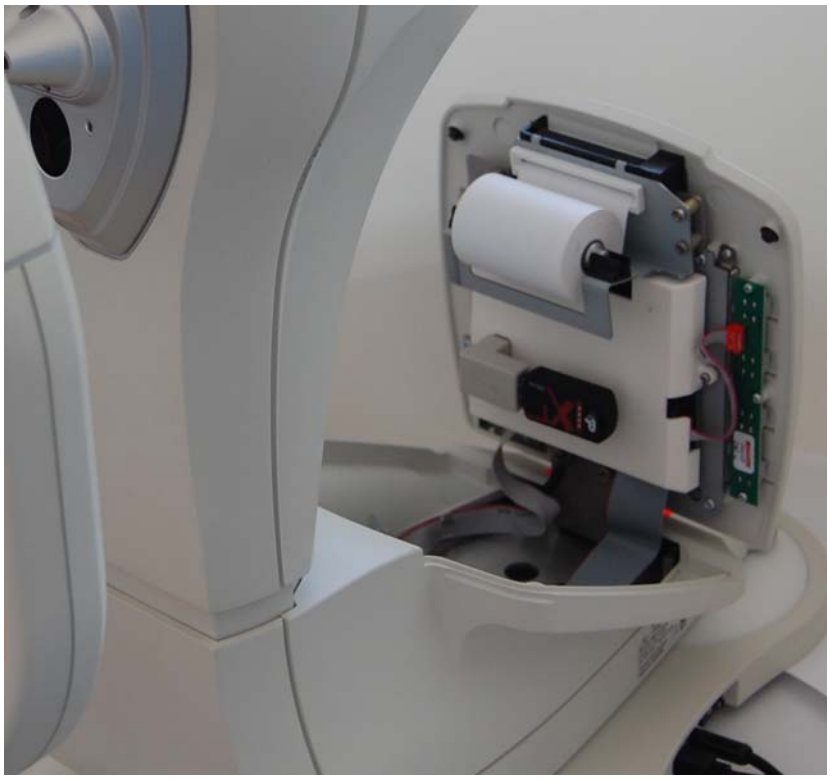


Abb. 15-4: Open the cover with the display

The following screen appears:

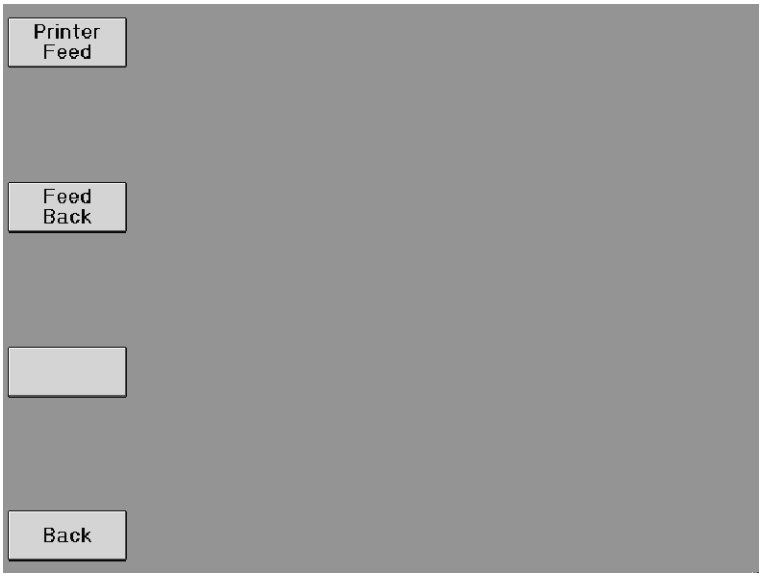
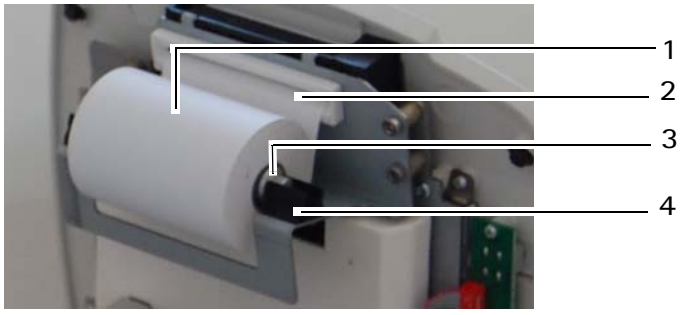


Abb. 15-5: Change printer paper

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.



1 Printer roller
2 White slot
3 Metal pin
4 Holder

Abb. 15-6: Remove and insert printer roller

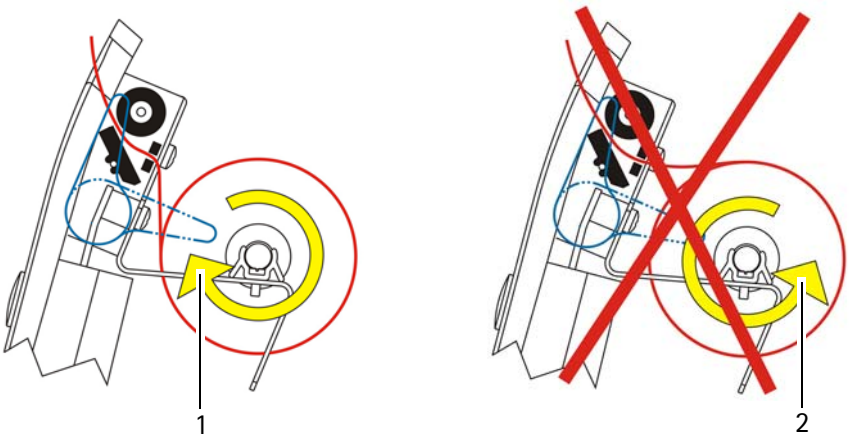
➔ Remove the feed roller (1) from the holder (4).

➔ Pullthe metal pin (3) out.

➔ Push the metal pin into a new printer roller and insert the printer roller into the holder (4).

➔ Slide the white paper through the white slot from below.

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



1 Proper paper guide
2 Wrong paper guide

Abb. 15-7: Insert the paper

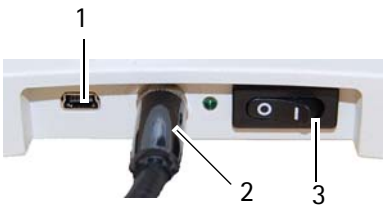
➔ Press the button "Printer Feed" so that the printer paper is pulled through the opening.

➔ Close the cover with the display, see *fig. 15-4, page 60*.

16 Dismantling, Transport and Storage

Before you transport or store the Corvis® ST you may have to dismantle it properly and lock the transport safety device.

16.1 Removal



- ➔ Switch off the Corvis® ST 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 computer/Laptop (1).
- ➔ Open the cover with the display.

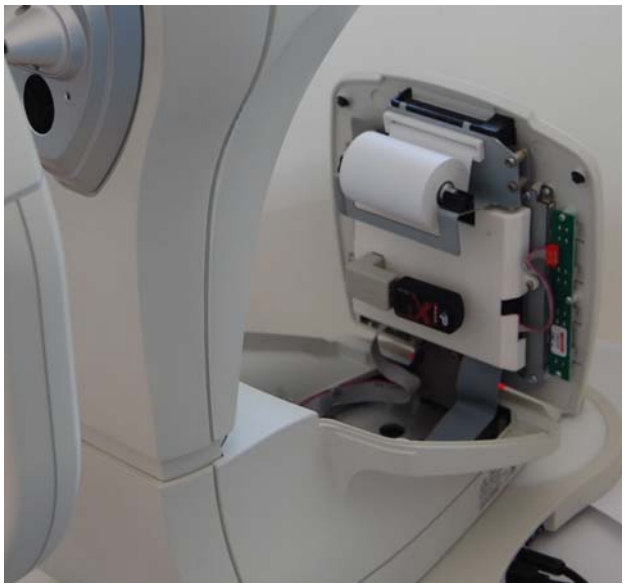
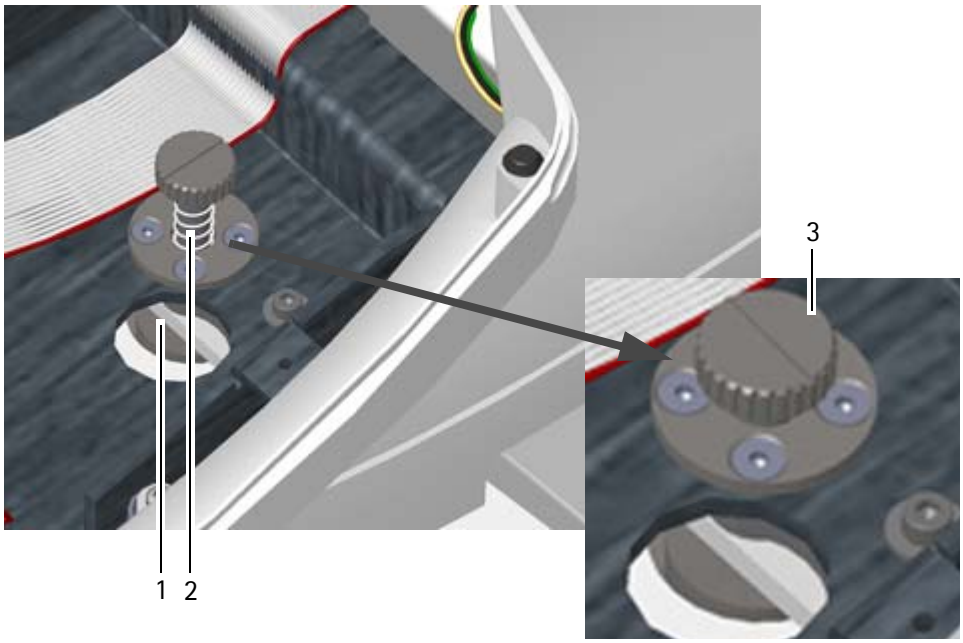


Abb. 16-1: Open the cover with the display

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

➔ Lock the transport safety device (2).

Press down gently on 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. 16-2: Transport safety device

➔ Close the cover with the display, see *fig. 16-1, page 62*.

16.2 Transport and Storage

16.3 Information on Transport and Storage

Storage conditions

Ambient temperature range	-10 – +55°C
Relative humidity, including condensation	10 – 95%
Air pressure range	700 – 1060 hPa

Transport conditions

Ambient temperature range	-40 – +70°C
Relative humidity, including condensation	10 – 95%
Air pressure range	500 – 1060 hPa

Note

Equipment damage due to incorrect lifting

If the Corvis® ST is lifted by the head rest, it can break off.

➔ Grab the Corvis® ST 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® ST professionally.

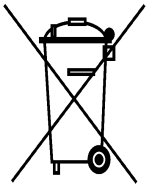
➔ Store the Corvis® ST according to the storage conditions.

➔ Avoid placing near radiators and moisture.

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

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

17 Disposal of Used Devices



In accordance with Directive 2012/19/EU 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.

18 Troubleshooting

Attention

Persons or equipment damage due to incorrect troubleshooting

- ➔ Do not plug in or unplug any cables while the Corvis® ST 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® ST not connected to the power supply. Power failure or power outlet is not active.	➔ Plug power cord into the outlet or into the connector on the Corvis® ST. ➔ Inform the in-house electrician. ➔ Check that the connector is plugged in properly.

19 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® ST carries a warranty to which you are entitled in accordance with the legal provisions.
- If any unauthorized persons interfere with the Corvis® ST, 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 computer hardware and supplied software.
- Make transport damage claims to the shipping company during or immediately after delivery. Have the damage confirmed on the bill of lading, 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.

19.1 Liability for proper function or damages

OCULUS will only accept responsibility for the safety, reliability and serviceability of the Corvis® ST if the unit 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® ST. OCULUS shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorized personnel; if the Corvis® ST 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.

20 Technical Data

Measure Mode

IOP + pachymetry

Tonometer

Measuring range	6 to 60 mmHg
Working distance	11 mm
Internal fixation light	red LED

Scheimpflug camera

Frame Rate	4330 frames/s
Measuring range	8.5 mm horizontally
Pachymeter measuring range	300 to 1200µm
Measuring points	576 per image
Display resolution	576 x 200 pixels
Light source	blue LED (470 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 – +35 °C
Humidity	30 – 90 %
Air pressure	800 – 1060 hPa

Storage conditions

Ambient temperature range	-10 – +55 °C
Relative humidity, including condensation	10 – 95%
Air pressure range	700 – 1060 hPa

Transport

Ambient temperature range	-40 – +70 °C
Relative humidity, including condensation	10 – 95%
Air pressure range	500 – 1060 hPa

Measuring head

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

Power adapter15 V DC

Mean Well (05150285)	
Mains connection	100 - 240 V
Frequency	50/60 Hz
Max. power consumption	max. 90 W
Output	15 V DC

Computer

Use a computer which is in conformity with the DIN EN 60950 standard.

Recommended computer specifications (for optional software)	Core i5-42000M, 2.5 GHz, 4GB, 500GB, Windows® 7, Intel HD graphics 4600

Other information

Dimensions W x D x H	266 x 538 x 495 to525 mm (10.5 x 21.2 x 19.5- to 20.7 in)
Weight	approx. 14 kg (30.8 lbs)
Printer	Thermal printer
Display	TFT - LCD approx. 150 mm
Contraindications	none noted
Lifecycle expectancy	up to 10 years

CE in accordance with EC Directive 93/42/EEC for Medical Devices

The unit is a class IIa product.

CE 0123

Conformity assessment: Directive 93/42 / EEC: Annex II without section 4.

21 Appendix

21.1 Correction Calculation of the Tonometrically calculated IOP

The Corvis® ST program offers the option to save the tonometrically measured IOP in the data of an examination and to correct it by Central Corneal Thickness (CCT). Different correction formulae can be applied for this. The corrected IOP value and the IOP change are also saved.

The correction formulae according to Shah, Ehlers, and the Dresdener correction formulae approximate the actual IOP related to corneal thickness from the measured value.

As the table is imported, a linear relationship will be adopted for the variates. It is sufficient to define a start value and an end value with the associated correction values.

21.2 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.

Produced in consideration of permissible deterioration during or caused by the EMC testing without affecting the essential performance criteria

- 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® ST.

➔ 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® ST 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® ST.

To be in compliance with the requirements of the IEC 60601-1-2 6.1 and 6.2 the following types of equipment, accessories, power adapters and cables must be used.

Order number	Description	
72100 72200	Corvis® ST	
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
05200601	USB cable	
015692000010	USB FS MED Isolator	
05150285	Power Supply	15 V DC; 6 A

21.3 Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions and Immunity for the Corvis® ST

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2: 2015, based to table 1		
The OCULUS Corvis® ST is intended for operation in the electromagnetic environment specified below. The user of the Corvis® ST 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® ST 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	

Electromagentic immunity, IEC 60601-1-2: 2015, based on table 4			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	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%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electromagentic immunity, IEC 60601-1-2: 2015, based on table 5, 8			
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/ output lines	± 2 kV ---------- ± 1 kV	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	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Corvis® ST requires continued operation during power mains interruptions, it is recommended that the Corvis® ST be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagentic immunity, IEC 60601-1-2: 2015, based on table 4, 5

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
Conducted RF IEC 61000-4-6	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz	V_{eff} = 3 V	Portable and mobile RF communications equipment should be used no closer to any part of Corvis® ST, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz		$d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 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® ST is used exceeds the applicable RF compliance level above, the Corvis® ST 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® ST.

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® ST, IEC 60601-1-2:2007, table 6

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

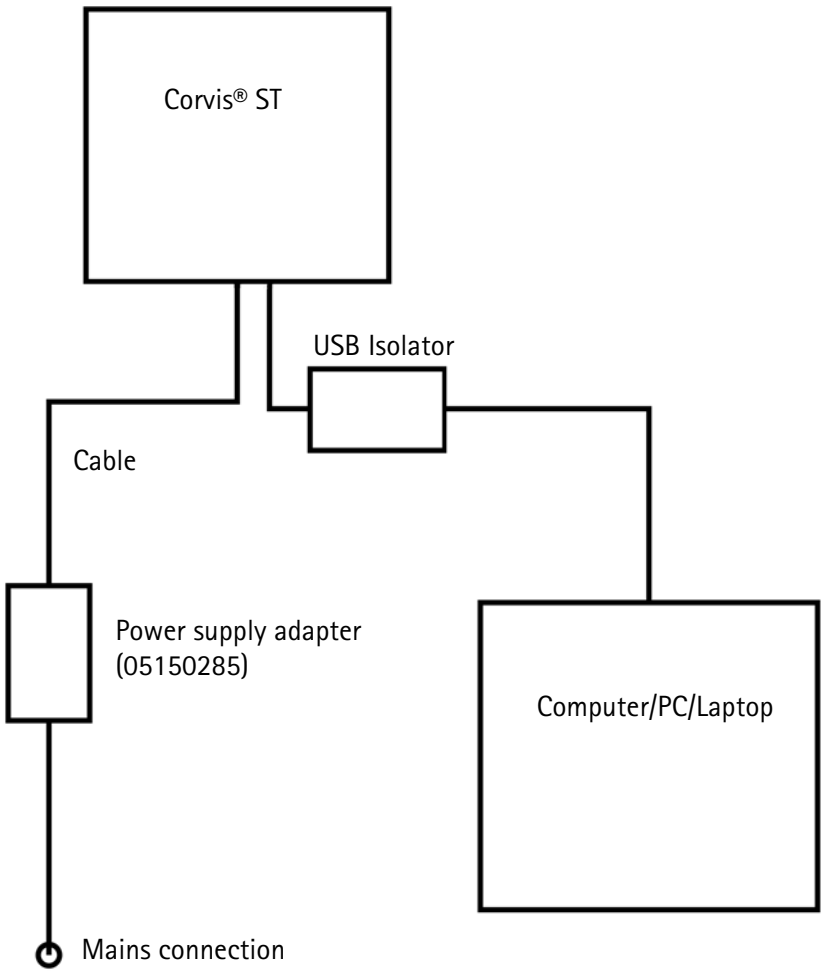
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

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.

21.4 Description of the Connection



21.5 Data sheet Power Supply Adapter (05150285)

MEAN WELL

90W AC-DC High Reliability Medical Adaptor **GSM90B series**

■ Features

- Universal AC input / Full range
- 2 pole AC inlet IEC320-C8
- Medical safety approved (2 x MOPP between primary to secondary)
- Suitable for BF application with appropriate system consideration
- Low leakage current <100uA
- No load power consumption<0.15W
- Energy efficiency level VI
- Comply with EISA 2007/DoE,NRCan, AU/NZ MEPS, EU ErP and meet CoC Version 5
- Built-in active PFC function
- High efficiency up to 91%
- Fanless design with -30~+60℃ working temperature
- Class Ⅱ power (without earth pin)
- Protections: Short circuit / Overload / Over voltage / Over temperature
- Fully enclosed plastic case
- LED indicator for power on
- 100% full load burn-in test
- Optional lock type DC plug
- 3 years warranty

■ Applications

- Mobile clinical workstation
- Oral irrigator
- Portable hemodialysis machine
- Breath Machine
- Medical computer monitor

■ Description

GSM90B is a highly reliable, 90W desktop style single-output green medical adaptor series. This product is equipped with a 2-pin (no FG) standard IEC320-C8 power plug, adopting the input range from 80VAC to 264VAC. The entire series supplies different output voltages between 12VDC and 48VDC that can satisfy the demands for various kinds of medical electrical devices. The circuitry design meets the international medical standards (2*MOPP), having an ultra low leakage current (<100uA), fitting the medical devices in direct electrical contact with the patients.

With the efficiency up to 91% and the extremely low no-load power consumption below 0.15W, GSM90B is compliant with USA EISA 2007/DoE, Canada NRCan, Australia and New Zealand MEPS, EU ErP,and meet Code of Conduct (CoC) Version 5. The supreme feature allows the adaptor to save the energy when it is either under the operating mode or the standby mode. The entire series utilizes the 94V-0 flame retardant plastic case, providing the double insulation that effectively prevents electrical shock. GSM90B is approved with the international medical safety certificates.

■ Model Encoding

GSM90B 12 -P1M

- DC plug type: P1M: Plug for standard model,2.5ψ x5.5ψ x11mm,c+,tuning fork type; Optional plug type available by customer requested
- Output voltage
- IEC320-C8 AC inlet
- Output wattage
- Series name

File Name:GSM90B-SPEC 2016-03-16

WELL

90W AC-DC High Reliability Medical Adaptor **GSM90B series**

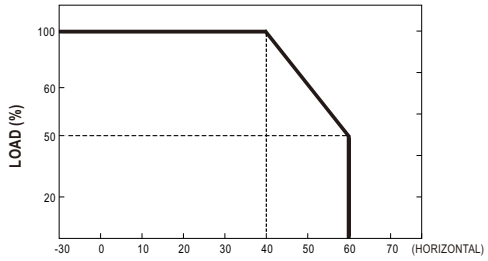
FICATION

NO.		GSM90B12-P1M	GSM90B15-P1M	GSM90B19-P1M	GSM90B24-P1M	GSM90B48-P1M
	SAFETY MODEL NO.	GSM90B12	GSM90B15	GSM90B19	GSM90B24	GSM90B48
	DC VOLTAGE Note.2	12V	15V	19V	24V	48V
	RATED CURRENT	6.67A	6A	4.74A	3.75A	1.87A
	CURRENT RANGE	0 ~ 6.67A	0 ~ 6A	0 ~ 4.74A	0 ~ 3.75A	0 ~ 1.87A
	RATED POWER (max.)	80W	90W	90W	90W	90W
T	RIPPLE & NOISE (max.) Note.3	120mVp-p	150mVp-p	180mVp-p	200mVp-p	240mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±4.0%	±3.0%	±2.5%
	LINE REGULATION Note.5	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
	LOAD REGULATION	±5.0%	±5.0%	±4.0%	±3.0%	±2.5%
	SETUP, RISE TIME Note.6	1000ms, 50ms / 230VAC 1500ms, 50ms / 115VAC at full load				
	HOLD UP TIME (Typ.)	20ms / 230VAC 20ms / 115VAC at full load				
	VOLTAGE RANGE Note.7	80 ~ 264VAC 113 ~ 370VDC				
	FREQUENCY RANGE	47 ~ 63Hz				
	POWER FACTOR (Typ.)	PF>0.91 / 230VAC PF>0.95 / 115VAC at full load				
	EFFICIENCY (Typ.)	88%	89%	89%	90%	91%
	AC CURRENT (Typ.)	1.3A / 115VAC 0.6A / 230VAC				
	INRUSH CURRENT (Typ.)	30A / 115VAC 65A / 230VAC				
	LEAKAGE CURRENT(max.)	Touch current < 100μA/264VAC				
ION	OVERLOAD	110 ~ 150% rated output power				
		Protection type : Hiccup mode, recovers automatically after fault condition is removed				
	OVER VOLTAGE	105 ~ 135% rated output voltage				
		Protection type : Shut down o/p voltage, re-power on to recover				
	OVER TEMPERATURE	Shut down o/p voltage, re-power on to recover				
ENT	WORKING TEMP.	-30 ~ +60℃ (Refer to "Derating Curve")				
	WORKING HUMIDITY	20% ~ 90% RH non-condensing				
	STORAGE TEMP., HUMIDITY	-40 ~ +85℃, 10 ~ 95% RH				
	TEMP. COEFFICIENT	±0.03% / ℃ (0 ~ 40℃)				
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes				
' &	SAFETY STANDARDS	ANSI/AAMI ES60601-1 / ES60601-1-11, TUV EN60601-1 / EN60601-1-11 approved				
	ISOLATION LEVEL	Primary-Secondary: 2xMOPP				
)	WITHSTAND VOLTAGE	I/P-O/P: 4KVAC				
	ISOLATION RESISTANCE	I/P-O/P:100M Ohms / 500VDC / 25℃/ 70% RH				
	EMC EMISSION	Compliance to EN55011(CISPR11) class B, EN61000-3-2,3, FCC PART 15 class B,CAN ICES-3(B)/NMB-3(B)				
	EMC IMMUNITY	Compliance to EN61000-4-2,3,4,5,6,8,11, EN55024, EN60601-1-2, EN61204-3 medical level, criteria A				
S	MTBF	405.6K hrs min. MIL-HDBK-217F(25℃)				
	DIMENSION	145*60*32mm (L*W*H)				
	PACKING	0.45Kg; 30pcs/14.5Kg/1CUFT				
OR	PLUG	See page 3 ; Other type available by customer requested				
	CABLE	See page 3 ; Other type available by customer requested				

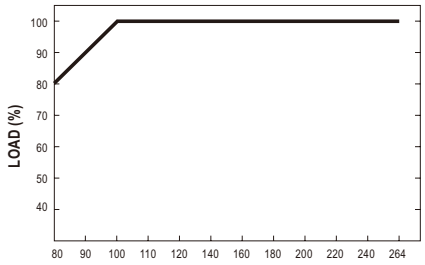
1. All parameters are specified at 230VAC input, rated load, 25℃ 70% RH ambient.

MEAN WELL 90W AC-DC High Reliability Medical Adaptor **GSM90B series**

■ Derating Curve

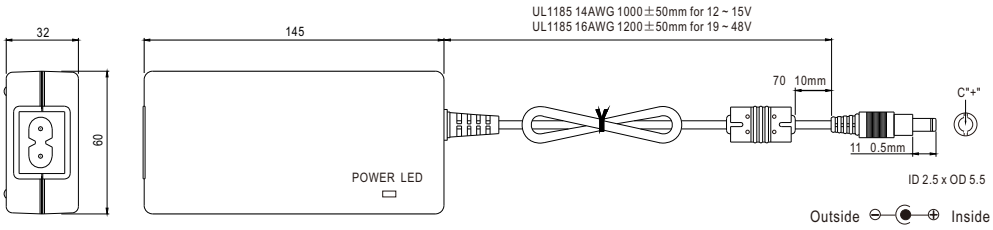


■ Static Characteristics



■ Mechanical Specification

Case No. GS90A Unit:mm



■ Plug Assignment

Standard plug: P1M

P1M	
P/N	OUTPUT
CENTER	+

Optional lock type plug: P2S
SWITCHCRAFT S761K plug equivalent

■ Installation Manual

Please refer to : http://www.meanwell.com/webnet/search/InstallationSearch.html

File Name:GSM90B-SPEC 2016-03-16

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