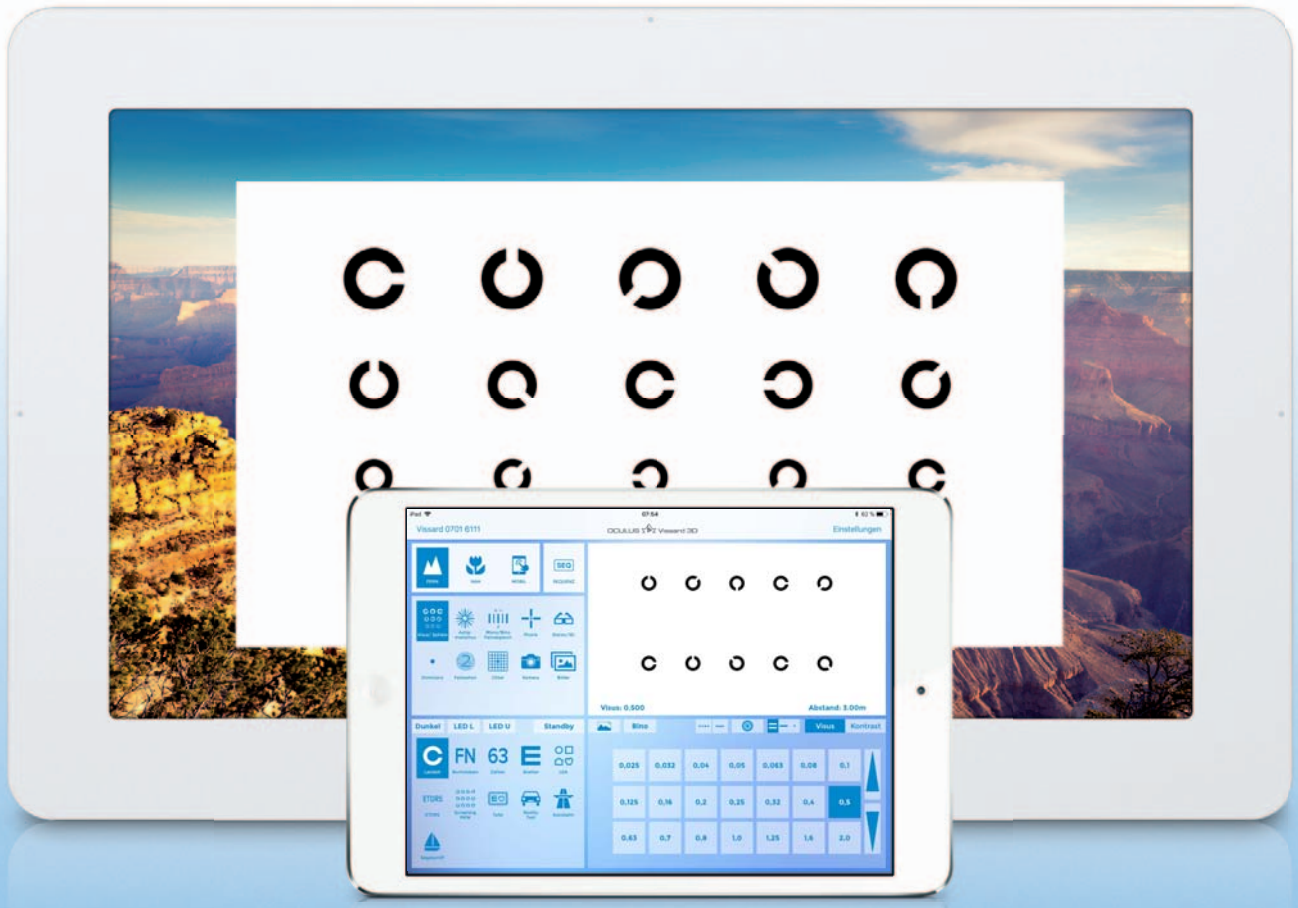
OCULUS | Vissard



INSTRUCTION MANUAL

Vision Testing Device

OCULUS®

Preface

The OCULUS Vissard has been manufactured and tested according to strict quality criteria.

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

This instruction manual describes the procedure for conducting subjective eye examination with the Vissard.

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

If you have any questions or would like additional information about your device, please do not hesitate to contact us by mail or fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

Item Number: G/16040/EN
Revision 02
Release: 06.06.2023

Inhaltsverzeichnis

1 Scope of Delivery

Component	Order Number
Vissard 3D consisting of: ■ Patient display, distance Available models:	
■ Vissard 3D, linear polarisation	16030
■ Vissard 3D, circular polarisation	16031
■ Vissard RG	16050
Instruction Manual	G/16040/XXXX/EN
Vissard 3D/Vissard RG: Fuse 1.25 A time-lag	05100170
Optional ■ Vissard PHI ■ Holder for receiver ■ Data cable for phoropter ■ iPad	 16090 016595001043 026522501003 10012081

We reserve the right to make changes to the scope of delivery as a part of any technical improvements.

➔ If transport damage is discovered from the shipment, please file a complaint with the shipping company immediately.

➔ Have the damage confirmed on the bill of lading so that an orderly handling of the complaint for damages is possible.

For more information regarding shipping and handling, see *sect. 12, page 60*.

2 Graphic Symbols

2.1 On the Equipment / Type Plate

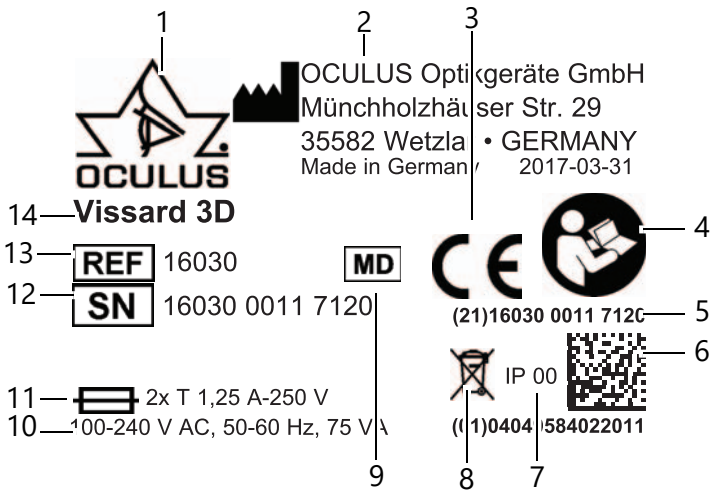
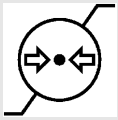


Fig. 2-1: Type Plate (example)

1 Manufacturer's logo
2 Manufacturer's address
3 CE European Conformity
4 Heed Instruction Manual
5 UDI number
6 Matrix for device identification
7 Protection class and level of protection
8 Disposal in household trash is prohibited
9 Medical Device
10 Power supply unit
11 Fuses
12 Serial number of the device
13 Device type
14 Name of device

Buttons for the Service menu
For more information about the service buttons, refer to the *User Guide*.

2.2 On the packaging

Pictogram	Description	Pictogram	Description
	Permitted temperature range for transport		Permitted temperature range for storage
	Keep dry		Humidity
	Transport upright		Air pressure
	Fragile		

3 Layout of the Documentation

- **Instruction Manual:** The design of the unit is described in detail in this document. The Instruction Manual also includes basic instructions and all safety-related instructions for the use of the Vissard.

Attention

All safety-related instructions for the use of the Vissard are described in this Instruction Manual. It is therefore imperative that you read and understand the whole Instruction Manual before you use the Vissard.

Terminology

Vissard: All components belonging to the Vissard system
Patient display: Device that displays the vision test to the patient
Control unit: Unit for the examiner, with the Vissard program (iPad)
Battery: Rechargeable battery

4 Safety Instructions

➔ Carefully read through the Instruction Manual.
➔ Keep the documentation in a safe place in the vicinity of the unit.
➔ Observe the legal regulations with regard to accident prevention.

4.1 Pictograms in this manual

Warning
Indicates a potentially hazardous situation that can lead to irreversible bodily injury.

Attention
Denotes a potentially hazardous situation which can easily result in minor physical injury or property damage.

Note
Indicates a situation that can lead to incorrect examination results, instructions for use and useful or important information.

Denotes important information about the product and its use, which require special attention.

> This symbol denotes menu paths and screenshots. Example for starting a new examination:
> Button [Visual acuity/Sphere] > Button [Landolt]
> which means:
> ➔ Press the button [Visual acuity/Sphere].
> ➔ Press the button [Landolt].

4.2 Safety Instructions for Use

Attention

Risk of personal injury or property damage due to improper operation

➔ Observe the following safety instructions.

Warning

Risk of personal injury or property damage due to equipment modifications that could jeopardize safety

Changes or modifications may only be done by OCULUS Service and its authorized dealers.

➔ This equipment may not be modified without the permission of the manufacturer.

Any serious-incident that has occurred in relation to the device should be reported to the manufacturer (vigilance@oculus.de) and the competent authority of the region in which the user and/or patient is established.

4.3 Instructions for operating personnel

➔ Make certain that the Vissard is used exclusively by personnel that have the training and practical experience to safely and properly operate the equipment.

4.4 Transport and storage instructions

Refer to the notes in *sect. 12, page 60*.

➔ Put the Vissard 3D/Vissard RG down so that it cannot fall over.

4.5 Instructions for setup and connection

➔ The Vissard may only be installed and connected by OCULUS or its authorized dealer.

➔ Use the Vissard only in rooms in which mobile devices are permitted, or the usage is not restricted.

➔ Do not use or store the Vissard in damp rooms, *sect. 12, page 60*.

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

➔ Do not put the Vissard, 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.

➔ Only operate the Vissard in rooms used for medical purposes after they have been set up according to the VDE Regulations 0100-710.

➔ Do not operate the equipment included in the packing list in explosive environments, in the presence of combustible anaesthetics or volatile solvents such as alcohol, benzene, etc.

- ➔ Patient display, distance: Protect the unit against dust. There is a risk of fire.
- ➔ Use only a mains cable that meets the requirements of IEC 60227-1, Type 53, min. 0.75 m² and of IEC 60320-1.
- ➔ Position the Vissard so that the mains plug is readily accessible. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.
- ➔ Do not use excessive force when connecting the electrical plug. If a connection is not possible, check whether the plug fits the jack. If you find damage to the plug connector, have the damage corrected by our service department.

4.6 Information about the patient environment

The patient environment is the room in which contact between the patient and any part of the system, or between the patient and another person coming into contact with the system can take place.

Use devices that conform to IEC 60601-1 in the patient environment. If a device is to be used that does not meet the IEC 60601-1 standard, use an isolating transformer.

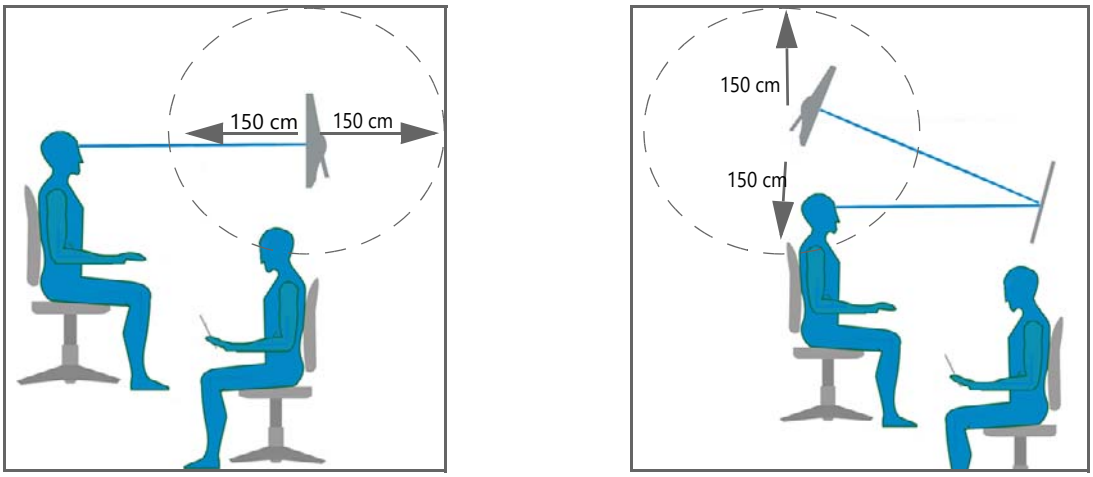


Fig. 4-1: Patient environment

4.7 Information for operation of an ME system

The Vissard components form a medical-electrical system (ME system) in accordance with IEC 60601-1. If you connect additional devices, e.g. a phoropter, these devices become part of the ME system.

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

Control unit

There are magnets in the control unit whose magnetic fields could lead to the impairment of cardiac pacemakers, defibrillators and other medical devices and apparatus.

➔ Always maintain a minimum distance of 15 cm between your medical device and the control unit.

4.8 Instructions for operation

➔ Before initial operation: Let OCULUS or an authorized dealer train you in the operation of the Vissard.
➔ Never operate damaged Vissard components.
➔ Only operate the equipment after your have read and understood the Instruction Manual.
➔ Only operate the components of the Vissard with the original accessories supplied by us and only when the unit is in a technically perfect condition.
➔ Make sure that the surface does not sustain damage, e.g. by being dropped or by sharp-edged objects. Do not sit on the unit.

Patient display, distance

➔ Protect the unit against dust. There is a risk of fire.
➔ Do not touch the test person and the unit simultaneously.
➔ Do not touch or press on the surface of the screen, if possible, as this could damage it.
➔ In the event of severe storms (lightning strike): Unplug the power cord. Take hold of the plug, do not pull on the cable.

Mobile components

➔ Use only the power supply unit specified in the scope of delivery.
➔ Do not press too hard on the surface of the monitor, e.g. with your finger or with a stylus, as this could cause damage to the monitor.

4.9 Instructions for charging the mobile components

➔ Use the supplied USB cable and power supply unit to charge the rechargeable battery. For more information, refer to *sect. 10.2.2, page 49*.
➔ Do not use damaged cables.

The mobile components and their power supply unit have been designed according to current standards and surface temperature limits.

➔ Bear in mind that even within the permitted temperature range, prolonged contact with a heated surface over a longer period of time can become unpleasant or can cause burns.
➔ Do not place a device or a power supply unit under a blanket, under a pillow, or under your body, for example, while it is connected to the power supply.

- ➔ Make sure that the device and the power supply unit are situated in a well-ventilated room during the battery charging process and when the unit is in use.
- ➔ Be extremely careful if your body does not immediately react to high temperatures and heat.

4.10 Instructions for maintenance

To ensure satisfactory and reliable operation, we recommend: Have the components of the Vissard checked every two years by our service department or an authorized dealer. If an error occurs which you are unable to correct, label the components of the Vissard as "out of order" and contact our service department, *sect. , page 63*.

- ➔ Use only the following fuse:
  Vissard 3D/Vissard RG: Fuse 1.25 A time-lag, Order number 05100170

Control unit

Do not attempt to change the rechargeable battery yourself, as the battery could sustain damage, which in turn can lead to overheating and cause injury. The lithium-ion battery must only be changed by the manufacturer or by an authorized service partner.

4.11 Instructions for disassembly and disposal

- ➔ When disconnecting the unit from the electricity supply, do not pull on the cable, but take hold of the respective plug or loosen the screwed connections. Take hold of the plug, do not pull on the cable.
- ➔ Vissard 3D/Vissard RG: The device may only be disassembled and reassembled by OCULUS service person or an authorized dealer.
- ➔ Dispose of the Vissard components in accordance with legal regulations.
- ➔ Recycle or dispose of the lithium-ion batteries used in the mobile components separate to household waste.

4.12 Note on electrical safety

Attention

Risk of injury due to electric shock

- ➔ Do not touch the device, or the cables or sockets with wet hands or any other wet body part.

Attention

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

Connecting the Vissard with non-medical electrical equipment to form a medical electrical system must not result in a patient safety level below that prescribed by IEC 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.
- ➔ Control unit: Only use the respective power pack specified in the scope of delivery.

If you use a new control unit for the Vissard that is not supplied by OCULUS, you must have it checked for electrical safety. Call OCULUS Service for this purpose.

Attention

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

- ➔ Do not use a multiple socket extension cord.

Electromagnetic compatibility (EMC / cables)

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

Portable and mobile RF communications devices (high frequency) can affect medical-electrical devices, *sect. 16, page 66*.

- ➔ 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 components of the Vissard function correctly.

Control unit

Radio interference/malfunctions: Emissions emanating from the control unit can impair the operation of other electronic devices and cause such other devices to malfunction.

Interference with medical devices:

There are magnets in the mobile components whose magnetic fields could lead to the impairment of pacemakers, defibrillators and other medical devices and instruments.

- ➔ Always maintain a minimum distance of 15 cm between your medical device and the control unit.
- ➔ Ask your doctor or the device manufacturer for detailed information about your medical device.
- ➔ If you suspect that the iPad interferes with your cardiac pacemaker, defibrillator or any other medial device, stop using it.

5 Intended Use

The Vissard is used to test visual acuity for subjective eye examination.
It has the following testing options:

- Vision tests with Landolt rings, numerals, letters, LEA symbols, and similar.
- Astigmatism tests
- Monocular and binocular fine adjustment tests
- Phoria tests
- Stereo tests
- Eye dominance tests
- Colour vision screening
- Images and a fixation video (Vissard 3D and Vissard RG only)
- Contrast sensitivity testing under photopic conditions
- Light and dark refraction (Vissard 3D and Vissard RG only), with and without glare

The Vissard must only be used for the purpose specified in this Instruction Manual.

➔ Only operate the device using original accessory parts supplied by us, and when the device is in technically perfect working order
➔ Observe the safety instructions given above.

5.1 Intended medical indication

The device is suitable as an aid for testing subjective visual functions and for assessing visual quality.

5.2 Contraindication

None known

5.3 Possible side effects

None known

5.4 Patient group

Children from 3 years up to geriatric patients. No restrictions on weight and health status. The patient must be awake and able to answer.

6 Device Description

6.1 Overview of Device Components

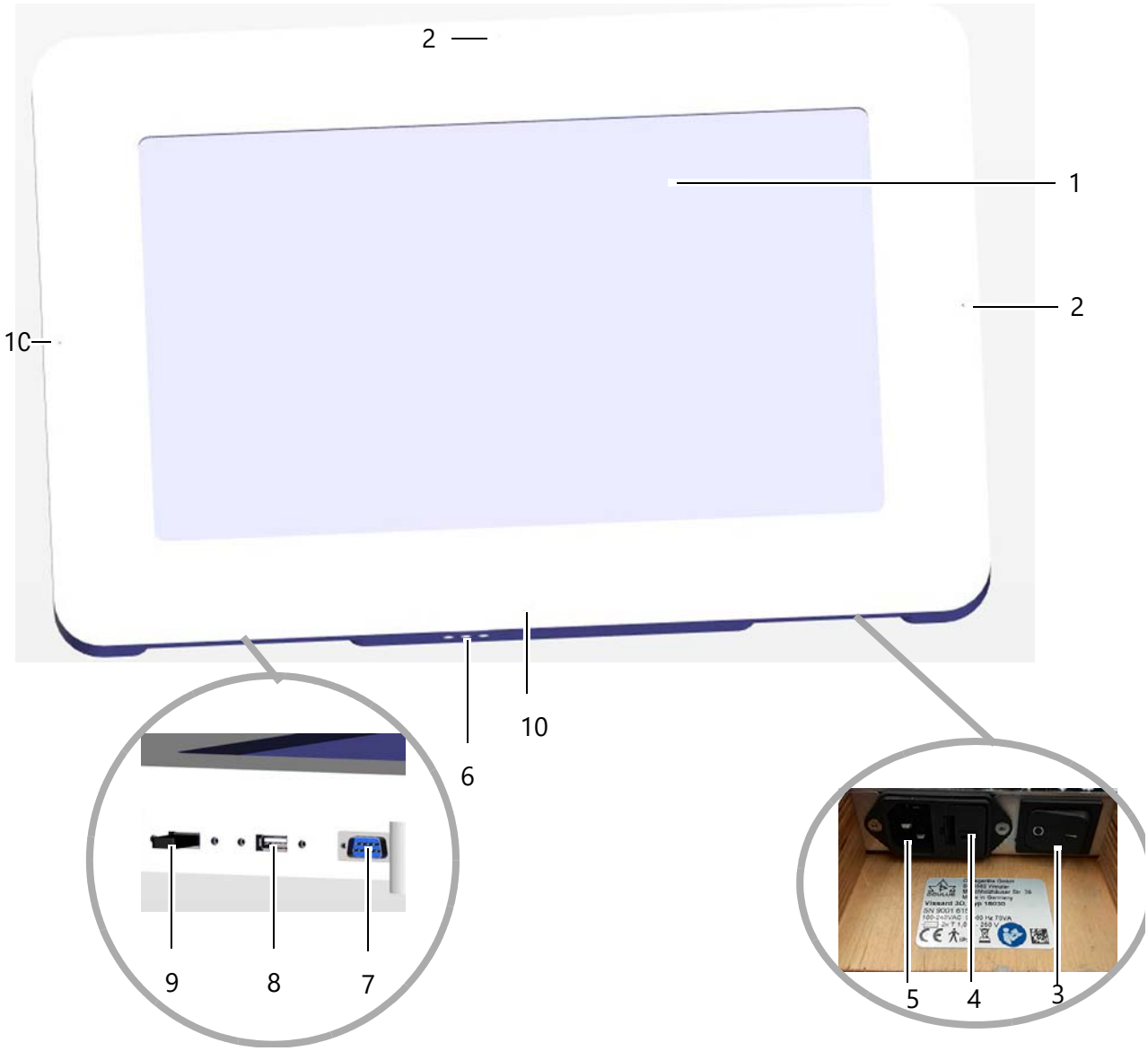


Fig. 6-1: Overview Vissard 3D/Vissard RG

1	Monitor	6	Service buttons
2	Brightness sensor	7	RS232 port for phoropter
3	Mains connection	8	Network port
4	Fuses	9	2 x USB port
5	On/off switch	10	LED for glare

Fig. 6-2: Overview: Control unit

1 Standby button
2 Touchscreen
3 Connection jack, e.g. for charger cable
4 Home button

6.2 How the Vissard Vision Screening Unit Works

The Vissard is a vision screening unit with an extensive range of tests.

It works with two hardware components and one software component:

- The control unit (iPad) with the Vissard app
- The patient display (distance and/or near vision)

The patient display is attached to the wall. The distance from the patient to the patient display can be set individually.

The examiner enters the tests that are to be presented to the patient via the control unit. The patient views these tests on the patient display and the examiner views them on the control unit.

The examiner documents the test results separately, e.g. hand-written on a test block.

LEDs for glare: These LEDs are used when you conduct a test with glare.

Brightness sensors: The brightness sensors measure the ambient brightness.

For the 3D and binocular tests, the image separation is generated differently depending on the Vissard version.

- Vissard 3D: Through linear or circular polarization
- Vissard RG: Use of the anaglyph method (red-green separation)

Attention

The company OCULUS Optikgeräte GmbH cannot be held responsible for the further use of the data acquired with and the evaluations calculated with the Vissard in any form whatsoever.

7 Installation and Connection

Attention

Risk of injury /damage to the unit if it is installed incorrectly.

- ➔ Before using the Vissard for the first time, the Vissard system must be installed and connected by our service department or by an expert authorized by OCULUS.
- ➔ Vissard 3D/Vissard RG:
  Make sure that there is proper ventilation. Do not cover the ventilation openings.
  Make sure that the unit is properly secured to the wall.

Incorrect examination results due to incorrect settings

If you temporarily dismount the Vissard 3D/Vissard RG and want to remount it, the correct settings could change.

- ➔ After dismounting the unit, have it remounted by OCULUS Service or an authorized dealer.

Note

Risk of damage to the device if not handled correctly

- ➔ Do not expose the components of the Vissard to any vibrations, shocks, contaminants, moisture, or high temperatures.
- ➔ Do not drop it.
- ➔ Handle the device with care.

7.1 Set up

- ➔ Place the patient display so that direct light cannot affect the measurement.
- ➔ Make sure the examination is free from reflections. Darken the examination room, if necessary.
- ➔ Make sure that the patient is sitting straight in front of the patient display and looks towards the centre of the screen, *fig. 7-1, page 22*.

Ambient temperature

The ambient conditions for operation are given in *sect. 15, page 64*.

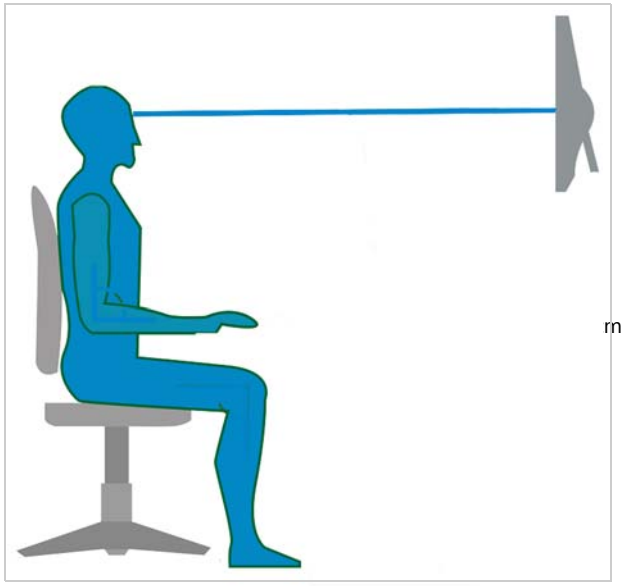
- ➔ Before installing the unit, take a look at the transport and storage temperature, and the temperature in the room in which the unit is to be installed.

Patient position

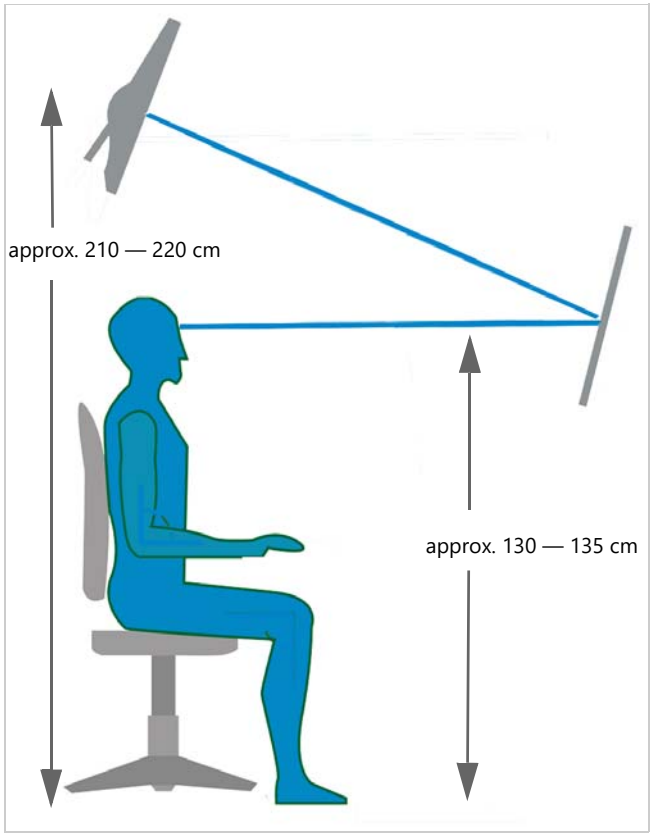
The distance from the patient to the patient display can be adjusted with the Vissard software to suit the room. The adjustment range depends on the Vissard model that is in use.

Model	Adjustment range
Vissard 3/DVissard RG	300 to 800 cm

➔ Make sure that the patient is sitting straight in front of the patient display and looks towards the centre of the screen.



Patient position: Straight, looking toward the centre with the Vissard 3D/Vissard RG



Patient position: Vissard 3D/Vissard RG with deflection mirror

Fig. 7-1: Patient positions

7.2 Electrical Connection

Warning

Injury caused by electric shock

➔ To avoid the risk of electric shock, this unit must only be connected to a mains supply with protective earth.

Attention

Electrical safety hazard

- ➔ Do not use the Vissard directly next to other devices and do not stack the Vissard on top of other devices.
- ➔ If you do use the Vissard in the vicinity of, or stacked on other devices, you must ensure that the Vissard is working properly.
- ➔ Mobile Vissard components: Use only the power supply unit specified in the scope of delivery, *sect. 16.1, page 66*.
- ➔ Do not use a multiple socket extension cord or power strip to connect the Vissard.

Connect the patient display Vissard 3D/Vissard RG

Warning

Risk of injury caused by electric shock if the wrong power cable is used

- ➔ Use only a mains cable that meets the requirements of IEC 60227-1, Type 53, min. 0.75 m^2 and of IEC 60320-1.

Note

Risk of equipment damage due to incorrect connection

If you do not connect the components of the Vissard 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.
- ➔ Please pay attention to the specifications on the nameplate.

If the plug is faulty, contact OCULUS Service or an authorized dealer to repair the damage.

- ➔ Plug in the power plug. When doing so, hold of the plug and not the cable.

Connect the control unit

The control unit is connected to the patient display via Bluetooth or Wi-Fi. This connection will be set up by OCULUS.

The control unit has a rechargeable battery for power supply. You must charge the control unit from time to time by connecting it to the AC power.

7.3 Turning On and Turning Off

7.3.1 Switching the Control Unit On and Off

Turning On:

➔ Press the Standby button.
➔ Unlock the unit.
➔ Enter a code, if necessary.

Turning Off:

➔ Close the Vissard app.
➔ Press the Standby button.

7.3.2 Turning On and Turning Off the Vissard 3D/Vissard RG

Turning On:

➔ Switch on the Vissard 3D/Vissard RG at the On/Off switch.

Turning Off:

➔ Switch off the patient display for distance at the On/Off switch.

Fully disconnect from the mains, e.g. for cleaning purposes:

➔ Switch off the patient display for distance at the On/Off switch.
➔ Unplug the power cord. Take hold of the power plug for this purpose; do not pull on the cable.

7.4 Install the Vissard App

To use the Vissard app and to be able to download other apps in addition to the Vissard app, you'll need to

- be connected to the Wi-Fi with your iPad, *sect. 7.4.2, page 25*
- use your own **personal Apple ID** with your own password, or create a login if you don't already have one, *"Creating your ohn Apple ID" on page 26*
- download the Vissard app under your own Apple ID

7.4.1 On the iPad

The following description shall provide instructions on how to install the Vissard app on your iPad and how to prepare your iPad for the Vissard app updates.

Minimum requirement for the installation:

- iPad with current iOS version

Note

OCULUS cannot be held liable for damage incurred as a result of incorrect installation.

➔ Follow these instructions when performing an installation.

7.4.2 Connect to Wi-Fi

To be able to update apps or download new apps, the iPad must be connected to the Internet. You'll therefore need to connect your iPad to the Wi-Fi. (Alternatively, you can use a data cable to connect it to a PC with an Internet connection - not described in these instructions. For more information, refer to the operating manual for your iPad).

To be able to use the iPad on the Wi-Fi, you will need to connect it.

➔ Select the iPad app >Settings.

➔ Click on [Wi-Fi].
Various Wi-Fi networks in your area will be displayed.

➔ Case 1: If your iPad is registered on the Wi-Fi and enabled, proceed to the steps described in *"Creating your ohn Apple ID" on page 26*

If your iPad is already connected to a (your) Wi-Fi, this Wi-Fi name will appear under the field where you can switch your Wi-Fi reception on and off. It will also be marked with a blue checkmark.

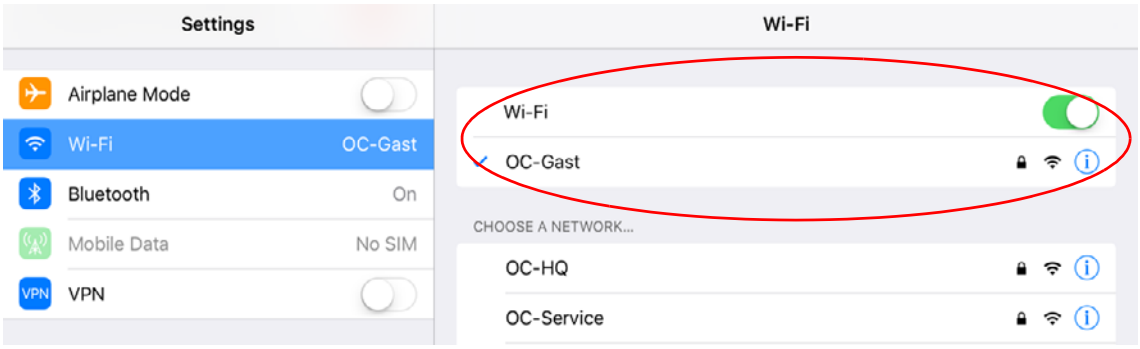


Fig. 7-2: Case 1:Wi-Fi is registered and enabled

➔ Case 2: If your iPad is registered in the Wi-Fi but not enabled, enable "Wi-Fi".

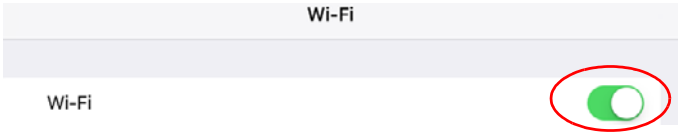


Fig. 7-3: Case 2: Wi-Fi is registered and not enabled.

➔ Case 3: If your iPad is not yet registered in the Wi-Fi, enable "Wi-Fi".

➔ Type in the Wi-Fi that you wish to connect your iPad to.

➔ Enter the password (or login data) for the Wi-Fi.

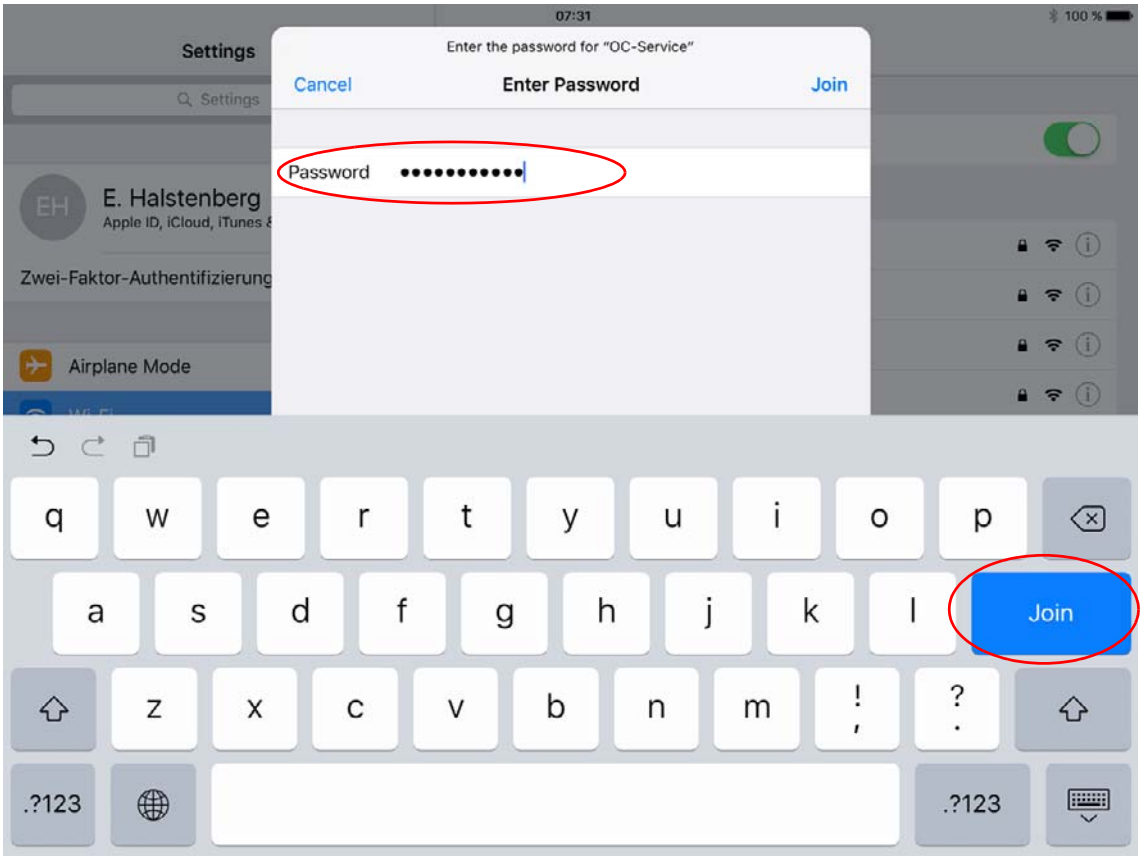


Fig. 7-4: Enter Wi-Fi password

➔ Click on [Join].

7.4.3 Using the Vissard app with your own Apple ID

Requirements:

- Your iPad must be registered on an active Wi-Fi, see also *fig. 7-2, page 25*.
- You will need an email address that you are able to access.
- A valid phone number is required to verify your identity.

Creating your ohn Apple ID

If you do not yet have a personal Apple ID, you can create your own Apple ID with your own password. You will need it in order to re-download the Vissard app.

For more information on creating an Apple ID, visit the Apple website here:

- https://appleid.apple.com/

Downloading the Vissard app

➔ Log on with your own Apple ID.
➔ Open the App Store.
➔ In the search field, type in (for example): Vissard.

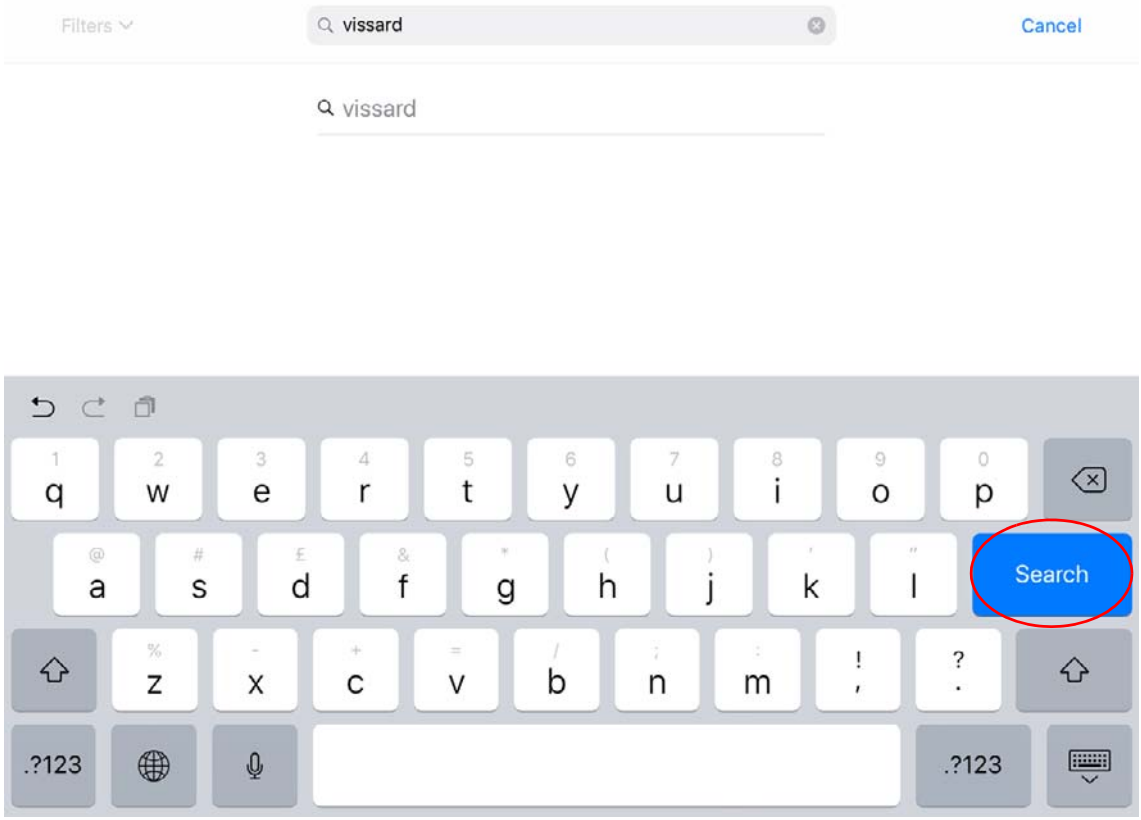


Fig. 7-5: Finding the Vissard app

➔ Click on [Search].
The following dialogue appears:

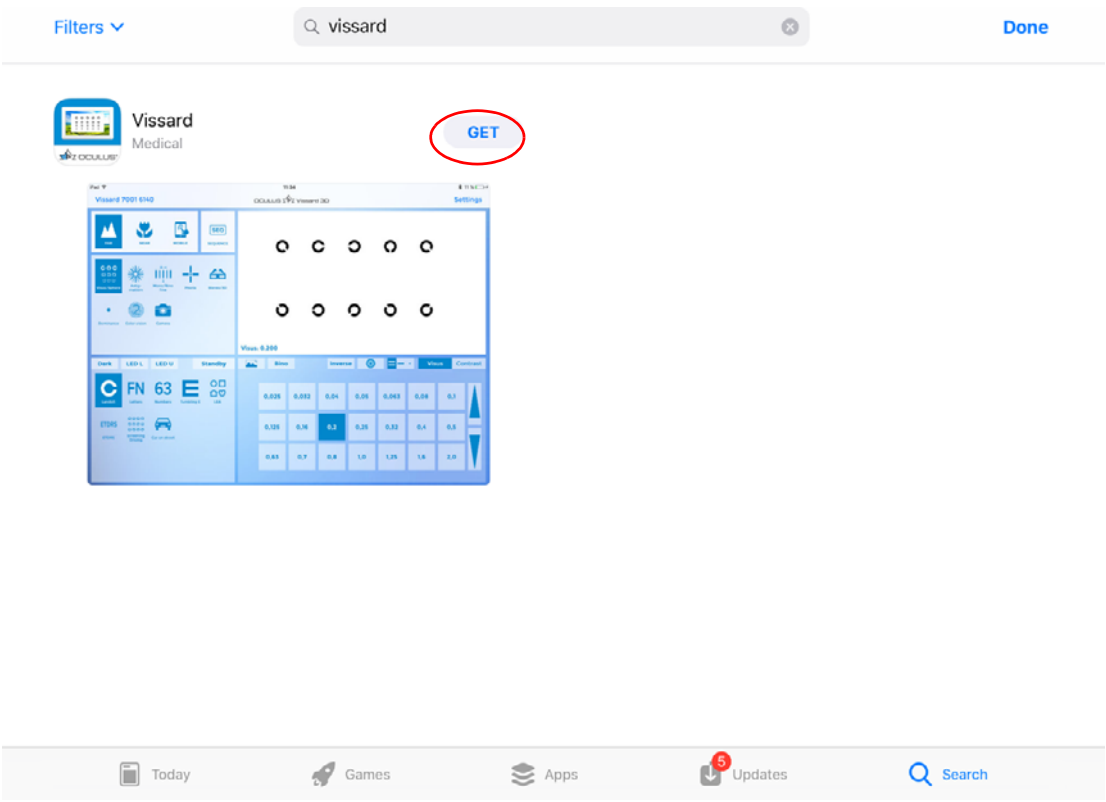


Fig. 7-6: Downloading the Vissard app

➔ To download the Vissard app, go to [Get] > [Install]. You may need to enter your (Apple account) password.
If the following icon appears, the Vissard app is being downloaded.

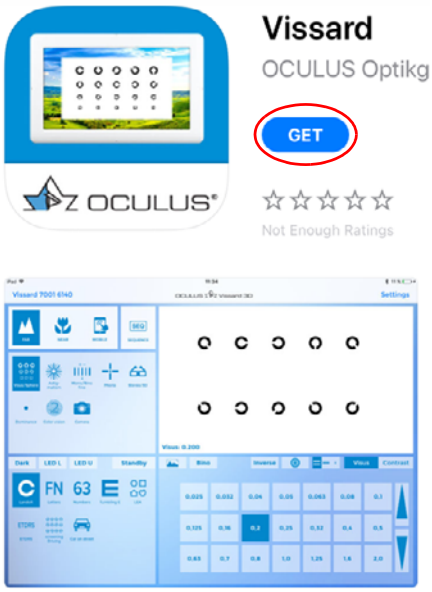


Fig. 7-7: Vissard app being downloaded

After the download, you will see the Vissard app on the user interface of your iPad and be able to use it.

8 Operating the Vissard Program

This section describes how to

- start the Vissard program, *sect. 8.2, page 29*
- operate the multi-touch display of the control unit, *sect. 8.2, page 29*
- operate the elements of the Vissard program in general, *sect. 8.3, page 30*

Note

The Vissard program is not designed to specify possible therapies, without further professional examination and additional medical findings or diagnostic tests.

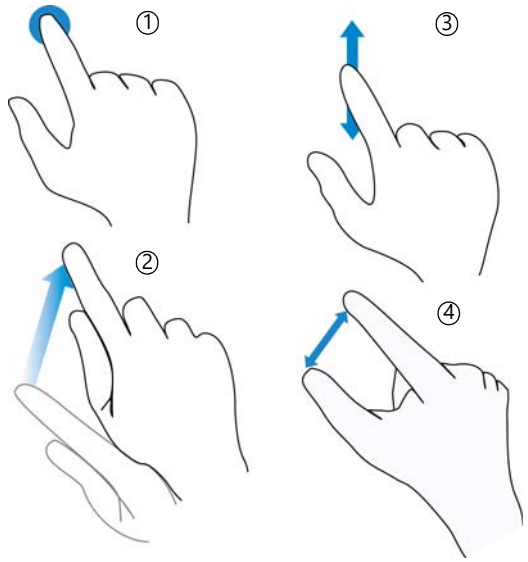
8.1 Starting the Vissard Program

Before starting the program, you must have switched on the Vissard components. You use the control unit to start the Vissard program.

➔ Tap on the Vissard app.

8.2 Operation of the Multi-Touch Display at the Control Unit

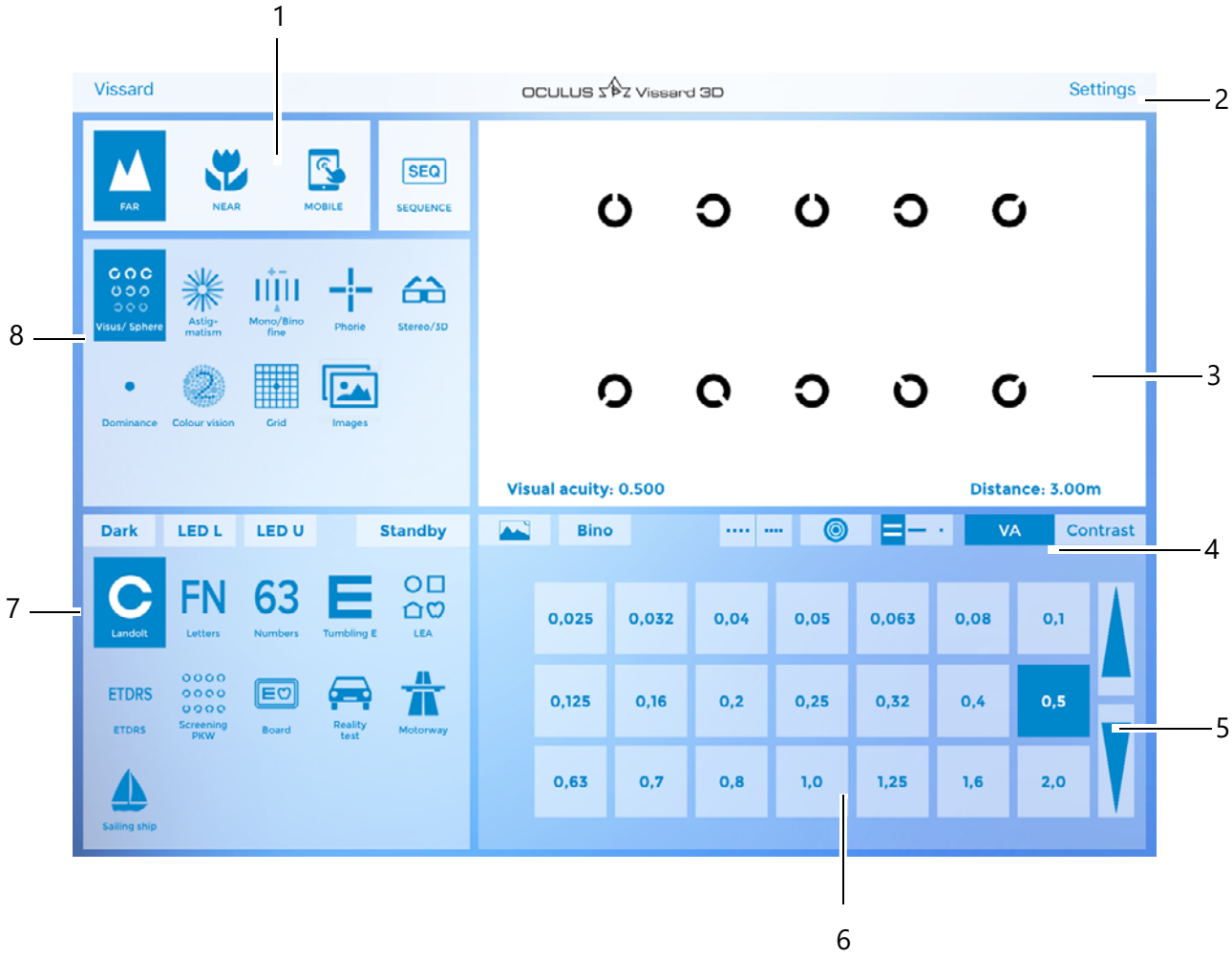
The examiner uses the control unit to control the Vissard program. You can operate the multi-touch display with the following gestures.



1 Tap
2 Swipe
3 Move
4 Pinch to zoom

Fig. 8-1: Operation of the multi-touch display (graphic from the iPad User Manual)

8.3 Using the Elements of the Vissard Program



1 Test selection presets
2 [Settings] button
3 Test image shown to the patient
4 Supplementary setting options for a test
5 [Up] and [Down] buttons
6 Setting options for the presently activated test; here: visual acuity
7 Test selection
8 Selection of the test group

Fig. 8-2: Areas in the Vissard program; Example: Visual acuity test

The program's user interface is divided up into six areas. You will find these six areas in the display for every test group. The contents of the six areas change depending on the test group that has been selected.

[Settings] button (2)

Depending on the constellation in which you use your Vissard components, you can change the various settings. For more information, refer to *sect. 8.4, page 34*.

Test selection presets (1)

You can preset the display of the test groups and tests with these buttons. The appropriate tests are presented. You can also activate camera mode.

Column name	button	Description
FAR		Distance vision tests
NEAR		Near vision tests, 30 – 120 cm

The display depends on the previously entered settings.

Patient test field (3)

The test chart that the patient sees on the patient display is displayed here.

Select test group (8)

You can select a group of tests here.

➔ Tap on the appropriate button to select the test group, *sect. 8.5, page 41.*
The test selection (7) is adapted accordingly.

For more information about the individual tests and test groups (8), refer to the *User Guide*.

Select test (7)

You can select a specific test for the test group here. The test selection is automatically adapted to the previously selected test group.

➔ Tap on the appropriate button to select the test, *sect. 8.5, page 41.*

For more information about the individual tests (7), refer to the *User Guide*.

Supplementary information or setting options for a test (4)

Buttons, with which you can modify the presently active test, are displayed here. The buttons are automatically adapted to the previously selected test. Depending on the test, supplementary buttons may not be displayed here.

Button	Function
Dark	You need the [Dark] button to test the dark refraction.
LED L LED U	You switch on the respective LED with these buttons. You need these to simulate glare for various visual tasks.
Standby	You can switch the patient display to a standby mode with this button. The display turns black. When you switch "standby" off again, the last test that you used reappears.
	Display a wallpaper.
Bino	Change over from monocular to binocular test presentation or vice-versa.
	Select between two different spacings of the optotypes to detect separation difficulties (crowding).
	Display the Verhoeff ring.
	■ Two line optotype presentation ■ One line optotype presentation ■ Single optotype presentation
Visus Contrast	Change over from visual acuity levels to contrast levels or vice-versa.
R <> L	Change test presentation for the left or right eye.

Button	Function
Inverse	Show the display inversely.
Pol/RG	Switch the 3D mode from polarisation mode to red-green mode.

Change present test setting (6)

Control elements, with which you can modify the present test, e.g. change the visual acuity levels for a visual acuity test, are displayed here.

Button with visual acuity levels:

➔ Tap multiple times on a button. The presented optotype changes, e.g. the gap position of the Landolt ring or the digit.

➔ Tap on the other button to select a visual acuity level.

[Up] and [Down] buttons (5):

➔ Tap on these buttons to return to the previously displayed or to proceed to the next visus level.

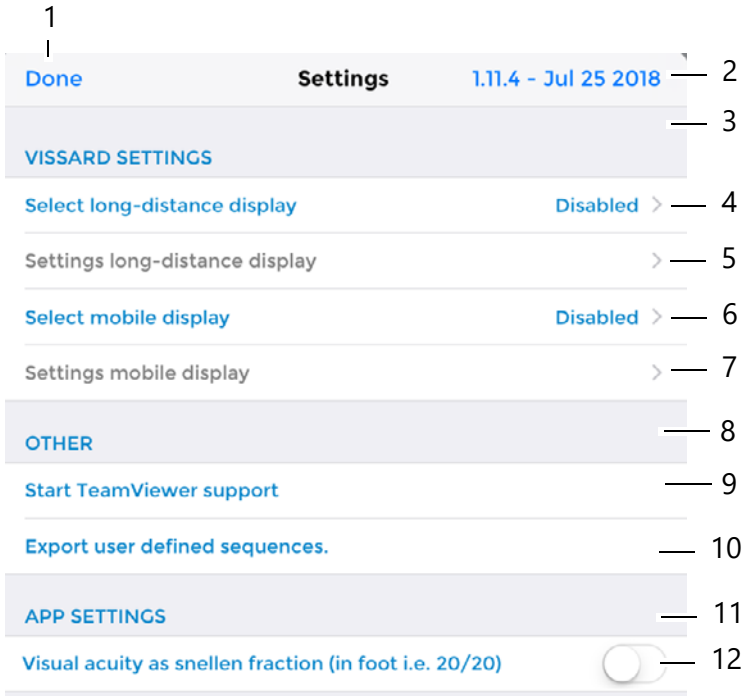
Sliders

➔ Move the slider, e.g. to change the size of the display.

8.4 Change Settings

Depending on the constellation in which you use your Vissard components, you can change the various settings.

➔ Tap on the [Settings] button, *fig. 8-2, page 30, item 2.*
The following display appears.



1	[Done] button	7	Mobile display settings
2	Software version	8	Other settings
3	Vissard settings	9	Start TeamViewer support for remote service
4	Select long-distance display	10	Export of user defined sequences
5	Long-distance display	11	App settings
6	Select mobile display	12	Switching Visus

Fig. 8-3: "Settings" display

Greyed out settings cannot be changed.

End setting

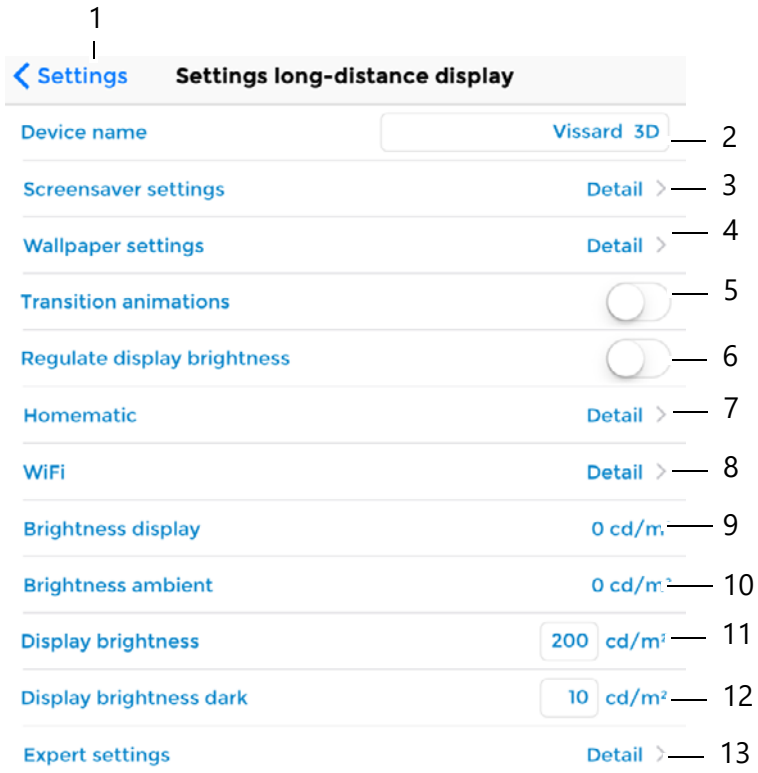
➔ Tap on the [Done] button (1).
The settings are saved. You are returned to the Vissard program.

8.4.1 Select long-distance Display

➔ Tap on "Select long-distance display" [>] to open the list of available long-distance displays *(fig. 8-3, page 34, item 4)*.
➔ Select the desired long-distance display from the list.
➔ Return to the menu.
The long-distance display is selected.

8.4.2 Change Settings for the long-distance Display

➔ Tap on "Long-distance display" [>] *(fig. 8-3, page 34, item 5)*.
The following display appears.



1 (Settings] button
2 Device name field
3 Option "Screensaver settings"
4 Option "Wallpaper settings"
5 Option "Transition animations"
6 Option "Regulate display brightness"
7 Settings for the Homematic function
8 Wi-Fi settings
9 "Brightness display" settings
10 "Brightness ambient" settings
11 "Display brightness" settings
12 "Display brightness dark" settings
13 "Expert settings"

Fig. 8-4: "Settings" display

[Settings] button (1)

➔ Tap the field to return to the settings.

Enter the device name (2)

The name of the device is displayed here. Modification is not possible.

Option "Screensaver" (3)

You can activate a screensaver here. You can either activate a default screensaver or a screensaver of your own.

➔ Tap on "Detail" [>].
➔ Tap on "None" [>] to deactivate this item.

Default screensaver:

➔ Tap on "Default screensaver" [>].
➔ Select an image.
It is then bordered in blue and is used as the screensaver.

"Own screensaver":

➔ Tap on "Own screensaver" [>].
➔ Select your own photo or video from the photos folder on your iPad.
It is loaded and you can then use it as your screensaver. Depending on the quality and resolution of the image, or the length of the video, the transfer with Bluetooth may take several minutes.

Option "Wallpaper" (4)

Here you can select which wallpaper appears on the screen of the Vissard 3D and Vissard RG. You can select either a default wallpaper or your own wallpaper.

➔ Tap on "Detail" [>].

Default wallpaper:

➔ Tap on "Select default wallpaper" [>].
➔ Select an image.
It is then bordered in blue and is used as the default wallpaper.

"Own wallpaper":

➔ Tap on "Transfer wallpaper" [>].
➔ Select your own photo from the photos folder on your iPad.
It is loaded and you can use it as your wallpaper. Depending on the quality and resolution of the image the transfer with Bluetooth may take several minutes.

Option "Transition animations" (5)

You can activate a transition animation here.

➔ Activate this option if a transition animation is to be displayed.

Option "Regulate display brightness" (6)

Here, you can activate the monitoring of the ambient brightness and regulate the display brightness dependent on the ambient brightness.

➔ Activate this function.
This is displayed in the field "Brightness display" (9).

Settings for the Homematic function (7)

You can enter the following Homematic settings. Please contact OCULUS Service if you have any questions.

- IP Homematic Zentrale: Network address
- Port: The port is generally already automatically entered (8181).
- Example of Homematic programs: Enter the name of the program that is given by the Homematic, e.g. "Light on" for photopic examinations or "Light off" for mesopic examinations. The lighting in the examination room is automatically adjusted.

➔ Tap on "Homematic" [>]
➔ Select the desired options.
If you have not activated the function, this line stays empty.

Wi-Fi settings (8)

You can enter Wi-Fi specifications here

- SSID: Example of a WIFI/network name
- Password: If a * is displayed, it means that a password is stored in the Vissard. If you overwrite it here, it will also be overwritten in the Vissard.
- Encryption: Encryption
- Pairwise: Encryption parameters
- Group: Encryption parameters

➔ Tap on "WIFI" [>].
➔ Select the options that you want to be displayed.

"Brightness display" (9) and "Brightness ambient" (10) settings

The actual value measured by the sensor is shown here.

"Display brightness" (11) and "Display brightness dark" (12) settings

You can enter the value for the display brightness here. You thus define fixed values for the light or dark refraction. With the [Dark] button in the supplementary test settings, you can switch from light and dark conditions during the refraction, see *page 32*.

Expert settings (13)

You can change the following settings in the expert settings:

- Distance
- Polarisation (Vissard 3D only)
- Mirror display horizontal

To change the long-distance display and the mobile display settings, the respective display must be connected with the iPad.

➔ Tap on the [Expert settings] button (13).
➔ Enter the password "oculus".

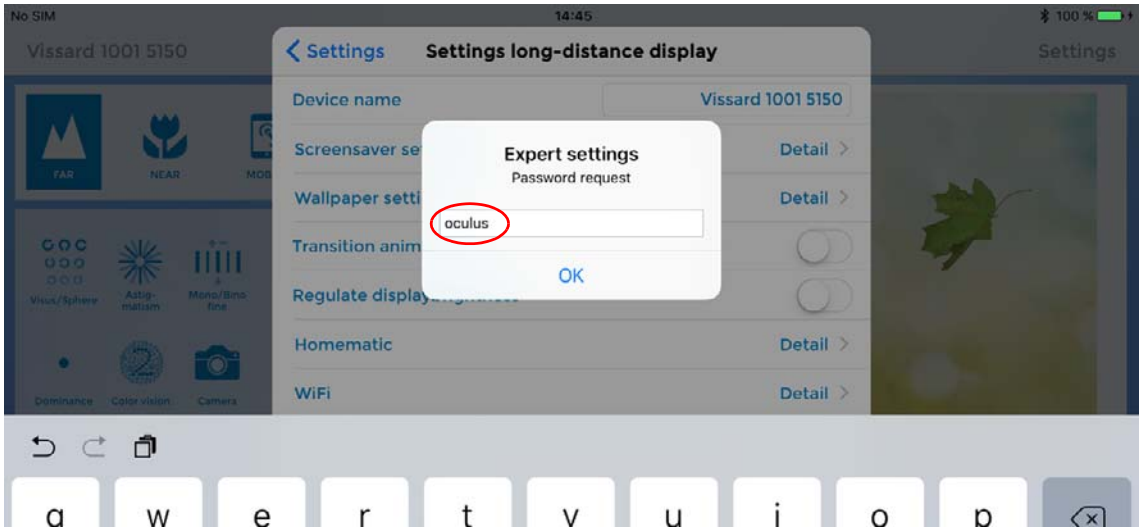
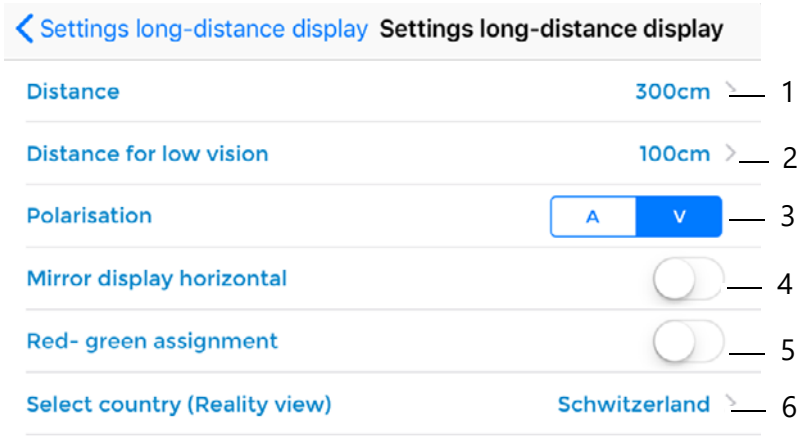


Fig. 8-5: Enter password

➔ Confirm with [OK].

The following display appears.



1 Field for setting the test distance
2 Distance for low vision
3 Selection of the polarisation
4 Option "Mirror display horizontal"
5 Option "Polarisation assignment, or Change red-green filter"
6 Country selection

Fig. 8-6: Expert settings – long-distance display settings

Set the test distance (1)

The distance from the patient to the patient display can be set to suit the room with the Vissard software.

Adjustment range	
Vissard 3D/Vissard RG	300 to 800 cm

➔ Tap on "Distance" [>].
➔ Select the desired distance. The distance is specified in 10 cm increments.

Setting test distance for low vision test persons (2)

The distance between the test person to the test display can - adapted to a low vision test person - be adjusted.

Adjustment range	
Vissard 3D/Vissard RG	25 to 300 cm

➔ Click on “Distance for low vision” [>].
➔ Select the test distance required. The distance is set in steps of 5 cm.

Change polarisation direction (3)

You can change the initial polarisation assignment for the right and the left eye here.

➔ Tap on "Polarisation" [>]
➔ Select the desired polarisation direction.

Mirror display horizontal (4)

If you are working with a deflection mirror, you can mirror the presentations here.

➔ Activate this option if you want to mirror the test image horizontally.

Change the polarisation assignment or red-green assignment (5)

Depending on red/green or polarisation filter, you can change the assignment for the right or for the left eye here.

➔ Activate this option, if necessary.

Country selection (Reality View) (6)

You have the option to select a Reality Test specific to a country.

➔ For example, click on “Switzerland” [>].
➔ Select the country required.

End expert settings

➔ Tap on the button [Settings long-distance display]. This returns you to the Settings screen.

End setting

➔ Tap on the button [Settings] > [Done].
The settings are saved. You are returned to the Vissard program.

8.5 Test Group Overview

The Vissard program offers a number of test groups that are made up of different tests.

You can select the desired test group in the field for selection of the test group *(fig. 8-2, page 30, item 6)*.

Fig. 8-7: "Test group overview" (Example: Vissard3D)

The Vissard program has the following test groups.

Test group	Brief Description
Visus/Sphere	The visual acuity tests are performed for distance vision, intermediate vision and near vision.
Astig-matism	These tests are used to test whether the patient has an astigmatism.
Mono/Bino fine	Different simultaneous fine adjustment tests are offered.
Phoria	The phoria tests test for possible deviation of the eyes with respect to each other. You can thus detect horizontal and vertical heterophoria.

Test group	Brief Description
	The stereo tests are used to test stereoscopic vision.
	The dominance test is used to determine which eye is dominant.
	You can activate a colour vision test with Ishihara colour charts. This function is not available for the Vissard MOBIL/Vissard LECTUS.
	Function test to check the field of vision
	Select between 2D, 3D and standard images and a video.

9 Examination Procedure

Caution

Risk of injury if the unit is not correctly mounted and secured.

➔ Vissard 3D/Vissard RG: Before use, check that the patient display has been correctly mounted and secured. Never put an incorrectly mounted and secured patient display into operation. Call OCULUS Service, if necessary.

Caution

Incorrect examination results due to improper operation

➔ Before initial operation: Let OCULUS or an authorized dealer train you in the operation of the Vissard.

➔ Switch on the patient display and the control unit, *sect. 7.3, page 24*.

➔ Start the Vissard program, *sect. 7.3, page 24*.

➔ Make sure that the patient display is clean and clearly legible.

➔ Prepare a template (e.g. test block or digital test template) for noting down the test results.

9.1 Prepare the Patient

➔ Check to be sure that any adaptation disorder has been resolved.
➔ Check the patient's glasses for damage or dirt.
➔ Explain the procedure and the optotypes to the patient. You can show the patient the following picture

A ring with a gap in it is used as the test symbol (optotype). The gap can appear in eight different positions.
Please tell me where the gap is.

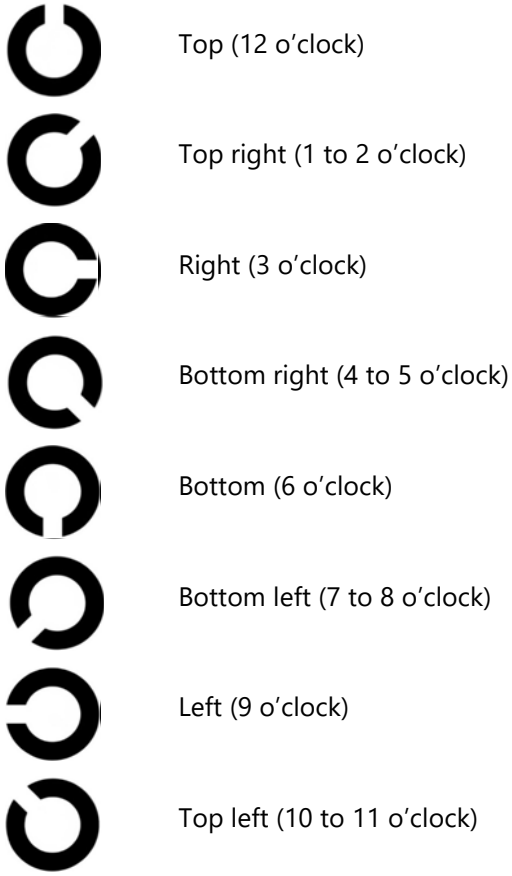


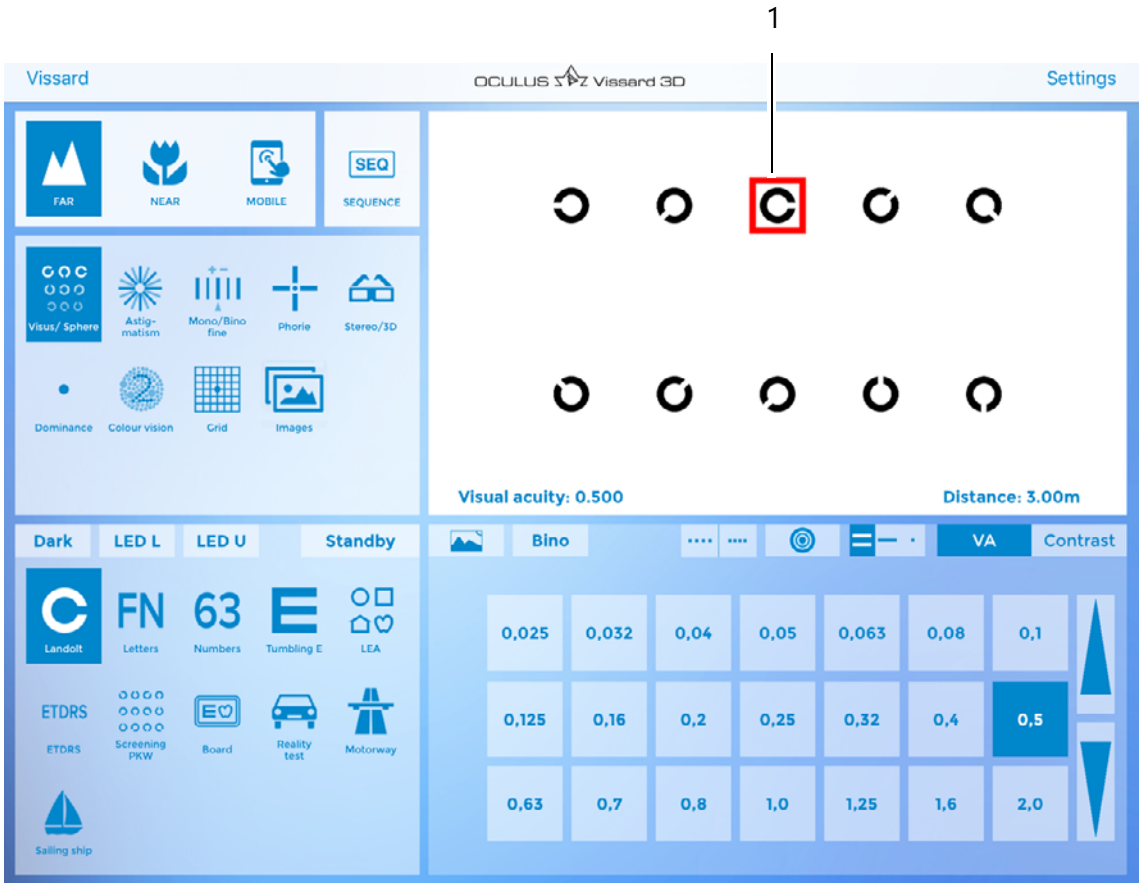
Fig. 9-1: Example: Landolt rings explained

➔ Seat the patient correctly in front of the patient display.
Make sure that the patient is sitting straight in front of the patient display and looks towards the centre of the screen,
see *fig. 7-1, page 22*.

9.2 Mark the Optotype

You can mark the optotype that you want the patient to look at. A red square appears around the optotype in question.

➔ Lightly tap the selected optotype on the control unit.



1 Marked optotype

Fig. 9-2: Mark the optotype

A red square appears around the optotype on the control unit and on the patient display.

When you let go again, the marking disappears.

9.3 Carry out the examination

➔ Select a test group, e.g. Visus/Sphere *sect. 8.5, page 41*.

➔ Select a test, e.g. Landolt, see *sect. 10, page 46*.

➔ Perform the test steps.

➔ Note down the results.

9.4 Finishing the Exam

➔ Select a new test group for the next examination.

➔ To close the Vissard app, press the Home button on the iPad.

10 Cleaning, Disinfection and Maintenance

This chapter explains how to clean and maintain the Vissard components.
Disinfection and sterilisation are not necessary.

10.1 Cleaning

Attention

Risk of electric shock if the components of the Vissard are not completely disconnected from the mains for these jobs.

➔ Switch off the Vissard components, *sect. 7.3, page 24*.
➔ Pull the power plug before cleaning and maintenance. Take hold of the power plug for this purpose; do not pull on the cable.

➔ Pay attention to the product descriptions or instructions for use of the products that you use for care and cleaning.
➔ Do not clean the Vissard with aggressive, chlorine-containing, abrasive or sharp cleaning agents.
➔ Do not use glass cleaner or cleaning agents used for automobiles or industrial cleaners.

Required materials

- Soft, lint-free, dry cloth
- Patient display, distance: Damp cloth with mild detergent

Cleaning intervals

- Once a month, or when necessary
- Plus, for mobile components: Clean the mobile components immediately if they come into contact with substances that cause staining (for example dirt, ink, makeup or creams).

Cleaning

➔ Clean the surfaces of the unit with a soft, lint-free cloth.

Note

Risk of damage due to moisture

Moisture can damage the unit if it is sprayed directly onto it.

➔ Spray the cleaning solution onto a cleaning cloth only, not directly onto the unit.

➔ Remove heavy soiling on the unit with a damp cloth.
➔ Then immediately wipe the unit dry with the dry cloth.
➔ Proceed with care, so that you do not damage the surfaces.

10.2 Care and Maintenance

The Vissard is designed so that no special maintenance is necessary. For safety reasons, we recommend that the illumination and electrical values be checked every two years.

10.2.1 Replacing the Fuse

You can replace a blown fuse.

Attention

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

- ➔ Turn off the Vissard, *sect. 7.3, page 24*.
- ➔ Pull out the mains plug before you change the fuse. Take hold of the power plug for this purpose; do not pull on the cable.
- ➔

Risk of fire if the wrong fuse is used

- ➔ Use only the following fuse:
  Vissard 3D/Vissard RG 1.25 A time-lag, Order number 05100170.

Fig. 10-1: Fuse Holders

- ➔ Turn off the Vissard, *sect. 7.3, page 24*.
- ➔ Unplug the power cord.
- ➔ Disconnect the power cable from the Vissard.
- ➔ Press the catches (2) together.

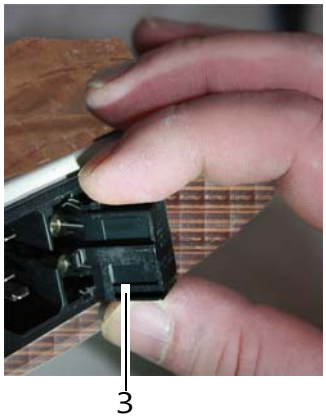


Fig. 10-2: Pull out the fuse holder

- ➔ Pull the fuse holder (3) out.

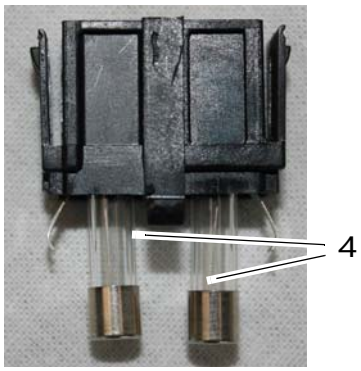


Fig. 10-3: Replace the defective fuse

- ➔ Replace the blown fuse.
  A blown fuse is indicated by burnt-out filaments (4).
- ➔ Insert the fuse holder (3). Make sure it fits properly. The pin (2) must fit in the recess.
- ➔ Connect the Vissard to the mains.
  You can now turn on the Vissard and start doing exams.

10.2.2 Maintenance of the Mobile Components: Charge Rechargeable Battery

Display the charge status

You can display the charge status of the rechargeable battery on the iPad.

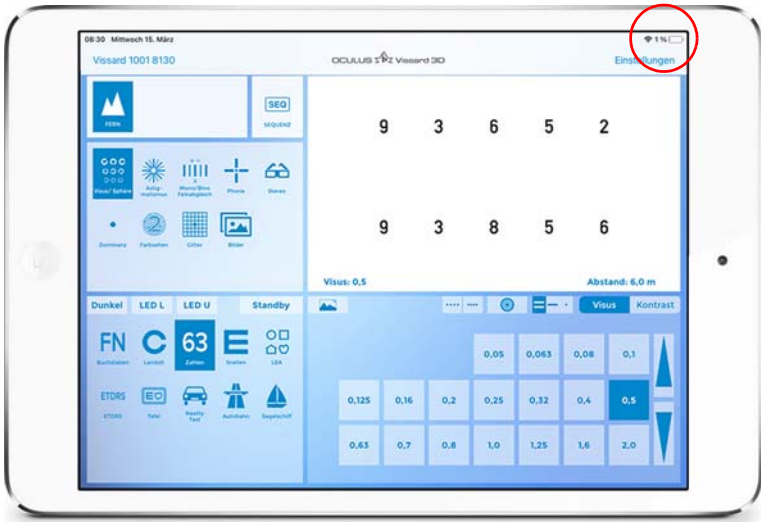


Abb. 10-4: Display of the charge status

Charge the rechargeable battery

Attention

Risk of electric shock

The use of damaged batteries, cables or chargers, or charging the device in damp or hot environments can cause electric shock, fire or injury and can damage the unit and other objects.

- ➔ Do not charge the mobile components in damp or hot environments.
- ➔ Make sure that the power plug and the USB cable have been properly connected to the power and to the mains.
- ➔ Do not touch the parts with damp hands or other damp body parts.

Attention

Risk of fire

- ➔ Do not put the components, the battery or the cables down onto devices that produce heat, heaters (e.g. radiators), microwaves or similar.
- ➔ Do not use the mobile components while charging is in progress.
- ➔ Make sure that no metallic objects, e.g. keys or coins, touch the battery poles.

Attention

Risk of injury

- ➔ Do not, under any circumstances, try to open the mobile components and repair them yourself. Disassembly of the mobile components can lead to injury and to permanent damage to the unit.
- ➔ Contact OCULUS or an authorized dealer if your mobile components are damaged, are not working properly, or have come into contact with any liquids.
- ➔ Avoid situations in which your skin comes into contact with a device or a power supply unit, if the latter has been in operation for a longer period of time, or is connected to a power source. Avoid prolonged contact with the skin. Be extremely careful if your body does not immediately react to high temperatures and heat.
- ➔ Do not place a device or a power supply unit under a blanket, under a pillow, or under your body, for example, while it is connected to the power supply.
- ➔ Make sure that the device and the power supply unit are situated in a well-ventilated room during the battery charging process and when the unit is in use.

Note

- ➔ Do not subject the device and the battery to very high or very low temperatures, see *sect. 12, page 60*.
- ➔ Do not directly connect the plus and the minus pole.
- ➔ Disconnect the charger from the power supply when it is not in use.
- ➔ Use the battery for the intended purpose only.
- ➔ If the battery has not been used for a longer period of time, it will no longer work correctly. Charge and use the battery regularly.
- ➔ If the unit has not been in use for a longer period of time, the battery will discharge. In that case, charge the battery before use.

Charge battery

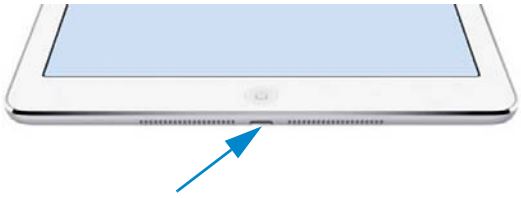


Fig. 10-5: Control unit: Plug in the charger cable

- ➔ Connect the power supply unit with the charger cable.
- ➔ Plug in the power plug. When doing so, take hold of the plug and not the cable.
- ➔ Click the charger cable into the port.

Note

Risk of equipment damage due to incorrect connection

If you do not connect the control unit correctly and voltage is present, the unit can sustain damage after just a short period of time.

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

➔ Please pay attention to the specifications on the nameplate.

If the plug is faulty, contact OCULUS Service or an authorized dealer to repair the damage.

11 Troubleshooting

Attention

Risk of personal injury or damage to property due to improper fault correction

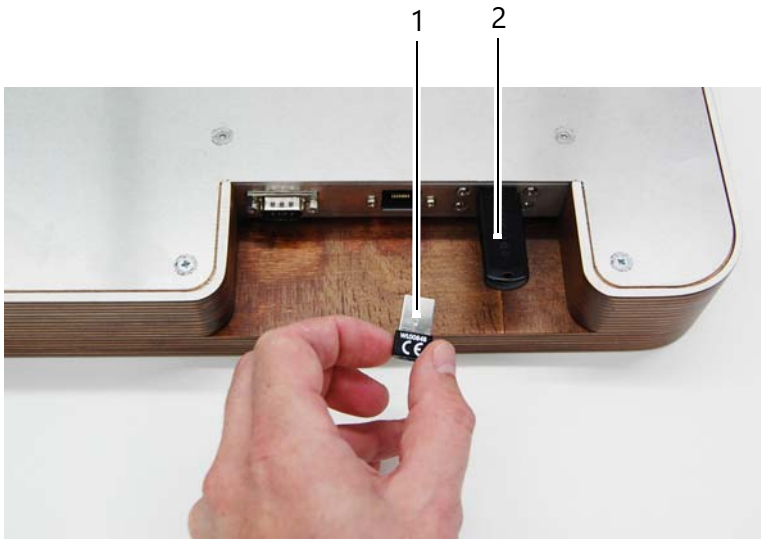
➔ If an error occurs which you are unable to correct by following the instructions below, label the device as "out-of-order" and contact our service department or an authorized dealer.

Fault	Possible cause	Remedy
Vissard 3D/Vissard RG		
Image is not displayed	Unit is switched off, Standby is switched on	■ Switch on the unit
	Power cable is not plugged in	■ Plug in the power cable
	Socket is faulty	■ Call the in-house technician.
The unit shuts itself off suddenly	The power supply is automatically shut off after 15 minutes if no signal is present	■ Switch on the unit
	Power supply fault	■ Check the control settings of the power supply ■ Check the power supply; call the in-house technician, if necessary
Control Unit		
■ Charging interrupted ■ Screen turning dark ■ Temperature warning ■ Apps are closing	Operating temperature exceeded, unit is lying e.g. in the sun.	■ Let the unit cool down
■ The charger cable is getting hot	Plug is dirty	■ Disconnect the cable ■ Clean the connection with a soft, dry, lint-free cloth
■ Device does not charge	Charger cable is defective	■ Change the charger cable
■ The latest version of the Vissard software is not installed		■ Install the latest version of the Vissard software, *sect. 11.1, page 53*
■ The Bluetooth connection is not stable	The Bluetooth connection is not correctly paired	■ Pair the Bluetooth connection, *sect. 11.2, page 56*

11.1 Installation of the Vissard Software Update on the Vissard 3D/ Vissard RG

You have received the latest update of the Vissard software from OCULUS on an USB stick. You must install this software update in the Vissard 3D/Vissard RG (Vissard for short). Proceed as follows:

➔ Switch off the Vissard.
➔ Use the ports at the underside of the Vissard



1 Wi-Fi stick
2 USB stick with software update

Fig. 11-1: Ports at the underside of the Vissard

➔ Remove one of the sticks (1).
➔ Plug in the USB stick with the software update.
➔ Switch on the Vissard.
The following screen is displayed:

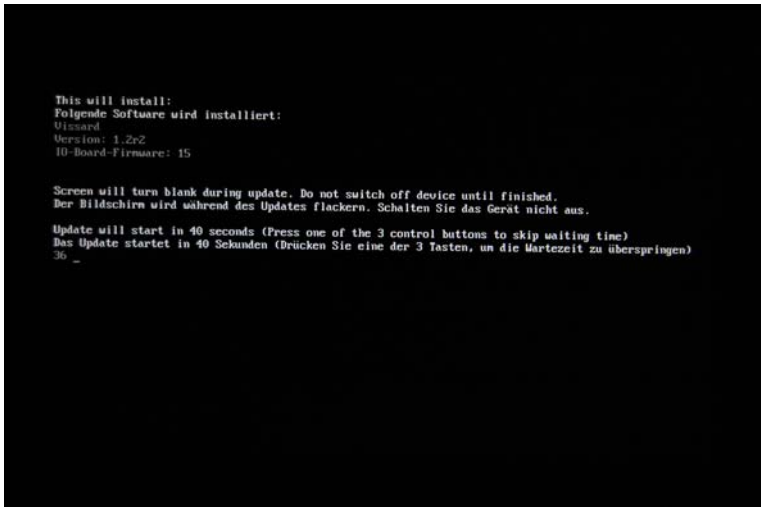


Fig. 11-2: Installation display

➔ Wait: The software update will be installed automatically. During the installation, the following screens appear:

1 Display after successful installation

Fig. 11-3: Successful installation

➔ When the message "Vissard Firmware has been successfully installed" appears on the display, switch off the Vissard.

➔ Wait for at least four seconds and remove the USB stick, *fig. 11-1, page 53, item 2*.

➔ Insert the stick you removed before the update, *fig. 11-1, page 53, item 1*.

➔ Switch on the Vissard. The software is updated.

Fig. 11-4: Vissard 3D display

You can now establish a paired Bluetooth connection (pairing), *sect. 11.2, page 56*.

11.2 Perform Pairing

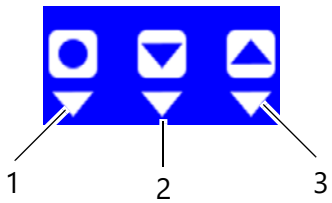
Pairing provides a stable Bluetooth connection to the Vissard. To do this, you need to change a few parameters once on the Vissard and on the iPad. You need both the iPad and the Vissard for the settings.

➔ Use the service buttons at the underside of the Vissard.

1 Service button "Confirm"
2 Service button "Down"
3 Service button "Up"

Fig. 11-5: Service buttons at the underside of the Vissard 3D/Vissard RG

The service buttons are also displayed on the screen.



1 Service button "Confirm"
2 Service button "Down"
3 Service button "Up"

Fig. 11-6: Display of the service buttons on the screen of Vissard 3D/Vissard RG

➔ Open the Vissard app on the iPad.

Fig. 11-7: Open the Vissard app on the iPad

➔ Go to "Settings", and select option "Select long-distance display" *(sect. 8.4, page 34)*.
A list of devices within the range for a Bluetooth connection is displayed.

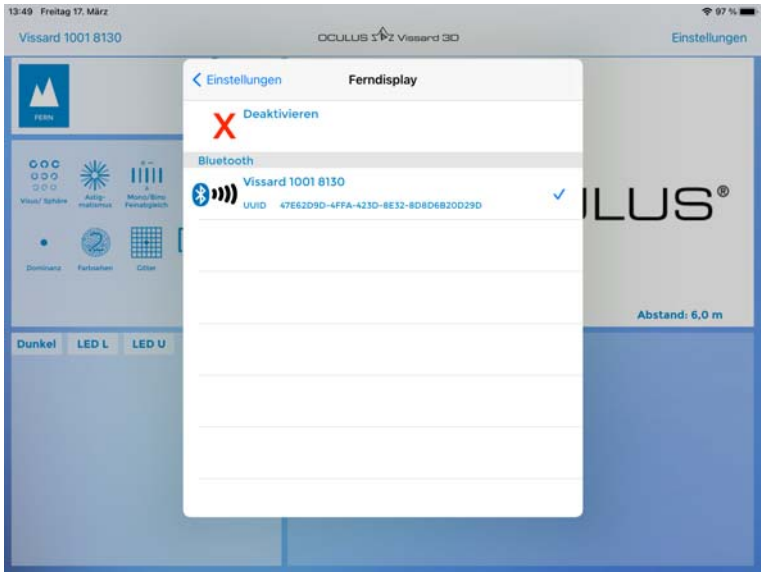


Fig. 11-8: Selecting available devices

Devices checked with a green tick already have a Bluetooth connection established. Re-pairing is not required.
For unchecked devices, a Bluetooth connection must first be established before these devices can be used.

Proceed the pairing as follows:

➔ Select the device to establish a Bluetooth connection with.
A pairing request appears on your iPad.

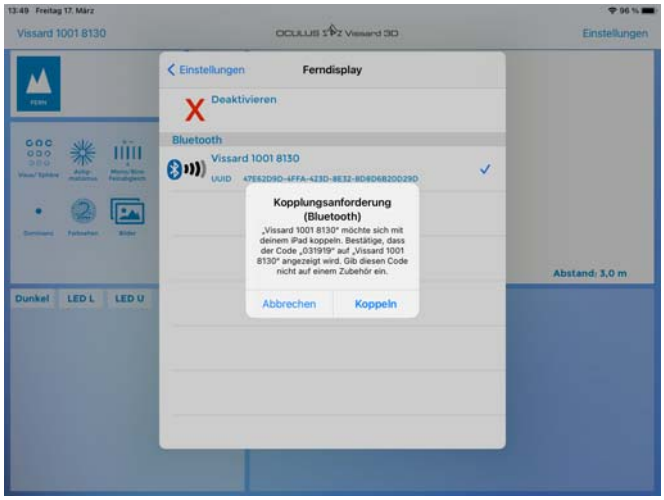


Fig. 11-9: Pairing request on the iPad

➔ Please acknowledge by selecting [Pair].

At the same time, a “Bluetooth pairing request” message appears on your Vissard.

Fig. 11-10: Bluetooth pairing request

➔ Conform it with [Pair].
To do this, use the service buttons beneath the screen *(fig. 11-5 and fig. 11-6, page 56)*.

When pairing has been completed, the following message appears at the Vissard:

Fig. 11-11: Bluetooth: Connected

The connected device is displayed in the Vissard software at the iPad.

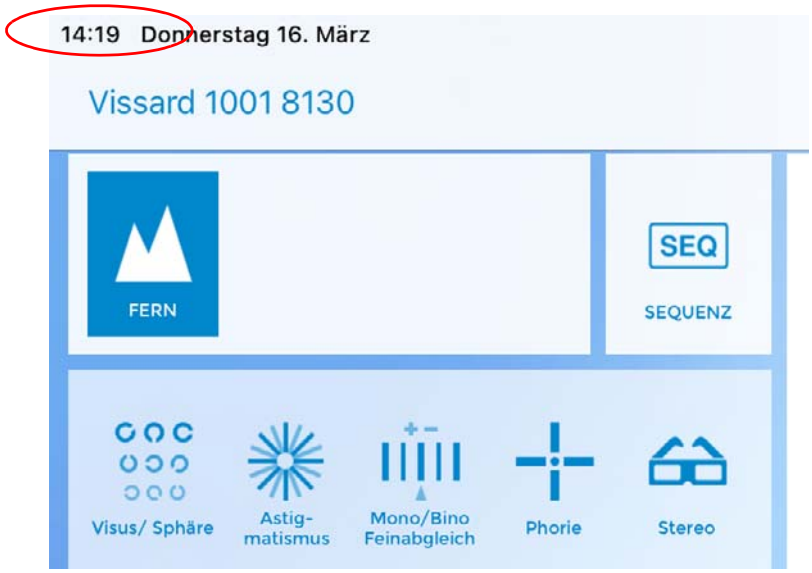


Fig. 11-12: Display of the connected device

12 Transport and Storage

The Vissard must be properly dismantled and packed before being transported or stored.

Attention

Risk of injury resulting from incorrect transport or storage

➔ Place the device in such a way that it cannot fall over.

Equipment damage due to improper transport and storage

➔ Avoid shocks, vibration and dust.
➔ Avoid high temperatures and moisture.
➔ Transport the Vissard carefully.
➔ Observe the transport and storage conditions.
➔ Avoid kinks in the cable during storage.
➔ Avoid proximity to devices that can produce heat, e.g. heaters/ radiators.
➔ Avoid moisture.
➔ Vissard 3D/Vissard RG: Do not touch the surface of the screen, if possible, as this could damage it.
➔ Do not expose the mobile components to direct sunlight for any length of time.

Have it remounted by OCULUS Service or an authorized dealer only.

12.1 Transport and Storage Conditions

Storage and transport temperature	-10°C to +55°C
Relative humidity, including condensation	10% to 95%
Air pressure	500 to 1060 hPa

The control unit cannot withstand the temperature conditions for storage according to ISO 15004-1. Do not store the control unit in conditions in which temperatures higher than +45°C or lower than -20°C could occur.

➔ Do not expose the mobile components to direct sunlight for any length of time.

12.2 Disassembly

Attention

Incorrect examination results caused by improper dismounting and remounting

If you temporarily dismount the Vissard 3D/Vissard RG and want to remount it, the correct settings could change.

➔ Let only OCULUS Service or an authorized dealer dismount and, if applicable, remount the unit.

To dismount, proceed as follows:

➔ End the current session.

➔ Turn the device off

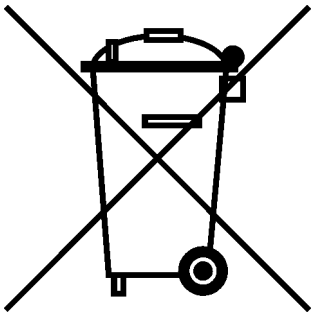
➔ Switch off the Vissard components, *sect. 7.3, page 24*.

➔ Switch off the patient long-distance display, *sect. 7.3.2, page 24*.

➔ Unplug the power cord. Pull only on the plugs and not on the cables.

12.3 Transport and Storage

13 Disposal



In accordance with Guideline 2012/19/EG of the European Parliament and of the Council, and also the Law of the Federal Republic of Germany on the Commercialization, Recall and Environmentally Compatible Disposal of Electrical and Electronic Equipment, old electrical and electronic equipment must be sent out for recycling and may not be disposed of in household trash.

➔ Dispose of the Vissard components in the proper manner.

14 Terms of Warranty and Service

14.1 Terms of Warranty

Please note the following guarantee provisions:

- Prior to and while operating the device, it is important that you heed the Instruction Manual and safety instructions.
- In accordance with legal regulations, you are entitled to a warranty for the Vissard.
- If modifications are made to the Vissard by unauthorized persons, all warranty claims shall be voided. Improper modifications and repairs may result in considerable hazards to users and patients.
- Any entitlement to a warranty shall also be void if unauthorized persons interfere with the hardware and software supplied.
- Any transport damage must be reported immediately to the shipping company. Have the transport damage noted on the bill of lading so that complaint handling and compensation of damages can proceed in an orderly manner.
- In general, our Business and Shipping Terms applicable on the date of purchase shall apply.

14.2 Assumption of Liability for Functions and Damage

OCULUS will only accept responsibility for the safety, reliability and serviceability of the Vissard if the unit is used in compliance with the following terms:

- Only use the equipment in conformance with this Instruction Manual.
- There are no parts either on or inside the Vissard that require maintenance or repair by the user. If assembly work, modifications, adjustments, repairs, changes or service are performed by unauthorized personnel, or if the Vissard is improperly maintained or handled, then any liability by OCULUS is voided.
- If the above-referenced work is performed by authorized persons, then a certification of the work shall be requested from this service technician which shall state any changes to factory defaults or to operating ranges. This certification must contain the date of

performance and statement of the performing company, with signature.

- If requested, OCULUS will provide to the service technician a list of spare parts and additional descriptive material for this purpose.
- Make certain that only original OCULUS parts are used.

15 Technical Data

Vissard 3D/Vissard RG	
LCD monitor (patient)	24"
Resolution	1920 x 1080 pixels (FHD)
Brightness	2 – 320 cd/m²
Test distance	3.0 – 8.0 m (in 0.1 m stages)
Control	iPad, phoropter (NIDEK RT-5100/RT-3100 and RT-6100)
Dimensions (W x D x H)	680 x 54 x 448 mm (26.8 x 2.1 x 17.6 in)
Weight	approx. 10 kg (22 lbs)
Max. power consumption	40 W
Voltage	100 – 240 V AC
Frequency	50/60 Hz
Fuse (Order number 05100170)	1.25 A time-lag
USB ports	5 V, max. 500 mA
Ambient conditions ■ Temperature ■ Humidity ■ Air pressure	 +10°C to +35°C 30% to 90% 800 to 1060 hPa

Other information for Vissard

Contraindication	None known
Lifecycle expectancy	Up to 10 years

Power cable for Vissard

Use only a power cable that meets the requirements of the applicable standard	IEC 60227-1, type 53, min. 0.75 m^2 IEC 60320-1

Classification according to IEC 60601 - 1

Type of protection against electric shock	
■ Vissard 3D/Vissard RG	I
■ Control Unit	II
Level of protection against harmful penetration of water	IP 20
Vissard LECTUS: Application device	Type B

CE in accordance with Regulation (EU) 2017/745 on Medical Devices

CE

The unit is a Class I product.
Conformity assessment procedure: (EU) 2017/745 MDR, Annex II and III

16 Appendices

16.1 Electromagnetic Compatibility (EMC)

Medical electric equipment is subject to special precautionary measures regarding EMC and must be installed and operated according to the EMC instructions contained in the accompanying paperwork.

No particular measures are required for OCULUS equipment and systems.

Portable and mobile HF communications equipment can affect medical electrical equipment. The Vissard user can make a significant contribution to avoiding electromagnetic interference by keeping a minimum distance of 30 cm between the portable and mobile HF telecommunication devices (transmitters) and the device.

Attention

The use of accessories, converters, and cables that do not meet OCULUS specifications can result in increased emissions or a reduced interference immunity of the Vissard's components.

➔ Only use accessories, converters and cables that meet OCULUS specifications

The use of accessories, transformers and cables specified by OCULUS with any devices other than the Vissard components can lead to an increased emission at the other devices.

➔ Do not use the OCULUS-specified accessories, converters and cables for any device other than the components of the Vissard.

The interference immunity in accordance with IEC 60601-1, 5.2.2.9.a) has not been tested for this ME system.

Control unit

Radio frequency interference

Heed any information plates and signs that prohibit or restrict the use of mobile devices (for example in healthcare facilities or in the vicinity of blasting operations). Despite the fact that the iPad is designed, tested and produced with the proviso that the requirements regarding radio frequency emissions are met, such emissions from the iPad can impair the operation of other electronic devices and cause these other devices to malfunction. Therefore, switch off the iPad or activate flight mode, so that the iPad does not emit radio signals when you are in an aircraft or when you are requested to do so by supervisors.

Interference with medical devices

The iPad contains components that emit electromagnetic radiation. There are magnets at the bottom left half and also magnets at the front right of the iPad, which could lead to the impairment of cardiac pacemakers, defibrillators and other medical devices and apparatus. The iPad Smart Cover and the iPad Smart Case also contain magnets. These electromagnetic fields and magnets could lead to the impairment of cardiac pacemakers, defibrillators and other medical devices and apparatus. Always maintain a safe distance between your medical device and the iPad, the iPad Smart Cover and the iPad Smart Case. Consult your doctor or the device manufacturer to get more exact information about your medical device. If you suspect that the iPad interferes with your cardiac pacemaker, defibrillator or any other medial device, stop using it.

To ensure compliance with the requirements of IEC 60601-1-2 6.1 and 6.2, the following devices, accessories, converters and cables must be used:

Order Number	Description
16030	Vissard 3D, linear polarisation
16031	Vissard 3D, circular polarisation
16050	Vissard RG
10012081	Control unit (iPad)

16.2 Guidelines and Manufacturer's Declaration Electromagnetic Interference Emission and Interference Immunity

Electromagnetic radiation		
The Vissard from the company OCULUS is approved for operation in the electromagnetic environment specified below. The user of the Vissard should ensure that it is used only in such an environment.		
Emission measurements	**Compliance**	**Electromagnetic environment - Guidelines**
HF emissions in acc. with CISPR 11	Group 1	The equipment uses high-frequency energy exclusively for its internal operation. Therefore, its HF emissions are very low and it is unlikely that neighbouring electronic equipment will be affected.
HF emissions in acc. with CISPR 11	Class B	
Harmonic current emissions in acc. with IEC 61000-3-2	Class A	
Voltage variations/flicker emissions in acc. with IEC 61000-3-3	are met	

Electromagnetic immunity			
Immunity tests	**DIN EN 60601-Test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	The interference immunity of this ME system has not been tested.	Floor should be of wood or concrete or be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electric interference / bursts per IEC61000-4-4	± 2 kV for power lines 100 kHz repetition frequency ± 1 kV for input and output cables		The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges per IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage		The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations per IEC 61000-4-11	0% U_τ; 1/2 Period bei 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 Period and 70% U_τ; 25/30 Period single-phase: bei 0 degrees 0% U_τ; 250/300 Period		The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the Vissard requires proper operation even after a power failure, then it is recommended that you power the Vissard from an uninterrupted power supply or from a battery.
Magnetic field at power frequency of (50/60 Hz) per IEC61000-4-8	3 A/m 50 Hz oder 60 Hz		Magnetic fields at the power frequency should correspond to typical values similar to those in a business and hospital environment.
Note: U_τ is the mains alternating voltage before application of the test level			

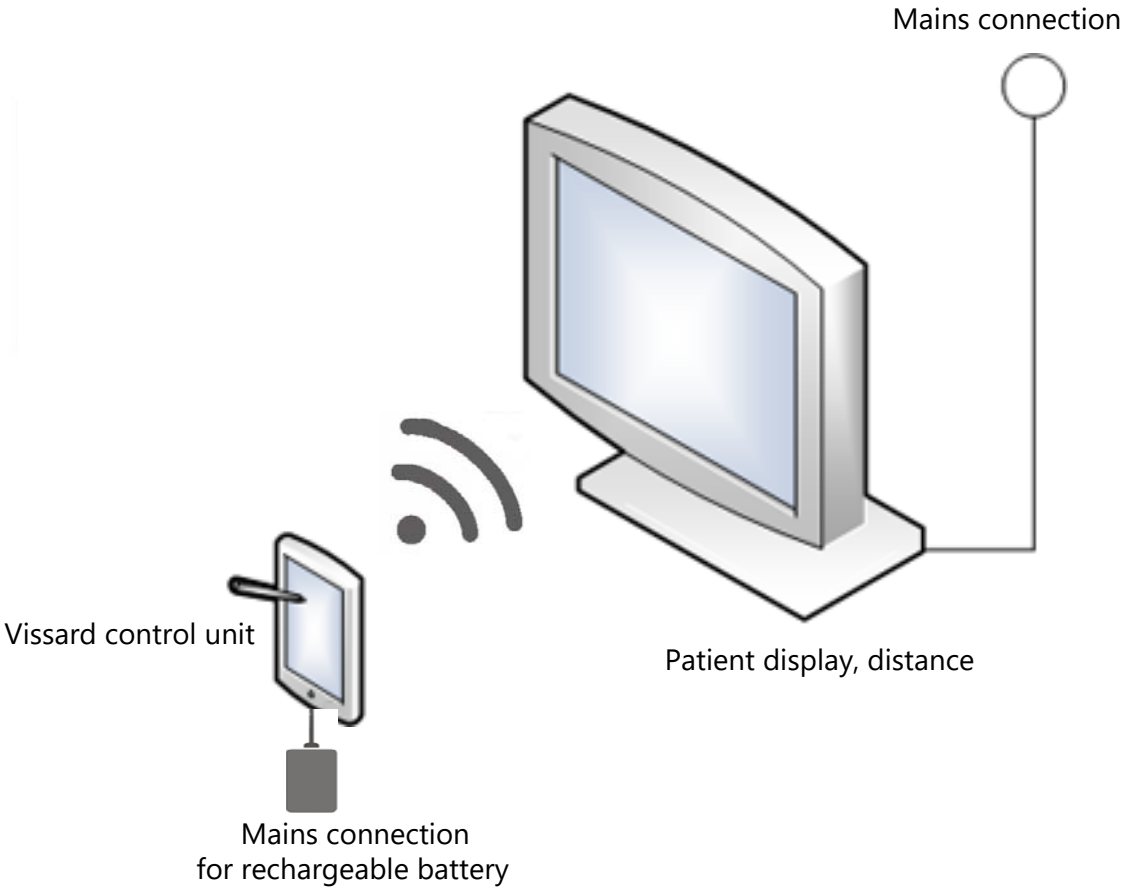
Electromagnetic immunity			
Interference immunity tests	**DIN EN ISO 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Conducted HF interference per IEC 61000-4-6	3 Veff 150kHz to 80MHz 6 V in ISM and amateur radio -Frequency bands between 150 kHz and 80 MHz 80% AM at 1kHz	The interference immunity of this ME system has not been tested.	Portable and mobile radio equipment, including the cables, should not be used any closer to the Vissard than the recommended separation distance calculated according to the applicable equation for the transmission frequency. Recommended separation distance: $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ for 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ for 800 MHz to 2.5 GHz with P being the power rating of the transmitter in watts (W) in accordance with the transmitter manufacturer's specifications, and d being the recommended separation distance in metres (m). The field strength from fixed RF transmitters, as determined by an on-site test (a), should be less than the compliance level (b) in each frequency range. Interference is possible in the vicinity of devices that bear the following pictogram: 
Emitted HF interference per IEC 61000-4-3	3V/m 80MHz to 2.7GHz 80% AM at 1kHz		
Note 1:	At 80 Hz and 800 MHz the greater frequency range applies.		
Note 2:	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and humans.		

a. The field strengths of stationary senders, such as base stations of radio telephones and mobile terrestrial radio equipment, amateur radio stations, AM- and FM-radio and TV transmitters in theory cannot be accurately predicted. In order to determine the electromagnetic environment with respect to the stationary transmitters, a study of the site must be considered. If the measured field strengths at the site where the Vissard is used exceed the compliance level above, then the Vissard should be monitored to verify proper and orderly operation. If unusual operating reactions are observed, then additional measures may be necessary, such as a changed alignment or a different site for the Vissard.

b. Over the frequency range of 150 kHz to 80 MHz the field strength should be less than 3 V/m.

Recommended separation distances between portable and mobile HF telecommunications devices and the Vissard			
The Vissard is intended for operation in an electromagnetic environment in which the HF interference parameters are controlled. The user of the Vissard can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF-telecommunications equipment (transmitters) and the device - depending on the output power of the communications equipment, as specified below.			
	Separation distance depending on transmitter frequency in m		
Power rating of the transmitter W	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 whose maximum rated power is not stated in the above table, the recommended separation distance d in metres (m) can be determined by use of the equation belonging to the particular column, wherein P is the maximum rated power of the transmitter in Watts (W) according to information by the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz the greater frequency range applies. Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and humans.			

16.3 Connection Diagram



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