OCULUS Twinfield® 3
Perimeter

INSTRUCTION FOR USE

OCULUS®

Preface

The Twinfield® 3-Perimeter has been manufactured and tested in accordance with the strictest quality criteria. You have chosen a modern, technically mature product.

Using the device correctly is essential for safe operation. Therefore, familiarise yourself with the contents of these instructions for use before use. Pay particular attention to the safety instructions.

- These instructions for use describe the management of patient data, the presets in the Twinfield® 3 program, and the measurement process.
- Information that goes beyond the operating concept can be found in the user manual for the Twinfield® 3-Perimeter.

You can also use the software described here for the predecessor model of the Twinfield® 3-Perimeter, with some restrictions.

The illustrations shown here may deviate slightly from the actual device delivered.

If you have any queries or require further information regarding your device, phone us, send us an e-mail or fax us. Our service team is happy to help.

OCULUS Optikgeräte GmbH

Item number: 10044018
Revision: 00
Released: 17/09/2025

Table of contents

1 Scope of delivery

Standard scope of delivery
Twinfield® 3 Perimeter
Manual button
Corrective lens set (12 pieces)
Eye patch
USB cable with ferrite chokes
Dust protection cover
Attachment kit
Instructions for use
Power supply
Floating licence key

Optional accessories
All-in-one PC
Laptop incl. control software, mouse and mouse pad
Tablet (Windows)
Tablet holder
Ophthalmic table (230V or 115V)
Lifting column
Narrow-rimmed lens case
Disposable eye patches

Optional software licenses
SPARK strategy
DICOM PACS module for Twinfield® 3
Glaucoma Staging Program (GSP)
Threshold Noiseless Trend (TNT)

We reserve the right to change the supplied contents as part of technical developments.

- If transport damage is found during delivery, report this immediately to the transport company and have it confirmed on the consignment note so that proper claims settlement is possible.
- Keep the original packaging for return shipping in the event of service or repair.

2 Safety

All safety-relevant instructions for using the device are only described in the device's instructions for use.

- ➔ Read the instructions for use carefully.
- ➔ Keep the instructions for use easily accessible near the device.
- ➔ Observe the statutory accident prevention regulations.

2.1 Symbols

2.1.1 On the device and type plate

Fig. 1: Type plate (example)

Symbol	Description	Symbol	Description
	Name and address of the manufacturer		Protection class
09/01/2025	Date of manufacture	REF	Item number
CE	CE marking	SN	Serial number
	Follow the instructions for use	#	Model number
	Disposing with household waste prohibited	MD	Medical device
	Application part type B		
	UDI number (example) consisting of: UDI-PI (product identifier), Machine-readable matrix code UDI-DI (device identification)		

2.1.2 On the packaging

Symbol	Description
	Protect from moisture
	Transport upright
	Fragile
	Permissible temperature range for transport
	Permissible temperature range for storage
	Humidity limit
	Air pressure, limit

2.1.3 In this manual

Caution
Indicates a potentially dangerous situation that can cause minor bodily injury.

Attention
Indicates situations that can cause device damage or incorrect examination results.

Indicates important application notes and important information about the device.

> = menu paths

[ ] = buttons and controls

→ = cross references

2.2 Safety instructions for use

Caution

Incorrect operation can injure people or damage the device .

➔ Observe and follow the safety instructions in these instructions for use.

Caution

Unauthorised modifications to the device may result in personal injury or damage to the device.

➔ Do not modify this device or the corresponding ophthalmic table without the manufacturer's permission.

➔ Only OCULUS Service or an authorised dealer is entitled:

- to rebuild or otherwise modify the device or the associated ophthalmic table.
- install software or software updates.

Report all serious incidents that occurred in conjunction with the product to the manufacturer (vigilance@oculus.de) and the authority responsible in the Member State in which you and/or your patient reside.

2.2.1 Information regarding operating an ME system

The Twinfield® 3 and a connected computer form a medical electrical system (ME system) according to IEC 60601-1. If you connect additional devices, such as a printer, those devices become part of the ME system.

➔ Ensure that all devices in the ME system meet the requirements of IEC 60601-1 or IEC 62368-1.

2.2.2 Information regarding electrical safety

The special power supply unit of the device must be used as the power supply. Other connection types are not permitted.

Caution

Personal injury or damage to property due to incorrect level of safety

Connecting the Twinfield® 3 with 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 IEC 60601-1. If this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

➔ Ensure that connections to non-medical devices are established correctly.

➔ Only use the power supply that is supplied as standard.

➔ Use only a computer that meets the specifications in these instructions for use, → *"10 Technical data" on page 41*.

Caution

Personal injury or damage to property due to unsafe multi-sockets

If you are using a multi-socket to connect the Twinfield® 3, you must adhere to the following instructions:

- ➔ Use a multi-socket that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multi-socket on the floor.
- ➔ Do not use more that one multi-socket.
- ➔ Only plug the Twinfield® 3 and the computer that is being used, if applicable, into the multi-socket.
- ➔ The multi-socket must be supplied via an isolating transformer.
- ➔ If you are using your own computer or a new computer for the Twinfield® 3, you must have the electrical safety checked. Contact OCULUS customer service.

Caution

Personal injury or damage to property due to electromagnetic interference

Portable and mobile RF communications equipment can affect medical electrical equipment, *Chap. 10, page 41* thereby compromising electromagnetic compatibility (EMC/cables).

- ➔ Ensure that portable and mobile RF communications equipment does not cause interference.
- ➔ If necessary, keep a distance from RF communication devices to ensure that the Twinfield® 3 functions correctly.

2.3 Information regarding cyber security

Note

Observe the regulations, guidelines and recommendations of the competent authorities responsible for information security and the protection of critical infrastructures in your country.

The device is designed to work independently without the need for an Internet connection, network access or portable media. It works exclusively via a connected computer.

If the computer is connected to the internet or other network for other purposes, you are responsible for ensuring that the connection is secure and controlled.

2.3.1 Precautions against unauthorised access

To increase the cyber security of the device:

➔ Secure the device against unauthorised access by unauthorised persons.

Observe the precautions:

- Secure the computer with a strong password (e.g. at Windows startup).
- Choose a complex password of at least 12 characters that contains letters, numbers and special characters. Avoid words from the dictionary.
- Do not choose a name or device name for a password (for example, “Pentacam”).
- Change the default password after the first authentication.
- Change the password regularly.
- Do not write down the password in an accessible place.
- Use unique passwords for different user accounts.
- Usernames or passwords must not be shared with colleagues or others, even if permitted by law and provider policy to view the same type of information (e.g. two operators reviewing the same patient samples).
- Enable a screen saver that requires the password to be re-entered when deactivated.
- Set an appropriate time setting for starting the screensaver (e.g. 10 minutes), taking into account operating conditions such as the duration of the examination and patient flow.
- Lock the computer when leaving the workstation or when the device is not in use (shortcut: Windows logo key + 'L') to prevent unauthorised access to electronic protected health information (ePHI).
- Train operators in data protection and the handling of personal data.
- If necessary, contact the IT department of your healthcare facility.

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

- Do not connect to the Internet while the device is in use. This is considered misuse!
- If the computer is connected to the internet for any other purpose, the user is responsible for data security.

- If the computer is integrated into a local network, the user is responsible for data security.
  The following precautions must be observed (as a minimum):
  - Preferably connect the computer to the network via a cable connection and not via a wireless connection.
  - Use robust security methods, including Advanced Encryption Standards, with a strong network key, even for wired connections (not just for Wi-Fi connections).
  - Using a firewall (software or hardware) is recommended.
  - Observe the instructions for integration into an IT network (→ *"G Instructions for integration into an IT network" on page 52*).

The IT department of the healthcare facility should implement a risk management system in accordance with IEC 80001-1 to support the secure integration of medical IT networks. To ensure patient safety and data integrity, this includes:

- Assessing risks
- Enforcement of access controls
- Securing networks
- Application of software updates
- Monitoring incidents
- Protecting data
- Management of device life cycles, and
- Employee training

The Manufacturer Disclosure Statement for Medical Device Security (MDS2) is available on request for detailed safety information.

2.3.3 Ensuring device security

➔ Ensure that the device is secured against unauthorized access (→ *"2.3.1 Precautions against unauthorised access" on page 12*).
➔ Protect the device and attached systems from malicious software.
➔ Implement new software versions when they are available.
➔ Implement operator access only on a need-to-know basis.

The Healthcare Organisation's IT Department is responsible for implementing controls for the handling and disposal of media and assets.

2.3.4 Data responsibility

Operators should avoid entering unnecessary identifying data. Whenever possible, data should be de-identified and linked to the sample ID instead of the patient. Use only the input data that is essential for the intended purpose.
Operators have access to sensitive patient data (ePHI).

➔ Do not take any snapshots, screenshots, or images (e.g. using another device) of the information displayed on the device.

Data shall be deleted on a regular basis according to the Healthcare Organisation's deletion policy, if respective data are processed by the device.

The Healthcare Organisation's IT Department is responsible for deleting unused user accounts.

Only authorised personnel are allowed to take backups. The Healthcare Organisation's IT Department shall manage the location of each backup in order to

respond to potential data subject requests. Backups and archive files are required to be transmitted and stored securely.

2.3.5 Reporting and handling security incidents

Operators must inform their Healthcare Organisation's IT Department about any suspected or confirmed privacy or security breaches, including suspected or compromised user accounts, and report any service outages or access issues.

- If accounts are deemed compromised, devices are lost, or unauthorised access has been discovered or assumed, the Healthcare Organisation's IT Department locks or changes the user login criteria and issues new login information so that the user can safely access his or her account.

3 Device description

3.1 Parts of the device

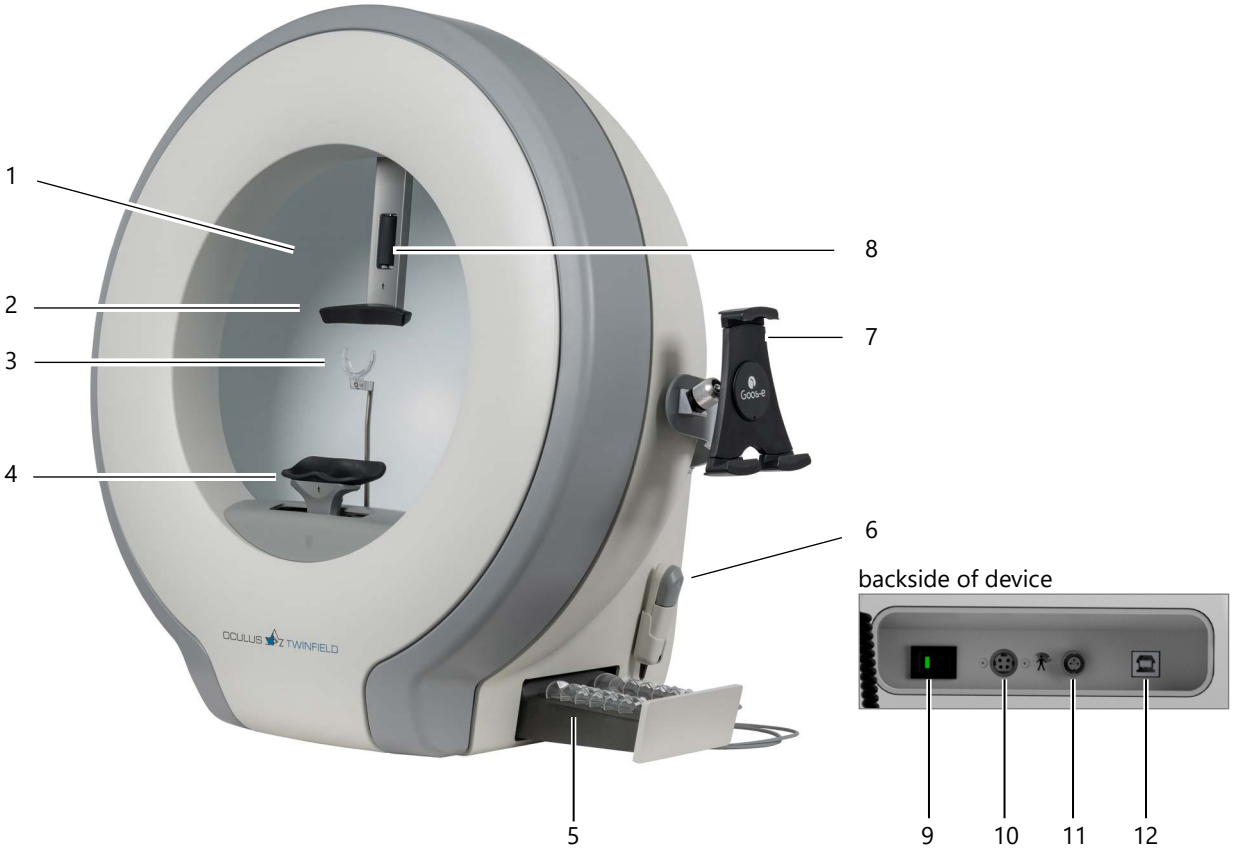


Fig. 2: Parts of the device

No.	Description	No.	Description
1	Projection surface (Perimeter hemisphere)	7	Tablet holder (optional)
2	Forehead rest	8	Adjustment knob for adjusting the forehead rest
3	Holder for corrective lens	9	On/off switch
4	Chin rest	10	Power connection
5	Storage for corrective lenses	11	Connection for manual button
6	Manual button in holder	12	Connection for PC/laptop

3.2 Device with ophthalmic table (ME system)

Fig. 3: Twinfield® 3 with ophthalmic table

With the device version Twinfield® 3-Perimeter with ophthalmic table, these form a medical electrical system (ME system). This ME system has been compiled and built by OCULUS for its application and is intended for this application only.

Also observe the operating instructions for the ophthalmic table.

3.3 Functionality of the device

The Twinfield® 3 is a hemispherical projection perimeter for visual field testing. The device uses the principle of rear surface projection. Various projectors are mounted on a movable arm. Each position of the perimeter hemisphere can be controlled. The perimeter hemisphere has a radius of 30 cm and is illuminated homogeneously in accordance with the Goldmann standard (referenced to an ambient luminance of 10 cd/m^2). The stimuli are mapped exactly with precise reproducibility of the test point locations – an absolute prerequisite for reliable visual field findings.

The device is computer-controlled and is connected via the USB interface.

The Twinfield® 3perimeter meets the requirements of ISO12866.

3.4 Intended Purpose

The device is intended exclusively for the use specified in this manual and in compliance with the safety instructions.

3.4.1 Intended Use

The Twinfield® 3 perimeter is designed for testing the visual field of the human eye. Twinfield® 3 permits kinetic and static, as well as automatic and manual visual field examinations for this purpose.

3.4.2 Intended medical indication

The Twinfield® 3 is intended as a measuring device for the visual field to assist in the detection, monitoring and treatment of eye diseases, including but not limited to glaucoma, maculopathies and related neurological disorders.
The Twinfield® 3 is not intended to be used as the sole diagnostic method for any disease.

3.4.3 Contraindications

None known

3.4.4 Possible side effects

None known

3.4.5 Intended users

The Twinfield® 3 is intended exclusively for use in:

- Ophthalmology practices
- Clinics
- With opticians or optometrists

The Twinfield® 3 is intended for use by trained personnel:

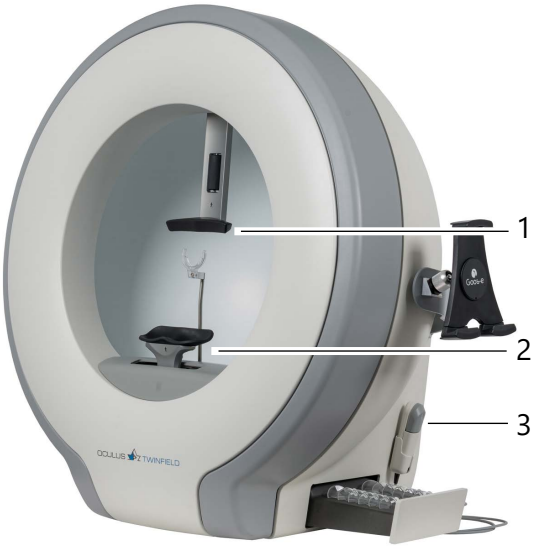
- Who can guarantee proper handling due to their knowledge, training and practical experience.
- Who have been instructed by OCULUS staff or an authorised dealer prior to using for the first time.

3.4.6 Patient group

Children from age 5. No upper limit.
No restrictions on weight, health and condition.
The patient must be awake and able to understand and to look into a fixation target.

3.5 Application parts

Application parts are the parts of the device that come into contact with the patient.



1	Forehead rest
2	Chin rest
3	Manual button

Fig. 4: Application parts

The forehead rest, chin rest and manual button are type B application parts.

4 Setup and Installation

Caution

Incorrect setup and installation may result in incorrect measurements or even damage to the device.

➔ Have the device installed and connected by our service department or by a specialist authorised by OCULUS.

4.1 Unpack and Setup

➔ Keep the original packaging for later reuse.

➔ Do not lift or carry the device by the forehead support or chin rest.

Damage to the device due to incorrect handling of the device

➔ Do not expose the device to vibrations, impacts, contamination, moisture, or high temperatures.

➔ Handle the device with care.

Device damage due to condensation after transport or storage

➔ After transport or storage, let the device rest for about 3-4 hours at the place of installation so that the device can adapt to the ambient conditions. The optical components can mist up due to severe temperature differences from cold to warm areas.

Set up the device so that

➔ it is level and straight and cannot fall over.
The table or base provided must be designed to support this load. Note the weight and dimensions of the device → *"10 Technical data" on page 41*

➔ it is protected from dripping, gushing or splashing water.

➔ the mains plug is easily accessible, therefore the device can be easily disconnected from the power supply (e.g. for maintenance work).

➔ a reflection-free examination is ensured and no direct light can influence the measurement. It must be able to darken the examination room.

➔ the device is not placed directly next to other devices.
If you use the device in the vicinity of other devices, you must ensure that the device functions faultlessly.

- Do not stack the device.
- Do not place heavy objects or the device itself onto the connection cable.
- Germany only: Operate the Twinfield® 3 in rooms used for medical purposes if VDE 0100-710 installation procedures have been observed.
- Do not operate the devices included in the delivery in areas where explosions may occur, where there are inflammable anaesthetics or volatile substances such as alcohol or petrol nearby.

4.2 Ambient and operating conditions

Temperature	+10 – +35°C
Air humidity	30 – 90%
Air pressure	800 – 1060 hPa

4.3 Information regarding the patient environment

Patient environment is the area in which patients can come into contact with any part of the system or between the patient and another person who is in contact with the system.

Attention

Use devices that comply with IEC 60601-1 in the patient environment. If a multi-socket is to be used or if a device that does not comply with the IEC 60601-1 standard is to be used, use an isolating transformer.

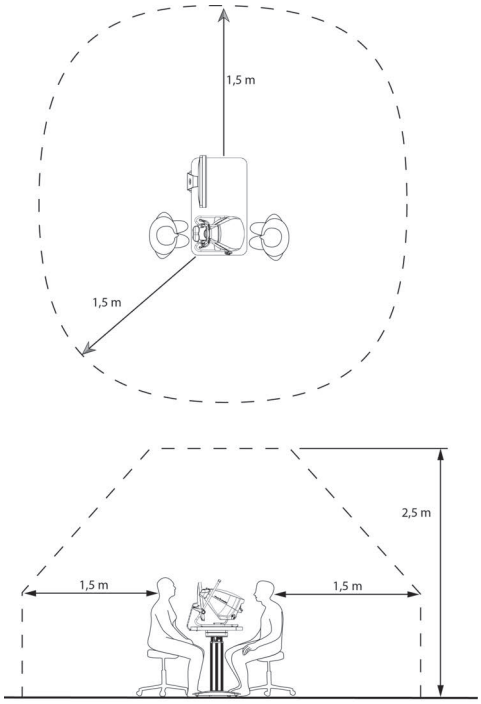


Fig. 5: Patient environment (for example, with Smartfield)

4.4 Installation

Warning! Risk of electrical shock!

Unsuitable cables, power supplies and sockets can endanger electrical safety.

- ➔ Only use the power supply unit or an identical one that is included in the scope of delivery of the device.
- ➔ Ensure that all devices in the ME system meet the requirements of IEC 60601-1 or IEC 62368-1.
- ➔ The mains cable used must meet the requirements of IEC 60227-1, type 53, 0.75 mm^2 min. and IEC 60320-1, type C7.
- ➔ The power cord should not be in contact with hot surfaces (e.g. heater).
- ➔ When using a multi-socket:
  - It must comply with the requirements of IEC 60601-1.
  - Do not place on the floor.
  - Use a maximum of one multiple socket.
  - Only plug the device and the computer that is being used, if applicable, into the multi-socket.
- ➔ The socket used must have a faultless protective conductor connection.

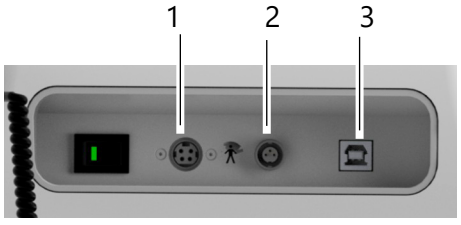
Device damage due to improper connection

If you do not connect the device properly and voltage is present, the device can be damaged quickly.

- ➔ Do not connect electrical plug connections using excessive force.
- ➔ The mains plug must be plugged in completely into the socket.
- ➔ If a plug is damaged, contact the OCULUS customer service department or an authorised dealer to repair the damage.

- ➔ If you are using a computer that was not supplied by OCULUS together with the Twinfield® 3, first install the software on the computer before connecting the device to the computer; see *Software installation*.
- ➔ On the computer that controls the Twinfield® 3-Perimeter, no other software may run in the foreground in parallel with the examination program (screensaver, user programs, etc.).
  Power-saving modes (BIOS or Windows) must be deactivated.
- ➔ Only connect tablets approved by OCULUS.

1. Connect the computer via USB cable.
2. Insert the low-voltage plug of the supplied desktop power supply into the power connector and plug the mains plug into a mains socket.
3. Insert the manual button plug into the socket.



1	Power connection
2	Connection for manual button
3	Connection for computer

Fig. 6: Connections

5 Measurement process

Caution

Incorrect measurements due to improper operation

➔ Before first use obtain instruction on operation the device from OCULUS or an authorized dealer.

5.1 Switching on

1. Switch on the device; then the connected computer.
   With the device version Twinfield® 3 with ophthalmic table, the main switch for switching the ME system on and off is located at the bottom of the table base.

Fig. 7: Main switch at the base of the table (if an OCULUS Ophthalmic Table is used)

2. Wait until the operating system has loaded completely and patient data management is shown on the screen.

5.2 Creating or selecting patient data

3. Create patients in the patient data management system or select the patient from the list.
   ➔ Observe the instructions for use of the patient data management system.
4. Open the device software by clicking on [Perimeter].

5.3 Preparing the examination

➔ Make sure that no interfering light falls into the perimeter's field of view.
➔ Slightly darken the room for an optimal result.
➔ Ensure a calm atmosphere during the examination so that the patient is not distracted.

➔ Clean and disinfect the chin rest and forehead pad, if you haven't already done so → *"6.3 Disinfection" on page 36*

5.4 Explaining the examination procedure

5. Explain the examination procedure to the patient or play the audio explanation in the device software.

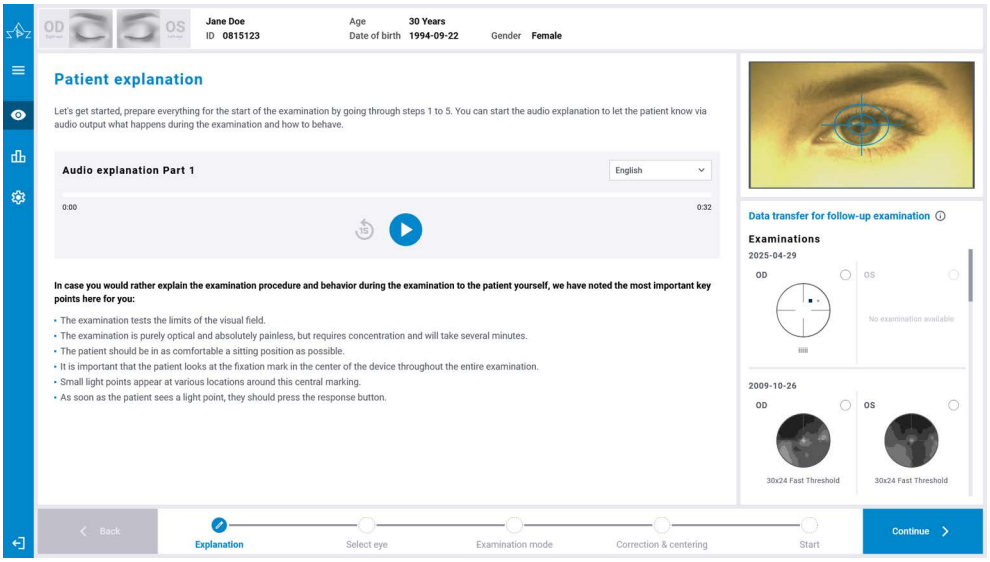


Fig. 8: Patient explanation

6. Cover the eye that is not to be examined with an eye patch.

5.5 Positioning the patient

7. The patient should sit in front of the device in a comfortable, upright position and place their arms to the right and left of the device.

8. Ask the patient to place their chin on the chin rest and to lean their forehead against the forehead rest.

⚠ **Do not touch the patient and the device at the same time.**

Examination of the left eye: right recess of the chin rest
Examination of the right eye: left recess of the chin rest

The patient should see the fixation marks (four red dots) in the centre of the perimeter hemisphere with the eye that is to be examined.

➔ The forehead rest can be moved forward or backward manually. Only adjust the forehead rest manually in exceptional cases..

Fig. 9: Adjust forehead rest

Fig. 10: Position the patient

9. Place the manual button in one of the patient's hands.
10. Check that the chin and forehead are positioned correctly.

Loss of vision can be caused by incorrect patient positioning. If the distance between the eye and the perimeter is too great (due to incorrect positioning of the forehead attachment), the patient cannot be guaranteed a full view.

5.6 Selecting eye

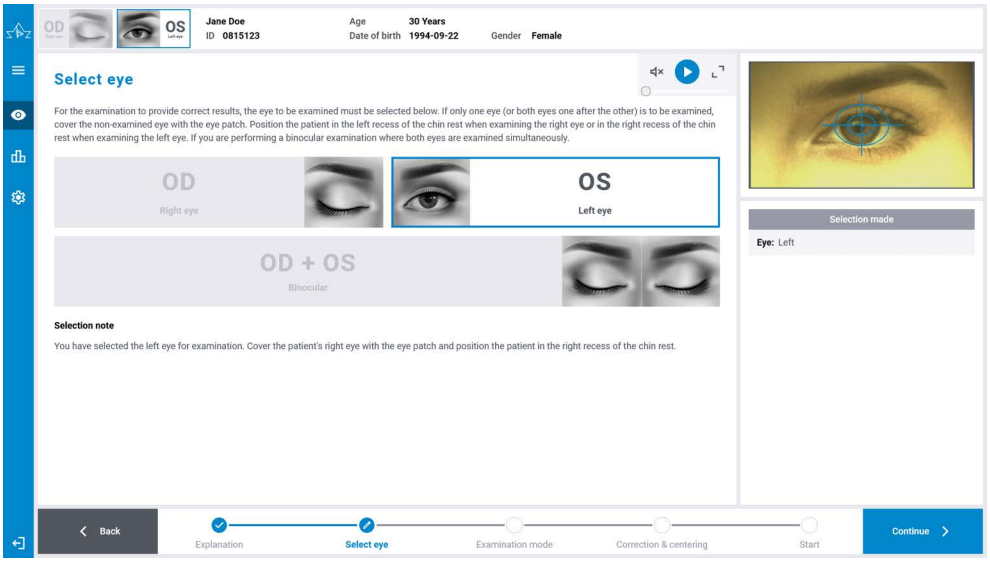


Fig. 11: Selecting eye

11. Select the eye to be examined.
12. Click on [Continue].

5.7 Selecting the examination mode, fixation checking and interval time

13. Select the appropriate examination mode for the examination.

- Choose an examination from the favourites list

(You can create your own favourites → User manual.)

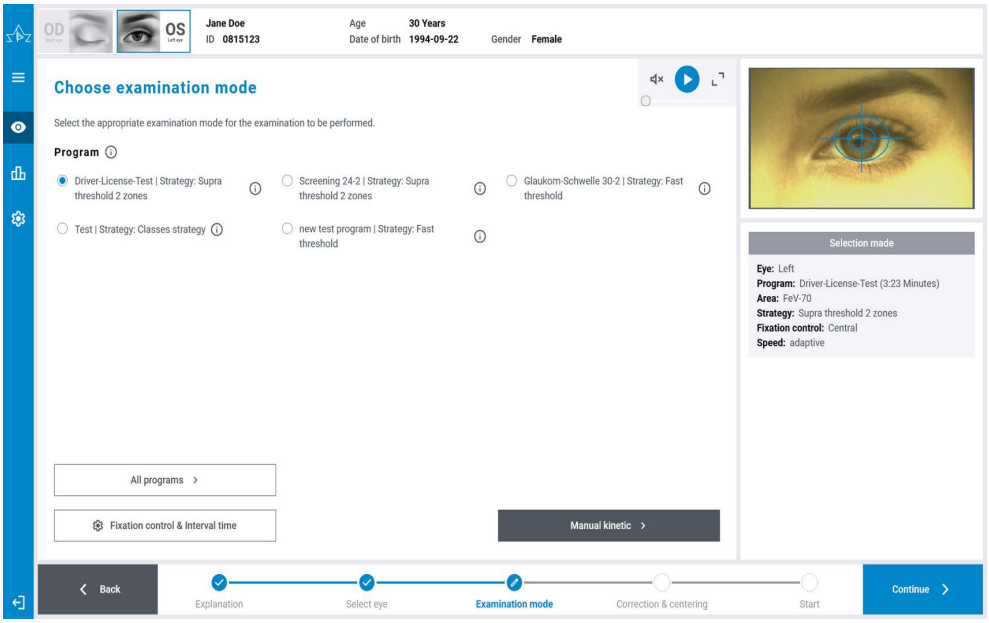


Fig. 12: Selecting the examination mode, fixation checking and interval time

- or click on [Alle Programme/All programs] to call up the list of all available programs.

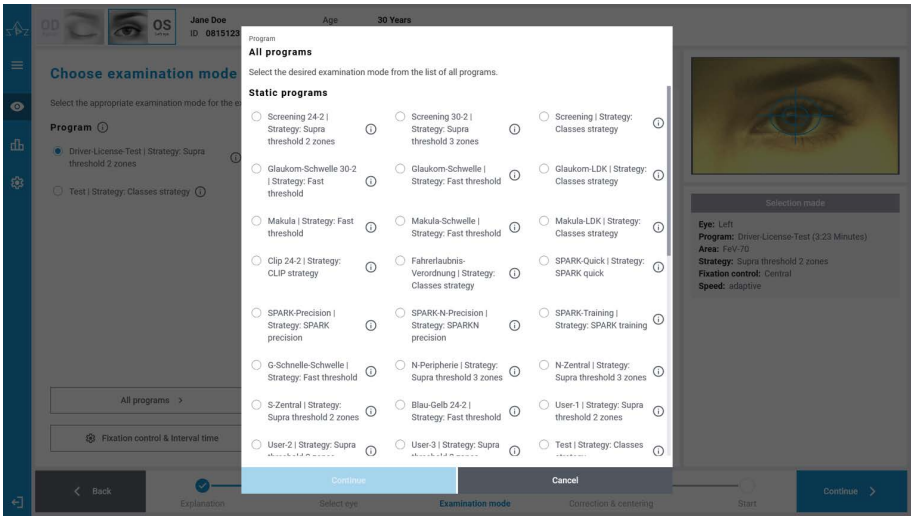


Fig. 13: Select from all programs

14. Select a program and confirm the selection with [Continue].

15. Click on [Continue].

5.8 Entering the correction and centering the patient

The light increment sensitivity can only be measured correctly if the individual test points are displayed sharply on the retina. The patient may require an appropriate corrective aid for this.

The patient can wear their contact lenses (not coloured) during the examination.

People who wear glasses can also wear their own glasses during the examination under the following circumstances:

- ✓ Lenses sufficiently large
- ✓ No tinted lenses
- ✓ No multifocal lenses
- ✓ No varifocal lenses

16. Centre the pupil in the camera image.
If necessary, press the arrow keys to move in the desired direction.

If the patient's pupil is not detected automatically (Pupil: Not determined), the pupil can be found manually using the 'Pupil measurement' function.

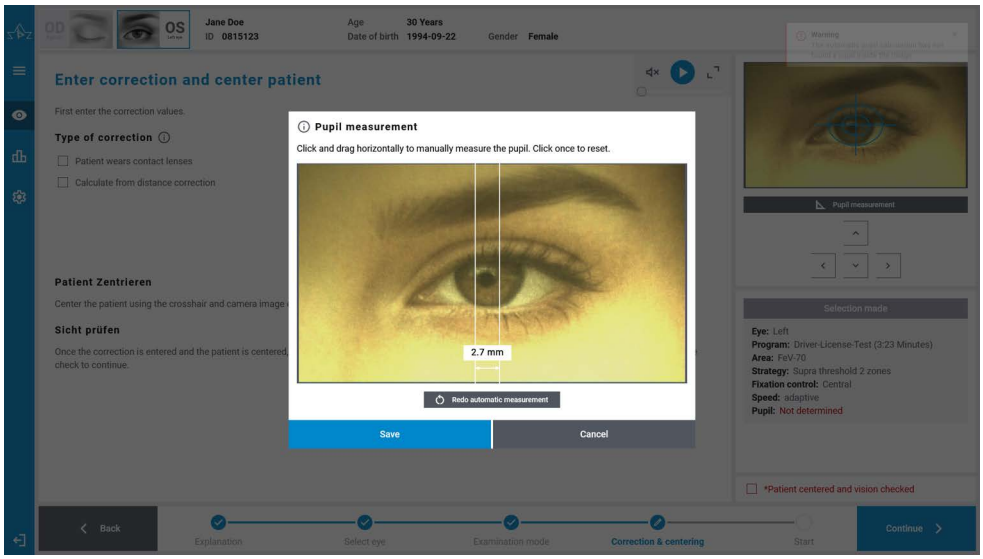


Fig. 14: Manually pupil measurement

17. Enter the corrective lens to be used.
In order to determine the required corrective lens, the precise refraction of the eye to be examined must be known. This can either be determined from a recent refraction test or can be based on current glasses prescription.

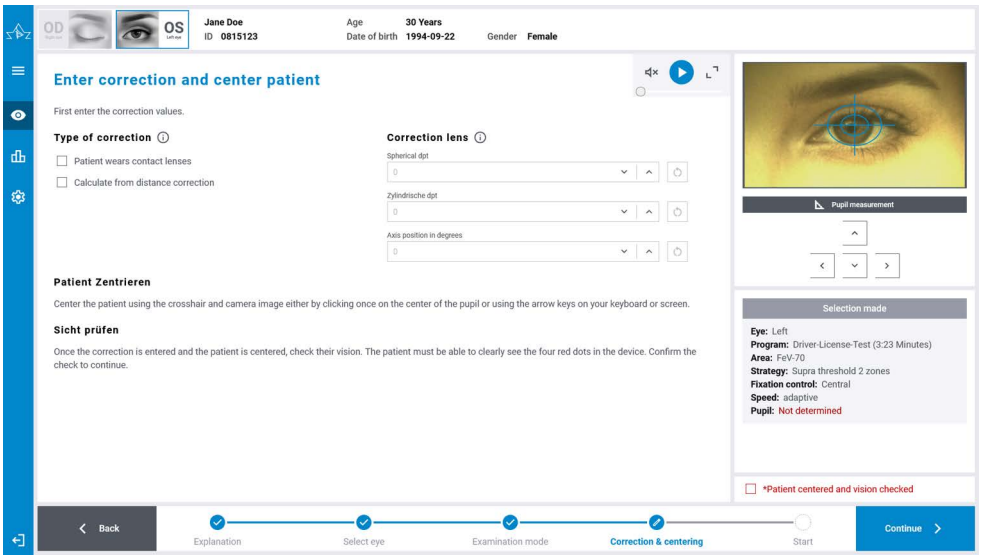


Fig. 15: Enter correction

➔ Tick [Berechnung aus Fernkorrektur/Calculate from distance correction].

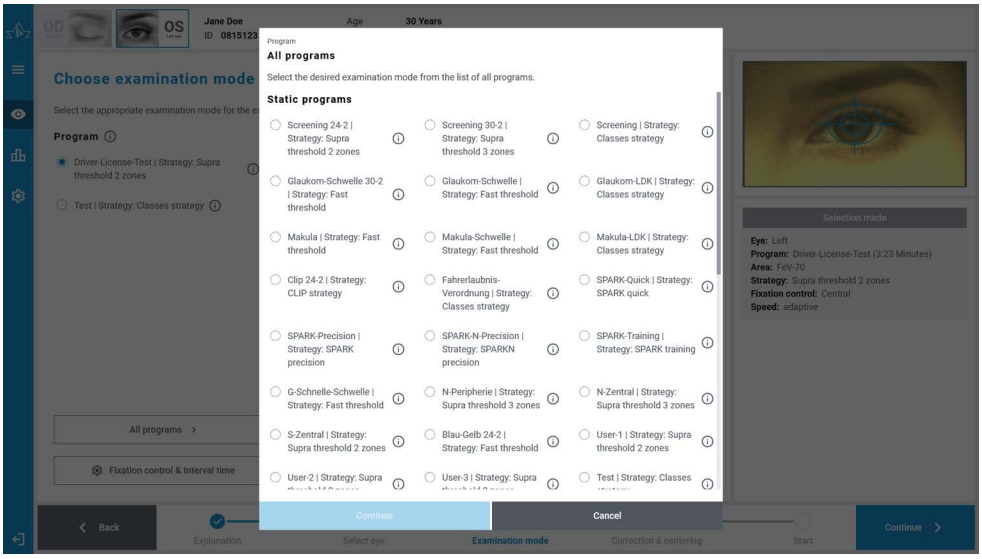


Fig. 16: Distance correction

➔ Enter the refraction values in the distance correction column.
The software calculates the required corrective lens from the entered values.

As the accommodation capability reduces drastically with increasing age, an age-appropriate addition for distance correction is required as of an age of around 40. The values for this are as follows:

- Age 40 - 50: approx. +1.00 dpt addition
- Age 50 - 60: approx. +2.00 dpt addition
- Age 60 and over: approx. +3.00 dpt addition

18. If necessary, tick [Proband trägt Kontaktlinsen/patient wears contact lenses].

5.9 Inserting the corrective lens

➔ Only use special narrow rim lenses that fit exactly into the lens holder of the perimeter.

The visual field periphery is always examined without a corrective lens.

After the examination, you will be asked to remove the corrective lens and the corrective lens holder. The condition for this is that the correction values have been entered in the "Korrekturglas/Corrective lens" field.

19. Place the corrective lens holder upright in the device.

20. Remove the corrective lens with the previously determined correction value from the drawer on the side of the device.

21. Insert the corrective lens into the holder.

Fig. 17: Raise lens holder

Fig. 18: Insert corrective lens

- Distance between eye and corrective lens max. 1 cm.
- Position centrally in front of the patient's eye.
- The eyelashes must not touch the lens.
- The patient must look into the middle of the fixation marks.

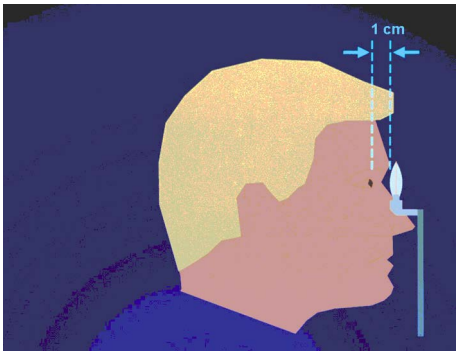


Fig. 19: Distance between eye <-> corrective lens

22. Press [Weiter/Continue].

5.10 Starting the examination

23. Check the data entered in the window on the right (selection made). If there are any errors, go back one step.

24. Explain the following examination to the patient and what they should pay attention to. Alternatively, play the audio explanation in the device software.

➔ The patient should always press the manual button when they perceive a point of light.

➔ The patient can pause the examination by pressing and holding the manual button. The examination continues once they release the manual button again.
➔ The patient should always look at the centre of the four red dots during the examination.

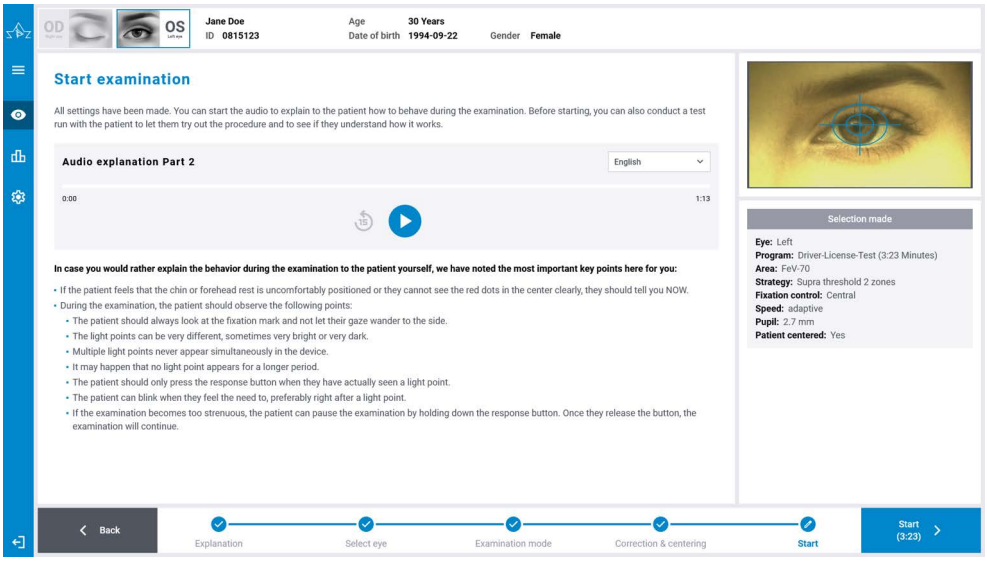


Fig. 20: Starting the examination

25. Press [Start], if
- ✓ all values are correct,
- ✓ the patient has understood the task, and
- ✓ the chin rest and forehead rest are set comfortably.

Or:
First, perform a [Testlauf/Test run] to assess whether the patient has understood the examination procedure.

5.11 Determining the threshold value

Depending on the selected examination program (static measurements or combined measurements), the central threshold value is then determined. This step is skipped for purely kinetic measurements.

The central or peripheral threshold value is determined and displayed in the following window:

Fig. 21: Display of the measured threshold value (Example of a class measurement)

26. Confirm and close the window.

➔ Select the [Wiederholen/Repeat] button if the measured threshold value deviates greatly from the age-appropriate normal threshold.

27. Inform the patient that the examination is starting and press the [Start] button.
➔ The selected examination program runs.

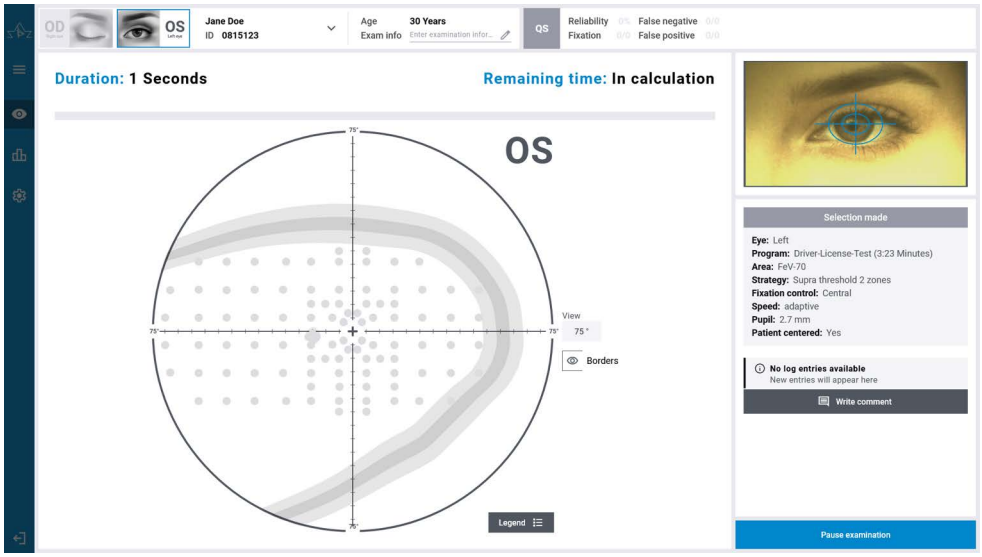


Fig. 22: Examination is ongoing

5.12 Pausing the examination

➔ Press [Untersuchung pausieren/Pause examination] to interrupt the examination.

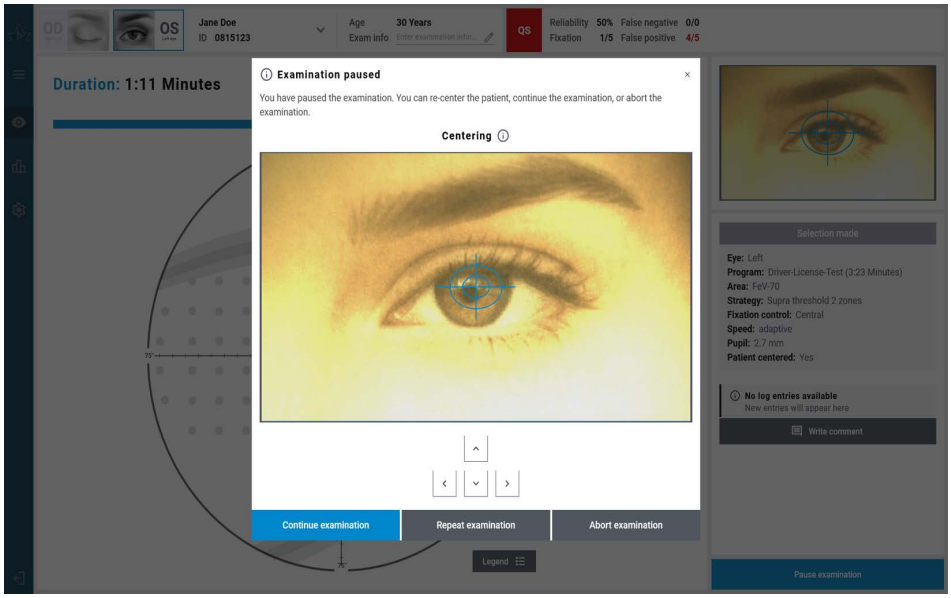


Fig. 23: Examination paused

5.13 Finishing the examination

When the examination is finished,

➔ the patient can tilt their head back.

Evaluate examination:

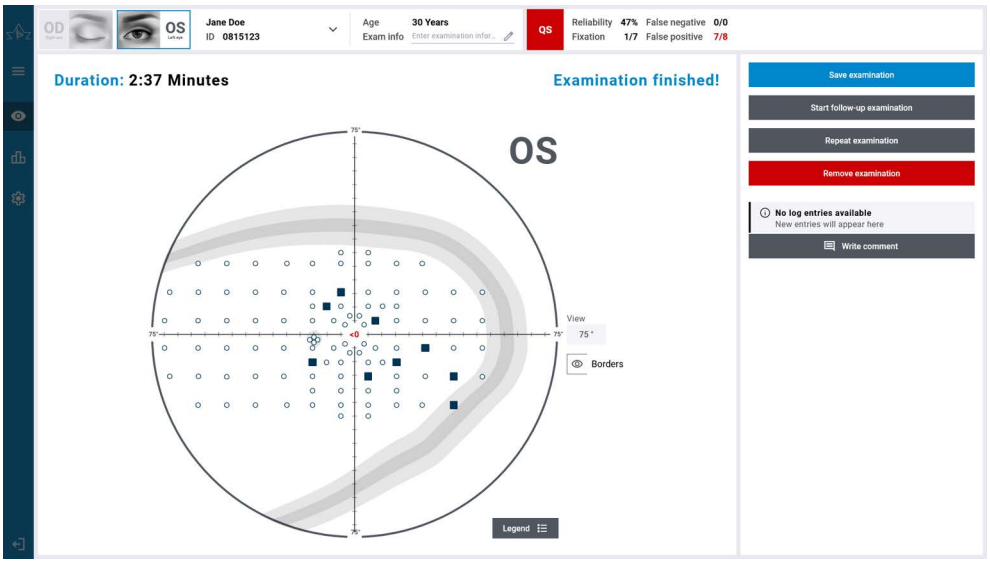


Abb. 24: Examination finished

Inspection points unremarkable		➔ Save examination
Inspection points remarkable		➔ Start follow-up examination
		➔ Repeat examination
		➔ Remove examination

Once the examination has been saved, the examination data can be retrieved via patient data management.

5.14 Re-examination

If the examination has been saved, you will then have the option of performing a re-examination if necessary.

1. Select the [re-examination] button.

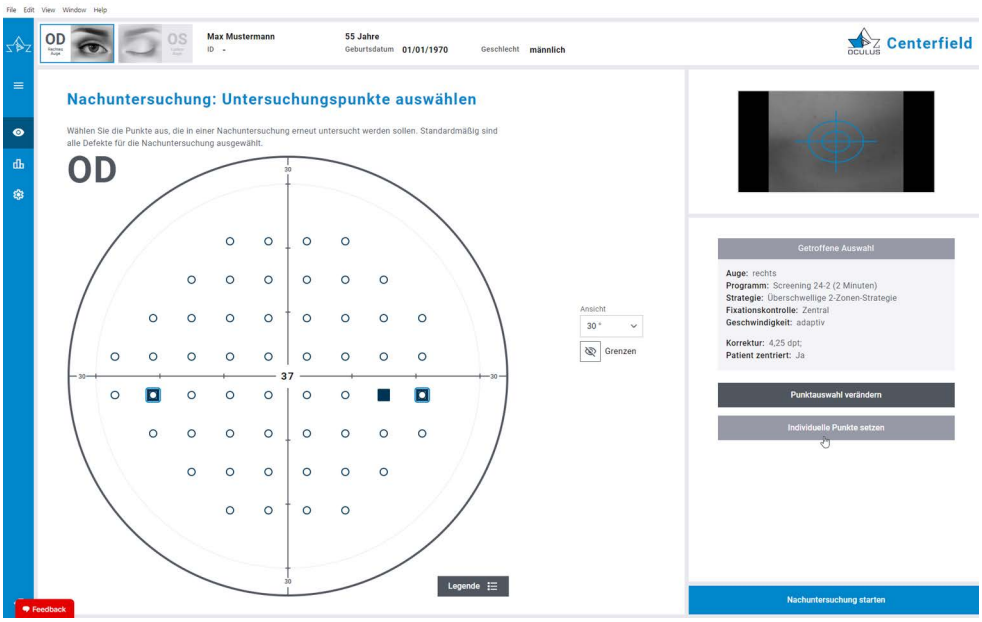


Fig. 25: Re-examination

2. Select follow-up examination mode. In the screen shown above, two additional buttons can be seen on the right.
   - Change point selection
   - Set individual points

3. Reinsert the corrective lens if it was previously removed from the holder.
4. Inform the patient that the examination is being continued.
5. Press the [Nachuntersuchung starten/Start re-examination] button and, if necessary, confirm the confirmation prompt as to whether the corrective lens has been inserted.

   The examination continues.
   Depending on the test point grid, it may again be necessary to remove the corrective lens from the holder after a corresponding prompt from the program.

After completing the re-examination, the system then asks whether the examination should be saved *(→ "5.13 Finishing the examination" on page 31)*.

5.15 Manual kinetic examination

To determine the location and size of a scotoma more precisely, for example, you can perform a “Manual Kinetic Examination.”

1. Start a new examination as described in → “5.2 Creating or Selecting Patient Data” on page 22 ff.
   ➔ From the programs Select “Manual kinetic examination.”
2. Select the mode for performing the kinetic examination from the drop-down menu in the examination screen.

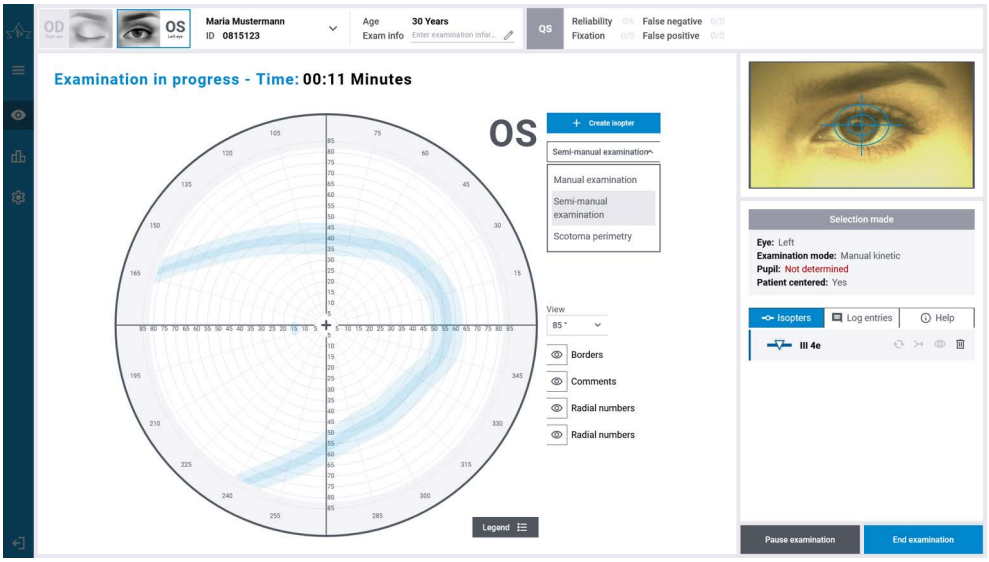


Abb. 26: Select kinetic analysis mode

3. Click [Create Isopter].
   The isopters determine the path and appearance of the moving stimulus.
4. Set the parameters (size, brightness, level) of the stimulus and confirm with [Add].

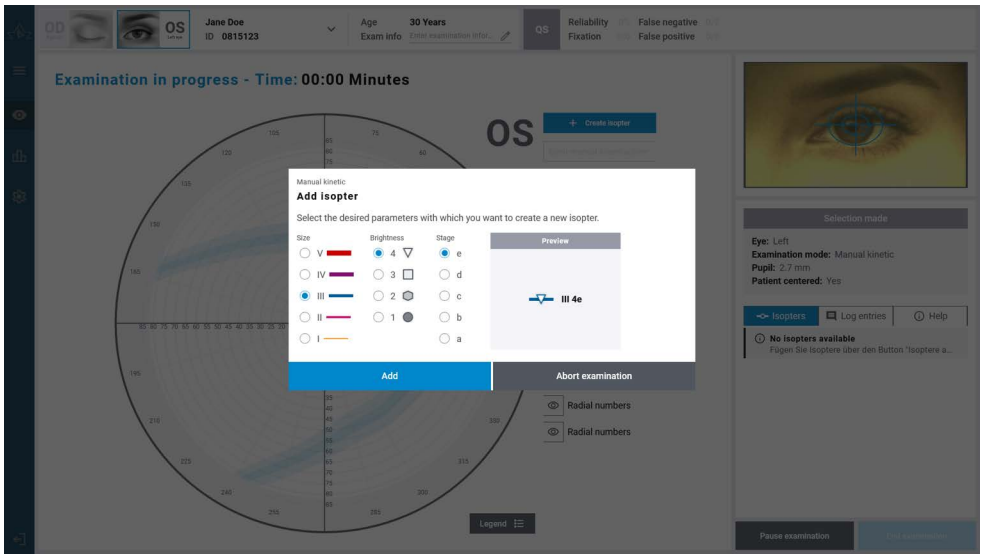


Fig. 27: Select stimulus parameters

After completing the manual kinetic examination, the query appears again asking whether the examination should be saved.

5.16 Switching off

1. Close the device software and patient data management.
2. Shut down the operating system.
3. Switch off the device at the on/off switch or switch off the ME system at the main switch of the table base.
4. Cover the device with the dust protection cover provided.

6 Cleaning, disinfection and maintenance

No sterilisation is necessary for the Twinfield® 3.

Caution

There is a risk of electric shock if the Twinfield® 3 is not disconnected from the mains power supply at all poles for these tasks.

➔ Switch off the Twinfield® 3.

➔ Remove the mains plug from the mains socket.

⚠ **Hold the plug; do not pull the cable!**

6.1 Intervals for cleaning, disinfection and maintenance

Cleaning	
Activity	**Time period**
Cleaning the chin rest, forehead rest and hemisphere	Once a month or as required

Disinfection	
Activity	**Time period**
Eye patch	After each examination
Disinfecting the forehead rest	After each examination
Disinfect the chin rest (when used without paper)	After each examination
Disinfect the housing	As required

Maintenance	
Activity	**Time period**
Check of the photometric and electrical values by OCULUS Service or an authorised dealer	Every 2 years (recommended)

6.2 Cleaning

➔ Observe the product descriptions and instructions for use of the agents and devices that you use for device or accessory care, cleaning and disinfection.

➔ Do not clean the device with aggressive, abrasive or sharp cleaning agents or with agents containing chlorine.

6.2.1 Required materials and agents

For disinfection we recommend:
mikrozid® sensitive wipes premium Fa. Schülke & Mayr GmbH various packsizes: e.g. 2x 50 pieces in soft packaging, order no. 59882

Reordering consumables:
Disposable eye patches, order no.

6.2.2 Cleaning the chin rest and forehead rest

1. Moisten a lint-free cloth with a cleaning agent for plastic surfaces with antistatic effect or a mild soap solution (water with a few drops of usual dishwashing detergent).
2. Wipe the chin rest and forehead rest.

6.2.3 Clean the inner surface of the projection bowl

Note

The matte white inner surface of the projection hemisphere is particularly sensitive.

➔ Cover the device with the dust protection cover provided after the examination.
➔ Do not use a cleaning spray containing alcohol.
➔ Do not allow any liquid to enter the projection hemisphere.

If cleaning is required:

1. Moisten a lint-free cloth with a cleaning agent for plastic surfaces with antistatic effect or a mild soap solution (water with a few drops of usual dishwashing detergent).
2. Carefully wipe the inner surface.
   ⚠ **Avoid pressing too hard. Do not make frequent movements to avoid creating shiny spots.**

6.3 Disinfection

Special wipes that are suitable for disinfecting medical devices are suitable for disinfecting all surfaces (except for the Plexiglas in the projection hemisphere).

Note

The disinfectant solution can damage the device surface if it sprayed directly onto it.

➔ Always spray the disinfectant solution onto a cleaning cloth, not directly onto the device.

6.4 Maintenance

In order to guarantee faultless and safe functions, we recommend:

➔ Let our customer service department or an authorised dealer inspect the device every two years.

Caution

There is a risk of electric shock if the Twinfield® 3 is not disconnected from the mains power supply at all poles for these tasks.

➔ Switch off the Twinfield® 3.

➔ Remove the mains plug from the mains socket.

⚠ **Hold the plug; do not pull the cable!**

7 Troubleshooting

Warning!

A damaged or faulty device can cause personal injury and/or incorrect measurements.

If a fault occurs, which you cannot rectify:

- ➔ Mark the device as out of order.
- ➔ Contact OCULUS customer service or your authorised dealer.
- ➔ Do not use a faulty device!

Fault	Possible cause	Solution
Device does not switch on.	No connection between the device and the power supply.	Plug the mains cable into the socket or the rubber connector into the device.
	Power cut or socket not active	Contact the building electrician.
	Computer USB cable not connected correctly.	Check that the connection is correct.
No functions when pressing the mains switch but the light on the mains switch does illuminate.	The device was switched off and on again too quickly.	Wait around 5 seconds between switching off and on again.
The manual button does not react to being pressed.	The manual button is not plugged into the socket on the device properly and screwed tight.	Check the connection, plug in the cable again and screw tight.
The camera image is too dark.	The camera brightness settings are incorrect	Re-adjust the brightness (see the *User manual*).
Area lighting not active.	The device is in standby mode	Move the mouse or press any key.
	The Twinfield® 3 program (examination program) has not been started.	Start the examination program *(Chap. 5, page 22)*.
After starting the Twinfield® 3program, the dialogue box opens: "No communication with the Twinfield®!".	Power supply has no power.	Check that the control lamp on the power supply is on. If not, supply the power supply unit with power. Check that the power cable is correctly plugged into the Perimeter.
	Connection cable (USB cable)Twinfield® 3/computer not plugged in properly.	Check that the USB plug is inserted correctly.
	Software/hardware problems.	Switch off the device, restart the computer. As soon as patient data management is active, switch on the device. The initialization window displays “Boot.”

8 Transport, packaging and disposal

Note

Incorrect transport or storage can damage the device!

- ➔ Avoid impacts, vibrations and contamination.
- ➔ Avoid high temperatures and humidity. Do not store near radiators (or other heat sources).
- ➔ Observe the transport and storage conditions.
- ➔ Check the device for damage after each transport.

8.1 Dismantling and packing

1. Switch off the device (→ *"5.16 Switching off" on page 34*).
2. Remove the mains plug from the mains socket.
   ⚠ **Hold the plug; do not pull the cable!**
3. Disconnect the manual button, depending on the version: to the computer or the controller.
4. Store or transport the device in its original packaging.

8.2 Transport and storage conditions

	Transport	Storage
Ambient temperature	-40°C – +70°C	-10°C – +55°C
Relative humidity (including condensation)	10% – 95%	10% – 95%
Air pressure	500 hPa – 1060 hPA	700 hPa – 1060 hPA

8.3 Disposal

In accordance with Directive 2012/19/EC of the European Parliament and Council from 4th July 2012, and in accordance with German law governing the marketing, return and environmentally compatible disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste.

- ➔ Dispose Twinfield® 3 of properly.

9 Warranty conditions

Please note our General Terms and Conditions (GTC) on our website www.oculus.com

10 Technical data

The technical data of the ophthalmic table can be found in the associated instructions for use.

Technical specification	
Weight (without table and PC components)	ca. 29 kg
Dimensions (W x D x H) (without ophthalmic table)	748 x 592 x 787 mm
Interface	USB

Expected shelf life	10 years

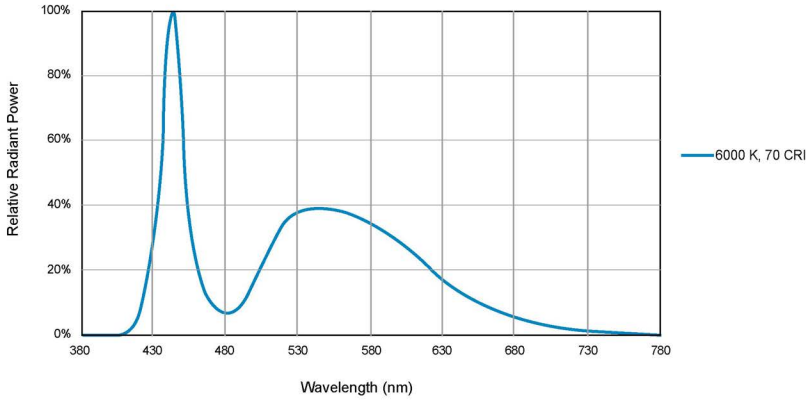
Measuring range	
Perimeter ball radius	300 mm
Meridian	Adjustable from 0°-360°
Max. eccentricity	90° (full field of view)

Stimulus	
■ Stimulus size	Goldmann I, II, III, IV, V
■ Stimulus colour	white, blue, red
■ Brightness Ls	0 – 3180 cd/m² (0 – 10 000 asb)/1 dB
■ Rendition time	200 ms/user-defined (0.2 s/0.5 s/0.8 s/adaptive)
■ Rendition speed	adaptive / fast / normal / slow / user-defined
■ Rendition speed (kinetic perimetry)	2°/s (Goldmann-Standard)
■ Distance	300 mm

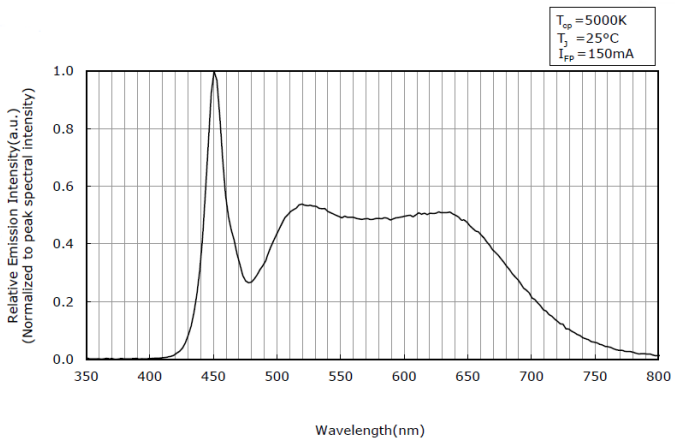
Environment	
■ Brightness L_B by Goldmann	10 cd/m² (31,4 asb) - white 100 cd/m² (314 asb) - yellow
■ Environment colour	white, yellow

Power supply	
Voltage	24 V DC; 5 A
Max. power consumption	45 W

Spectral distribution of the projector LED (white)



Spectral distribution of the backlight (white)



Power supply	
Type	Mean Well GSM120A24-R7B
Item number	10042451
Mains connection	100-240 V AC 1,4-0,7 A
Frequency	50/60 Hz
Max. power consumption	120 W
Output	24 V DC / 5 A / 120 W max.

Classification in accordance with IEC 60601-1

Type of protection against electric shock: Protection class	2
Degree of protection against electric shock	Type B

Recommended computer specifications

The IT equipment (computer, monitor etc.) must meet the requirements of IEC 62368-1 or IEC 60950.

At least	Intel® Core™ i5, 500 GB SSD, 8 GB RAM, Windows® 11, Intel® HD Graphics
Recommended screen size	24"
Recommended screen resolution	1920 x 1080 pixels (Full HD)
Interface	USB

CE marking

In accordance with Regulation (EU) 2017/745 on medical devices

CE

The device is a product in class I.
Conformity assessment procedure in accordance with (EU) 2017/745 (MDR), Annexes II and III

Annex

A Electromagnetic compatibility (EMC)

Medical electrical equipment is subject to special precautions with respect to EMC, and must be installed and operated according to the EMC instructions contained in the accompanying paperwork.

OCULUS devices and systems are suitable for environments in professional healthcare facilities, e.g. medical practices or clinics, except in the vicinity of RF surgical equipment and outside the RF-shielded room of an ME system for magnetic resonance imaging.

No special measures need be observed for OCULUS devices and systems.

Portable and mobile RF communications equipment can affect medical electrical equipment and impair its performance.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The user of the device can help prevent electromagnetic interference by maintaining the following minimum distance between portable and mobile RF communications equipment (transmitters) and the device, in accordance with the maximum output power of the communications equipment:

➔ Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) must not be closer than 30 cm (12 inches) to any part of the device.

Definition of minimum operating quality or significant performance characteristics:

- A short interruption to the USB connection during the examination is permissible, as it does not affect the diagnosis, treatment or monitoring.

Caution

Using accessories, transformers and cables that are not specified by OCULUS can cause increased emission or reduced immunity for the OCULUS device. Likewise, the use of the accessories, transformers and cables specified by OCULUS in conjunction with devices other than the OCULUS device may result in increased emissions or reduced immunity for the other devices.

➔ Only use the accessories, transformers and cables specified by OCULUS.

➔ Do not use OCULUS-specified accessories, transducers, and cables with devices other than the OCULUS device.

In order to ensure compliance with the requirements in IEC 60601-1-2 6.1 and 6.2, you must use the following devices, accessories, transformers and cables:

Order number	Description	
10037257	Twinfield® 3	
10042451	Mean Well GSM120A24-R7B power supply	24 V / 5 A
10039993	USB cable Twinfield® 3	

B Electromagnetic interference

Emitted interference measurements	Compliance	Electromagnetic environment - guidelines
The OCULUS Twinfield® 3 is intended for operation in the electromagnetic environment specified below. The user of the Twinfield® 3 should ensure that it is being used in such an environment.		
RF emissions per CISPR 11	Group 1	The device uses high frequency energy only for its internal functions. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic devices.
RF emissions per CISPR 11	Class B	
Emissions of harmonics per IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	complies	

C Electromagnetic immunity

Immunity tests	Test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 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 (50/60 Hz) magnetic field in accordance with 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 commercial or hospital environment.
Electrical fast transients/bursts in accordance with IEC 61000-4-4	± 2 kV for mains cables 100 kHz repetition frequency ± 1 kV for signal input and signal output components	± 2 kV ---------- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges per IEC 61000-4-5	± 1 kV symmetrical voltage ± 2 kV Common mode voltage	± 1 kV ± 2 kV	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 in accordance with IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degrees 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degrees 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment If the user of the Twinfield® 3 requires continued operation during power cuts, we recommend powering the Twinfield® 3 from an uninterruptible power supply or battery.
Note: U_τ is the A.C. mains voltage prior to applying the test level			

Immunity tests	Test level	Compliance level	Electromagnetic environment - guidelines
Conducted HF transients in accordance with IEC 61000-4-6 Radiated HF transients in accordance with IEC 61000-4-3	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM bands and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	V_{eff} = 3 V	Portable and mobile HF communications equipment should be used no closer to any part of the Twinfield® 3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ for 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the rated output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The field strength for fixed radio transmitters should be less than the compliance level in each frequency range (b) as determined by an electromagnetic site survey (a). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: Note 2:	The higher frequency range applies at 80 Hz and 800 MHz. 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 telephones and land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, a site survey should be considered. If the measured field strength in the location in which the Twinfield® 3 is used exceeds the aforementioned compliance level, the Twinfield® 3 should be observed to verify normal operation.
If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Twinfield® 3.
b. Over the frequency range of 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

D Recommended separation distances

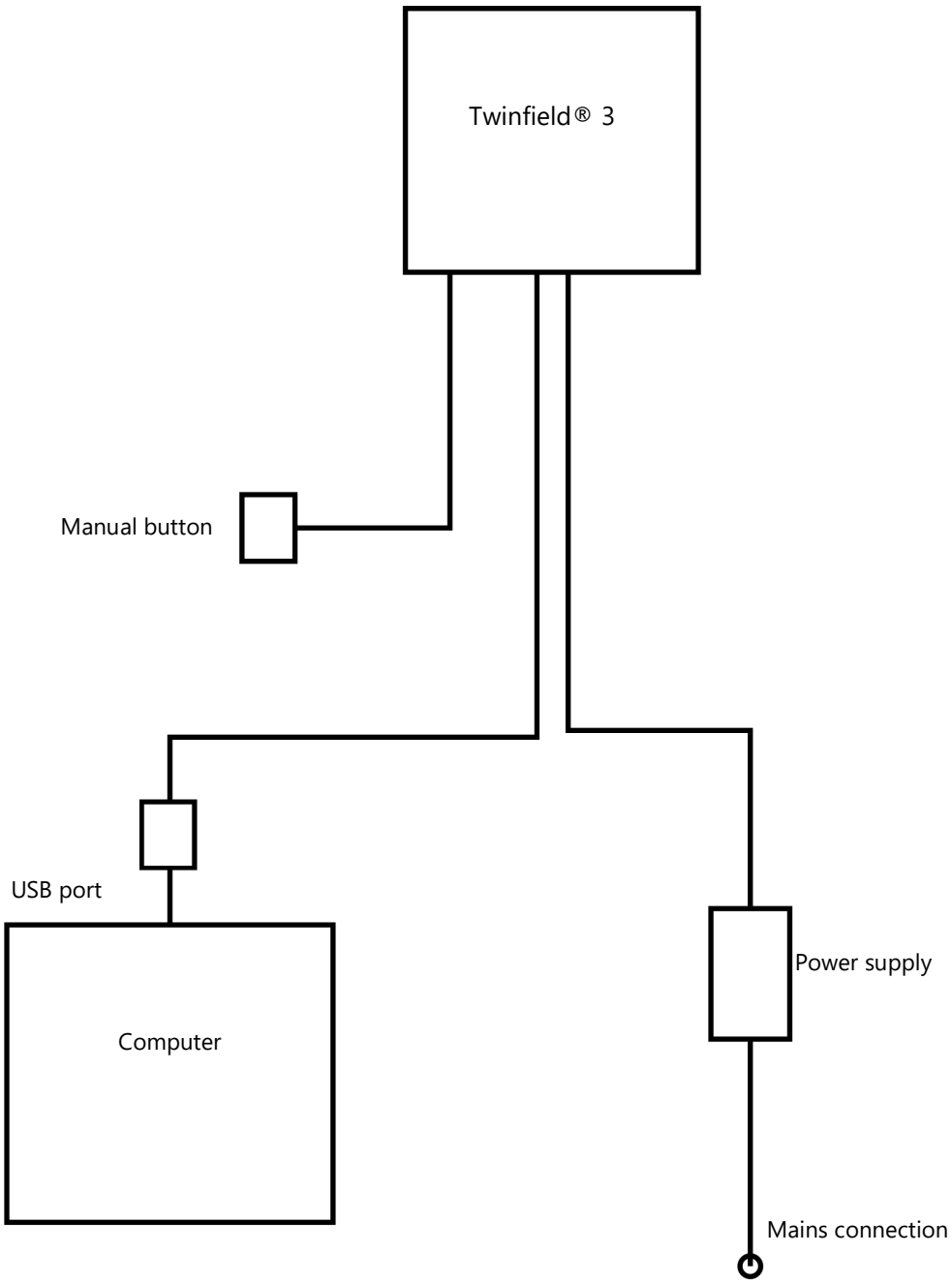
Recommended separation distances between portable and mobile RF telecommunications equipment and the Twinfield® 3

The Twinfield® 3 is intended for use in an electromagnetic environment in which RF transients are controlled. The Twinfield® 3 user can make a significant contribution to avoiding electromagnetic interference by keeping a minimum distance of between the portable and mobile RF telecommunication devices (transmitters) and the device, depending on the communication device's output power as specified below.

	Separation distance according to the transmission frequency in m		
Transmitter rated output 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 with a maximum rated output not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the relevant column, where P is the maximum transmitter rated output in watts (W) according to the transmitter manufacturer's specifications.
Note 1: The higher frequency range applies at 80 MHz and 800 MHz.
Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

E Connection diagram



F Power supply data sheet

MEAN WELL 120W AC-DC Reliable Green Medical Adaptor **GSM120A series**

Energy Verified Rendement Énergétique Vérifié

EN60601-1 ANSI/AAMI ES60601-1 IEC60601-1 TPTC004

Features

- 3 pole AC inlet IEC320-C14, Class I power unit
- Medical safety approved (2 x MOPP) according to ANSI/AAMI ES60601-1 and IEC/EN60601-1
- Extremely low leakage current
- No load power consumption<0.15W
- Energy efficiency level VI and meet CoC Version 5
- -30~+70℃ wide range working temperature
- Protections: Short circuit / Overload / Over voltage / Over temperature
- LED indicator for power on
- Lifetime > 95 K hours
- Various DC plug quick adapter accessory available (Plug kit sold sperately, please refer to : https://www.meanwell.com/upload/pdf/DC_plug.pdf)
- 3 years warranty

Applications

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

Description

GSM120A is a highly reliable, 120W desktop style single-output green medical adaptor series. This product is equipped with a 3-pin (with FG) standard IEC320-C14 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 (<100μA), fitting the medical devices in direct electrical contact with the patients.

With the efficiency up to 91.5% and the extremely low no-load power consumption below 0.15W, GSM120A 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. GSM120A is approved with the international medical safety certificates.

Model Encoding

GSM120A 12 -R7B

- DC plug type
  - R7B: Standard model,Power DIN 4Pin with lock type
  - Other options available by customer requested (see Page 4~5)
- Output voltage
- IEC320-C14 AC inlet
- Rated wattage
- Series name

File Name:GSM120A-SPEC 2020-08-03

MEAN WELL 120W AC-DC Reliable Green Medical Adaptor **GSM120A series**

SPECIFICATION

ORDER NO.		GSM120A12-R7B	GSM120A15-R7B	GSM120A20-R7B	GSM120A24-R7B	GSM120A48-R7B
OUTPUT	SAFETY MODEL NO.	GSM120A12	GSM120A15	GSM120A20	GSM120A24	GSM120A48
	DC VOLTAGE Note.2	12V	15V	20V	24V	48V
	RATED CURRENT	8.5A	7A	6A	5A	2.5A
	CURRENT RANGE	0 ~ 8.5A	0 ~ 7A	0 ~ 6A	0 ~ 5A	0 ~ 2.5A
	RATED POWER (max.)	102W	105W	120W	120W	120W
	RIPPLE & NOISE (max.) Note.3	100mVp-p	120mVp-p	180mVp-p	180mVp-p	200mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±5.0%	±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	1500ms, 30ms / 230VAC 2000ms, 30ms / 115VAC at full load				
	HOLD UP TIME (Typ.)	40ms / 230VAC 24ms / 115VAC at full load				
INPUT	VOLTAGE RANGE Note.7	80 ~ 264VAC				
	FREQUENCY RANGE	47 ~ 63Hz				
	POWER FACTOR (Typ.)	PF>0.93 / 230VAC PF>0.97 / 115VAC at full load				
	EFFICIENCY (Typ.)	88%	89%	89%	90%	91.5%
	AC CURRENT (Typ.)	1.4A / 115VAC 0.7A / 230VAC				
	INRUSH CURRENT (Typ.)	Cold start 35A / 115VAC 70A / 230VAC				
	LEAKAGE CURRENT(max.)	Earth leakage current < 115 μA/264VAC , Touch current <100 μA/264VAC				
PROTECTION	OVERLOAD	105 ~ 160% 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				
ENVIRONMENT	WORKING TEMP.	-30 ~ +70℃ (Refer to "Derating Curve")				
	WORKING HUMIDITY	20% ~ 90% RH non-condensing				
	STORAGE TEMP., HUMIDITY	-40 ~ +85℃, 10 ~ 95% RH non-condensing				
	TEMP. COEFFICIENT	±0.03% / ℃ (0~40℃)				
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes				
	OPERATING ALTITUDE Note.8	3000 meters				
SAFETY & EMC (Note. 10)	SAFETY STANDARDS	IEC60601-1, TUV EN60601-1, ANSI/AAMI ES60601-1(3.1 version), CAN/CSA-C22.2 No. 60601-1:14 - Edition 3, EAC TP TC 004 approved				
	ISOLATION LEVEL	Primary-Secondary: 2xMOPP, Primary-Earth: 1xMOPP				
	WITHSTAND VOLTAGE Note. 9	I/P-O/P:4KVAC I/P-FG:2KVAC O/P-FG:0.5KVAC				
	ISOLATION RESISTANCE	I/P-O/P:100M Ohms / 500VDC / 25℃/ 70% RH				
	EMC EMISSION	**Parameter**	**Standard**	**Test Level / Note**		
		Conducted emission	En55011 (CISPR11), FCC PART 15 / CISPR22, CAN ICES-3(B)/NMB-3(B)	Class B		
		Radiated emission	EN55011 (CISPR11), FCC PART 15 / CISPR22, CAN ICES-3(B)/NMB-3(B)	Class B		
		Harmonic current	EN61000-3-2	Class A		
		Voltage flicker	EN61000-3-3	-----		
	EMC IMMUNITY	EN60601-1-2, EN61204-3				
		Parameter	**Standard**	**Test Level / Note**		
		ESD	EN61000-4-2	Level 4, 15KV air ; Level 4, 8KV contact		
		RF field susceptibility	EN61000-4-3	Level 3, 10V/m(80MHz~2.7GHz) Table 9, 9~28V/m(385MHz~5.78GHz)		
		EFT bursts	EN61000-4-4	Level 3, 2KV		
		Surge susceptibility	EN61000-4-5	Level 3, 1KV/Line-Line, 2KV/Line-FG		
		Conducted susceptibility	EN61000-4-6	Level 3, 10V		
		Magnetic field immunity	EN61000-4-8	Level 4, 30A/m		
		Voltage dip, interruption	EN61000-4-11	100% dip 1 periods, 30% dip 25 periods, 100% interruptions 250 periods		
OTHERS	MTBF	368.5K hrs min. MIL-HDBK-217F(25℃)				
	DIMENSION	167*67*35mm (L*W*H)				
	PACKING	0.6Kg; 20pcs/13.0Kg/0.89CUFT				
CONNECTOR	PLUG	See page 4~5 ; Other type available by customer requested				
	CABLE	See page 4~5 ; Other type available by customer requested				

NOTE

1. All parameters are specified at 230VAC input, rated load, 25℃ 70% RH ambient.
2. DC voltage: The output voltage set at point measure by plug terminal & 50% load.
3. Ripple & noise are measured at 20MHz by using a 12" twisted pair terminated with a 0.1μf & 47μf capacitor.
4. Tolerance: includes set up tolerance, line regulation, load regulation.
5. Line regulation is measured from low line to high line at rated load.
6. Length of set up time is measured at first cold start. Turning ON/OFF the power supply may lead to increase of the set up time.
7. Derating may be needed under low input voltages. Pleas check the derating curve for more details.
8. The ambient temperature derating of 3.5℃/1000m with fanless models and of 5℃/1000m with fan models for operating altitude higher than 2000m(6500ft).
9. Optional for 1.5KVAC with BF rated.
10. The power supply is considered as an independent unit, but the final equipment still need to re-confirm that the whole system complies with the EMC directives. For guidance on how to perform these EMC tests, please refer to "EMI testing of component power supplies." (as available on http://www.meanwell.com)

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G Instructions for integration into an IT network

The device, in conjunction with the connected computer and the device software running on it, forms a programmable electrical medical system (PEMS) according to IEC 60601-1.

Please note the section → *"2.3 Information regarding cyber security" on page 12* in the 'Security' chapter in the device's instructions for use.

Observe the following instructions for integrating the PEMS into an IT network:

The purpose of integrating the PEMS into an IT network can be:

- Licensing by local license server
- Storage and retrieval of the examination data on a local network drive
- Printing
- Data export
- DICOM workflow

Required characteristics of the IT network into which the PEMS is to be integrated:

- Favour a wired LAN connection
- IPv4 network
- Fast Ethernet (at least 100 Mbit/s)

Required configuration of the IT network into which the PEMS is to be integrated:

- Licensing: Required open ports: 3968 TCP; 51371 - 51372 UDP
- Storage, printing, data export: File and Printer Sharing for Microsoft Networks (SMB 3.0 or higher - required opened port: 445]
- DICOM Storage Service Class = PACS
- DICOM Worklist Management Service class (Modality Worklist Server)

Technical specifications of the network connection with the PEMS, including the specifications for data security:

- Read the section on cyber security (page 12) in the 'Security' chapter in the device's operating manual.
- See the "Floating License Key - License management for software options" operating manual
- See the device specific DICOM interface description

The intended flow of information between PEMS, the IT network and other devices in the IT network and the intended routing through the IT network

- Licence handling from the local licence server to PEMS and vice versa
- Storage and data export to local network storage and loading from local network storage
- Printing on the local printer

List of hazard situations that result from the IT network being unable to provide the features that are required to fulfil the purpose of integrating the PEMS into to meet the IT network:

- Data loss
- Unsuitable data exchange
- Data corruption
- Unsuitable temporal data allocation
- Unexpected data reception
- Unauthorised access to data

Connection of the PEMS to an IT network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

The responsible organisation should identify, analyse, evaluate and control these risks.

Subsequent changes to the IT network could introduce new risks and require additional analysis.

Changes to the IT network include:

- Changes to the IT network configuration
- Connecting additional items to the IT network
- Disconnecting items from the IT network
- Updating equipment connected to the IT network

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