OCULUS | Twinfield® 2

INSTRUCTION MANUAL

Measuring and Analysis System for the Visual Field Examination

OCULUS®

Preface

The Twinfield® 2- Perimeter has been manufactured and tested according to strict quality criteria. You have selected a modern and well-engineered product.

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

- The PeriVision software is not able to control the perimeter, i.e. all control elements documented in this operating manual, which are directly or indirectly related to conducting an examination, are either not present, or are inactive in the PeriVision software.
- More detailed information above and beyond the operating concept can be found in the user manual for the Twinfield® 2 Perimeter.

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

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

OCULUS Optikgeräte GmbH

Item Number: G/56920/XXXX/EN
Revision: 02
Release: 12.08.2024

Table of Contents

1 Scope of Delivery

Component
Twinfield® 2
Lens holder for inserting trial lenses
Accessories Twinfield® 2, consisting of ■ Hand-held button for Twinfield® 2 ■ Eye patch ■ Replacement bulb (halogen) 12V / 20W for Twinfield® 2 ■ Dust cover ■ Med. tabletop power supply ■ USB cable with ferrite bead ■ Replacement bulb (halogen) 20 W,12 V, G4
Equipment Twinfield® 2, consisting of ■ Instruction manual Twinfield® 2 ■ Perimeter Patient manual ■ Twinfield® 2 data USB stick
USB FS MED Isolator
2-pin EU power cable
Fastening set
CLIP Strategy

Optional Component
SPARK strategy
Module DICOM PACS for Twinfield® 2
Glaucoma Staging Program (GSP) network license
Threshold Noiseless Trend (TNT) network license
Floating License Key
All-in-One-computer for Twinfield® 2
Laptop (state-of-the-art)
Ophthalmic table Twinfield® 2 PC 115 V
Ophthalmic table for Twinfield® 2 and PC left version 115 V
Ophthalmic table for Twinfield® 2 and laptop 115 V

Optional Component
Ophthalmic table for Twinfield® 2 and laptop left version 115 V
Lift column for Twinfield® 2, 115 V

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

- If you find transport damage upon delivery, immediately file a claim with the transport company.
- Have the damages noted on the bill of lading so that your claim for damages can be handled properly.

➔ Remove the unit and its accessories from the packaging and keep the packaging. You can then ship or transport the unit in the proper manner for any servicing or repairs that may arise, avoiding unnecessary damage and costs.

- The patient data management software version is shown on the "Settings" screen **within the patient data management program**.
- The software version of the Twinfield® 2 program is shown on the "Change Settings" screen **within the Twinfield® 2 program**.

2 Symbols

2.1 On the Device / Name Plate

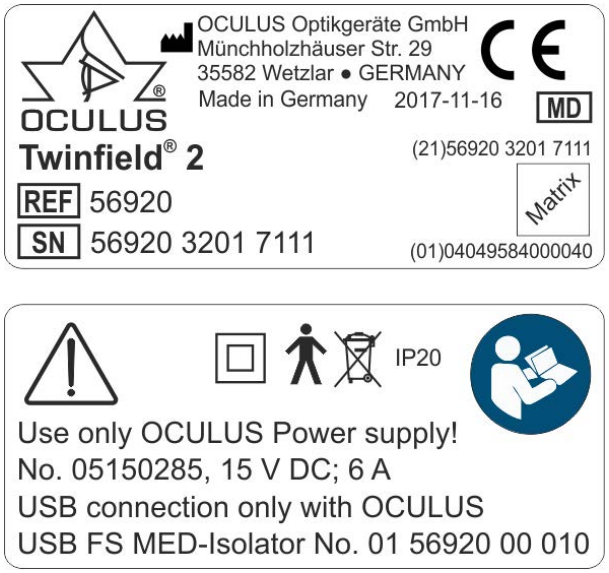


Fig. 2-1: Name plate (example)

Symbol	Description	Symbol	Description
	Manufacturer		Protection class
	Date of manufacture	IP XX	Type of protection
CE	Conformité européenne (EC Conformity)	REF	Article number
	Follow instruction for use	SN	Serial number
	Disposal in household trash is prohibited	MD	Medical device
	Applied part type B		Attention
	UDI number (example) consisting of: UDI-DI (Device-Identification) UDI-PI (Product Identifier) machine-readable matrix code		

2.2 On the Packaging

Symbol	Description
	Keep dry
	This way up
	Fragile
Transport 	Limit of temperature for transport
Lagerung 	Limit of temperature for storage
	Limit of humidity
	Limit of air pressure

3 Structure of the Documentation

A folder containing a set of documentation is supplied with your Twinfield® 2 Perimeter:

- **Quick Guide:** The measuring procedure is described in the form of a checklist in this document. This document is intended to help you when doing measurements, so that you don't forget to do any important work steps, thus ensuring that the measuring results can be correctly analyzed.
- **Instruction Manual:** The design of the unit is described in detail in this document. The instruction manual also gives you general information about working with the patient data management system and all safety-related instructions for use of the Twinfield® 2 Perimeter.
- **User Guide:** All features of the examination and analysis software are described in the user guide, along with detailed information about the Patient Data Management system.
- **Software Installation:** The introduction to the Software Installation describes how to install the Twinfield® 2 perimeter software and the associated drivers.
- Manual **Floating License Key**: Information on the use of the Twinfield® 2 within networks.

4 Safety Instructions

This chapter contains a summary of the most important safety-related information.

Caution

All safety-related instructions for use of the Twinfield® 2 Perimeter are given in the instruction manual for the unit. It is therefore imperative that you read and understand the whole instruction manual before you use the Twinfield® 2 Perimeter.

- ➔ Carefully read through the Instruction Manual.
- ➔ Keep the Instruction Manual, the Quick Guide and the User Guide in good condition near the unit.
- ➔ Observe the legal regulations with regard to accident prevention.

4.1 Used Pictograms

Caution

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

Note

Denotes situations which could result in incorrect findings, user instructions and useful, or other important information.

Identifies important information about the product and its usage, which require special attention.

> This symbol denotes menu paths and screen shots. Example: Call up a new patient:
>
> Twinfield® 2 > Examination > New Patient
>
> That is:
>
> - ➔ Open the Twinfield® 2 program.
> - ➔ In the menu list, select the "Examination" menu item.
> - ➔ Click on "New Patient / End".

The term "computer" is used for "netbook", "laptop" or "PC".

4.2 Safety Instructions for Use

Caution

Personal injury or property damage due to improper operation.

➔ Observe the following safety instructions.

Caution

Personal injury or property damage due to equipment modifications related to safety.

➔ No modifications may be made to this device 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.

4.2.1 Instructions to Operating Personnel

- This device is intended exclusively for use by trained and qualified ophthalmologists.
- The operator must be an expert on the anatomy and physiology of the eye and must have in-depth knowledge of the specific device and its intended purpose.

4.2.2 Transport and Storage Instructions

➔ Refer to the notes in *sect. 15, page 59*

4.2.3 Instructions regarding the Set-up and Electrical Connection

➔ Only OCULUS or an authorized dealer is allowed to set up and to connect the Twinfield® 2.

➔ Do not use or store the Twinfield® 2 in damp rooms.

➔ Keep the Twinfield® 2 away from water that may drip, surge or splash and make sure that no liquids can enter the Twinfield® 2 device. Do not place any containers with liquid either close to or on the Twinfield® 2 device.

- ➔ Germany only: Operate the Twinfield® 2 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 anesthetics or volatile substances such as alcohol or petrol nearby.
- ➔ Only use a power cord which meets the requirements of the standards IEC 60227-1, Type 53, min. 0.75 mm^2 and IEC 60320-1.
- ➔ Set up the Twinfield® 2 so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.
- ➔ Do not force any plug connections.

  If you are unable to make a plug connection, check whether the plug fits the socket.

  If you detect damage to the connection, you should let our service personnel repair the damage.
- ➔ Use only the OCULUS USB FS MED isolator (no. 01 56920 00 010) for a USB connection

4.2.4 Patient environment information

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

Caution

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

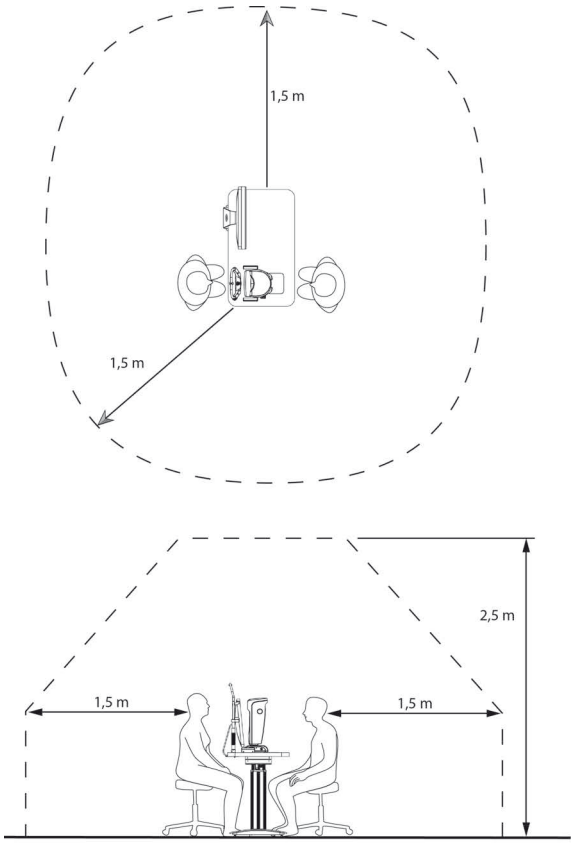


Fig. 4-1: Patient environment

4.2.5 Information about the operation of an ME system

The Twinfield® 2 and a connected computer form a medical electrical system (ME system) according to DIN EN 60601-1. If you connect additional devices, such as, for example a printer, those devices become part of the ME system.

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

4.2.6 Instructions for Operation

- ➔ Before initial operation: Let OCULUS or an authorized distributor provide necessary training for operation of the Twinfield® 2.
- ➔ Never operate a damaged Twinfield® 2.
- ➔ Only operate the Twinfield® 2 using original accessory parts supplied by us, and when the device is in technically correct working order.

  Use only the supplied power adapter.
- ➔ Do not touch the patient and the Twinfield® 2 simultaneously.
- ➔ Do not use the device if you have not understood the Instruction Manual.
- ➔ Do not place any heavy objects or the device itself on top of the connecting cable.

4.2.7 Notes on Maintenance

- ➔ When cleaning, use a damp cloth and make sure that no liquid enters the Twinfield® 2.
- ➔ To ensure that it functions correctly and safely we recommend the following: Have the Twinfield® 2 checked every two years by our service department or an authorized distributor. If an error occurs which you are unable to correct, label the Twinfield® 2 as "out of order" and contact our service department or an authorized distributor.

4.2.8 Instructions on Disassembly and Disposal

- ➔ When disconnecting electrical connections, pull on the respective plug instead of the cable itself.
- ➔ Dispose of the unit in conformance with legal requirements.

4.2.9 Instructions on Electrical Safety

The device must be powered using the special power adapter which comes with the device. Do not connect the device in any other way.

Caution

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

Connecting the Twinfield® 2 with its non-medical electrical equipment (for example data processing equipment) to 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.
- ➔ Only use the power adapter listed in the packing list.
- ➔ Use only a computer that meets the specifications given in this instruction manual, *sect. 17, page 62*.

Caution

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

If you use a multiple socket extension cord to connect the Twinfield® 2 to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Twinfield® 2 and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

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

If you are using a new computer for the Twinfield® 2, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Caution

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

Portable and mobile RF communications equipment can affect medical electrical equipment *sect. 18.1, page 65*.

- ➔ 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 Twinfield® 2 functions correctly.

4.3 Cybersecurity Instructions

The device itself was not designed to connect via a coupled computer to the internet or other network, or to portable media, as the device does not require a network or internet connection to function.

User who elect to connect the device coupled computer to the internet or other network for other purposes are responsible for ensuring that it is done so in a controlled manner.

4.3.1 Data responsibility

The device itself is not designed to connect with the internet, but only with a computer. It does not require the internet to function.

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

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

4.3.2 Device Security

It is the responsibility of the authorized user to ensure that the Twinfield® 2 device is not left unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to, ePHI.

4.3.3 User Responsibility

User names or passwords must not be shared with colleagues or others, even if they are permitted by law and provider policy to view the same type of information (e.g. two operators reviewing the same patient samples).

Operators have access to patients' ePHI and must not take snap-shots, screenshots or pictures (e.g. using another device) of any information viewed through the device.

Operators should not enter identifying data into the device. All the data on the device should be de-identified and relate to the sample id and not to the patient.

4.3.4 Reporting Device Security or Privacy Breaches

Operators must contact their local IT department and disclose any suspected or confirmed compromised user accounts, and any other privacy or security breaches.

4.3.5 Recovering from Compromised Accounts or Devices

When accounts are considered compromised, devices are lost, or unauthorized access is discovered or suspected, the Healthcare Organization's IT network administrators suspend and modify the user login criteria and issue new login credentials for the user to access their account securely.

4.3.6 Unavailable Service

Users should report unavailable service or prohibited access to information to their local Healthcare Organization's IT department.

4.3.7 Precautions for access control of the computer

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

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

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

- ➔ If you elect to connect the computer to the LAN or internet, you are responsible for ensuring data security.
- ➔ Prefer wired connections of the computer to the network.
- ➔ If you are using Wi-Fi connections nevertheless, please ensure the usage of adequate security methods (for example WPA2/AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- ➔ The usage of a firewall (software or hardware) is recommended.
- ➔ Heed the instructions for integration into an IT-Network, *sect. 18.5, page 74*.

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

Do not use the Twinfield® 2 with wireless technology, for example with wireless USB (connection between device and computer).

5 Intended Use

5.1 Intended Purpose

The Twinfield 2 is designed for testing the visual field of the human eye. Das Twinfield 2 permits kinetic and static, as well as automatic and manual visual field examinations for this purpose.

The Twinfield® 2 is intended for the use described in this instruction manual.

➔ Heed the safety instructions listed above.

5.2 Intended Medical Indication

The Twinfield® 2 is designed as a visual field measuring instrument for use in the diagnosis, monitoring and treatment of eye disorders, including but not limited to glaucoma, maculopathies and associated neurological problems. The Twinfield® 2 should not be used as the single diagnostic method for any disorder.

5.3 Contraindication

None known.

5.4 Possible side effects

None known.

5.5 Intended users

Make certain that the Twinfield® 2 is used exclusively in clinics and by clinical persons or eye specialists,

- who can guarantee proper handling due to their knowledge, training and practical experience.
- who have been instructed by OCULUS staff or an authorized dealer before the initial operation.

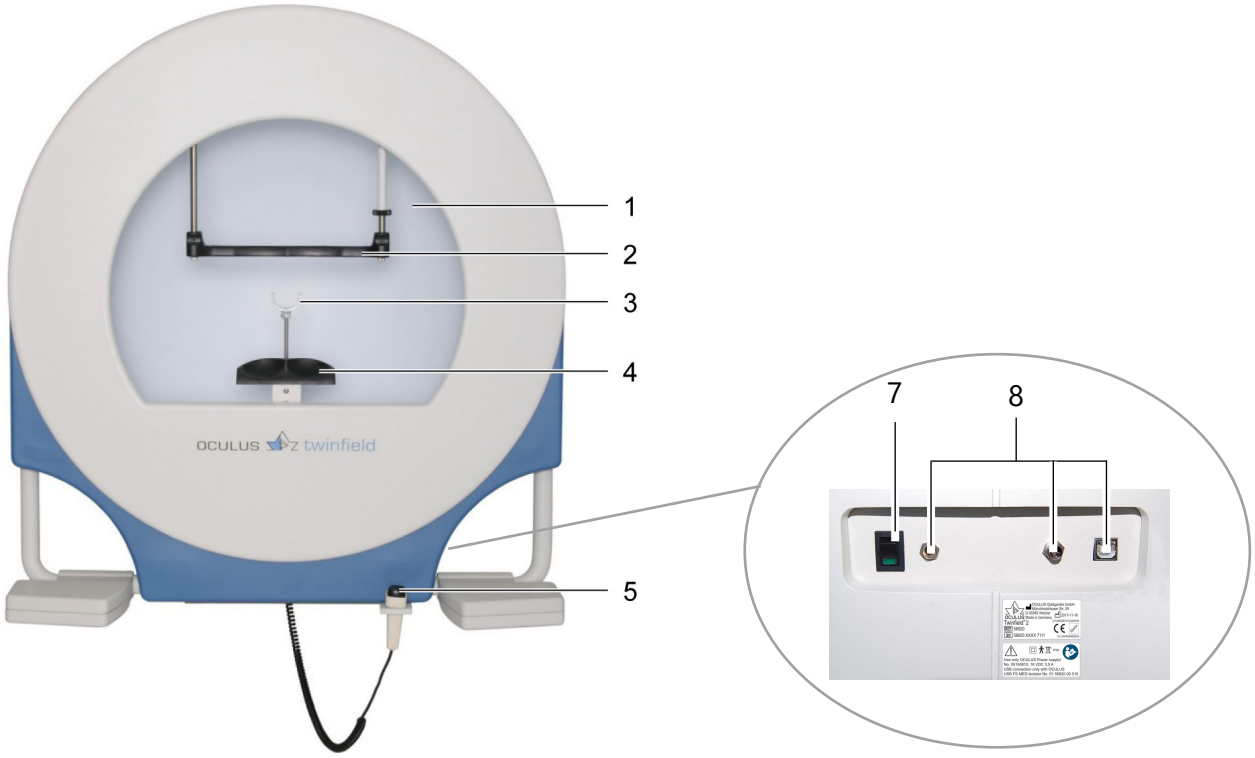
5.6 Patient group

Children from 5years up to geriatric patients. No restrictions on weight, health and condition: The patient is awake and able to understand and see a fixation object.

6 Device Description

6.1 Overview of Device Components

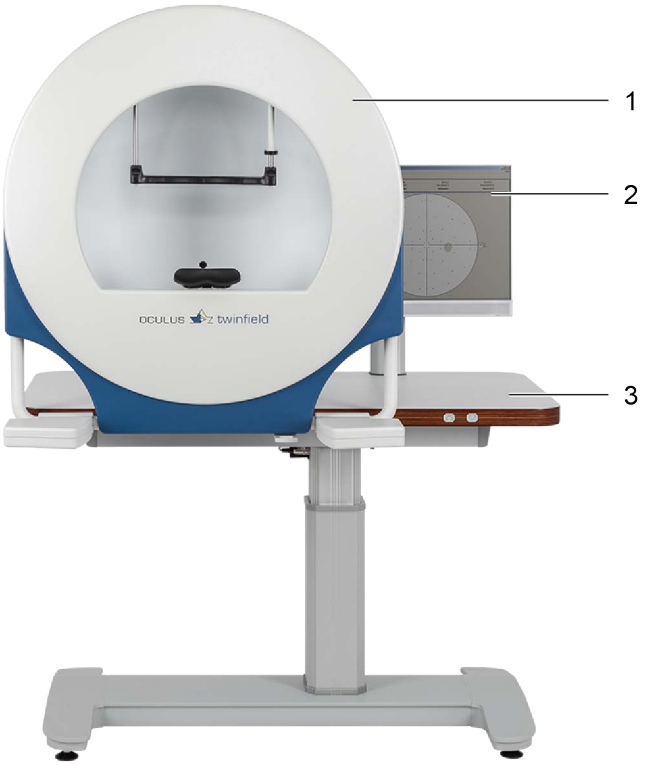
Device version without ophthalmic table



1 Perimeter bowl
2 Head rest
3 Lens holder for corrective lens
4 Chin rest
5 Hand-held button
6 Arm rests
7 ON/Off Switch
8 Connections

Fig. 6-1: Device components Twinfield® 2

Device version with ophthalmic table



1 Twinfield® 2 (see fig. 6-1)
2 Monitor
3 Ophtalmic table

Fig. 6-2: Device components Twinfield® 2 with ophthalmic table

In the version Twinfield® 2 with ophthalmic table, they make up a medical electrical system (ME system). This ME system was composed and assembled by OCULUS for their application and is intended for this application only.

Observe the instruction manual of the ophthalmic table.

6.2 How the Twinfield® 2 Perimeter works

The Twinfield® 2 Perimeter is a bowl-type projection perimeter that is used to examine the visual field. The back surface projection principle is used in the unit. Various projectors are mounted on a movable arm. Every position of the perimeter bowl can be accessed. The perimeter bowl has a radius of 30 cm and is homogeneously illuminated to the Goldmann standard (referenced to a background luminance 10 cd/m^2). The stimuli are presented accurately with exact reproducibility of the test locations - an absolute must for reliable visual field findings.

The unit is computer-controlled; connection to the computer takes place via the USB port.

The Twinfield® 2 Perimeter meets the requirements of ISO 12866.

6.3 PeriVision

The PeriVision software permits all examination data from the perimeters TAPcc, Easyfield, Centerfield and Twinfield® 2, developed by Oculus, to be loaded and displayed. Old TAP data can be viewed with the same user interface as that used for the new Twinfield® 2 examinations. The old data can be displayed in progression with or can be compared with the new examinations.

The PeriVision software is operated in exactly the same way as the Twinfield® 2 software. PeriVision, however, is not able to control the perimeter, i.e. all control elements documented in this operating manual, which are directly or indirectly related to conducting an examination are either not present, or are inactive in the PeriVision software.

6.4 Applied Parts

1 Head rest
2 Chin rest
3 Hand-held button
4 Arm rest (right)

Fig. 6-3: Applied parts

7 Before initial Use

Caution

Improper set-up may result in incorrect measurements or equipment damage

➔ Before you use the device for the first time, the Twinfield® 2 must be installed and connected by our service personnel or by an OCULUS-authorized specialist.

➔ Wait approx. 3-4 hours after transport before operating the Twinfield® 2 Perimeter. If the Twinfield® 2 Perimeter was stored in a cold room or vehicle during the cold time of the year, a significant change in temperature may cause condensation to appear on optical parts in the Twinfield® 2 Perimeter.

7.1 Install software

➔ Install the software first before you connect the unit to your PC. See *Software Installation*.

- No other software programs (screen saver, applications, etc.) must run simultaneously with the examination program in the foreground on the computer that controls the Twinfield® 2 Perimeter.
- Power-save modes (BIOS or Windows) must be deactivated.

7.2 Setup

Note

➔ Do not expose the Twinfield® 2 to any vibrations, shocks, contaminants, moisture, or high temperatures.

➔ Handle the optical device with care.

The Operating Instructions are found in *sect. 17, page 62*.

➔ Set up the Twinfield® 2 such that direct light cannot influence the measurement.

➔ As a rule you must ensure that any examination is conducted without interference from reflections. For this reason you should operate the Twinfield® 2 Perimeter in a dark room.

➔ Set up the Twinfield® 2 so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

➔ Place the Twinfield® 2 on a level surface.

7.3 Connect

Caution

Electrical safety hazard

- ➔ Do not use the Twinfield® 2 adjacent to or stacked with other equipment.
- ➔ If you have to use the Twinfield® 2 adjacent to or stacked with other equipment, verify the correct operation of the Twinfield® 2.
- ➔ Only use the power adapter listed in the list, *sect. 17, page 62*.
- ➔ Only use a power cord which meets the requirements of the standards IEC 60227-1, Type 53, min. 0.75 mm² and IEC 60320-1, Type C7.
- ➔ If you use a power strip to connect the Twinfield® 2: Use a power strip that complies with the requirements of DIN EN 60601-1.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Twinfield® 2 and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.
- ➔ Use a socket with a protective earth connection which is fully operating.

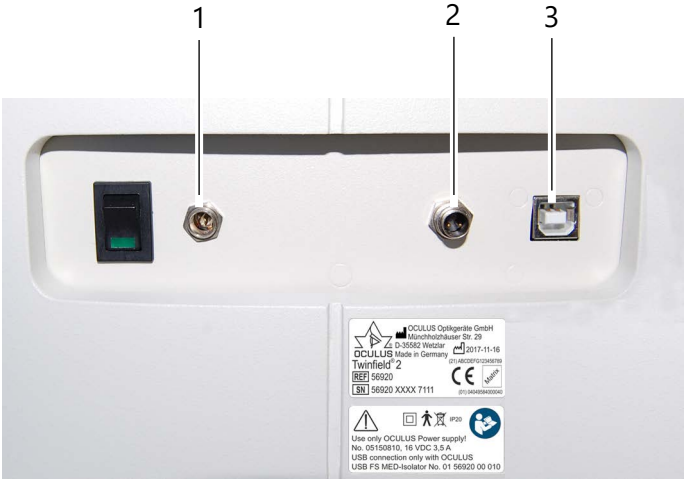
Note

Risk of equipment damage due to incorrect connection

If you do not connect the Twinfield® 2 properly, and the connection is live, the unit can be damaged within a short period of time.

- ➔ Do not use excessive force when connecting the electrical plug.
- ➔ Pay attention to the specifications on the nameplate.

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



1 Connection for the power supply
2 Connection for the hand-heldb button
3 Connection PC/Laptop
Fig. 7-1: Connections

➔ Connect the computer (3).
Connect the USB cable with the USB FS MED isolator.
Connect the isolator with the computer.

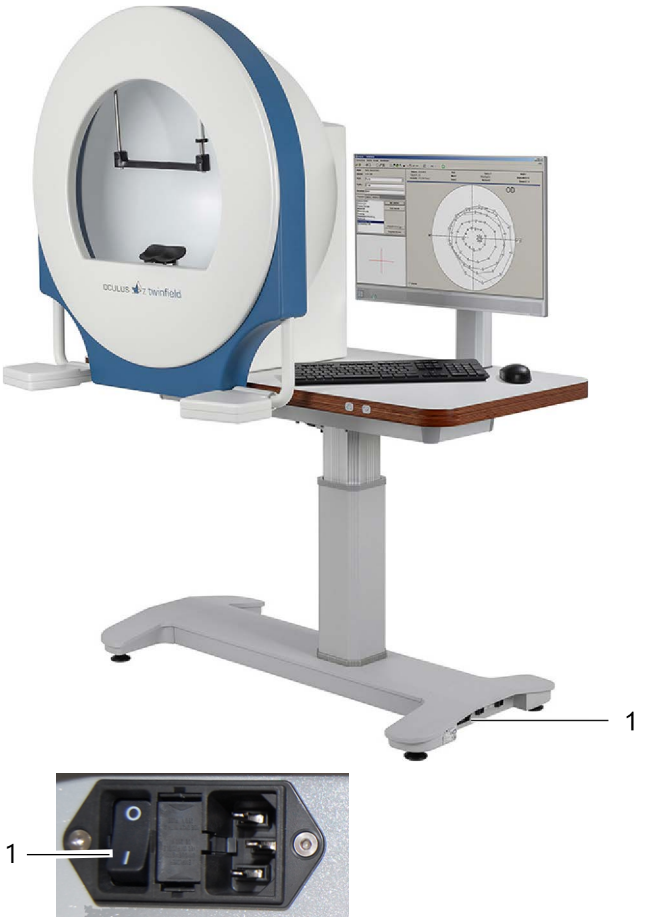
➔ Plug the low voltage connector of the supplied tabletop power adapter into the jack for the power supply (1).

➔ Plug the mains plug into a mains power outlet.

➔ Plug in the hand-held button at the jack at the back of the unit (2) and secure the plug into place by turning the knurled sleeve.

8 Daily Operation

8.1 Switching On the ME system



1 ON/Off Switch

Fig. 8-1: Main switch of the ME system

The version Twinfield® 2 with ophthalmic table features a main switch for switching the ME system on and off, located down on the base of the table.

➔ Switch the ME system on at the main switch on the base of the table.

8.2 Turning On the Twinfield® 2 Perimeter

➔ Switch on the PC or laptop.

➔ Wait until the operating system has booted up fully and the Patient Data Management screen appears.

➔ Turn the Twinfield® 2 Perimeter on at the main switch (Position ON).

8.3 Turning Off the Twinfield® 2 Perimeter

- ➔ Close the Twinfield® 2 program and Patient Data Management.
- ➔ Shut down the Windows operating system.
- ➔ Turn off the Twinfield® 2 Perimeter at the main power switch.
- ➔ Switch the ME system off at the main switch on the base of the table.
- ➔ Cover the device with the supplied cover after every use.

Caution

Risk of electric shock if the Twinfield® 2 is not completely disconnected from the mains for transport, cleaning, maintenance, disinfection and repair.

- ➔ Pull the power plug prior to these actions. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

8.4 Switching Off the ME system

- ➔ Switch the ME system off at the main switch on the base of the table.

9 Patient Data Management

You can enter and use patient data with the patient data management system.

For more information on Patient Data Management, refer to the *User Guide*.

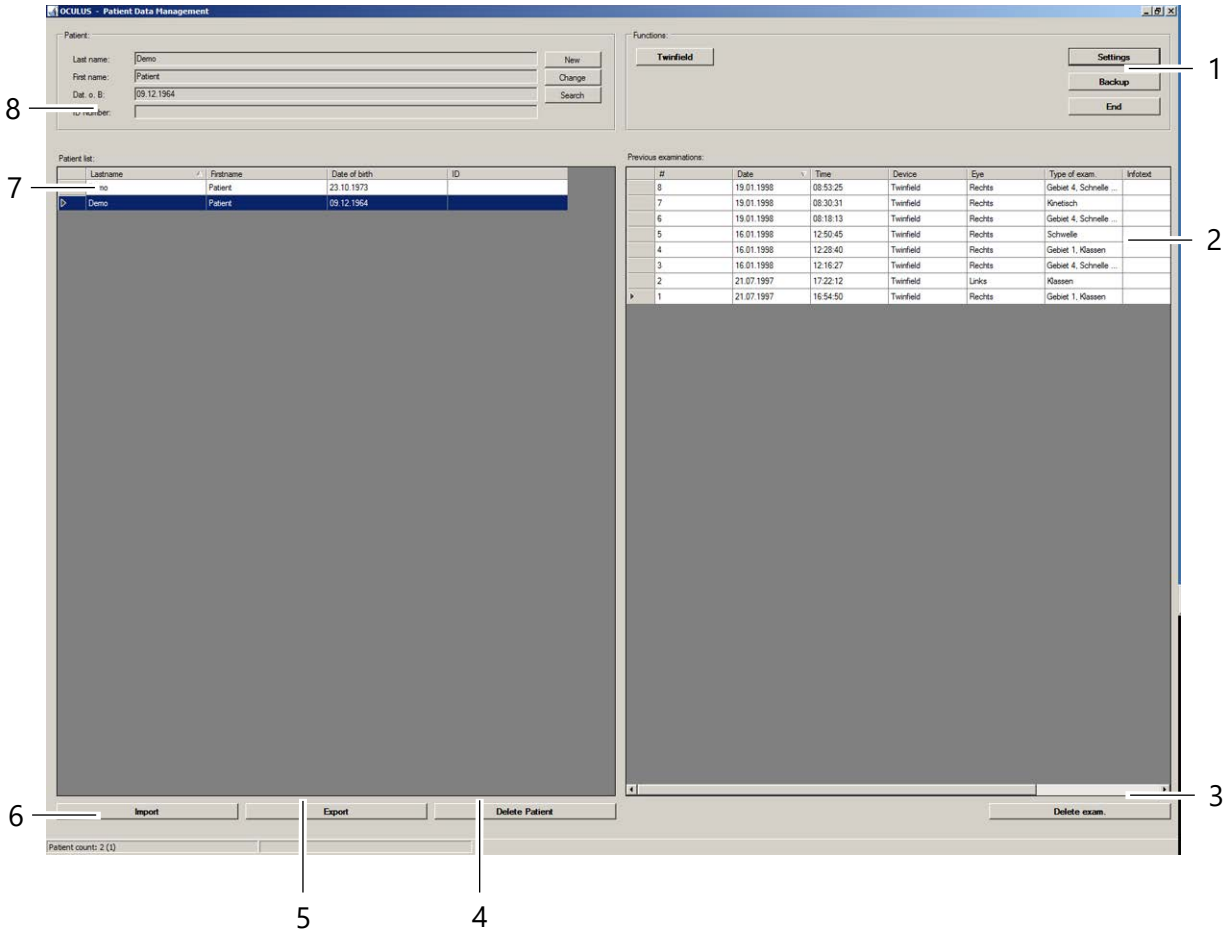
9.1 Starting Patient Data Management

You can enter and use the patient data with the patient data management.

After you have switched on the PC, it first loads the operating system.

➔ Click the Twinfield® 2 icon.

The user interface for the Patient Data Management appears.



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

Fig. 9-1: Patient Data Management user interface

To enter the Twinfield® 2 program, you must either enter a new patient (8) into the "Patient" group box or select an existing patient (7) from the list.

9.2 Entering new Patients

➔ To enter a new patient in Patient Data Management, click [New].

➔ Enter the patient's last name, first name and date of birth completely in the patient window (8).

Fig. 9-2: Entering patients

➔ Additionally you can enter an ID number for the patient.

➔ To accept the entries you have made, click [Save]. The patient you have just entered now appears in the patient list.

➔ Select this new patient from the patient list and start the Twinfield® 2 program *(sect. 10, page 35)*.

9.3 Selecting Existing Patients

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

Patient list:

Lastname	Firstname	Date of birth
0_Patient	Anonymous	11.07.1976
Demo	Patient	06.10.1976
Test	Tessa	23.03.1962
Test	Theo	12.09.1965
Vv	Bb	07.08.1968

Fig. 9-3: Patient list

➔ Click [Search] to quickly find the patient you require from the list.

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

Optionally you can search for the patient by entering his or her ID number, assuming that patient was assigned one when first entered.

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

9.4 Extended Patient Search: [Extended] checkbox

➔ Activate the [Extended] checkbox.

The screen displays additional search parameters which reference previous examinations, for example. The procedure is similar to entering a new patient name.

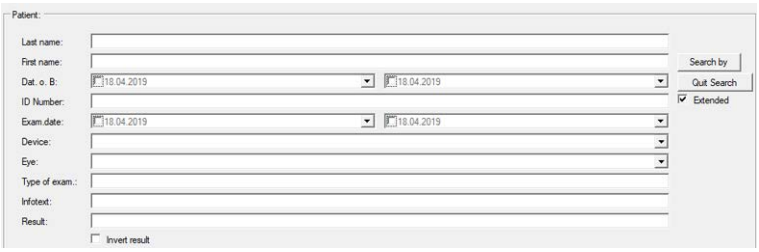


Fig. 9-4: Extended search

9.5 Rename Patient Data

After creating of the patient data, you can edit it.

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

➔ Change the entries in the individual boxes.

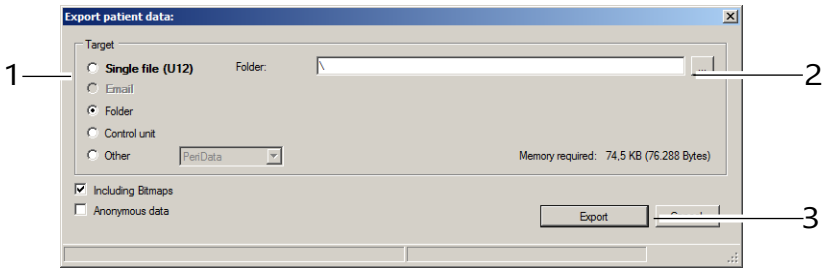
➔ Press the [Save] button.

9.6 Exporting Patient Data

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

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

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



1 Saving destination selection
2 Button to select a folder
3 [Cancel] and [Export] buttons

Fig. 9-5: "Export patient data" dialog

The default options for import and export of data are configured in the "Settings" field, see also the *User Guide*.

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

➔ Select the destination type (1) you would like for the exported data.

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

➔ Press the [...] button. (2).

➔ In the dialog that appears, select the folder or the file to which the patient data should be exported.

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

➔ Select whether the data with or without camera images and possibly to be exported anonymously.

➔ Click [Export] to export the data.

The patient and examination data have now been saved at the destination specified.

You can send data stored on the hard drive as an e-mail attachment.

9.6.1 Importing Patient Data

Import received patient and examination data in the Twinfield® 2 software. In case you keep patient data on a USB stick, you can import this data.

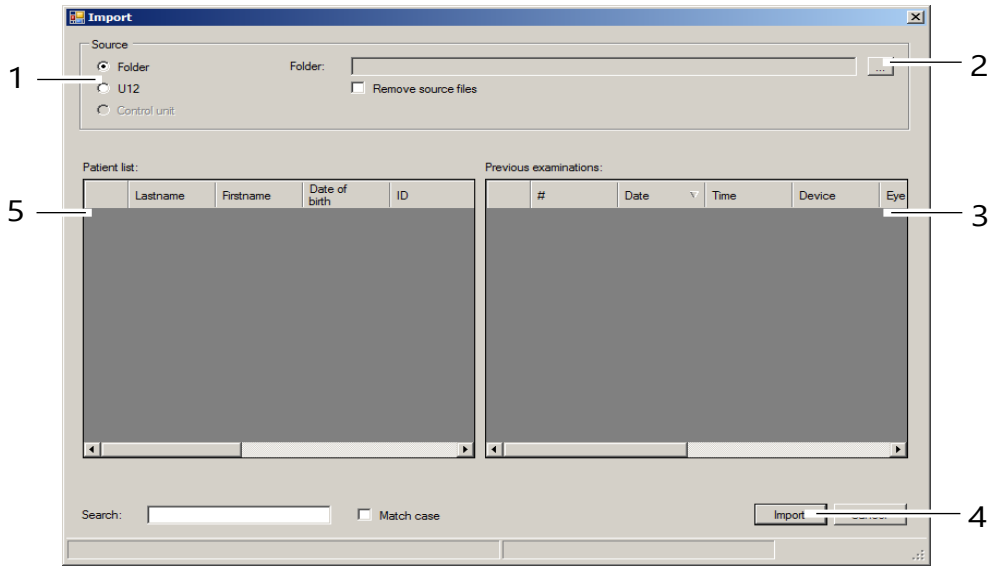
Note

Loss of data due to computer viruses

Computer viruses can cause loss of data.

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

➔ Press the [Import] button. The following dialog will be displayed:



1 Select the source of the data
2 [...] button to select a folder
3 Examinations list
4 [Import] button
5 Patient list

Fig. 9-6: "Import" dialog

The options for import and export of data are set as defaults in the “settings” field, see also the *User Guide*.

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

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

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

➔ Press the [...] button (2) to select a folder.

➔ In the dialog box, select the directory or the file where the patient data are located.

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

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

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

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

10 Twinfield® 2 Program

10.1 Starting the Twinfield® 2 Program

➔ After selecting a patient, start the Twinfield® 2 program by clicking on the [Twinfield] button in the "Functions" box *(fig. 9-1, page 30)*.

Fig. 10-1: Patient list

➔ Alternatively, you can start the Twinfield® 2 program by double clicking the patient you have selected.

Fig. 10-2: Twinfield® 2 program menu (upper section)

10.2 Load Existing Examination

➔ Select the menu item [Examination] and click [Load].
The dialog box "Load Examination" appears.

➔ Make a selection by clicking the required examination.

➔ Confirm your selection by clicking [OK], or by double clicking. The Twinfield® 2 program will load the examination you have selected.

11 Measuring Procedure

Caution

Risk of incorrect measurement due to incorrect use

➔ Before first use: Let OCULUS or an authorized distributor train you in the operation of the Twinfield® 2

11.1 Examination Preparations

11.1.1 Determine Required Correction

Correct measurement of the differential light sensitivity is only possible if the individual test points are focussed sharply on the retina. The patient may need suitable corrective lenses for this purpose. If the patient wears glasses, his own glasses may be used during the examination.

To determine the required correction, the exact refraction of the eye that is to be examined must be known. This can be taken either from a current refraction measurement, or from the patient's present ophtalmic lens strengths (distance vision correction).

As a patient's accommodation capacity greatly decreases with age, an age-related addition to the distance Rx is needed for patients aged approx. 40 and older. The following are guidelines for this:

- **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

➔ Click in the "Correction" field. The following dialog appears:

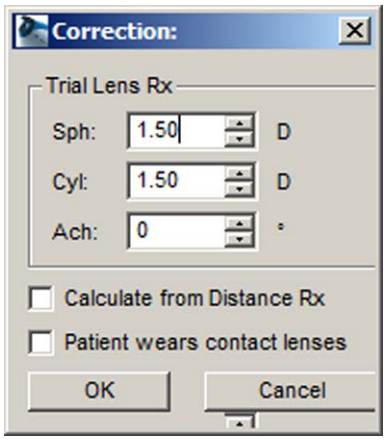


Fig. 11-1: Input of the known refraction values

➔ If you know the patient's refraction values: Enter the values into the fields in the „trial Lens Rx“ group box.

➔ Confirm by clicking [OK].

➔ If you don’t know the patient's refraction values: Activate the „Calculate from Distance Rx“ chekcbox.

➔ Enter the values into the fields in the „trial Lens Rx“ group box.

The following screen appears:

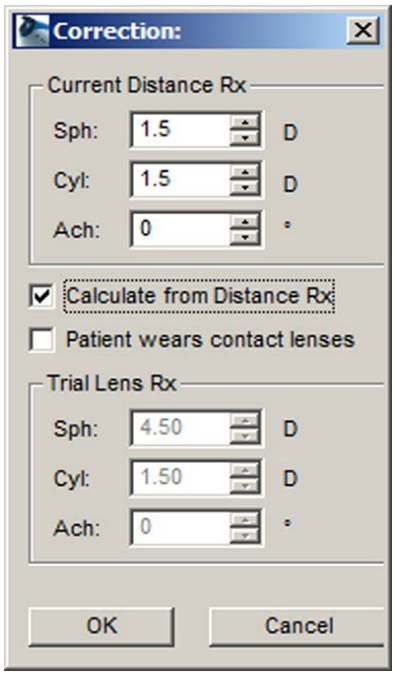


Fig. 11-2: Input of the correction when the checkbox [Calculate from Distance Rx] is activated

➔ Enter the patient's previously determined refraction values into the fields in the "Current Distance Rx" group box.

The values for the corrective lenses that are to be used are displayed in the fields of the "Trial Lens Rx" group box.

➔ Confirm by clicking [OK].

11.1.2 Insert Corrective Lens

Note

Only full aperture lenses, which fit perfectly into the lens holder of the Perimeter, may be used.

➔ Put the lens holder supplied with the unit into the appropriate slot in the Twinfield® 2 Perimeter.

➔ Place the required trial lens with the previously determined corrective power into the holder. The corrective lens should be centered and positioned as close to the patient's eye as possible. The eyelashes should not touch the lens.

The peripheral visual field is always examined without a corrective lens. After examination in the center, you will be asked to remove the corrective lens and the corrective lens holder. This is conditional upon inputting the correction values into the field "Corrective lens".

Note

The request to remove the corrective lens only appears if the correction values have been input into the field "Corrective lens".

The visual field examination can also be conducted with the patient's own glasses under the following conditions:

- Lenses large enough
- No toned lenses
- No multifocal glasses
- No varifocal glasses

11.1.3 Check Examination Conditions

➔ Make sure that no interfering light is getting into the perimeter's viewer.

➔ To achieve the best possible results, darken the room.

➔ Make sure that the examination takes place in a quiet atmosphere and that the patient is not distracted.

11.1.4 Select Examination Program

➔ Select the desired examination program on the "Program" tab panel.

Note

A description of how to write your own examination programs can be found in the user manual for the Twinfield® 2 Perimeter.

11.1.5 Prepare Patient

- ➔ Explain the examination procedure to the patient.
- ➔ Give the patient the hand-held pushbutton for the unit and ask him to hold it in one hand.
- ➔ Ask the patient to take a seat and make himself comfortable in front of the unit. He should sit as upright as possible.
- ➔ Cover the eye that is not being tested with the eyepatch.

11.1.6 Position Patient

- ➔ Ask the patient to place his chin on the chin rest.
  Examination of the left eye: right recess of the chin rest
  Examination of the right eye: left recess of the chin rest
- ➔ Ask the patient to place their arms on the armrests *(fig. 6-3, page 24)*.
- ➔ Ask the patient to lean rest his forehead against the head rest so that he sees the fixation marks (four red dots) in the center of the perimeter bowl with the eye that is to be examined.
  Only pull out the forehead rest in exceptional cases.
- ➔ Make sure that the distance from the eye to the corrective lens, or from the eye to the perimeter is no more than 1 cm.

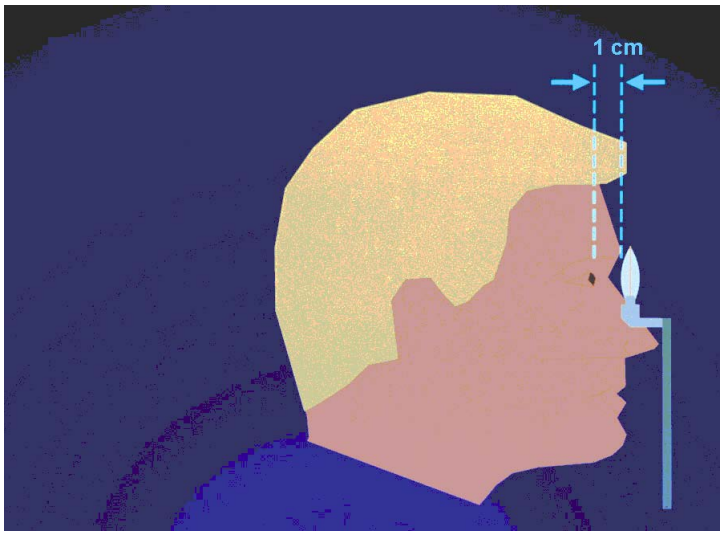


Fig. 11-3: Distance between eye and corrective lens

➔ You can sow see the center of the patient's eye in the camera image at the bottom left of the screen.

➔ Tell the patient to look towards the center of the fixation marks.

Note

Visual field losses in the top area could be caused by improper positioning of the patient. If the distance from the eye to the perimeter is too big (because the forehead rest has been pulled out, or the patient is not positioned properly), the patient may not have a full view into the unit.

11.1.7 Center the eye

➔ Select the eye that is to be examined in the "Eye" field of the Twinfield® 2 software.

➔ Click with the right mouse button in the camera image at the bottom left of the screen. The center of the pupil is automatically centered on the screen.

➔ Correct the position of the center of the pupil, if necessary, by pressing the appropriate arrow keys.

Note

➔ If necessary, adjust the camera image in the Twinfield® 2 program settings so that the camera image is moved in the same direction as that indicated by the arrow on the respective arrow key.

11.1.8 Measure the Pupil

To conclude the examination preparations, the pupil diameter must now be measured.

To do this:

➔ Click on the "Pupil" field with the left mouse button.

A window opens with the following message: "Please measure pupil using the CCD-Image."

➔ Confirm with the [OK] button.

The camera image is now fixed.

➔ Move the mouse pointer to the left edge of the pupil.

➔ Press and hold down the left mouse button. The left edge of the pupil is marked with a green line.

➔ Move the mouse pointer to the right edge of the pupil and stop pressing the mouse button there.
The right edge of the pupil is also marked with a green line and the measured pupil diameter is displayed in the "Pupil" field.

11.2 Start the Examination

➔ Now instruct the patient to press the hand-held pushbutton every time he sees a spot of light.

➔ Explain to him that he can interrupt the examination at any time by pressing and holding down the hand-held pushbutton. The examination is automatically resumed when he lets go of the hand-held pushbutton again.

➔ Click on the button [Start Exam.].
The following dialog appears so that you can check the data that you have entered:

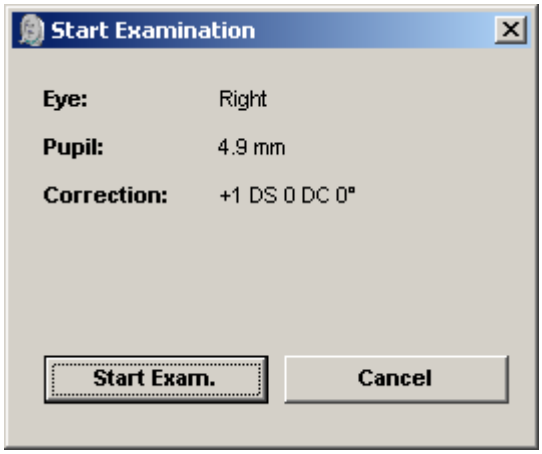


Fig. 11-4: Display of the general data

Note

Depending on the selected examination program, you can now select from a list box, whether the central threshold value or the peripheral threshold value is to be determined at the beginning of the examination.

➔ Check the data that have been entered. If you determine, for example, that you have selected the wrong eye, press the [Cancel] button.

➔ When all values have been entered correctly, ask the patient to once again look into the center of the four red dots.

➔ Press the button [Start Exam.].

The central or the peripheral threshold value is determined and is displayed in the following dialog box.

Fig. 11-5: Display of the measured threshold value

➔ If the measured threshold deviates considerably from the normal threshold for that age group, press the [Repeat] button.

Note

Depending on the selected examination program, you can also manually select the desired luminance class for the measurement from a list box.

➔ Tell the patient that the examination is about to start and press the [Start] button.

The examination program that you selected now starts to run.

Depending on the selected program, the associated examination area and if the patient needs corrective lenses, the following message may appear after the test has been completed in the visual field center:

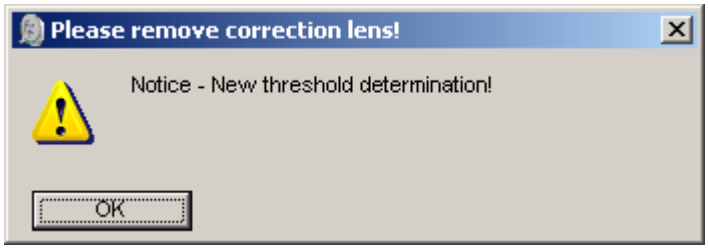


Fig. 11-6: Instruction to remove the corrective lens

➔ First remove the corrective lens with the lens holder.

➔ Then press the [OK] button.

The threshold is now measured again **without** the corrective lens and is once again displayed.

➔ Press the [Start] button to continue the examination.

11.3 Interrupting the Examination

➔ If you want to interrupt the examination, press the right mouse button.

The following confirmation dialog box appears:

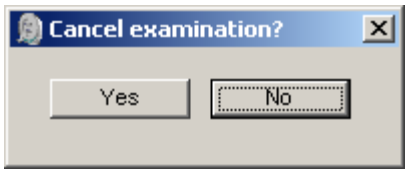


Fig. 11-7: Interrupting the Examination

➔ If the examination can be resumed, press the [No] button.

➔ To cancel the examination completely, press the [Yes] button.

11.4 Ending the Examination

After the examination has come to an end, the following dialog box appears:

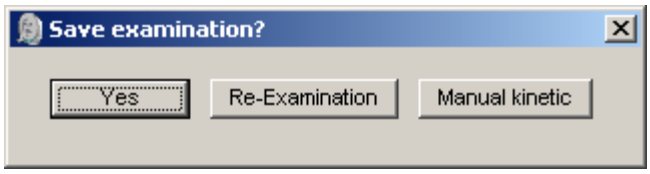


Fig. 11-8: Save the Examination Results

➔ Now decide how you want to proceed, based on the examination results.

➔ Tell the patient that the examination has been stopped and that he can relax.

11.5 Saving the Examination Data

If all examined test points were without pathological findings, or You have performed the desired re-examination or manual kinetic examination, you can now save the examination results. To do this:

➔ Press the [Yes] button.

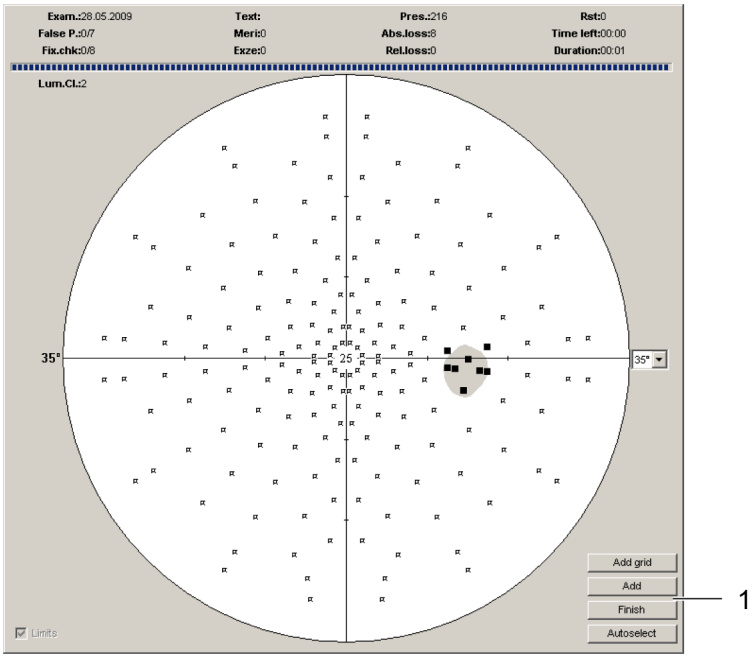
The examination data are saved and can be reloaded again later via the Patient Data Management System.

11.5.1 Re-Examination

If you want to re-examine abnormal test points again, you can conduct a re-examination. To do this:

➔ Press the [Re-Examination] button.

Four additional buttons appear at the bottom right of the map of the examination results.



1 Additional buttons

Fig. 11-9: Additional buttons for a re-examination

You can determine the points for the re-examination in several ways.

➔ Manually select the points in the test point grid with the left mouse button.

➔ Press the button [Autoselect]. The abnormal points are then automatically selected.

➔ Press the [Add] button to manually add more points that are not yet present in the test point grid.

➔ Click in the test point grid to define the additional test points.

➔ Press the button [Add grid] to add a predefined grid of test points.

In this case, an additional dialog appears in which you can select the test point grid:

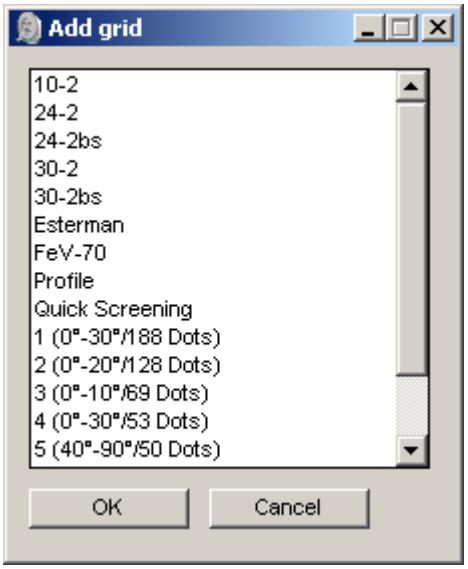


Fig. 11-10: Selection of the grid that is to be added for re-examination purposes

➔ Use the above options to define the points in the map that are to be tested during the re-examination.

➔ Finally, click on the [Finish] button.

The following dialog appears:

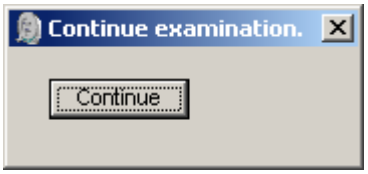


Fig. 11-11: Dialog "Continue examination"

➔ If you previously took the corrective lens out of the holder, re-insert it now.

➔ Tell the patient that you are now going to continue with the examination.

➔ Press the button [Continue] and, if applicable, confirm that you have re-inserted the corrective lens in the confirmation dialog box that then appears.

The examination is resumed. Depending on the test point grid, it may be necessary to remove the corrective lens out of the holder again when prompted to do so by the program.

After the re-examination has come to an end, a dialog box appears asking whether you want to save the examination results *(fig. 11-8, page 43)*.

11.6 Manual Kinetic Examination

To be able to determine e.g. the location and size of a scotoma with greater accuracy, you can conduct a "manual kinetic examination". During this examination a dot symbolizes the position of the stimulus. If the dot is black, then the stimulus is off. If the dot is white, the test mark is visible in the perimeter bowl. If the patient confirms seeing a dot, that dot is marked as a circle with a directional arrow. The arrow indicates the last direction of movement of the stimulus. The symbols change in size, brightness and color, based on the stimulus parameters.

➔ Press the button [Kinet. manual] (Manual Kinetic).

The following dialog box appears for selection of the examination parameters.

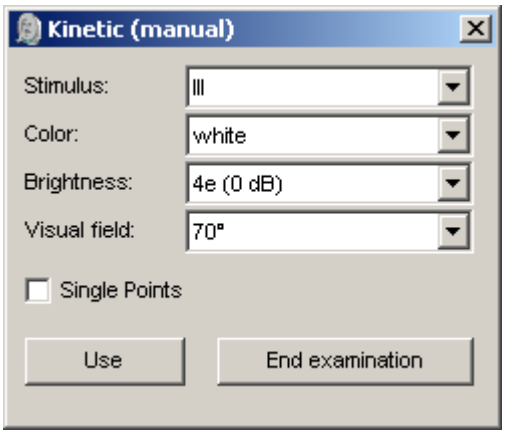


Fig. 11-12: Examination parameters "Kinetic (manual)"

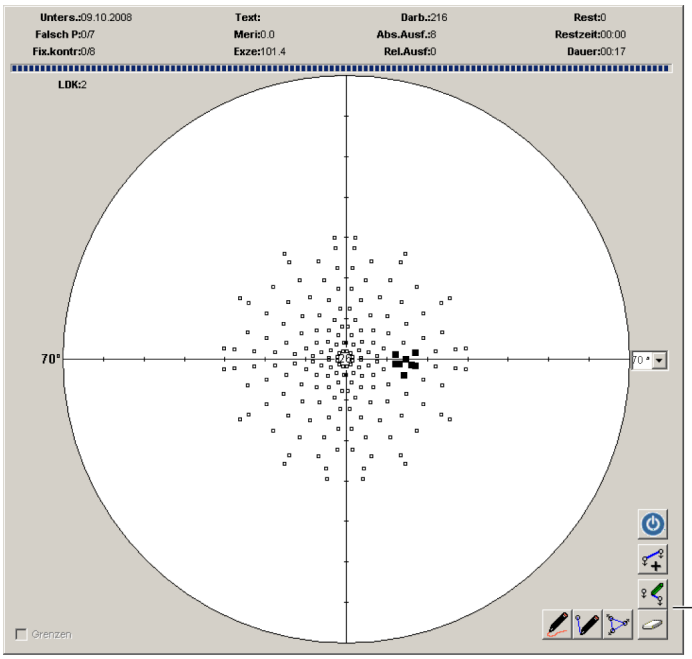
➔ Select the stimulus size, color and brightness, and the visual field area in the respective fields.

➔ Activate the checkbox [Single points] if you do not want the points of the isopter to be connected.

➔ Confirm your input by pressing the button [Use]. Alternatively, you can now end the examination completely by pressing the [End examination] button.

Seven additional buttons appear at the bottom right of the map of the examination results. You can define the area that

is to be examined and the examination mode with these buttons.



1 Additional buttons

Fig. 11-13: Additional buttons for a "manual kinetic examination"

11.6.1 Standard Examination Mode

In this mode, you can "draw" any curve with the mouse; the stimulus then follows the movement of the mouse (with a brief delay).

➔ Select the button  .

➔ Press and hold down the right mouse button and move the mouse to the starting point of the curve.

➔ Press the left mouse button to switch on the stimulus and then move the mouse along the desired curve.

11.6.2 Semi-Automatic Point Testing

In this mode, the stimulus moves in a straight line.

➔ Select the button  .

➔ Define the starting point by pressing the left mouse button and hold down the mouse button.

➔ Move the mouse in the desired direction.

➔ When you let go of the mouse button, the stimulus is switched on and moves from the starting point in the specified direction.

11.6.3 Semi-Automatic Scotoma Perimetry

The outer boundaries of a loss are automatically determined in this mode.

➔ Select the button  .

➔ Click as close to the center as possible in the area of the previously determined scotoma. The examination starts automatically and the outer boundaries of the loss are determined with eight points.

Note

Fixation tests are conducted in the center to monitor the fixation during the examination.

You can rework the examination results, or start another measurement, or end the manual kinetic examination with the additional buttons.

11.6.4 Deleting Individual Points

You can delete individual points from the map, e.g. if the patient accidentally pressed the hand-held pushbutton.

➔ Select the button  .

➔ Select the point in question in the map of the examination results. This is deleted from the map accordingly.

11.6.5 Redrawing the Isopters

The Twinfield® 2 software automatically generates the connecting lines between the isopters. In some cases, however, this cannot be done 100% correctly. You can then manually redraw the connecting lines. To do this:

➔ Select the button  .

➔ Now consecutively activate all of the points of an isopter. The points are connected to each other in the appropriate order.

11.6.6 Generating Another Isopter

You can generate additional isopters with other examination parameters.

➔ Select the button  .

The dialog box."Kinetic (manual)" appears again for selection of the examination parameters *(fig. 11-12, page 46)*.

➔ Define the parameters that are to be used for the next examination(s) and then, once again, select the desired examination mode.

11.6.7 Ending the Manual Kinetic Examination

➔ Press the button to end the manual kinetic examination. The following confirmation dialog box appears:

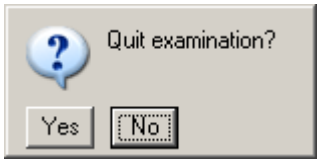


Fig. 11-14: Confirmation dialog box for ending the examination

➔ Press the [Yes] button if you are sure that you want to end the examination.

After the manual kinetic examination has come to an end, a confirmation dialog box appears, asking whether you want to save the examination *(fig. 11-8, page 43)*.

12 Cleaning, Disinfection and Maintenance

This chapter describes how to clean and disinfect the Twinfield® 2.

No sterilization is required.

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

12.1 Cleaning

Caution

Risk of electric shock if the Twinfield® 2 is not completely disconnected from the mains for these jobs.

➔ Turn the Twinfield® 2 off, *sect. 8.3, page 29*.

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

➔ Never use cleaning agents that are aggressive, contain chlorine or solvents, or are rough or abrasive.

12.1.1 Materials required:

- Cleaner for painted surfaces: mixture of equal parts mineral spirits and distilled water, with a few drops of household detergent if needed
- Anti-static cleaner for plastic surfaces
- Soap solution: water with a few drops of household detergent
- Soft, lint-free cloth

12.1.2 Cleaning intervals

➔ Clean the components of the Twinfield® 2 once a month or if necessary.

12.1.3 Prepare cleaning

Proceed as follows:

➔ Switch off the Twinfield® 2, *sect. 9, page 30*.

➔ Disconnect the power plug.

12.1.4 Cleaning the chin rest and the head rest

➔ Clean the chin rest and head rest after each examination.

Note

Cleaning spray with alcohol causes damage of the perimeter bowl.

➔ Do not use cleaning spray.

➔ Make sure that the cleaning agent does not get into the unit.

➔ Clean the chin rest and the forehead rest with a soap solution (or with alcohol, if very dirty).

Use a lint-free, damp cloth.

12.1.5 Cleaning the Painted Surfaces

If needed:

➔ Make sure that the cleaning agent does not get into the unit.

➔ Wipe down the outer surfaces of the unit with a damp cloth and with the cleaner for painted surfaces.

12.1.6 Cleaning the Inner Surface of the Perimter Bowl

The matt white surface of the projection bowl is extremely sensitive!

Recommendation:

➔ Cover the device with the supplied cover after every use.

If needed:

➔ Use the cleaner for plastic surfaces. Use a lint-free, damp cloth.

➔ Wipe the inner surfaces of the unit with a damp cloth carefully.

➔ Do not press too firmly. Frequent movement will cause glossy spots.

12.2 Disinfecting

Caution

Risk of electric shock if the Twinfield® 2 is not completely disconnected from the mains for these jobs.

➔ Turn the Twinfield® 2 off, *sect. 8.3, page 29*.

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

To disinfect all surfaces (except for Plexiglas in the perimeter bowl), we recommend the use of:

- Mikrozid sensitive wipes premium
  Fa. Schülke & Mayr
  Softpack 48 pieces
  Art. Nr. 165711
  Schülke & Mayr GmbH
  Phone +4940521000
  Fax: +494052100318
  E-Mail@schuelke.com
  www.schuelke.com

Note

Equipment damage caused by disinfectant solution

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

➔ Spray the disinfectant solution onto a cleaning cloth, do not spray it directly on the device.

➔ Disinfect after each examination
  - the chin rest
  - the head rest
  - the hand held button

➔ Disinfect the surface when needed.

12.3 Maintenance

➔ In order to ensure a safe function we recommend Service the Twinfield® 2 every two years by our service team or an authorized OCULUS distributor..

Caution

Risk of electric shock if the Twinfield® 2 is not completely disconnected from the mains for these jobs.

➔ Turn the Twinfield® 2 off, *sect. 8.3, page 29*.

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

Note

Damaged device may result in incorrect measurements

If an error occurs which you are unable to correct:

➔ Label the Twinfield® 2 as "out of order".

➔ Contact our service department or an authorized distributor.

➔ Never operate a damaged Twinfield® 2.

12.3.1 Changing the Background Illumination Bulb

Above the center of the forehead rest, there is a background illumination lamp under a cover.

➔ First close the program and turn off the unit in the proper manner.

Caution

The background illumination bulb may still be hot.

➔ Wait until the bulb has cooled down before you attempt to change it.

➔ Carefully remove the cover by pulling it downwards.

➔ Take hold of the background illumination bulb with a cloth and pull it out of the socket.

Note

The new bulb must be a halogen bulb of the type 59200 (12 V, 20 W.

➔ Insert the new bulb into the socket.

➔ Make sure that you do not touch the glass of the bulb with your fingers.

➔ If necessary, remove the front part of the unit by pulling it gently upwards and forwards.
➔ Finally, put the cover and the front part back into place.

13 Troubleshooting

Caution

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 authorised distributor.

Error	Possible cause	Remedy
No function when the power switch is pressed or the pilot lamp on the power switch is not lighting up.	The Twinfield® 2 Perimeter is not connected to the power supply.	Plug the power cable into the power outlet, or the inlet connector into the jack at the Twinfield® 2 Perimeter.
	Power failure or power outlet is not active.	Inform the in-house electrician.
	The USB- or the serial cable of the PC is not connected properly.	Check that the connector is plugged in properly.
No function when the power switch is pressed, but the pilot lamp on the power switch is lit.	The unit has been switched off and back on again too quickly.	Wait approx. 5 seconds before turning the unit back on again.
The printer is not printing.	Connecting cable from Printer to PC is not plugged in properly.	Plug in the cable.
	Ink cartridge empty.	Change the cartridge.
Hand-held button is not reacting when pressed.	The hand-held button is not properly plugged in and screwed tight in the jack at the unit.	Check the connection and plug in the cable again and screw it tight.
Camera image is too dark.	The camera brightness settings are incorrect.	Re-adjust the brightness (refer to the *User Guide)*.

Error	Possible cause	Remedy
Background illumination not active.	Unit is in standby mode.	Move the mouse, or press any key.
	The Twinfield® 2 program (examination program) has not been started.	Start the examination program *(sect. 11.2, page 41)*.
	Lamp is faulty.	Change the background illumination lamp *(sect. 12.3.1, page 53)*.
After you have started the Twinfield® 2 program, the following dialog box appears: "No communication with the Twinfield!"	No power to the mains adapter.	Check whether the indicator light on the power supply is on. If not, connect the power supply to the mains.
		Check whether the power supply cable is correctly attached to the Twinfield® 2 Perimeter.
	Connecting cable (USB cable) between the Twinfield® 2 and the PC is not plugged in properly.	Check whether the USB connector is properly inserted.
		Switch the Twinfield® 2 Perimeter off and restart the PC.
	Software/Hardware problems.	Switch the Twinfield® 2 Perimeter on as soon as Patient Data Management becomes active. When you start the Twinfield® 2 program, the message, "Load Bootloader" must appear.

14 Transport and Storage

The Twinfield® 2, must be properly dismantled and packed before being transported or stored.

14.1 Disassembly and Packing

- ➔ Select Patient > New Patient / End.
- ➔ Exit the Patient Data Management system.
- ➔ Power down the PC/laptop.
- ➔ Disconnect the power plug from the power jack.
- ➔ Disconnect the connections to the hand-held button, the netbook/PC/laptop or the control pad.
- ➔ Pack up the Twinfield® 2 in the original packing.

14.2 Storage conditions

Ambient temperature range	-10°C to +55°C
Relative humidity, including condensation	10% to 95%
Air pressure range	700 hPa to1060 hPa

14.3 Transport conditions

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

14.4 After Transport and storage

- ➔ Wait approx. 3-4 hours after transport before operating the Twinfield® 2 Perimeter. If the Twinfield® 2 Perimeter was stored in a cold room or vehicle during the cold time of the year, a significant change in temperature may cause condensation to appear on optical parts in the Twinfield® 2 Perimeter.

Note

Risk of equipment damage due to incorrect shipment or from improper storage

➔ Avoid shocks, vibrations, and contamination.

➔ Avoid high temperatures and humidity.

➔ Transport the Twinfield® 2 carefully.

➔ Store the Twinfield® 2 in compliance with the storage conditions.

➔ Avoid placing near heaters and moisture.

➔ Check the Twinfield® 2 for damage every time it has been transported.

15 Disposal of Used Devices

In accordance with Directive 2012/19/EC of the European Parliament and the Council of 4th of 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 the Twinfield® 2 in a compliant manner.

16 Terms of Warranty and Servicing

16.1 Terms of Warranty

The Twinfield® 2 was carefully manufactured using quality materials and modern production methods. Any software included in the delivery was tested by us and complies with technical standards. Please note the following warrantee provisions:

- Prior to and while operating the device it is important that you follow the user instructions, the instruction manual and safety instructions.
- The Twinfield® 2 carries a warranty to which you are entitled in accordance with the legal provisions.
- If any unauthorized persons interfere with the Twinfield® 2, all warranty entitlements shall be void. Any inappropriate modifications or repairs can cause grave danger to the user and patient.
- Any entitlement to a warranty shall also be void if unauthorized persons interfere with the PC hardware and software supplied.
- In the event of transport damage, we request that you notify the shipping company immediately and have the damage confirmed on the consignment note, to enable a proper claims settlement procedure.
- Overall, the general terms and conditions of business and delivery apply as per the date of purchase.

16.2 Assumption of Liability for Functions and Damage

OCULUS will only be liable for the safety, reliability and utility of the Twinfield® 2 if you have followed the instructions below:

➔ Use the unit in conformance with the Instruction Manual and the included User Guide.

- Except the described maintenance, see *sect. 12.3, page 53*, there are no user-serviceable parts either on or inside the Twinfield® 2. OCULUS shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorized personnel, if the Twinfield® 2 is maintained improperly or if it is handled incorrectly.
- If the work described above is carried out by persons authorized to do so, they must be requested to supply documentation detailing the nature and scope of repairs, and if applicable to specify modifications to the rated data or area of work. This certificate must bear a date, a signature, specify who carried out the work, and contain company information.

- On request, and for this purpose, OCULUS will supply authorized persons with spare parts lists and additional descriptions.

➔ Make certain that only original OCULUS replacement parts are used for any repairs or maintenance.

17 Technical Data

Classification of the ophthalmic table per IEC 60601 - 1 (VDE 0750)

Type of protection against electric shock	Protection class 1
Level of protection against damaging entry of solids and liquids	IP00

For more technical information on the ophthalmic table, refer to the corresponding instruction manual.

Measuring equipment

Weight	40 kg (88,1 lbs)
Dimensions (W x D x H)	790 x 723 x 850 mm (31.1 x 28.5 x 33.5 in)
Interface	USB
Perimeter bowl radius	300 mm)
Meridian	Adjustable from 0° - 360°
Eccentricity	90 ° (full field)
Power supply	15 V DC, 6 A
Lifecycle expectancy	Up to 10 years

Measuring parameters

Stimulus	
■ Stimulus size	Goldmann I, III, V
■ Stimulus colour	white, blue, red
■ Stimulus duration	200 ms/user defined(0.2 s/0.5 s/0.8 s/adaptiv)e
■ Stimulus luminance range Ls	0 – 318 cd/m² (0 – 1 .00 asb)/1 dB
■ Examination speed	adaptive / fast / normal / slow / user defined
■ Examination speed (automatic kinetic perimetry)	2°/s (Goldmann standard)
Background	
■ Background luminance	10 cd/m² (31,4 asb)
■ Background colour	white yellow (with additional filter)

Power adapter

Power adapter GSM90B15-P1M	05150285
AC input	80-264 V AC 47-63 Hz 65 W (without ophthalmic table)
DC output	15 V DC 6A 90 W max

Classification according to IEC 6060-1

Type of protection against electrical shock: Protection class	2
Level of protection against electrical shock	Type B
Level of protection against damaging water entry	IP20

Ambient operating requirements

Temperature	+10 °C to +35 °C
Humidity	30% to 75%
Air pressure	700 hPa to 1060 hPa

Transport conditions

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

Storage conditions

Ambient temperature range	-10°C to +55°C
Relative humidity, including condensation	10% to 95%
Air pressure range	700 hPa to1060 hPa

Computer

Use a computer which is in conformity with the IEC 62368-1 stan-

Recommended computer specifications	Intel® Core™ i5, 500 GB SSD, 8 GB RAM, Windows® 10, Intel® HD Graphics
Recommended screen size	24"
Recommended screen resolution	1920 x 1080 Pixel (Full HD)
Interface	USB

dard.

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

18 Appendices

18.1 Electromagnetic Compatibility (EMC)

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

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

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

Minimal performance quality and essential performance criteria

- A slightly disturbance of the analog camera of the Twinfield® 2 (slightly image noise on screen) during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short flicker of the illumination of the Twinfield® 2 during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short interruption of the USB connection during the examination is permissible because it will not affect the diagnosis, treatment and observation.

Caution

The use of accessories, transducers and cables not specified by OCULUS (for example as replacement parts) may result in increased emissions or decreased immunity of the Twinfield® 2.

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

The use of accessories, transducers and cables specified by OCULUS with devices other then the Twinfield® 2 may result in increased emissions or decreased immunity of the other device.

➔ Do not use the accessories, transducers and cables specified by OCULUS with devices other then the Twinfield® 2.

Attention

Recommended separation distances between portable and mobile RF communications equipment and the device.

The Twinfield® 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Twinfield® 2 as recommended below, according to the maximum output power of the communications equipment.

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) shall be kept no closer than 30 cm (12 in) to any part of the Twinfield® 2. Otherwise, the performance of this device may be impaired.

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

Order number	Description
56920	Twinfield® 2
05150285	Power adapter GSM90B15-P1M 15 V / 6 A
015692000010	USB FS Med isolator
10008835	USB cable with ferrite bead

18.2 Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions

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

Electromagentic immunity			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidances**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV ---------- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 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 IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Twinfield® 2 requires continued operation during power mains interruptions, it is recommended that the Twinfield® 2 be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagentic immunity			
Immunity test	**Test level**	**Compliance level**	**Electromagnetic environment - guidances**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{eff} 150 kHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz 3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	V_{eff} = 3 V	Portable and mobile RF communications equipment should be used no closer to any part of Twinfield® 2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1:	At 80 Hz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

Electromagentic immunity
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Twinfield® 2 is used exceeds the applicable RF compliance level above, the Twinfield® 2 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® 2. b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Twinfield® 2

The Twinfield® 2 in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Twinfield® 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Twinfield® 2 as recommended below, according to the maximum output power of the communications equipment.

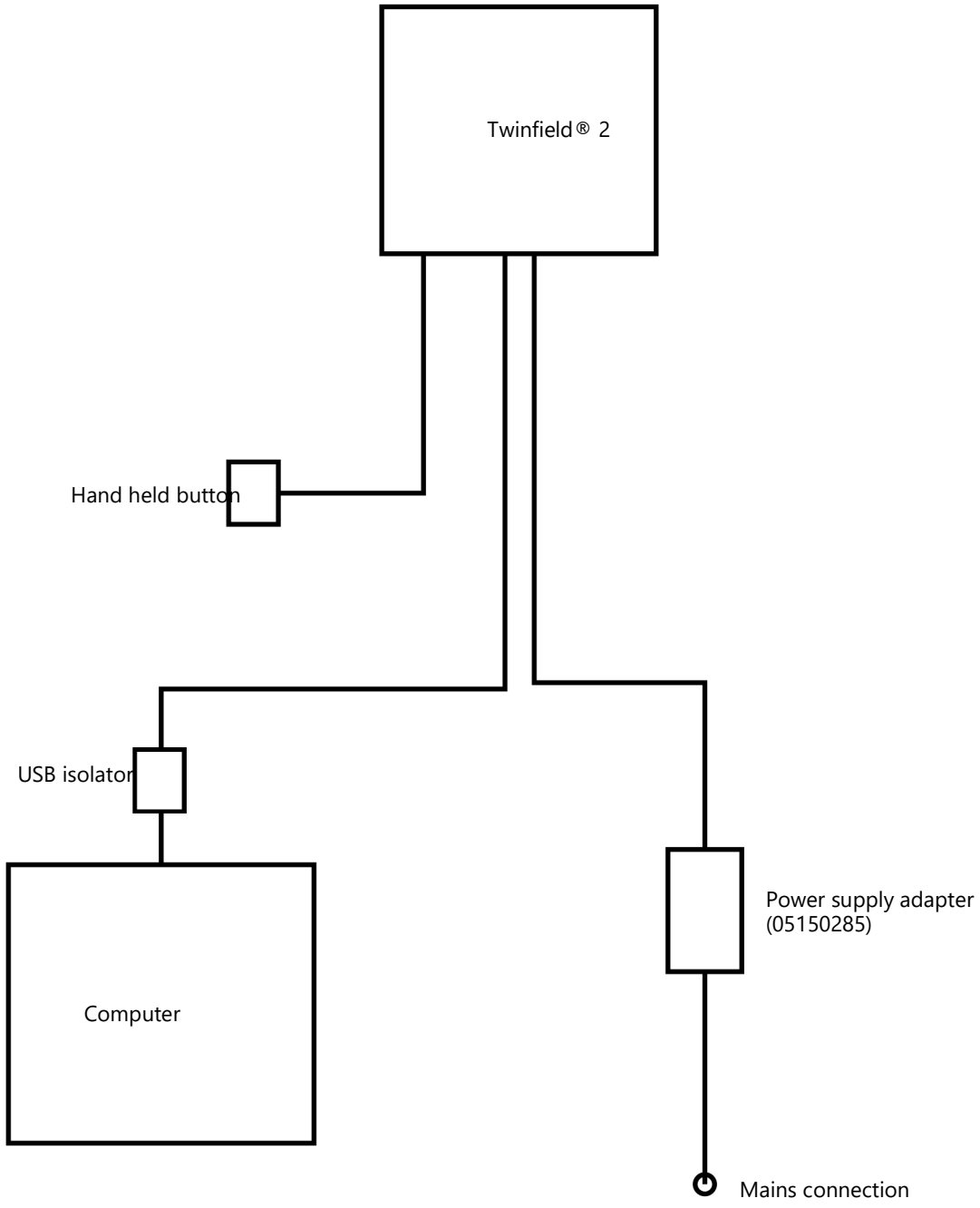
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

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

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

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

18.3 Description of the Connection



18.4 Data Sheet Power supply adapter GSM90B15-P1M (05150285)

MEAN WELL

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

■ Features

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

■ Applications

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

■ Description

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

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

■ Model Encoding

GSM90B 12 -P1M

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

File Name:GSM90B-SPEC 2016-03-16

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

SPECIFICATION

ORDER NO.		GSM90B12-P1M	GSM90B15-P1M	GSM90B19-P1M	GSM90B24-P1M	GSM90B48-P1M
OUTPUT	SAFETY MODEL NO.	GSM90B12	GSM90B15	GSM90B19	GSM90B24	GSM90B48
	DC VOLTAGE Note.2	12V	15V	19V	24V	48V
	RATED CURRENT	6.67A	6A	4.74A	3.75A	1.87A
	CURRENT RANGE	0 ~ 6.67A	0 ~ 6A	0 ~ 4.74A	0 ~ 3.75A	0 ~ 1.87A
	RATED POWER (max.)	80W	90W	90W	90W	90W
	RIPPLE & NOISE (max.) Note.3	120mVp-p	150mVp-p	180mVp-p	200mVp-p	240mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±4.0%	±3.0%	±2.5%
	LINE REGULATION Note.5	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
	LOAD REGULATION	±5.0%	±5.0%	±4.0%	±3.0%	±2.5%
	SETUP, RISE TIME Note.6	1000ms, 50ms / 230VAC 1500ms, 50ms / 115VAC at full load				
	HOLD UP TIME (Typ.)	20ms / 230VAC 20ms / 115VAC at full load				
INPUT	VOLTAGE RANGE Note.7	80 ~ 264VAC 113 ~ 370VDC				
	FREQUENCY RANGE	47 ~ 63Hz				
	POWER FACTOR (Typ.)	PF>0.91 / 230VAC PF>0.95 / 115VAC at full load				
	EFFICIENCY (Typ.)	88%	89%	89%	90%	91%
	AC CURRENT (Typ.)	1.3A / 115VAC 0.6A / 230VAC				
	INRUSH CURRENT (Typ.)	30A / 115VAC 65A / 230VAC				
	LEAKAGE CURRENT(max.)	Touch current < 100μA/264VAC				
PROTECTION	OVERLOAD	110 ~ 150% rated output power				
		Protection type : Hiccup mode, recovers automatically after fault condition is removed				
	OVER VOLTAGE	105 ~ 135% rated output voltage				
		Protection type : Shut down o/p voltage, re-power on to recover				
	OVER TEMPERATURE	Shut down o/p voltage, re-power on to recover				
ENVIRONMENT	WORKING TEMP.	-30 ~ +60℃ (Refer to "Derating Curve")				
	WORKING HUMIDITY	20% ~ 90% RH non-condensing				
	STORAGE TEMP., HUMIDITY	-40 ~ +85℃, 10 ~ 95% RH				
	TEMP. COEFFICIENT	±0.03% / ℃ (0 ~ 40℃)				
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes				
SAFETY & EMC (Note. 8)	SAFETY STANDARDS	ANSI/AAMI ES60601-1 / ES60601-1-11, TUV EN60601-1 / EN60601-1-11 approved				
	ISOLATION LEVEL	Primary-Secondary: 2xMOPP				
	WITHSTAND VOLTAGE	I/P-O/P: 4KVAC				
	ISOLATION RESISTANCE	I/P-O/P:100M Ohms / 500VDC / 25℃/ 70% RH				
	EMC EMISSION	Compliance to EN55011(CISPR11) class B, EN61000-3-2,3, FCC PART 15 class B,CAN ICES-3(B)/NMB-3(B)				
	EMC IMMUNITY	Compliance to EN61000-4-2,3,4,5,6,8,11, EN55024, EN60601-1-2, EN61204-3 medical level, criteria A				
OTHERS	MTBF	405.6K hrs min. MIL-HDBK-217F(25℃)				
	DIMENSION	145*60*32mm (L*W*H)				
	PACKING	0.45Kg; 30pcs/14.5Kg/1CUFT				
CONNECTOR	PLUG	See page 3 ; Other type available by customer requested				
	CABLE	See page 3 ; 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 0.1uf & 47uf 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 voltage. Please check the derating curve for more details.
8. 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)

File Name:GSM90B-SPEC 2016-03-16

18.5 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.

It is essential that you follow the section *"Cybersecurity Instructions" on page 18* of section "Safety Instructions" (page 12) in the device instruction manual.

Please note the following information for implementing an integration of 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:

- Prefer wired LAN connection
- IPv4 network
- Fast-Ethernet (100 Mbit/s minimum)

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

- Licensing: required opened 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 of data security:

- Refer to the section "Cybersecurity Instructions" (page 18) of "Safety Instructions" (page 12) in the device instruction manual.
- Refer to the "Floating License Key - License management for software options" instruction manual (if applicable)
- Refer to device specific DICOM interface description (if applicable)

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

- License handling from local license server to PEMS and vice versa
- Storage and data export to local network storage and loading from local network storage
- Printout to local printer

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

- Loss of data
- unsuitable data exchange
- Data corruption
- unsuitable temporal data allocation
- unexpected data reception
- unauthorized 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 organization should identify, analyze, 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 in IT-Network configuration
- connection of additional items to the IT-Network
- disconnecting items from the IT-Network
- upgrade and update of equipment connected to the IT-Network

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