OCULUS Easyfield® C/Easyfield® S

INSTRUCTIONS FOR USE

Examining the central field of vision

OCULUS®

Notes about these instructions for use

The Easyfield® 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!

The Easyfield® Perimeter user manual provides you with extensive information, particularly regarding the evaluation programs and the depictions of the examination results.

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 team is happy to help.

OCULUS Optikgeräte GmbH

Item number: GA/15000/XXXX/EN

Revision: 02

Released: 12/04/2023

Table of contents

1 Easyfield® Contents and delivery

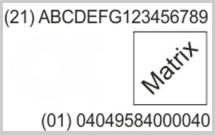
Product and accessories	Order number
Design: ■ OCULUS-Easyfield® C-Perimeter (with chin rest) ■ OCULUS-Easyfield® S-Perimeter	 15000 15005
Data carrier with software	15110/15120
Dust protection hood Easyfield® C Easyfield® S	1500011001 6010005001
Manual button	56517
Lens holder to insert corrective lenses with a slim edge	1500007000
Eye patch	44560
Easyfield® occluder, translucent	1500008001+002
Instructions for use User manual Software installation	GA/15000/XXXX/EN BH/15000/XXXX/EN SI/50000/XXXX/EN
USB cable	05200560
USB FS MED isolator	015692000010
GSM40A12-P1J power supply	10015234
Optional accessories	
Compact laptop stand	37499
Carrying case Easyfield® S	56936

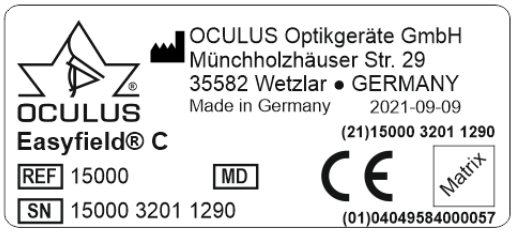
- If you discover transport damage upon delivery, report this to the transport company immediately.
- Confirm the damage on the delivery note in order to ensure that claims can be settled properly.

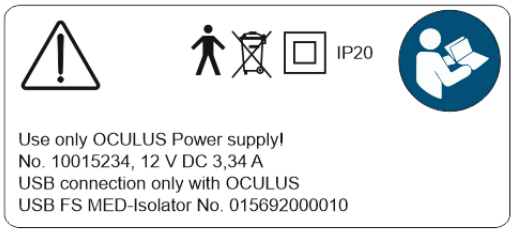
Note

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

2 Symbols on the device

Device symbols				Packaging symbols	
	Manufacturer		Protection class		Protect from moisture
	Date of manufacture	IP XX	Degree of protection		Transport upright
	Conformité européenne		Item number		Fragile
	Follow the instructions for use		Serial number		Permissible temperature range for transport
	Disposing with household waste is prohibited		Caution		Permissible temperature range for storage
	Application part B		Medical device		Humidity limit
	Sitting prohibited				Air pressure, limit
	Example: UDI number comprising the UDI-DI (device identification) UDI-PI (product identifier) machine-readable matrix code				Air pressure, limit





3 Layout of documentation

You receive a folder containing various documentation along with the Easyfield®-Perimeter:

- **Quick reference guide:** This document describes the measurement procedure in the form of a checklist. This document is intended to assist you with performing measurements so that you do not forget any important steps and that the measurement results can therefore be evaluated correctly.
- **Instructions for use:** This document describes the device layout in detail. Furthermore, the instructions for use provide fundamental instructions for working with patent data management, as well as all safety-relevant instructions for using the Easyfield®-Perimeter.

Caution

All safety-relevant instructions for using the Easyfield®-Perimeter are only described in the device's instructions for use. It is therefore obligatory to read and understand the instructions for use completely prior to using the Easyfield®-Perimeter.

- **User manual:** The user manual describes all of the options in the examination and evaluation software, as well as advanced instructions for patient data management.
- **Software installation:** The software installation instructions describe how to install the software for the Easyfield®-Perimeter and the corresponding drivers.

If you are working with a floating license key, the corresponding instructions describe how you can use it.

4 Safety instructions

This section provides a summary of the most important information for safety-related matters.

4.1 About this manual

- ➔ Read the instructions for use carefully.
- ➔ Keep the instructions for use, the quick reference guide and the user manual safely in the vicinity of the device.
- ➔ Pay attention to the statutory accident prevention regulations.

4.1.1 Pictograms used

Warning

Indicates a potentially dangerous situation that can cause irreversible bodily injury.

Caution

Indicates a potentially dangerous situation that can cause minor bodily injury or damage to property.

Note

Indicates situations that can cause incorrect examination results, usage instructions and useful or important information.

Indicates further information regarding the product or handling, to which special attention must be paid.

> This sign indicates menu paths and screen shots. Example for entering a new patient:
>
> ➔ Easyfield® > Examination > New patient
>
> Specifically:
>
> ➔ Open the Easyfield® program.
>
> ➔ In the menu bar, select the menu item “Examination”.
>
> ➔ Click “New patient”.

4.2 Safety instructions for use

Caution

Personal injury or damage to property due to incorrect operation

➔ Pay attention to the following safety instructions.

Personal injury or damage to property due to unsafe device modifications

➔ This device must not be modified without permission from the manufacturer.

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.

Information regarding operating staff

➔ Ensure that the Easyfield® is only used by people whose knowledge and practical experience ensure that safe handling is guaranteed.

Information regarding transport and storage

Pay attention to the information in *Chap. 15, page 47*.

Information regarding setup and connection

➔ Do not use the Easyfield® in damp rooms and do not leave the device there.

➔ Prevent dripping, splashing and spattering water in the vicinity of the Easyfield® and ensure that no moisture can penetrate the Easyfield®. Therefore, do not place any containers filled with liquid in the vicinity of or on the Easyfield®.

- Only operate the Easyfield® in spaces used for medical purposes if they are installed in accordance with VDE regulations 0100-710.
- Do not operate the devices supplied as standard in explosive areas, in the presence of inflammable anaesthetics or volatile solvents such as alcohol, benzine or similar.
- Only use a mains cable that meets the requirements of IEC 60227-1, type 53, min. 0.75 mm^2 and IEC 60320-1.
- Set the Easyfield® up so that the mains plug is easily accessible. You can therefore disconnect it from the mains easier for maintenance work.
- Do not force the electrical plug connections. If connection is not possible, check whether the plug fits the socket. If you discover damage to the plug connection, have it repaired by our customer service department.
- Only establish a USB connection to the OCULUS USB FS MED isolator (No. 01 56920 00 010).
- Only connect this device to a supply mains with a protective earth conductor.

Information regarding the patient environment

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

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.

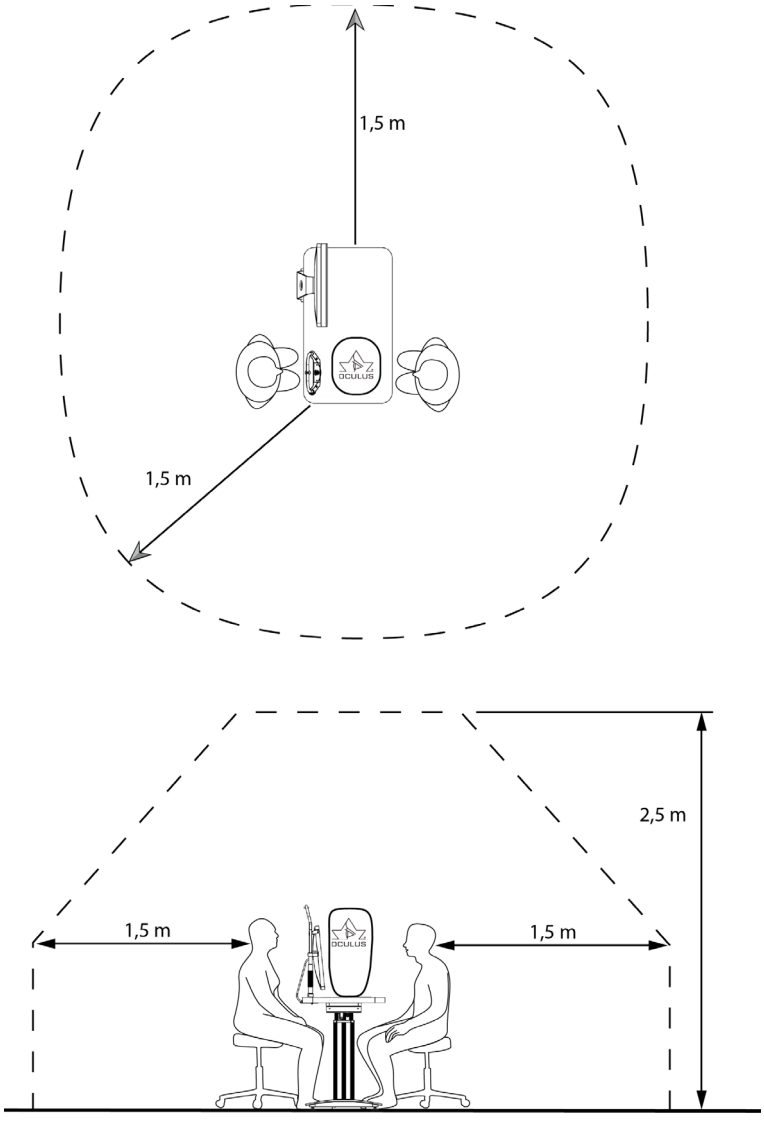


Fig. 4-1: Patient environment

Information regarding operating an ME system

The Easyfield® 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.

Information regarding operation

➔ Before first use: Let OCULUS or an authorised dealer train you in the operation of the Easyfield®.
➔ Never start a damaged Easyfield® up.
➔ Only operate the Easyfield® with the original accessories supplied by us and only when the unit is in technically perfect condition. Only use the power supply that is supplied as standard.
➔ Do not touch the patient and the device at the same time.
➔ Easyfield® S: Ensure that the device cannot fall over, e.g. by leaning or sitting on it.
➔ Only operate the device if you have understood the instructions for use.

On the computer that controls the Easyfield®-Perimeter, no other software may run in the foreground in parallel with the examination program (screensaver, user programs, etc.).

Information regarding cleaning and disinfection

There is a risk of electric shock if the Easyfield® is not disconnected from the mains power supply at all poles for cleaning or disinfection

➔ Switch the Easyfield® off, *Chap. 8.2, page 20*.
➔ Remove the mains plug prior to cleaning. Hold the plug to do this. Do not pull the cable.

Information regarding maintenance

➔ When cleaning with a damp cloth, ensure that no liquid can penetrate the Easyfield®.
➔ In order to guarantee faultless and safe functions, we recommend: Let our customer service department or an authorised dealer inspect the Easyfield® every two years. If a fault occurs, which you cannot rectify, mark the Easyfield® as out of order and inform our customer service department.

Information regarding dismantling and disposal

➔ Do not pull the cable when disconnecting electrical connections. Pull the relevant plugs.
➔ Dispose of the device according to the legal regulations.

Information regarding electrical safety

Caution

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

Connecting the Easyfield® 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, *Chap. 18, page 51*.

Caution

Using a multi-socket

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

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

- ➔ Use a multi-socket that complies with the requirements of IEC 60601-1, section 16.
- ➔ Do not place the multi-socket on the floor.
- ➔ Do not use more that one multi-socket.
- ➔ Only plug the Easyfield® and the computer that is being used, if applicable, into the multi-socket.

If you are using a multi-socket, it must be supplied via an isolation transformer.
If you are using a new computer for the Easyfield®, you must have the electrical safety checked. Phone OCULUS customer service for this.

Electromagnetic compatibility (EMC/cables)

Personal injury or damage to property due to electromagnetic interference

Portable and mobile HF communications equipment can affect medical electrical equipment, *Chap. 19, page 54*.

➔ Ensure that portable and mobile HF communications equipment does not cause interference.

➔ Recommendation: Maintain a minimum distance of 4 m. If the distance is less, you must ensure that the Easyfield® functions correctly.

4.3 Cyber security

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.

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

Data responsibility:

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

Do not connect to the internet while using the device. This is considered misuse.

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

Device security

It is the authorised user's responsibility to ensure that the Easyfield® device is not left unlocked, or otherwise unsecured when not in use, to ensure that unauthorised medical, professional, or other unauthorised personnel are not exposed to or gain access to ePHI.

User responsibility

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).

Operators have access to patients' ePHI and must not take snapshots, screenshots or pictures (e.g. using another device) of any information displayed using the device.

Operators should not enter identifying data into the device. All data on the device should be anonymised and relate to the sample ID and not to the patient.

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.

Recovering from compromised accounts or devices

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

Unavailable service

Users should report unavailable services or prohibited access to information to their local healthcare organisation's IT department.

Precautions

➔ To increase cyber security when using the device, take the following security measures, contact your administrator if necessary:

Precautions for access control of the computer

➔ Secure the computer with a password (for example when Windows starts up).

➔ Choose a complex password. A good password consists of eight characters and is 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, "Easyfield").

➔ Change the password regularly.

➔ Do not note the password in an accessible location.

➔ Use different passwords for different users.

➔ Enable the screensaver and use the option to make it obligatory to re-enter the password when exiting the screensaver.

➔ Choose an adequate time setting for starting the screensaver if the software session is inactive (e.g. 10 minutes).

An adequate time setting should consider the examination duration, number of patients, time between examinations, use of other devices in the examination room, several users, etc.

➔ Lock the computer if you are leaving the workstation (shortcut: Windows logo key + 'L')

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

- ➔ If you connect the computer to LAN or the internet, you are responsible for ensuring data security.
- ➔ Favour wired connections when connecting the computer to the network.
- ➔ If you are using Wi-Fi connections despite this, ensure that adequate security methods are used (for example, WPA2/ AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- ➔ Using a firewall (software or hardware) is recommended.
- ➔ Observe the instructions for integration into an IT network *(Chap. 19.5, page 62)*.

Note

Also note the regulations, instructions and recommendations of the Federal Office for Information Security with regard to protecting critical infrastructures.

Never use the Easyfield® with wireless technologies such as wireless USB.

5 Proper use

The Easyfield® is designed for the use described in these instructions for use. It is used to examine the field of vision of the human eye.

The Easyfield® provides pre-programmed combinations for frequently used examination routines. For example: Screening 24-2, SPARK Quick, macula. Your own routines can also be combined and saved as a program.

➔ Pay attention to the aforementioned safety instructions.

Intended medical indication

The Easyfield® is a diagnostic device to support detection and treatment of eye diseases including but not limited to glaucoma, macula diseases and neurological diseases that affect the field of vision.

Adverse side effects

None known

Contraindications

None known

Intended users

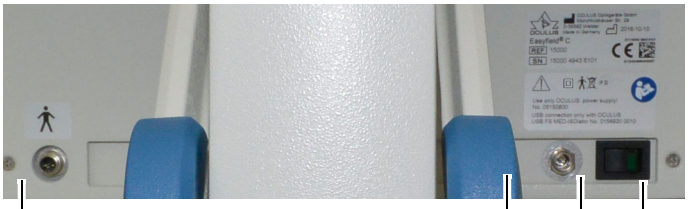
➔ Ensure that the Easyfield® is used exclusively in clinics and by eye specialists or opticians,

- 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

Patient group

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

6 Device description



1	*Forehead rest*	*6*	*Stand bar**
2	*Easyfield® occluder*	*7*	*On/off switch*
3	*Viewer with receptacle for corrective lens holder*	*8*	*Socket for external power supply*
4	*Chin rest**	*9*	*USB connection for netbook/PC/laptop*
5	*Adjuster for the forehead rest**	*10*	*Connection for manual button*

Fig. 6-1: Device overview Easyfield® C

** only Easyfield® C*

6.1 Easyfield® functions

The OCULUS Easyfield® has been designed for combined use as a screening device with full perimetric options for immediate re-examinations for suspicious results. You can use standard examination patterns and strategies for the central field of vision up to 30°.

The Easyfield® provides pre-programmed combinations for frequently used examination routines. For example: Screening 24-2, SPARK Quick, macula. You can also combine your own routines and save them as a program.

The integrated perimeter ball on the Easyfield® with a 30 cm radius and a distance correction lens meets the Goldmann standard. The device complies with ISO standard 12866 for perimeters.

The Easyfield® has a test point grid with 135 test points including 30-2 and 24-2, and additional test points in the 10° range (10-2 test point grid).

The Easyfield® can be used with a netbook, a laptop or a PC.

Viewer: The closed viewer means that the room does not have to be darkened.

Chin rest: The adjustable chin rest enables a comfortable examination posture for the patient.

Corrective lens holder: The corrective lens holder is attached easily and securely to the two receptacles.

Software principle

The Easyfield® works with two combined programs to process the values obtained and one analysis program:

- Patient data management:
  You can use this program to manage patient data.
- Easyfield® program:
  This program provides you with the examination results and most analysis results.
- TNT program:
  This program compares existing examinations and supports progression analysis.

Note

Data misuse

OCULUS Optikgeräte GmbH is not liable in any way for further use of the data recorded by the Easyfield® and calculated analyses.

Application parts

1 Chin rest (only Easyfield® C)
2 Manual button
3 Forehead rest
Fig. 6-2: Application parts

7 Prior to first use

Prior to using the Easyfield® for the first time, you must

- Install the software, *Chap. 7.1, page 17*
- Set the Easyfield® up, *Chap. 7.1, page 17*
- Connect the Easyfield®, *Chap. 7.3, page 17*
- Establish operational readiness, *Chap. è, page 20*
- Set up the firmware and drivers, *Chap. 7.4, page 20*

Caution

Incorrect measurements/device damage due to improper setup

➔ Prior to first use, note that installation and connection of the Easyfield® must have been completed by our customer service department or by a professional authorised by OCULUS.

7.1 Software installation

If you are working with a PC or a laptop, you must install the Easyfield® software. The Easyfield® software comprises the following programs that are installed together:

- Patient data management
- Easyfield® program
- TNT program

➔ Proceed as described in *Software installation*.

➔ Switch the PC or the laptop off again after installation.

7.2 Setup

The operating conditions are provided in *"Operating conditions" on page 52*.

➔ Remove the Easyfield® from the packaging.

➔ Place the Easyfield® on a flat surface.

➔ Dispose of the packaging material in an environmentally friendly manner.

7.3 Connection

You must connect the Easyfield® to the mains power and to the netbook, the laptop or the PC depending on the version.
A netbook is used as an example for connection and setup.

Warning

Personal injury due to electric shock caused by using an incorrect mains cable

➔ Only use a mains cable that meets the requirements of IEC 60227-1, type 53, min. 0.75 mm² and IEC 60320-1.

Caution

Risk to electrical safety

➔ Do not use the Easyfield® in the immediate vicinity of or stacked on other devices.

➔ If you use the Easyfield® in the vicinity of or stacked on other devices, you must ensure that the Easyfield® functions faultlessly.

➔ Only use the power supply that is supplied as standard, *Chap. 18, page 51*.

➔ If you are using a multi-socket to connect the Easyfield®: 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 Easyfield® and the computer that is being used, if applicable, into the multi-socket.

Note

Device damage due to improper connection

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

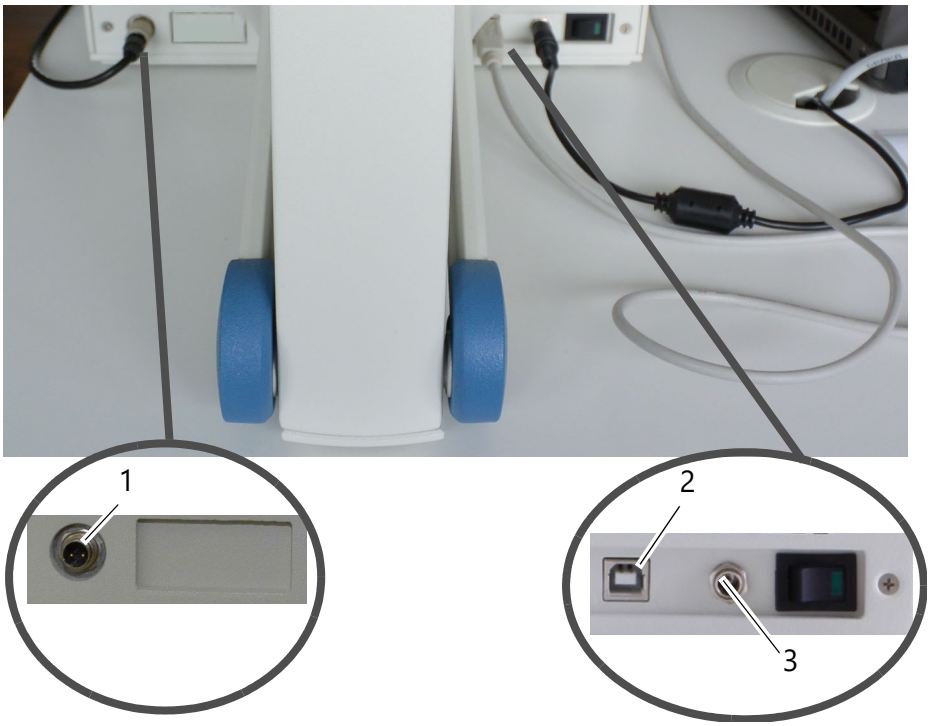
➔ Do not force the electrical plug connections.

➔ Pay attention to the specifications on the type plate.

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

➔ Connect the manual button (1).

➔ Connect the netbook (2).
To do this, connect the USB cable to the USB FS MED isolator. Connect this to the computer.



1 Connection for manual button
2 USB connection for netbook/PC/laptop
3 Connection for external power supply
Fig. 7-1: Connecting to the netbook

➔ Use the mains cable supplied (3) to connect the device to the mains.
➔ Ensure that the mains voltage corresponds to the mains voltage specified on the type plate.

If you are working with a netbook, you can skip the following steps. Proceed as described in *Chap. 8, page 20*.

7.4 Setup work when starting up for the first time

When you are connecting the Easyfield® to a PC for the first time, you must perform some setup work:

Deactivate power saving mode for the USB devices from the operating system in order to prevent communication problems.

➔ Proceed as described in *Software installation*.

8 Daily start-up

8.1 Switching the Easyfield® on

➔ Switch the notebook, the PC or the laptop on.

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

➔ Switch the Easyfield® on/off switch to on.

8.2 Switching the Easyfield® off

➔ Close the Easyfield® program and patient data management.

➔ Shut down the Windows operating system.

➔ Switch the Easyfield® on/off switch to off.

➔ Cover the device with the dust protection cover provided after the examination.

9 Patient data management

You can enter and use patient data via patient data management.

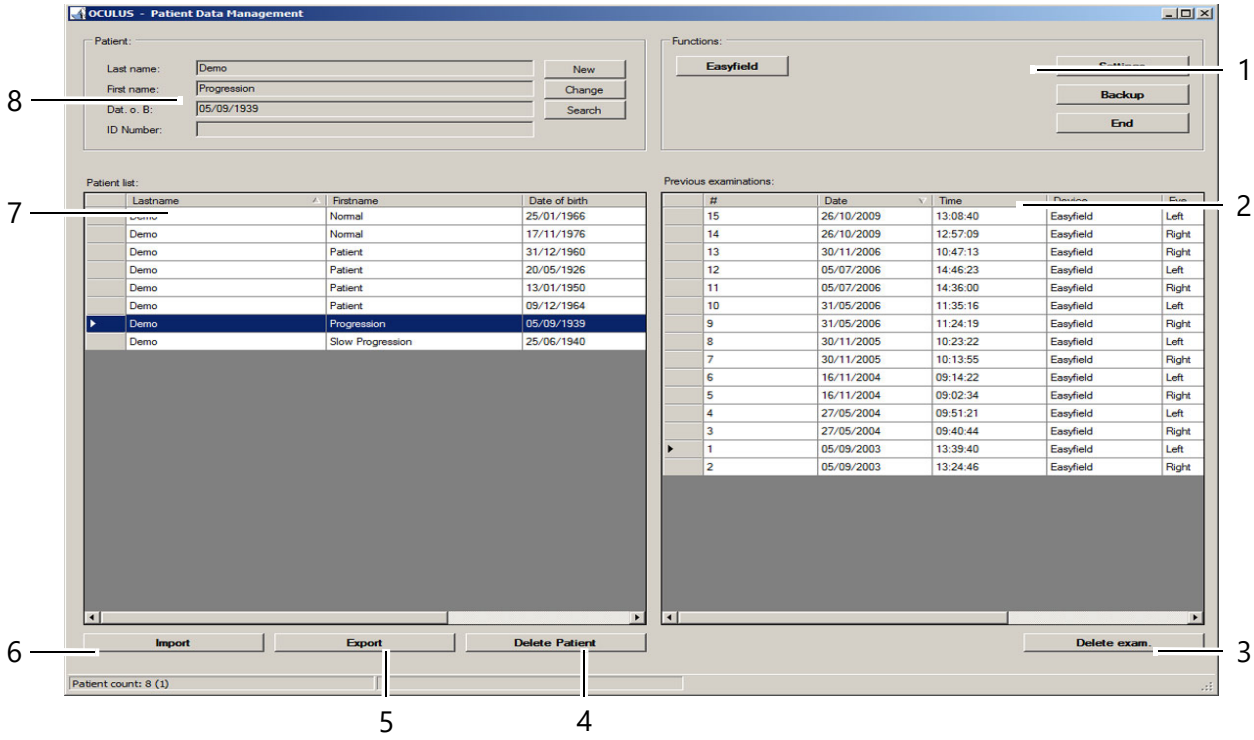
Further functions of patient data management are provided in *Chap. 12, page 38* and in the *User manual*.

9.1 Starting patient data management

The PC first loads the operating system.

➔ Press the Easyfield® icon if necessary: .

The patient data management user interface is displayed



1 "Functions" group box
2 Examination list
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

In order to be able to start the Easyfield® program later, you must first enter a new patient (8) or select an existing patient from the patient list (7).

Alternatively, you can also start the Easyfield® program without entering patient information. You must activate this option in advance in the patient data management settings. For more information about this, see the *User manual*. After you start the Easyfield® program, a window is displayed in which you can enter the patient's age.

If the [Easyfield (16 bit)] button is displayed in the "Functions" group box, you can access examinations that were performed with the previous software for the Easyfield®. For more information about setting this option, see the *User manual*.

9.1.1 Entering a new patient

➔ Press the [New] button to enter a new patient into patient data management.

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

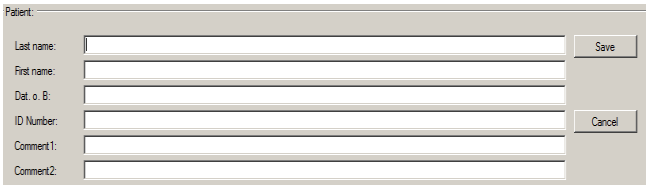


Fig. 9-2: Entering a patient

You can also enter an optional ID number for the patient.

➔ Press [Save] to save your entries. The new patient is displayed in the patient list.

➔ Select the new patient that you created and start the Easyfield® program.

9.1.2 Selecting an existing patient

The patient data list on the left-hand side of the screen lists all previously examined patients.

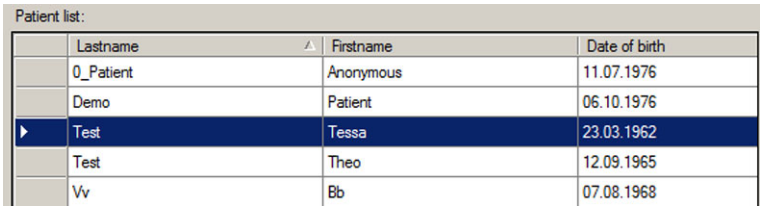


Fig. 9-3: Patient list

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

➔ Enter the patient's name or the first letter of the name in the "Last name" field.
Alternatively, you can search for the patient using an ID number if this was assigned when the patient was first created.

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

Extended patient search: [Extended] checkbox

➔ Select the [Extended] checkbox.

The screen displays additional search parameters which reference previous examinations, for example. Proceed as described for entering a patient name.

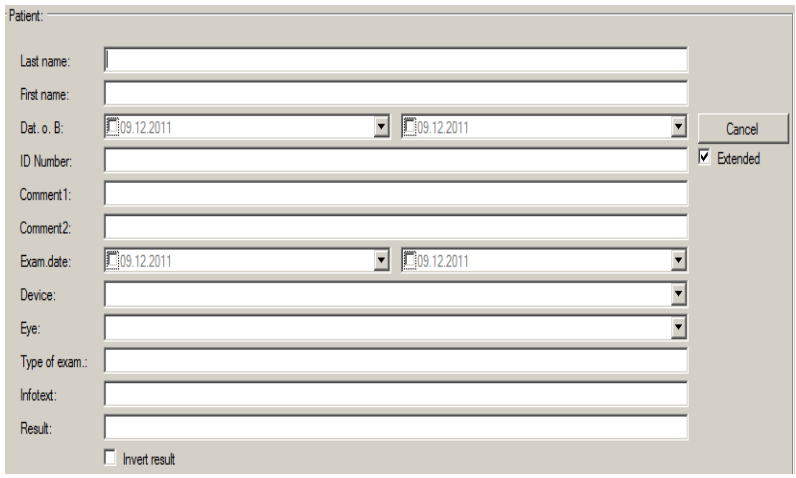


Fig. 9-4: Extended search

9.2 Starting the Easyfield® program

➔ After selecting a patient: Press the [Easyfield] button to start the Easyfield® program.

Fig. 9-5: Starting the Easyfield® program

or

➔ Double-click the selected patient name or an examination of a selected patient to start the Easyfield® program.

10 The Easyfield® program

You can access the menu bar from every screen in the Easyfield® program.

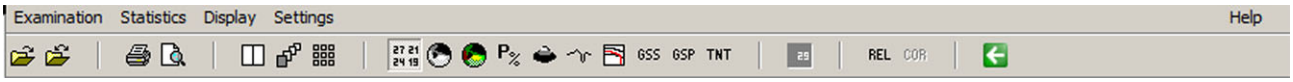


Fig. 10-1: Easyfield® program menu bar

The meanings and functions of the individual icons are provided in the *User manual*.

Loading existing examinations

➔ Select the [Examination] menu item and click [Load].
The “Load examination” dialogue box opens.
➔ Click the required examination to select it.
➔ Press [OK] or double-click to confirm.
The required examination is loaded into the Easyfield® program.

11 Measurement process

Caution

Incorrect measurements due to improper operation

➔ Before first use: Let OCULUS or an authorised dealer train you in the operation of the Easyfield®.

11.1 Examination preparations

11.1.1 Selecting the examination program

➔ Select the required examination program on the "Programs" tab.

For a description of how to create your own examination programs, see the *User manual* for the Easyfield®-Perimeter.

11.1.2 Determining the correction

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 contact lenses (not coloured) during the examination. People who wear glasses can also use their own glasses in some cases.

In order to determine the required correction aid, the precise refraction of the eye to be examined must be known. This can either be determined by measuring the refraction or can be based on the current eye values for glasses (distance Rx).

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

➔ Click the “Correction” field. The following screen opens:

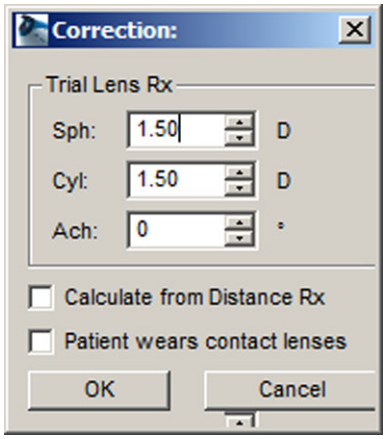


Fig. 11-1: Entering known refraction values

➔ If you know the patient’s refraction values: Enter the refraction values into the “Correction” group box.

➔ Press [OK] to confirm.

➔ If you do not know the patient’s refraction values: Select the [Calculate from Distance Rx] checkbox.

➔ Enter the refraction values that were determined previously for the patient in the “Current Distance Rx” group box fields. The following screen opens:

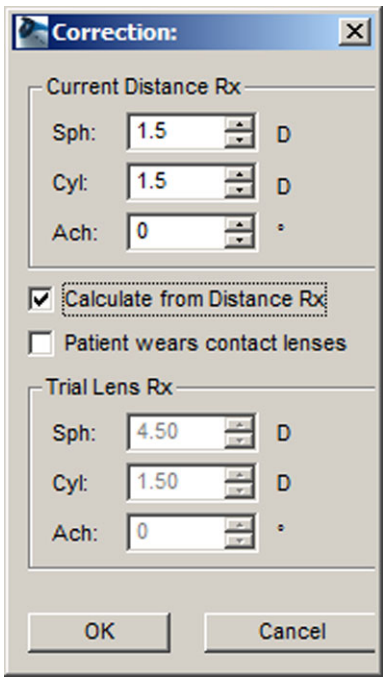


Fig. 11-2: Entering the correction if the checkbox is selected [Calculate from Distance Rx]

➔ Enter the refraction values that were determined previously for the patient in the “Current Distance Rx” group box fields. The values for the corrective aid to be used are output in the “Correction” group box fields.

➔ Press [OK] to confirm.

11.1.3 Inserting the corrective lens

➔ Insert the required narrow-edged lens with the correction value determined previously into the corrective lens holder that is supplied as standard.

➔ Insert the lens holder that is supplied as standard with the device into the viewer on the Easyfield®-Perimeter.

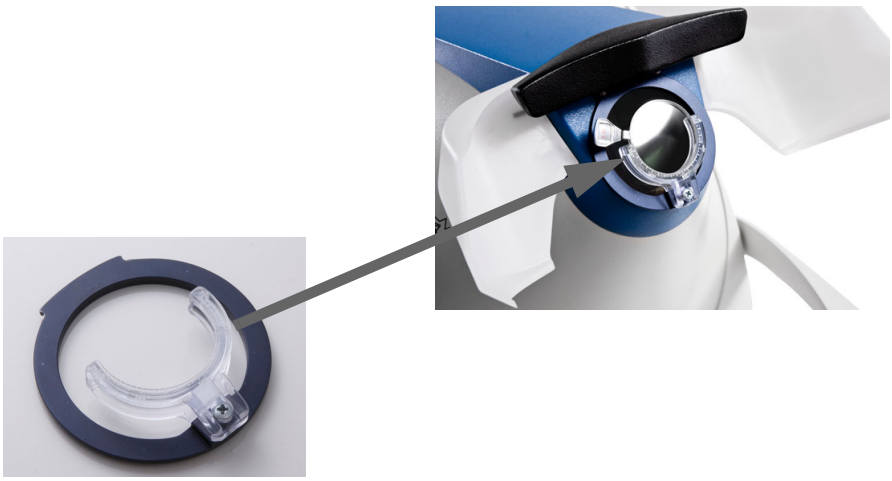


Fig. 11-3: Inserting the corrective lens holder with corrective lens

11.1.4 Preparing the patient

- ➔ Ensure that the chin and forehead rests, as well as the manual button have been disinfected before each examination.
- ➔ Ensure that the examination takes place in a quiet atmosphere and that the patient is not distracted.
- ➔ Explain the examination procedure to the patient.
- ➔ Give the patient the device's manual button in one hand.
- ➔ Ask the patient to get into a comfortable position in front of the device. They should sit upright if possible.

The Easyfield® occluders enable an examination without an eye patch.

Warning

Personal injury during servicing and maintenance work

Personal injury may occur if the device is used during service and maintenance work such as cleaning, disinfection and servicing.

- ➔ Do not use the device while performing service and maintenance work.

11.1.5 Positioning the patient

➔ Do not touch the patient and the device at the same time.

1 Chin rest (only Easyfield® C)
2 Forehead rest
3 Moveable measuring head
4 Adjustment knobs on the chin rest

Fig. 11-4: Positioning aids

➔ Only Easyfield® C:
Ask the patient to place their chin on the chin rest (1).
Adjust the moveable measuring head (3) and press the adjustment knobs on the chin rest (4) to position it.

➔ Only Easyfield® S:
Ask the patient to place their chin on the chin rest (1).
Adjust the moveable measuring head (3) into the best position for the patient.

➔ Ensure that the distance between the eye and the corrective lens or the eye and the perimeter is not more than 1 cm.

Fig. 11-5: Distance between eye and corrective lens

➔ Ask the patient to lean their forehead on the forehead rest (2) so that they can see the fixation marks (four red dots) in the centre of the perimeter hemisphere clearly with the eye that is to be examined. The patient is sitting properly if the patient's pupil is within the video section's red rectangle in the position window on the screen.

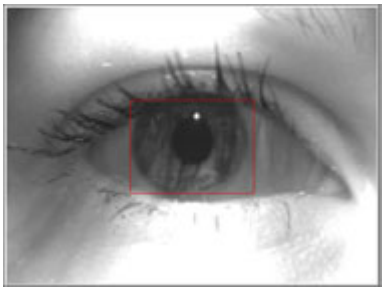


Fig. 11-6: Correct position: Patient eye in the video section

➔ Ensure that the patient's eye remains in the correct position throughout the examination. This is the only way to obtain correct measurement results.

➔ Advise the patient to look into the middle of the fixation marks.

Note

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), the patient cannot be guaranteed a full view.

11.1.6 Positioning the pupil

➔ Ask the patient to focus on the middle of the four red dots.
The pupil is positioned correctly when it is displayed in the red rectangle.

➔ Adjust the camera image's view settings in the Easyfield® program settings so that the eye movements can be displayed in such a way that they can be followed conveniently (mirrored or not mirrored).

11.1.7 Measuring the pupil

Measure the pupil diameter to complete the examination preparations. To do this:

➔ Move the mouse pointer to the left edge of the pupil in the indicated image.
➔ Press and hold 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 release the mouse button.
The right edge of the pupil is marked with a green line and the calculated pupil diameter is displayed in the "Pupil" field.

11.2 Starting the examination

➔ Advise the patient of the fact that the examination is now starting and to always press the manual button when they see a light dot flashing.
➔ Explain to them that they can pause the examination by pressing and holding the manual button. The examination continues once they release the manual button again.
➔ Click the [Start Exam.] button.

Fig. 11-7: [Start Exam.] button

The following dialogue box to check the data that you entered is displayed:

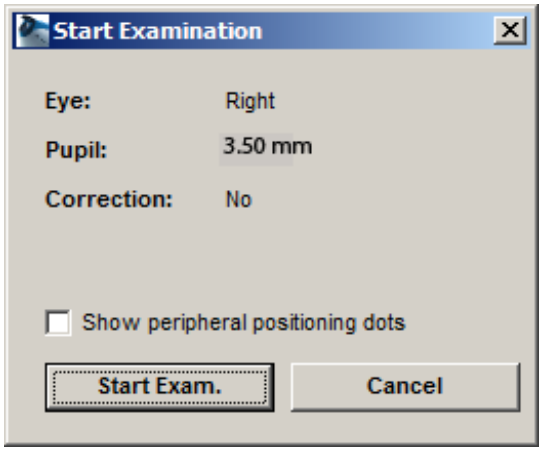


Fig. 11-8: Depiction of general data

Recommendation:

➔ Select the [Display peripheral positioning lights] checkbox.

The patient can use this function to check whether their examination position is correct. The LEDs form an illuminated ring. If they see an even ring, they are sitting properly.

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

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

➔ Press the [Start Exam.] button.

The central threshold value is determined and displayed in the following dialogue box.

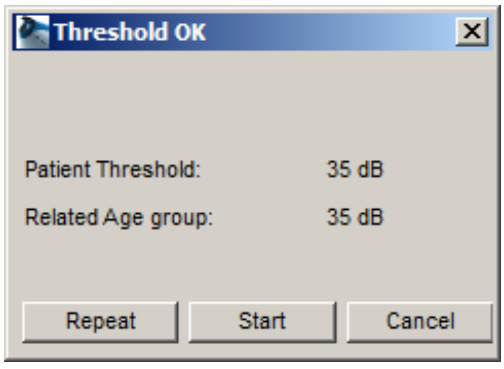


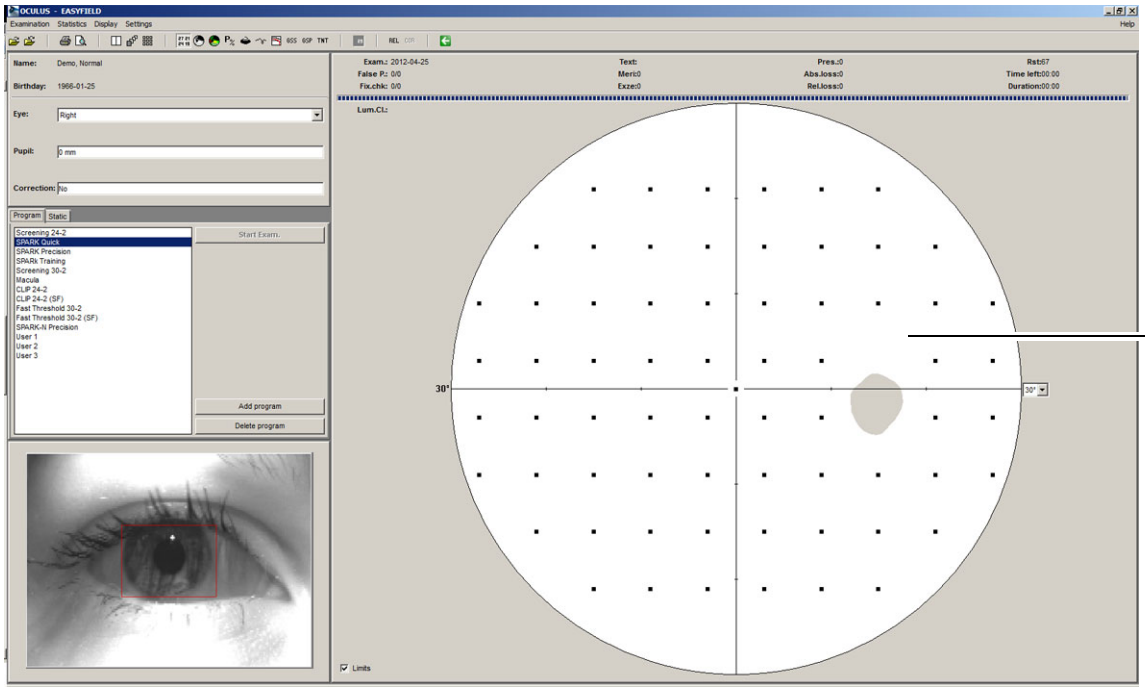
Fig. 11-9: Outputting the measured threshold value

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

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

11.3 Pausing the examination

If you wish to pause the examination: The cursor must be in the main frame in the Easyfield® program.



1 Main frame in the Easyfield® program
Fig. 11-10: Easyfield® program screen

➔ Right-click.
The following prompt is displayed:

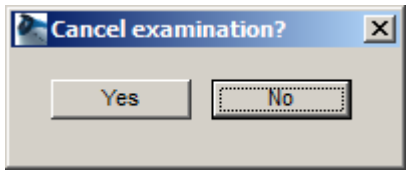


Fig. 11-11: Pausing the examination

➔ If the examination is to be continued, click the [No] button.
➔ If the examination is to be cancelled completely, click the [Yes] button.

11.4 Finishing the examination

Saving the examination data in the patient data

The following window is displayed once the examination is complete:

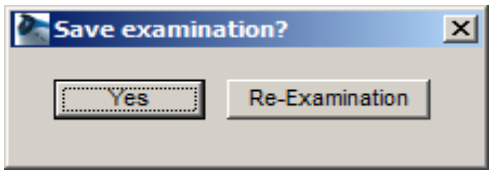


Fig. 11-12: Saving the examination

➔ Decide how you wish to proceed based on the examination result.

Printing the examination data directly

If you have performed an examination without entering patient data, the following window is displayed instead:

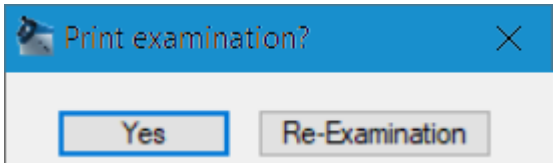


Fig. 11-13: Printing the examination (without patient data)

➔ Also decide how you wish to proceed in this case based on the examination result (print the examination result directly or perform a re-examination).

After you press [Yes] and print the examination, the following window is displayed:

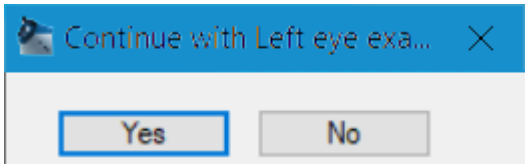


Fig. 11-14: Subsequent examination for the other eye

➔ Press [Yes] if you wish to examine the same patient's other eye directly.

Regardless of the examination

➔ Inform the patient that the examination is paused and that they can relax.

➔ Disinfect the chin and forehead rests after every examination, *Chap. 13.2, page 44*.

➔ Clean and disinfect the manual button after every examination, *Chap. 13.2, page 44*.

11.4.1 Saving the examination data

If all examined test points were normal or you have performed the required re-examination, save the examination data. To do this:

➔ Press the [Yes] button.

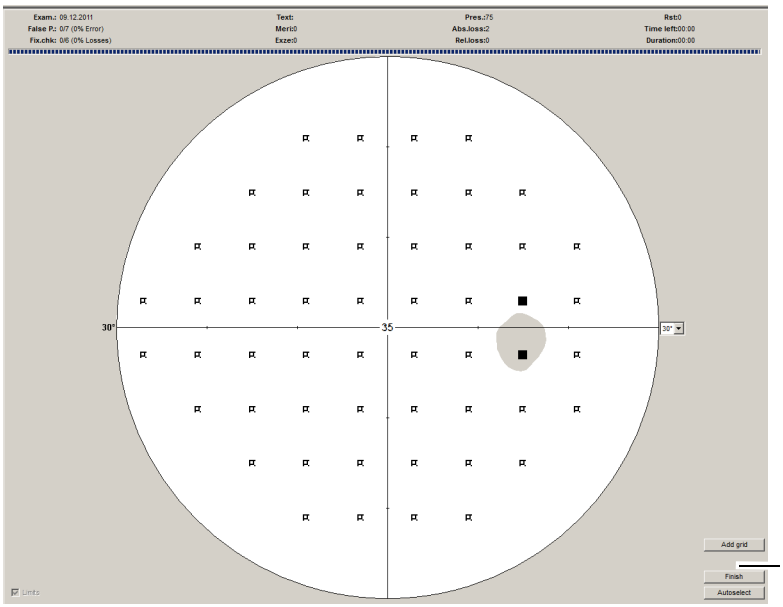
The examination data is saved and can be viewed later using the Easyfield® program.

The examination data can only be saved if measurement was started after entering patient data.

11.5 Performing a re-examination

If you wish to check suspicious test points, you can perform a re-examination. Proceed as follows:

➔ Press the [Re-Examination] button.
Three additional buttons are shown at the bottom right of the displayed examination results.



1 Additional buttons
Fig. 11-15: Additional buttons for a re-examination

You have various options for determining the points for the re-examination.

➔ Press the [Autoselect] button. The suspicious points are therefore selected automatically.
➔ Select the points manually in the test point grid using the mouse.
➔ Press the [Add] button to add further points manually, which are not present in the test point grid.
➔ Then click in the test point grid and define the additional test points in this way.

➔ Press the [Add grid] button to enter a predefined grid of test points.
In this case, an additional dialogue box is displayed, in which you can select the test point grid:

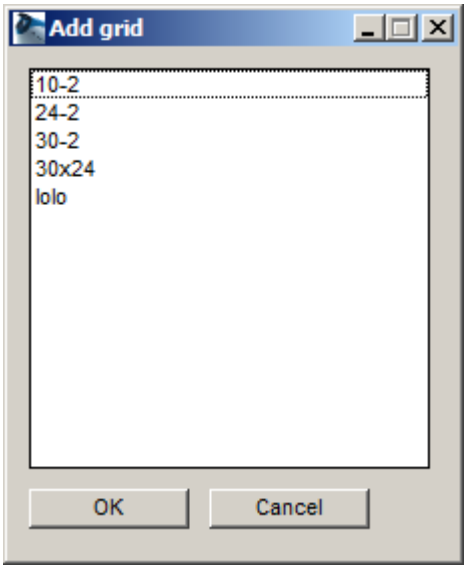


Fig. 11-16: Selecting the grid to be added for re-examination

➔ Use the aforementioned options to define the points to be tested during re-examination.
➔ Then click the [Finish] button.
The following dialogue box is displayed:

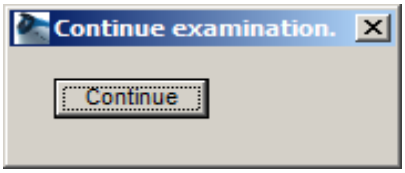


Fig. 11-17: "Continue examination." dialogue box

➔ If you have removed the corrective lens from the holder, insert this again.
➔ Inform the patient that the examination will continue.
➔ Press the [Continue] button and, if necessary, confirm the confirmation prompt as to whether you have re-inserted the corrective lens.
The examination continues.

After completing the re-examination, the system asks whether the examination should be saved *(Fig. 11-12, page 34)*.

12 Working with patient data management

This section describes how to use patient data management to

- Rename patient data, *Chap. 12.1, page 38*
- Export patient data, *Chap. 12.2, page 38*
- Import patient data, *Chap. 12.3, page 39*
- Back up patient data, *Chap. 12.2, page 38*

For more information regarding patient data management, see the *User manual*.

12.1 Renaming patient data

You can change patient data retrospectively after creating it.

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

➔ Change the entries in the individual fields.

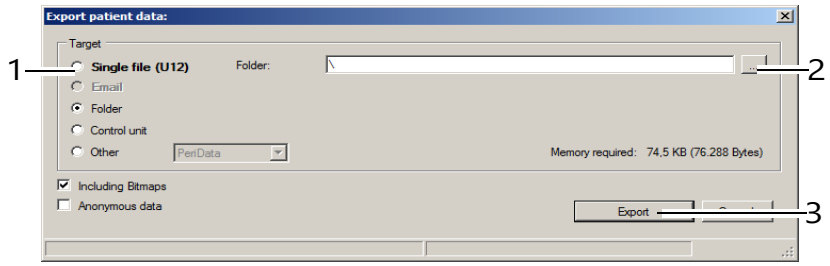
➔ Press the [Save] button.

12.2 Exporting patient data

In order to transfer patient and examination data to a different surgery, for example, you can export this data.

➔ Select the patient and, if necessary, one of the examinations in the relevant list.

➔ Press the [Export] button below the patient list. The following dialogue box is displayed:



1 Selecting the save target

2 [...] button to select the folder

3 Buttons for [Cancel] and [Export] checkbox

Fig. 12-1: "Export patient data" dialogue box

The import and export options are pre-set in the "Settings" area, also see the *User manual*.

You may not need to perform all of the following steps (e.g. selecting a directory) depending on the settings.

➔ In "Target" (1), select how you wish to export the data.

Recommendation: Use the "Single file (U12)" option to export the patient data.

➔ Press the [...] button (2) to select a folder.
➔ In the dialogue box, select the directory or file to which the patient data is to be exported, e.g. TOPO.DAT for the data and TOPO.BMP for the images.
➔ Press [OK] or [Open] to confirm.
➔ Press the [Export] button (3) to export the data.

12.3 Importing patient data

If you receive data on a USB stick for example, you can import this data. The patient data must be saved with a version of patient data management that can be read by the version of patient data management that is installed on your device. This means that the version of patient data management on your device must be the same or higher than the version that was used to save the patient data to the USB stick.

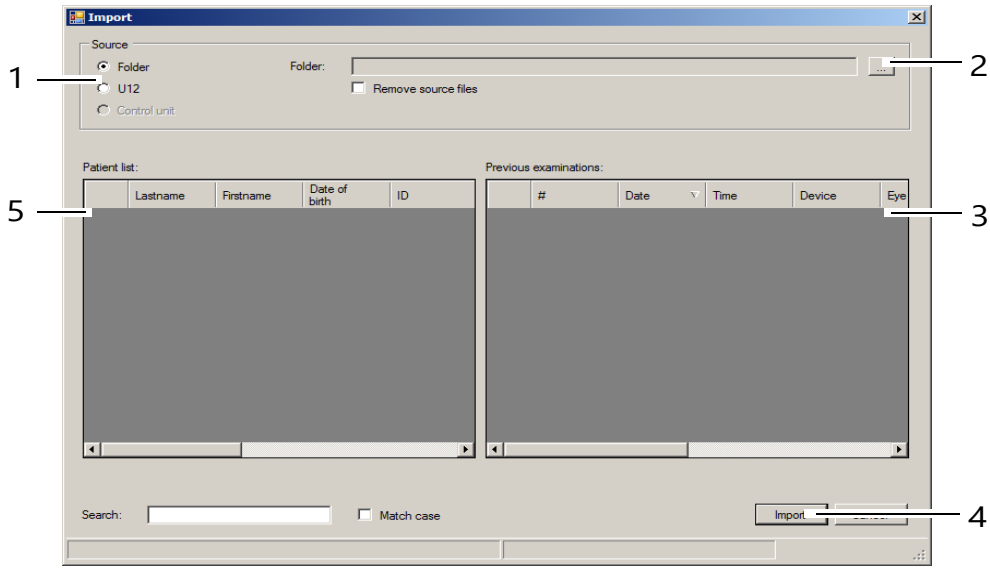
Note

Loss of data due to computer viruses

Computer viruses can cause a loss of data.

➔ Check that the USB stick is free of viruses before importing.

➔ Press the [Import] button. The following dialogue box is displayed:



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

Fig. 12-2: "Import" dialogue box

The import and export options are pre-set in the "Settings" area, also see the *User manual*.

➔ You may not need to perform all of the following steps (e.g. selecting a directory) depending on the settings.

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

Recommendation: Use the "Single file (U12)" option to import the patient data.

➔ Press the [...] button (2).
➔ In the dialogue box, select the directory or file in which the patient data is available.
➔ Press [OK] or [Open] to confirm.
The patients that were found and the corresponding examinations are displayed in the bottom part of the dialogue box.
➔ Press the [Import] button (4) to import the data.
The data is then available in patient data maintenance.

12.4 Storing data (backup)

You should back up all patient and examination data at regular intervals. If data loss occurs, you can use this function to restore the data from a previous backup. As the data backup required some time depending on the size of the database and the data to be backed up, perform a backup when the computer and the device are not required for some time.

Note

Loss of data due to computer viruses

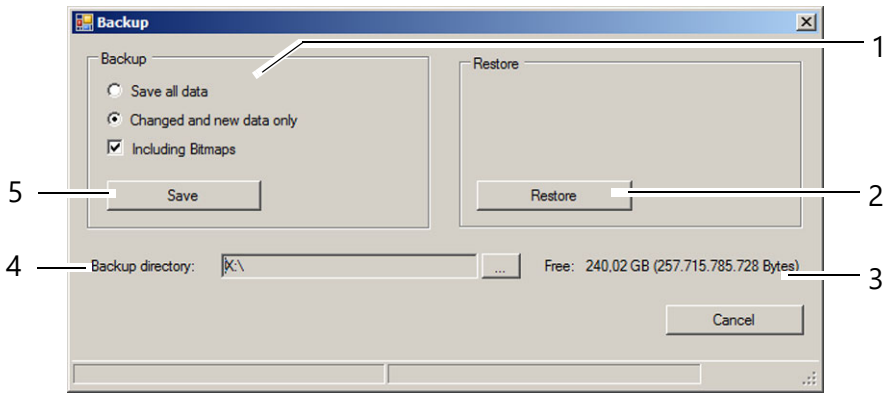
Computer viruses can cause a loss of data.

➔ Check that the storage medium (external hard drive, USB stick, etc.) is free of viruses before backing the data up.

The generally applicable rules for creating backup copies apply to a data backup using patient data management. The backup files must always be stored on a separate system (e.g. a USB stick with sufficient capacity).

12.4.1 Storing data

➔ Press the [Backup] button in the upper right part of patient data management. The following dialogue box is displayed:



1 Select the data to be backed up
2 [Restore] button
3 Free storage space indication
4 Backup directory and [...] button
5 [Save] button

Fig. 12-3: "Backup" dialogue box

➔ Select whether all data or only changed data is to be backed up.

Patient data management selects all backed up data records internally.

If you select the “Changed and new data only” option, only the data records that have not already been saved during a previous backup are saved.

- ➔ Press the [...] button to the right of the “Backup directory” field (4).
- ➔ In the dialogue box, select the directory to which the data is to be backed up.
- ➔ Press [OK] to confirm your selection.
- ➔ Press the [Backup] button (5) to save the data. The data that you selected previously is then saved to the relevant directory.

12.4.2 Restoring data

After data loss, the data from a previous backup can be read back into patient data management.

- ➔ Press the [...] button.
- ➔ In the dialogue box, select the directory in which the backed up data is stored.
- ➔ Press [OK] to confirm your selection.
- ➔ Press the [Restore] button (2) to read the data in again. All data in the selected directory is transferred to patient data management.

12.4.3 Automatic backup

In addition to the manual backup, there is also the option of executing the backup automatically when closing patient data management. The settings required for this can be made in the “Settings” area, see the *User manual*.

13 Cleaning, disinfection and maintenance

This section describes how you can clean and disinfect the Easyfield® and accessories.

Sterilisation is not required.

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

Warning

Personal injury during servicing and maintenance work

Personal injury may occur if the device is used during service and maintenance work such as cleaning, disinfection and servicing.

➔ Do not perform any service and maintenance work while the device is in use.

13.1 Cleaning

Caution

There is a risk of electric shock if the Easyfield® is not disconnected from the mains power supply at all poles for cleaning or disinfection

➔ Switch the Easyfield® off, *Chap. 8.2, page 20*.

➔ Remove the mains plug prior to cleaning. Hold the plug to do this. Do not pull the cable.

➔ Do not use aggressive, chlorinated, abrasive or caustic cleaning agents to clean the Easyfield®.

Required materials

- Cleaning agent for plastic surfaces with anti-static effect
- Cleaning agent for painted surfaces: Mixture of even parts methylated spirit and distilled water, with a few drops of normal washing-up liquid if necessary
- Soft cloth or lens brush
- Alcohol or lens cleaner

Cleaning intervals

➔ Clean the chin rest and forehead rest after every examination. Clean the housing and the accessories once per month or as required.

➔ Clean the manual button after every examination.

Cleaning

- ➔ Switch the Easyfield® off, *Chap. 8.2, page 20*.
- ➔ Remove the mains plug.
- ➔ When cleaning with a damp cloth, ensure that no liquid can penetrate the Easyfield®.
- ➔ Clean the plastic surfaces with a suitable cleaning agent.
- ➔ Clean the painted surfaces with the cleaning agent for paints.
- ➔ Clean the viewer lens with a soft cloth or a lens brush. Use alcohol or a lens cleaner if necessary.
- ➔ Clean the power supply with a dry, soft cloth.

13.2 Disinfection

Caution

There is a risk of electric shock if the Easyfield® is not disconnected from the mains power supply at all poles for cleaning or disinfection

- ➔ Switch the Easyfield® off, *Chap. 8.2, page 20*.
- ➔ Remove the mains plug prior to cleaning. Hold the plug to do this. Do not pull the cable.

Required materials (we recommend) or corresponding:

Pursept^{a}-A Xpress disinfectant wipes,
Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt I Germany
Phone: +49 40 52100-0
Fax: +49 40 52100-318
E-mail: info@schuelke.com
https://www.schuelke.com/gb-en/index.php

- ➔ Disinfect the chin rest and forehead rest after every examination. Disinfect the housing and the accessories as required.
- ➔ Disinfect the manual button after every examination.
- ➔ Disinfect the eye patch after every use.

13.3 Maintenance

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

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

Note

Incorrect examinations due to damaged devices

If you use a damaged device, the examinations may be incorrect.

If a fault occurs, which you cannot rectify

➔ Mark a damaged Easyfield® as out of order.

➔ Report the damage to OCULUS customer service or your authorised dealer.

➔ Only use an undamaged Easyfield®.

14 Troubleshooting

Caution

Personal injury or damage to property due to incorrect troubleshooting

➔ If a fault occurs, which you cannot rectify using the instructions below, mark the device as out of order and inform our customer service department or your authorised dealer.

Device damage due to misuse

➔ Never plug in or unplug gables or plugs while the PC or the Easyfield® is switched on. This could destroy the individual devices.

Fault	Possible cause	Remedy
No functions when pressing the mains switch or the light on the mains switch does not illuminate.	No connection between the Easyfield®-Perimeter and the power supply. Power cut or socket not active	Plug the mains cable into the socket or the rubber connector on the Easyfield®-Perimeter. Contact the building electrician.
No functions when pressing the mains switch but the light on the mains switch does illuminate.	PC USB cable not connected correctly. The device was switched off and on again too quickly.	Check that the plug is connected correctly. 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.

15 Transport and storage

Before you transport and store the Easyfield®, you must dismantle and pack it properly.

15.1 Dismantling and packing

➔ Select Patient > New patient / End.
➔ Close patient data management.
➔ Shut the notebook/the PC/the laptop down.
➔ Switch the device off, *Chap. 8.2, page 20*.
➔ Remove the mains plug from the mains socket.
Disconnect the connections to the manual button and the netbook/PC/laptop.
Hold the plug to do this. Do not pull the cables.
➔ Pack the Easyfield® in the original packaging.

15.2 Information regarding transport and storage

Storage

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

Transport

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

After storage and/or transport

➔ Only start the Easyfield® up again after around 3-4 hours following transport or storage. The optical components can mist up due to severe temperature differences between cold outdoor areas and warm rooms.

Note

Device damage due to improper transport and storage

➔ Avoid impacts, shaking and contamination.

➔ Avoid high temperatures and moisture.

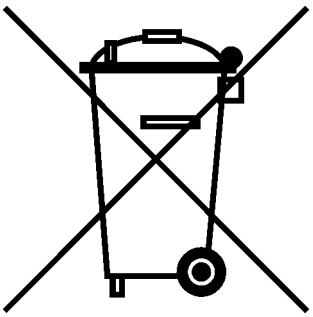
➔ Transport the Easyfield® properly.

➔ Store the Easyfield® in accordance with the storage conditions.

➔ Avoid being close to radiators and moisture.

➔ Check the Easyfield® for damage each time after transporting.

16 Disposal



In accordance with Directive 2012/19/EC of the European Parliament and Council, 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 of the Easyfield® properly.

17 Warranty conditions and service

17.1 Warranty conditions

The Easyfield® was manufactured with care and using high quality materials and modern production techniques. If software is supplied as standard, this has been tested by us and complies with the technical standards. Note the following warranty conditions:

- It is important that you observe the instructions for use, the user manual and the safety instructions prior to and while operating the device.
- In accordance with legal regulations, you are entitled to a warranty for the Easyfield®.
- If modifications are made to the Easyfield® by unauthorised people, all warranty claims shall be voided. Improper modifications and repairs may result in considerable hazards to users and patients.
- Any entitlement to a warranty shall also be void if unauthorised people interfere with the supplied PC hardware and software.
- Any transport damage must be reported to the transport company immediately. Confirm the damage on the delivery note in order to ensure that claims can be settled properly.
- In general, our Business and Shipping Terms on the date of purchase apply.

17.2 Liability for functions or damage

OCULUS will only accept responsibility for the safety, reliability and serviceability of the Easyfield® if you observe the following regulations:

➔ Only use the device in accordance with these instructions for use and the enclosed user manual.

- There are no parts either on or inside the Easyfield®, which require maintenance or repair by the user. If assembly work, modifications, adjustments, servicing, changes or repairs are performed by unauthorised personnel, or if the Easyfield® is maintained or handled improperly, any liability by OCULUS is voided.
- If the aforementioned work is performed by authorised people, request a certificate of the scope and type of repair, and, if necessary, the changes to the standard values or to the operating range from the service technician. This certification must contain the date, performance and company data with signature.

- Upon request, OCULUS will provide the service technician with a list of spare parts and additional descriptive material for this purpose.

➔ Ensure that only original OCULUS parts are used for servicing.

17.3 Manufacturer and service address

Additional information is available from our customer service department or from our authorised representatives.
Manufacturer and service address:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar
GERMANY
Tel. +49 641 2005-0
Fax +49 641 2005-255
E-mail: sales@oculus.de • www.oculus.de

18 Technical data

Measuring equipment

Weight	
■ Easyfield® S	4.6 kg
■ Easyfield® C (with chin rest)	7.4 kg
Dimensions (W x D x H)	
■ Easyfield® S	274 x 370 — 470 x 314 — 429 mm
■ Easyfield® C (with chin rest)	316 x 506 — 540 x 320 — 435 mm
Interface	USB, RS232
Perimeter ball radius	300 mm
Meridian	Adjustable from 0°-360°
Max. eccentricity	30°
Max. power consumption	26 W
Expected service life	10 years

Measurement parameters

Stimulus	
■ Stimulus size	Goldmann III
■ Stimulus colour	White
■ Rendition time	200 ms/user-defined (0.2 s/0.5 s/0.8 s/adaptive)
■ Brightness range/steps	0.03 – 3180 cd/m² (0.1 – 10 000 asb)/1 dB
■ Rendition speed	Adaptive / fast / normal / slow / user-defined
Environment	
■ Brightness	10 cd/m² (31.4 asb)
■ Environment colour	White,
■ LEDs	12, WU-7-730SWC, 2800 mcd, 20 mA

Power supply

Power supply	GSM40A12-P1J (10015234)
Mains connection	80 – 264 V AC 1 — 0.5 A
Frequency	47 – 63 Hz
Max. power consumption	46 W
Output voltage	12 V 3.34 A 40 W max.
Fuses	Integrated overload protection

Classification in accordance with IEC 60601 - 1 (VDE 0750)

Electric shock protection	Protection class 2
Application part insulation	Type B
Protection against foreign objects, contact and water	IP20

Operating conditions

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

Storage conditions

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

Transport

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

Computer

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

Recommended computer specifications	Intel® Core™ i5, 500 GB SSD, 8 GB RAM, Windows® 10, Intel® HD Graphics

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

The device is a product in product class I.

CE

Conformity evaluation procedure in accordance with (EU) 2017/745, MDR, Annex II and III

19 Appendices

19.1 Electromagnetic compatibility

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.

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

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

Definition of minimum operating quality or significant performance characteristics

- Minor interference on the device's analogue camera (slight image noise in the display) during the examination is permissible, as it does not affect the aforementioned function when used properly.
- A slight flicker of the device's lights during the examination is permissible, as it does not affect the aforementioned function when used properly.
- A short interruption to the USB connection during the examination is permissible, as it does not affect the aforementioned function when used properly.

Caution

Using accessories, transformers and cables that are not specified by OCULUS can cause increased emission or reduced immunity for the Easyfield®.

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

Using accessories, transformers and cables that are specified by OCULUS but with devices other than the Easyfield® can cause increased emission or reduced immunity for the other devices

➔ Do not use the accessories, transformers and cables that are specified by OCULUS with devices other than the Easyfield®.

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	
15000	OCULUS-Easyfield® C	
15005	OCULUS-Easyfield® S	
05200320	Cable with plug, EU standard	2.5m
05200210 (110 Volt)	Cable with plug, US standard	2.5m
015692000010	USB FS Med isolator	
10015234	GSM40A12-P1J power supply	see *"Power supply" on page 52*

19.2 Guidelines and manufacturer's declaration Electromagnetic immunity

Guidelines and manufacturer's declaration: Electromagnetic interference for the Easyfield®		
The OCULUS Easyfield® is intended for operation in the electromagnetic environment specified below. The user of the Easyfield® should ensure that it is being used in such an environment.		
Emitted interference Measurements	**Compliance**	**Electromagnetic environment - guidelines**
HF emissions in accordance with 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.
HF emissions in accordance with CISPR 11	Class B	
Harmonics emissions in accordance with IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions in accordance with IEC 61000-3-3	complies	

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 ± 15kV air discharge	± 8 kV ± 15kV	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 sections	± 2 kV ---------- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges in accordance with IEC 61000-4-5	± 1 kV symmetrical voltage ± 2 kV Asymmetrical 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 Easyfield® requires continued operation during power cuts, we recommend powering the Easyfield® from an uninterruptible power supply or battery.
Note: U_τ is the A.C. mains voltage prior to applying the test level			

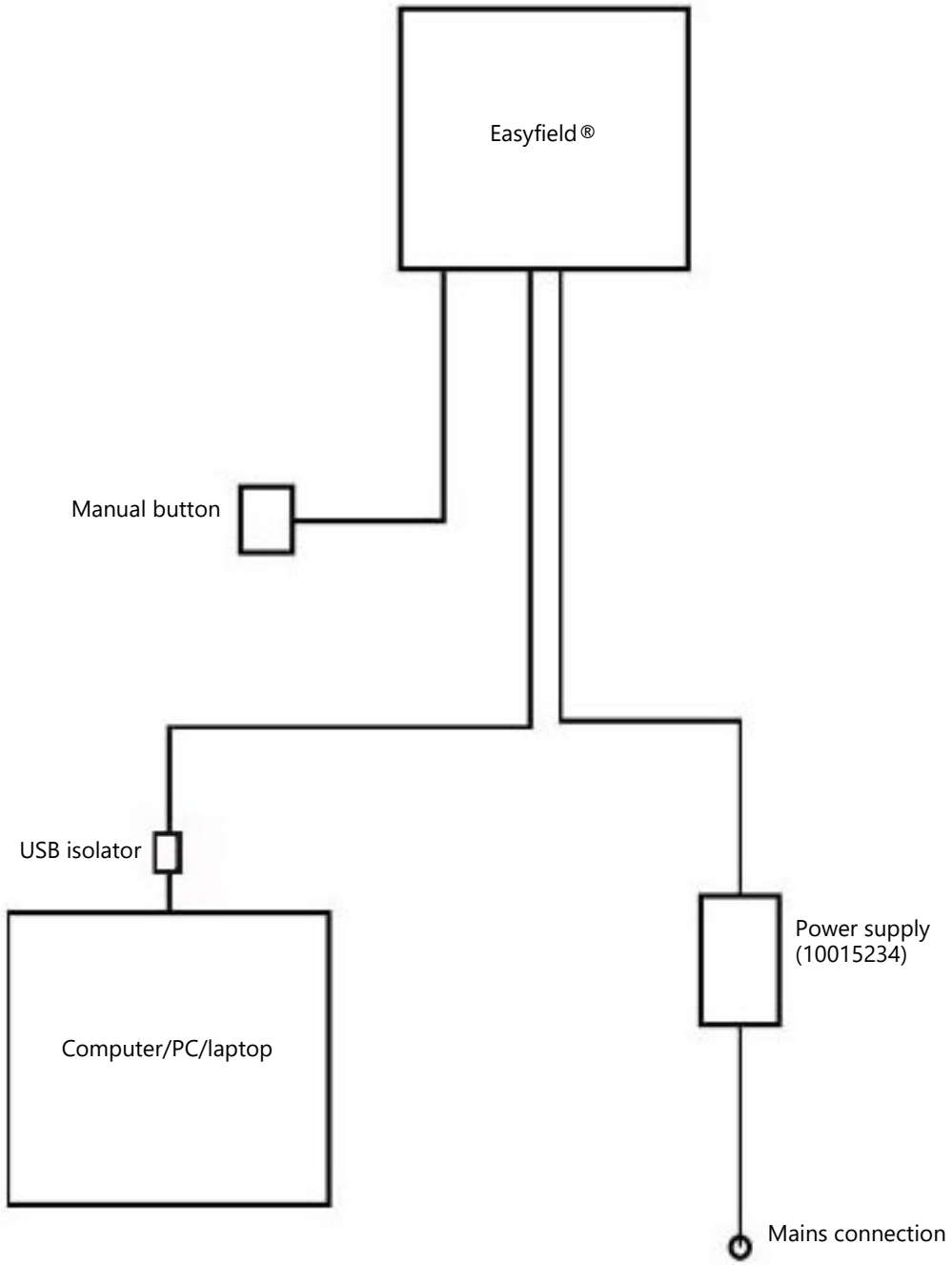
Electromagnetic immunity			
Immunity tests	**DIN EN 60601 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Conducted HF transients in accordance with IEC 61000-4-6	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM at 1 kHz	V_{eff} = 3 V	Portable and mobile HF communications equipment should be used no closer to any part of the Easyfield®, 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: 
Radiated HF transients in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz		
Note 1:	The higher frequency range applies at 80 Hz and 800 MHz.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a. Field strengths from fixed transmitters, such as base stations for radio 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 Easyfield® is used exceeds the aforementioned compliance level, the Easyfield® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Easyfield®.

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

Recommended separation distances between portable and mobile HF telecommunication equipment and the Easyfield®			
The Easyfield® is intended for use in an electromagnetic environment in which HF transients are controlled. The Easyfield® user can make a significant contribution to avoiding electromagnetic interference by keeping a minimum distance of between the portable and mobile HF 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			

19.3 Connection diagram



19.4 Data sheet for GSM40A12-P1J (10015234) power supply

MEAN WELL

40W AC-DC Single Output Medical Type

GSM40A series

■ Features :

- Universal AC input / Full range
- 3 pole AC inlet IEC320-C14
- High efficiency up to 91%
- Low leakage current <100μA
- Protections: Short circuit / Overload / Over voltage
- Fully enclosed plastic case
- Medical safety approved (MOPP level)
- Class Ⅰ power (with earth pin)
- LED indicator for power on
- No load power consumption<0.1W
- ErP step2 compliant (level Ⅴ)
- Meet EISA 2007 (Energy Independence and Security Act)
- 3 years warranty

SPECIFICATION

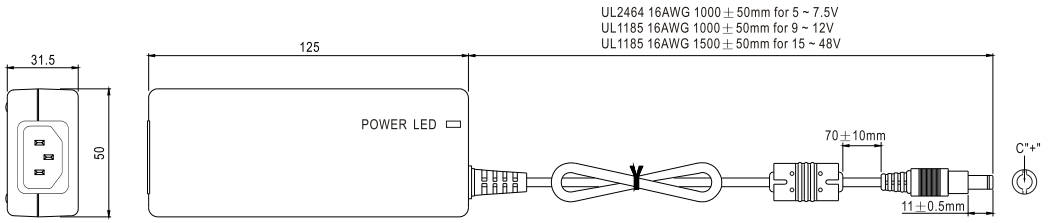
ORDER NO.		GSM40A05-P1J	GSM40A07-P1J	GSM40A09-P1J	GSM40A12-P1J	GSM40A15-P1J	GSM40A18-P1J	GSM40A24-P1J	GSM40A48-P1J
OUTPUT	SAFETY MODEL NO.	GSM40A05	GSM40A07	GSM40A09	GSM40A12	GSM40A15	GSM40A18	GSM40A24	GSM40A48
	DC VOLTAGE Note.2	5V	7.5V	9V	12V	15V	18V	24V	48V
	RATED CURRENT	5A	5.34A	4.45A	3.34A	2.67A	2.22A	1.67A	0.84A
	CURRENT RANGE	0.1 ~ 5A	0.1 ~ 5.34A	0.1 ~ 4.45A	0.1 ~ 3.34A	0.1 ~ 2.67A	0.1 ~ 2.22A	0.1 ~ 1.67A	0.1 ~ 0.84A
	RATED POWER (max.)	25W	40W	40W	40W	40W	40W	40W	40W
	RIPPLE & NOISE (max.) Note.3	100mVp-p	100mVp-p	100mVp-p	100mVp-p	100mVp-p	150mVp-p	180mVp-p	240mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±5.0%	±3.0%	±3.0%	±3.0%	±2.5%	±2.5%
	LINE REGULATION Note.5	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
	LOAD REGULATION	±5.0%	±5.0%	±5.0%	±3.0%	±3.0%	±3.0%	±2.5%	±2.5%
	SETUP, RISE TIME Note.7	1000ms, 30ms / 230VAC 1500ms, 30ms / 115VAC at full load							
	HOLD UP TIME (Typ.)	50ms / 230VAC 15ms / 115VAC at full load							
INPUT	VOLTAGE RANGE	80 ~ 264VAC 113 ~ 370VDC							
	FREQUENCY RANGE	47 ~ 63Hz							
	EFFICIENCY (Typ.)	81%	85.5%	86%	88%	88.5%	89.5%	90%	91%
	AC CURRENT (Typ.)	1A / 115VAC 0.5A / 230VAC							
	INRUSH CURRENT (Typ.)	65A / 230VAC							
	LEAKAGE CURRENT(max.)	Earth leakage current < 100μA/264VAC , Touch current < 100μA/264VAC							
PROTECTION	OVERLOAD	105 ~ 160% rated output power							
		Protection type : Hiccup mode, recovers automatically after fault condition is removed							
	OVER VOLTAGE	5.25 ~ 6.75V	7.88 ~ 10.13V	9.45 ~ 12.15V	12.6 ~ 16.2V	15.75 ~ 20.25V	18.9 ~ 24.3V	25.2 ~ 32.4V	50.4 ~ 64.8V
		Protection type : 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% / ℃ (0~50℃)							
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes							
SAFETY & EMC (Note. 6)	SAFETY STANDARDS	ANSI/AAMI ES60601-1 / 60601-1-11, TUV EN60601-1 / 60601-1-11 approved							
	WITHSTAND VOLTAGE	I/P-O/P:4KVAC I/P-FG:2KVAC O/P-FG:SHORT							
	ISOLATION RESISTANCE	I/P-O/P, I/P-FG:100M Ohms / 500VDC / 25℃/70% RH							
	EMC EMISSION	Compliance to EN55011(CISPR11) class B, EN61000-3-2,3, FCC PART 15 class 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	740K hrs min. MIL-HDBK-217F(25℃)							
	DIMENSION	125*50*31.5mm (L*W*H)							
	PACKING	0.29Kg; 40pcs/ 12.6 Kg/1.05CUFT							
CONNECTOR	PLUG	Standard type P1J: 2.1φ* 5.5φ* 11mm, tuning fork type, center positive for stock ; Other type available by customer requested							
	CABLE	See page 2 ; 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. 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. 7. 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.								

File Name:GSM40A-SPEC 2013-04-24

MEAN WELL 40W AC-DC Single Output Medical Type **GSM40A series**

■ Mechanical Specification

Case No. 974A Unit:mm



ID 2.1 x OD 5.5

Outside ⊖—◉—⊕ Inside

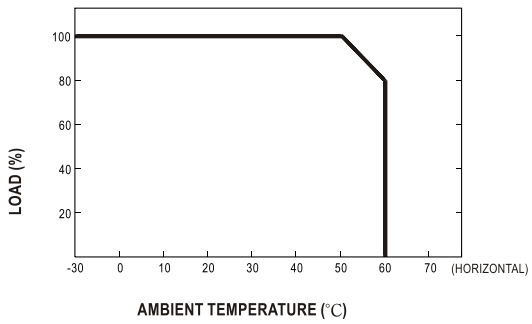
-V connected to AC FG

■ Plug Assignment

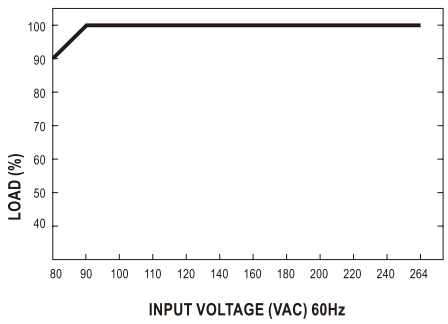
Standard plug: P1J

P1J	
P/N	OUTPUT
CENTER	+

■ Derating Curve



■ Static Characteristics



File Name:GSM40A-SPEC 2013-04-24

19.5 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 observe the (*"Cyber security" on page 10*) section in the "Safety instructions" section (*Page 4*) in the device operating manual.

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:

- Refer to the cyber security section (*Page 10*) in "Safety instructions" (*Page 4*) in the device 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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