OCULUS Easyfield® C/Easyfield® S

INSTRUCTION MANUAL

Examination of the Central Visual Field

OCULUS®

Notes on this instruction manual

The Easyfield® was manufactured and tested under 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 familiarize yourself thoroughly with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

The user guide of the Easyfield® perimeter will provide you with extensive information, especially about the evaluation programs and displays produced by the examinations.

Due to ongoing development your device might present minor differences compared to the information contained in this manual.

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

OCULUS Optikgeräte GmbH

OCULUS is certified according to DIN EN ISO 13485 and thus has established a high standard of quality for development, manufacture, quality assurance and service for our entire product line.

Table of contents

1 Scope of Delivery

Product and accessories	Order number
Version:	
■ OCULUS Easyfield® C perimeter (with chin support)	15000
■ OCULUS-Easyfield® S perimeter	15005
Data medium with software	15110/15120
Dust cover Easyfield® C	1500011001
Dust cover Easyfield® S	6010005001
Hand-held button	56517
Lens holder for inserting trial lenses	1500007000
Eyepatch	44560
Eye shield, translucent	1500008001+002
Instruction Manual	GA/15000/XXXX/EN 1219 Rev01
User Guide	BH/15000/0412/en
Software Installation	SI/50000/xxxx/en
USB cable	05200560
USB FS MED Isolator	015692000010
Power supply GSM40B12-P1J	05150805
Optional Accessories	
Compact Laptop Stand	37499
Carrying case for Easyfield® S	56936

- 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.

Note

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

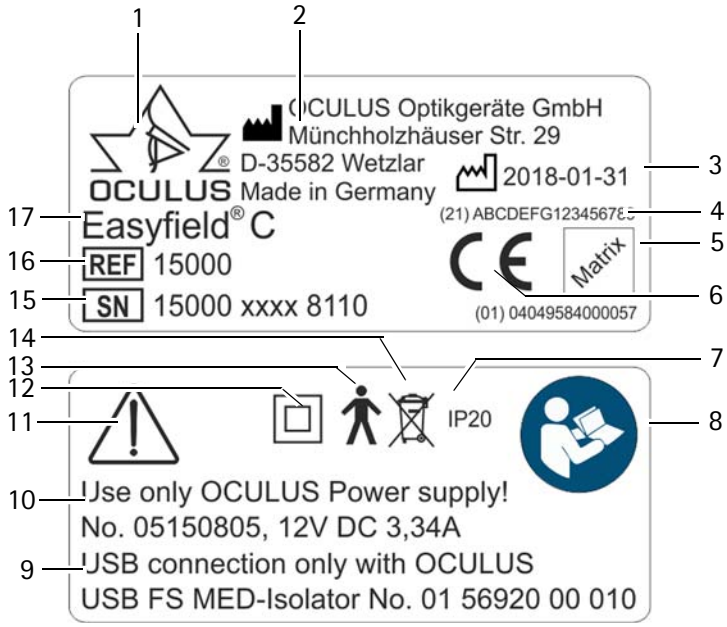
1.1 Software Version

This User Manual describes the following versions of the Easyfield®-Software together with patient data management:

- Easyfield®-Software: from Version 3.19
- Patient Data Management Version 6.08

- The software version for patient data management is displayed on the "settings" page **inside the patient data management**.
- The software version of the Easyfield®-Program is displayed on the "settings" page **inside the Easyfield®-Program**.

2 Reference numbers on the device



1	*Company logo*	10	*Power adapter with OCULUS no.*
2	*Company address*	11	*Safety symbol*
3	*Date of manufacturing*	12	*Protection class protection*
4	*UDI-Nummer*	13	*Type B unit*
5	*Matrix for device identification*	14	*Disposal in household trash is prohibited*
6	*CE Conformité Européenne*	15	*Serial number of the device*
7	*Degree of protection*	16	*Reference number*
8	*Heed Instructions Manual*	17	*Device name and device number*
9	*USB FS MED isolator with order no.*		

Fig. 2-1: Symbols: Example type plate Easyfield® C

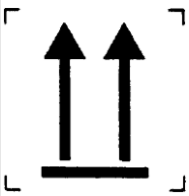
More symbols on the device

Applied part type B unit

Easyfield® S:
Make sure that the device cannot tip over by leaning against it or sitting on it.

Graphic symbols on packaging

keep dry



this way up

fragile

Transport

permitted temperature range: transport

Storage

permitted temperature range: storage

3 Structure of the Documentation

A folder containing a set of documentation is supplied with your Easyfield® perimeter:

- **Quick Guide:** In this document a checklist of the measurement procedure is supplied. The document is intended to help you familiarize with the equipment. The Quick Guide reminds you all important steps in order to obtain correct results.
- **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 Easyfield® perimeter.

Caution

All safety-related instructions for use of the Easyfield® 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 Easyfield® perimeter.

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

If you use a **Floating License Key**: information on the use of the Easyfield® within networks.

4 Safety instructions

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

4.1 In this handbook

➔ 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.

4.1.1 Used pictograms

Warning

Indicates a potentially hazardous situation that may result in irreversible injury.

Caution

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

Note

Denotes situations which could result in incorrect findings, denotes 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:

➔ Easyfield® > Examination > New Patient

That is:

➔ Open the Easyfield® program.

➔ In the menu list, select the "Examination" menu item.

➔ Click on "New Patient".

4.2 Safety Instructions for Use

Caution

Personal injury or property damage due to improper operation.

➔ Observe the following safety instructions.

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.

Instructions to operating personnel

➔ The e device may only be operated by personnel instructed to do so, who, with appropriate training, knowledge and practical experience, are able to ensure proper handling of the device.

Transport and Storage Instructions

Refer to the notes in *sec. 15, page 44*.

Instructions regarding the set-up and electrical connection

➔ Do not use or store the Easyfield® in damp rooms and do not store the unit in such areas.

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

➔ Germany: Only operate the Easyfield® 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 m² and IEC 60320-1.
- ➔ Set up the Easyfield® 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 department or authorized dealer repair the damage.
- ➔ Use only the OCULUS USB FS MED isolator (no. 01 56920 00 010) for a USB connection.

Patient environment information

Patient environment is the area where patients can come into contact with any part of a medical electrical equipment (ME equipment) or with another person being in contact with the ME equipment. In the patient environment, use devices that conform to IEC 60601-1. If a multiple power socket is to be used, or if a device is to be used that does not meet the IEC 60601-1 standard, use an isolating transformer.

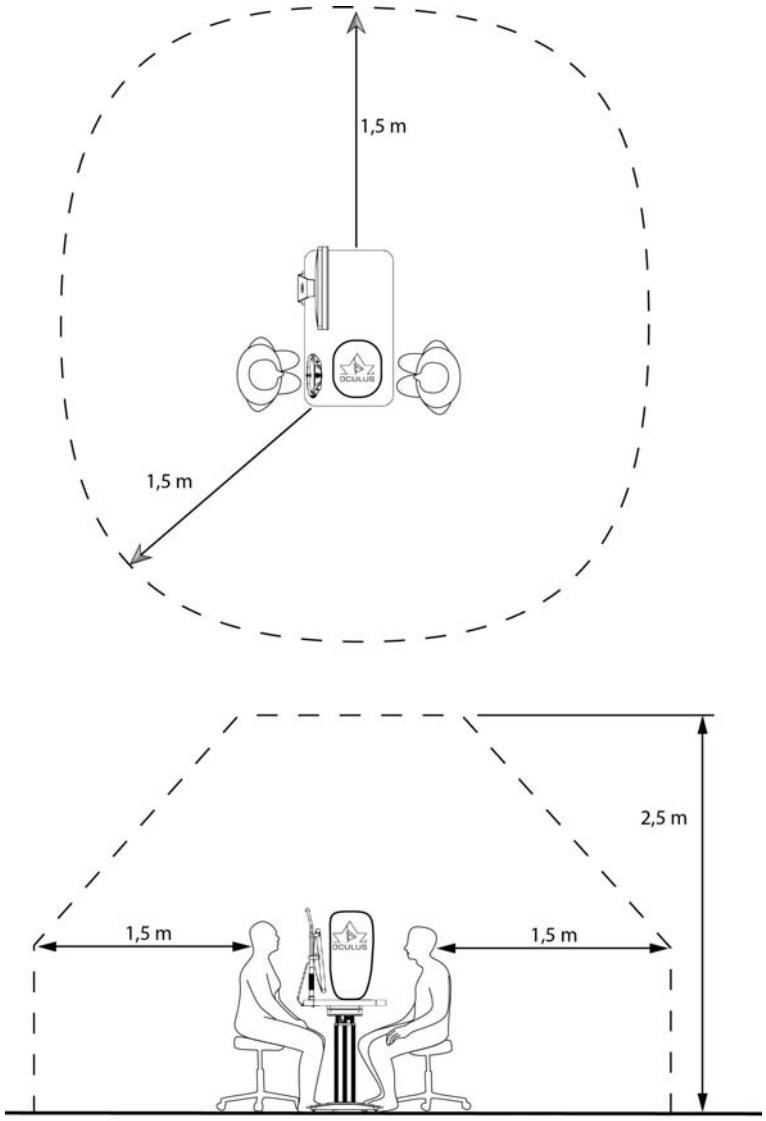


Fig. 4-1: Patient environment

Information about the operation of an ME system

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

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

Instructions for operation

- ➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the Easyfield®.
- ➔ Never operate a damaged Easyfield®.
- ➔ Only operate the Easyfield® using original accessory parts supplied by us, and when the device is in technically correct working order.
- ➔ Do not touch the patient and the Easyfield® simultaneously.
- ➔ Make sure that the device cannot tip over by leaning against it or sitting on it.
- ➔ Do not use the device if you have not understood the Instruction Manual.

Notes on maintenance

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

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.

Instructions on Electrical Safety

Caution

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

Connecting the Easyfield® with its non-medical electrical equipment (e.g. data processing equipment) to a medical electrical system must not result in a patient safety level below that prescribed by DIN EN ISO 60601-1. If making this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ Only use the power adapter listed in the packing list.
- ➔ Use only a computer that meets the specifications given in this instruction manual, *sec. 18, page 48*.

Caution

Use of a multiple socket extension cord

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

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

- ➔ Use an extension cord that complies with the requirements of DIN EN ISO 60601-1: 20005, section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Easyfield® 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 Easyfield®, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Electromagnetic Compatibility (EMC/Cables)

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

Portable and mobile RF communications equipment can affect medical electrical equipment *sec. 18, page 48*.

- ➔ 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 Easyfield® functions correctly.

Cybersecurity

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

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

Precautions for access control of the computer

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

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

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

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

Note

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

5 Intended Use

The Easyfield® is intended for the use described in this Instruction Manual. It is designed for testing the visual field of the human eye.

The Easyfield® offers pre programmed combinations for often needed examination routines. For example: Screening 24-2, SPARK Quick, Macula. Custom routines can also be combined and saved as programs.

No other software programs (screen saver, applications, etc.) must run simultaneously with the examination program in the foreground on the computer that controls the Easyfield® perimeter.

Only operate the device using original accessory parts supplied by us, and when the device is in technically correct working order.

➔ Note the safety instructions listed above.

Contrindication

None known.

6 Device Description

1	*Forehead rest*	6	*Stand support**
2	*Eye shield*	7	*Power On/Off switch*
3	*Perimeter cone with mounts for correction lens holder*	8	*Port for external power supply*
4	*Chin rest**	9	*USB port for connection with netbook/PC/laptop*
5	*Chin rest adjustment knob**	10	*Port for connection with hand-held button*

Fig. 6-1: Overview Easyfield®

** Easyfield® C only*

6.1 Operation of the Easyfield®

The OCULUS Easyfield® has been designed for combined use as a screening unit with all associated options for immediate follow-up examination of suspicious findings. The most common examination grids and strategies for the central visual field up to 30° can be accessed.

The Easyfield® offers pre programmed combinations for often needed examination routines. For example: Screening 24-2, SPARK Quick, Macula. You can also combine your own routines and then save them as a program.

The integrated perimeter bowl of the Easyfield® with its 30 cm radius and a distance-correcting lens meets the Goldmann standard. The unit complies with the ISO Norm 12866 for perimeters.

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

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

Perimeter cone: Due to the closed construction it is not necessary to darken the room for the exam.

Chin rest: The adjustable chin rest ensures increased maximum patient comfort during the exam.

Corrective lens holder: The corrective lens holder can be easily and securely suspended from the two mounts.

Software principle:

The Easyfield® operates with two programs acting in concert to process the supplied values and an analysis program:

- Patient Data Management

  Use this program to manage the patient data.
- Easyfield® program:

  This program performs the examination and most of the result analysis.
- TNT program:

  This program compares existing exams and provides support in a progression analysis.

Note

Misuse of data

OCULUS Optikgeräte GmbH can not be held liable in any form for further use of the data recorded by a Easyfield® and for the evaluations it has calculated.

Applied parts

1 *Chin rest (Easyfield® C only)*
2 *Hand-held button*
3 *Forehead rest*

Fig. 6-2: Applied parts

7 Preliminary steps

Before the initial operation of the Easyfield® you must first -

- Install the software *sec. 7.1, page 16*
- Set up the Easyfield® *sec. 7.2, page 16*
- Connect the Easyfield® *sec. 7.3, page 16*
- Ensure operational readiness, *sec. 8.1, page 19*
- Set up firmware and drivers, *sec. 7.4, page 19*

Caution

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

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

7.1 Install the software

If you are working with a PC or laptop, you must install the Easyfield® software. The Easyfield® software consists of the following programs which are installed together.

- Patient Data Management
- Easyfield® program
- TNT program

➔ Proceed as described in the *Software Installation*

➔ After installing the software, restart the PC or laptop.

7.2 Set-up

The Operating Instructions are found in *"Ambient operating requirements" page 49*.

➔ Remove the Easyfield® from the packaging.

➔ Place the Easyfield® on a level surface.

➔ Dispose of the packing material in a proper manner.

7.3 Connect

You must connect the Easyfield® to the power supply, and depending on the configuration, to the netbook, the laptop or PC. Connection and set-up will be demonstrated using the example of a netbook connection.

Warning

Electrical safety hazard due to wrong power cord

➔ Only use a power cord which meets the requirements of the standards IEC 60227-1, Type 53, min. 0,75 m² and IEC 60320-1.

Caution

Electrical safety hazard

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

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

➔ Only use the power adapter listed in the list, *sec. 19, page 51*.

➔ If you use a power strip to connect the Easyfield®: 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 Easyfield® and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

Note

Risk of equipment damage due to incorrect connection

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

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

➔ Pay attention to the specifications on the nameplate.

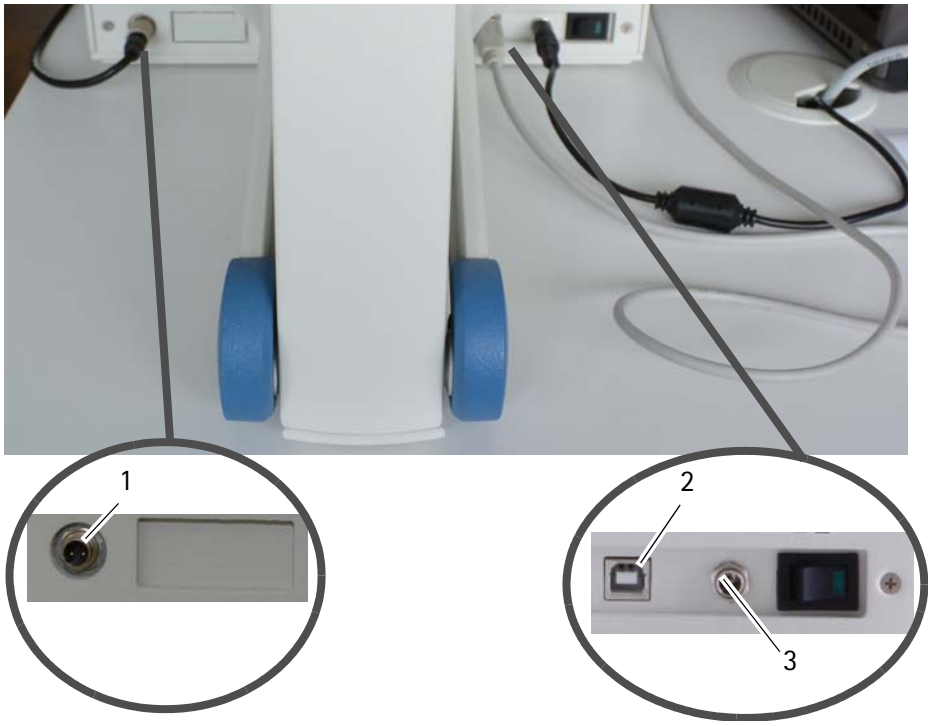
If the electrical plug is damaged, contact our service department or an authorized dealer to repair the damage.

➔ Connect the hand-held button (1).

➔ Connect the netbook (2).

Connect the USB cabe with the USB FS MED isolator.

Connect the isolator with the computer.



1 Port for hand-held button

2 USB port for connection with netbook/PC/laptop

3 Port for external power supply

Fig. 7-1: Connect to the netbook

➔ Connect the power supply to the unit with the supplied power cable (3).

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

If you are working with a netbook, you can skip the following steps. Proceed as described in *sec. 8, page 19*.

7.4 Setup tasks for Initial Start-Up

When you connect the Easyfield® with a PC for the first time, you will have to perform several set up steps.

To avoid communications problems, deactivate the power saver mode of the USB units of the operating system.

➔ Proceed as described in the *Software Installation*.

8 Daily operation

8.1 Switching on Easyfield®

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

➔ Wait until the operating system has started completely and the Patient Data Management screen appears.

➔ Switch on the Easyfield® at the On/Off switch.

8.2 Switching off Easyfield®

➔ Close the Easyfield® program and the Patient Data Management.

➔ Shut down the Windows operating system.

➔ Switch off the Easyfield® at the On/Off switch.

➔ After the exam, cover the unit with the provided dust hood.

9 Patient Data Management

Use the Patient Data Management to input and manipulate patient data.

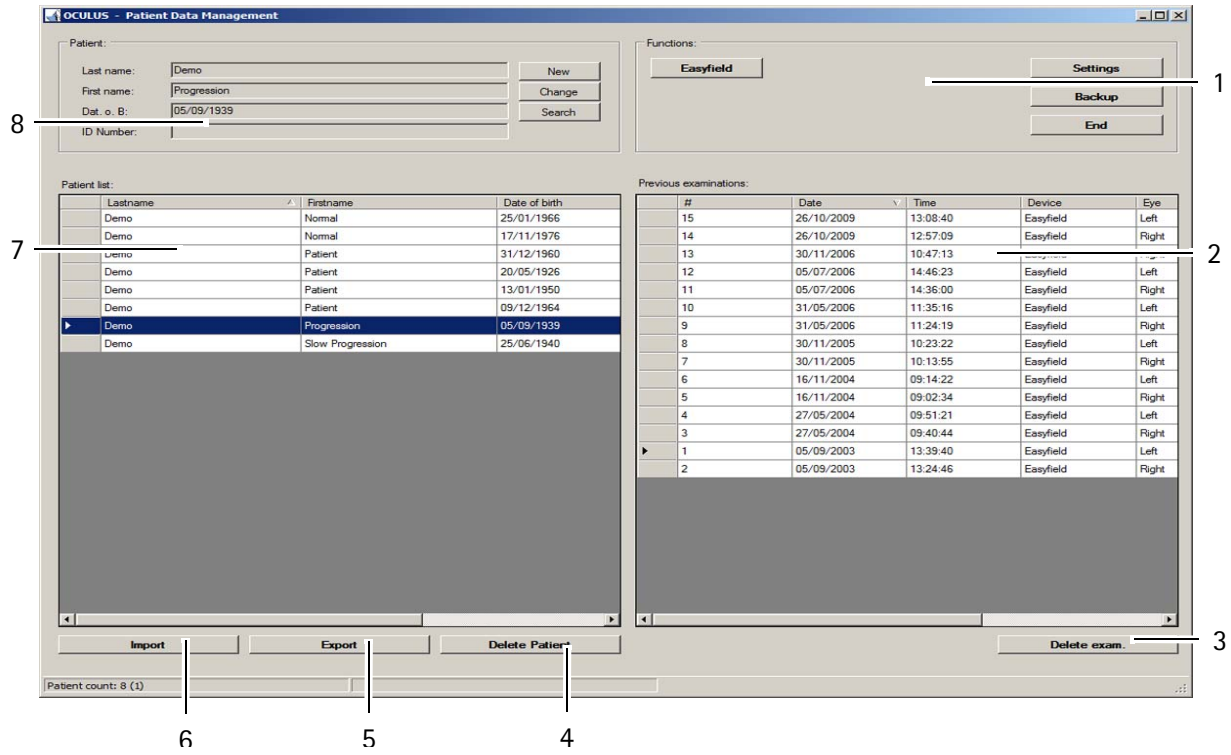
Additional functions of the Patient Data Management system are found in *sec. 12, page 35* and in the *User Guide*.

9.1 Starting Patient Data Management

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

➔ If necessary, click on the Easyfield® icon: .

The user interface for the Patient Data Management will be 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 data*

Fig. 9-1: User interface for Patient Data Management

In order to start the Easyfield® program, you must first enter a new patient (8) or select a patient already present in the patient list (7).

If the [Easyfield (16 bit)] button is displayed in the "Functions" group field, you can refer back to exams with the previous software of the Easyfield®. How to set this as a default option is described in the *User Guide*.

9.1.1 Enter a new patient

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

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

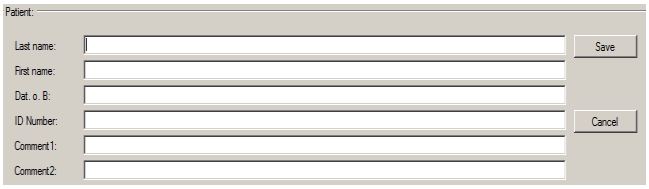


Fig. 9-2: Entering patients

Optionally, you can enter an ID number or additional comments for the patient.

➔ To save the data you entered, click [Save]. The patient you have just entered now appears in the patient list.

➔ Select the newly entered patient from the patient list and start the Easyfield® program.

9.1.2 Select an existing patient

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

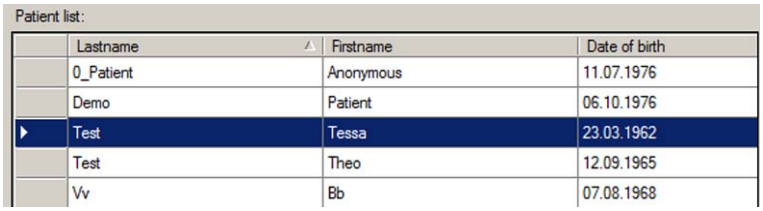


Fig. 9-3: Patient list

➔ Choose [Search] to quickly find the patient you are looking for in 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 using an ID number, assuming that one was assigned when the patient was first recorded.

➔ In the list, that appears, click the entry you were searching for to transfer the patient's name to the patient window. This also brings up a list of all previous examinations for that patient in the examination window (bottom right side).

Extended patient search: [Extended] checkbox

➔ Click on the checkbox [Extended].

The screen displays additional search parameters which reference previous examinations, for example. Proceed as for the input of a patient name.

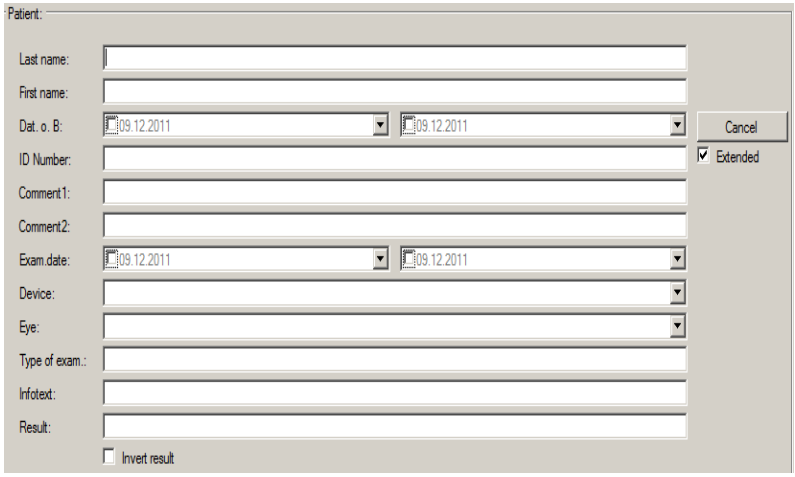


Fig. 9-4: Extended search

9.2 Starting the Easyfield® program

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

Fig. 9-5: Start the Easyfield® program

or

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

10 The Easyfield® program

You can get to the menu list from any screen of the Easyfield® program.

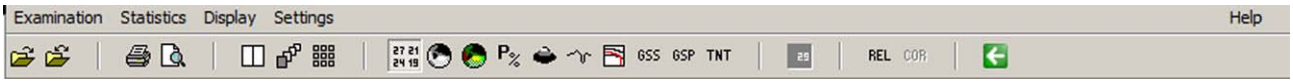


Fig. 10-1: Menu list with function buttons

The meaning and function of the individual symbols are found in the *User Guide*.

Loading previous examinations

➔ 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 Easyfield® program will load the examination you have selected.

11 Measurement Procedure

Caution

Risk of incorrect measurement due to incorrect use

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

11.1 Preparing the Examination

11.1.1 Selecting the Examination program

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

A description of how to write your own examination programs can be found in the *User Guide* of the Easyfield® perimeter.

11.1.2 Determining the Required Correction

Correct measurement of the differential light sensitivity is only possible if the individual test points are focused sharply on the retina. The patient may need suitable corrective lenses for this purpose. It is possible to wear contact lenses (not colored ones); in certain conditions the patient´s 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 opthalmic 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 years and older. The following are guidelines for this:

- **Aged 40 – 50 years:** approx. +1.00 D addition
- **Aged 50 – 60 years:** approx. +2.00 Daddition
- **Aged oved 60 years:** approx. +3.00 D addition

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

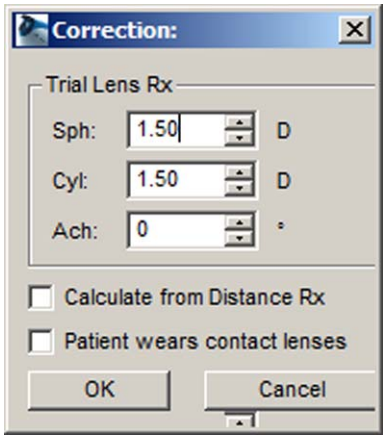


Fig. 11-1: Input of the known refraction values

➔ 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:

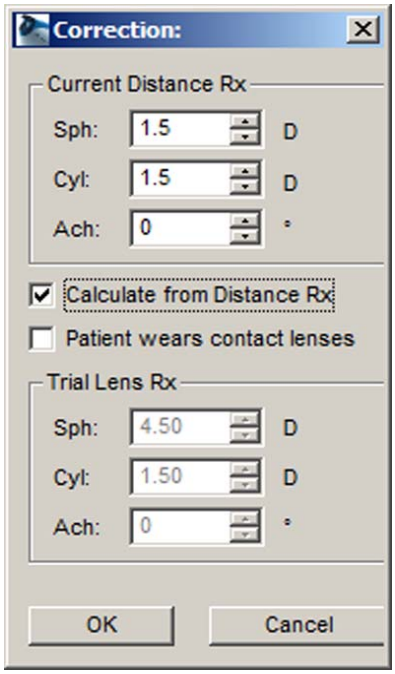


Fig. 11-2: Input of the correction when the checkbox [Calculate from Distance Rx] is activated

➔ 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].

11.1.3 Inserting the Corrective Lens

➔ Place the required trial lens with the previously determined corrective power into the lens holder included in the delivery.

➔ Fasten the lens holder to the perimeter cone of the Easyfield® perimeter using the available mounts.

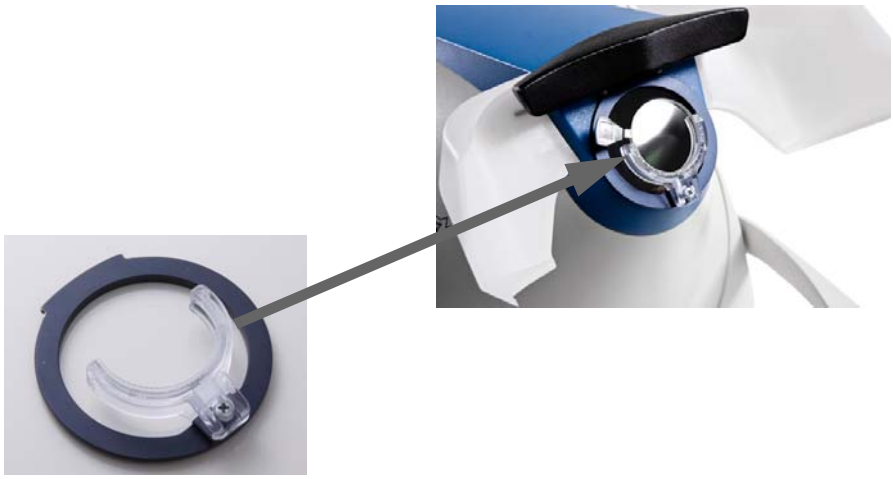


Fig. 11-3: Insert corrective lens holder with corrective lens.

11.1.4 Preparing the Patient

➔ Check that the forehead and chin rest and the hand held button have been cleaned and disinfect before each examination.

➔ Make sure 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 hand-held button for the unit and ask him to hold it in one hand.

➔ Ask the patient to comfortably take a seat in front of the unit. The patient should sit as upright as possible.

The eye shields allow to perform the examination without an eye patch.

Warning

Risk or personal injury during service or maintenance works

If you use the device during service or maintenance works (cleaning, disinfection and maintenance) personal injury may occur.

➔ Do not use the device during service or maintenance works.

11.1.5 Positioning the patient

➔ Do not touch the patient and the Easyfield® simultaneously.

1 Chin rest
2 Forehead rest
3 Moving cone
4 Adjusting knobs on the chin rest

Fig. 11-4: Positioning aids (Easyfield® C)

➔ Easyfield® C only:

Ask the patient to place his chin on the chin rest (1).

Adjust the moving cone (3) and the press the adjusting knobs on the chin rest (4) for the optimal positioning of the patient.

➔ Easyfield® S only:

Ask the patient to place his forehead on the forehead rest.

Adjust the moving cone for the optimal positioning of the patient.

➔ Make sure that the distance between the eye and the corrective lens, or the eye and the perimeter is no greater than 1 cm.

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

➔ Ask the patient to lean rest his forehead against the forehead rest (2) so that the fixation marks (four red dots) in the center of the perimeter bowl are clearly visible with the eye that is to be examined.

The patient is sitting in the correct position when the patient's pupil lies within the red rectangle of video monitor frame.

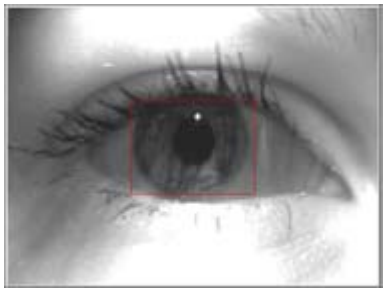


Fig. 11-6: Correct position: patient´s eye in the video frame

➔ During the whole examination: Check the correct position of the patient's pupil to get correct measurement results.

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

Note

Visual field losses in the upper area could be caused by improper positioning of the patient. If the distance from the eye to the perimeter is too large (because the patient is not positioned properly), the patient may not have a full view into the unit.

11.1.6 Positioning of the pupil

➔ Ask the patient to fixate on the middle of the four red points.

The pupil is correctly positioned when it is displayed in the red square.

Note

➔ If necessary, adjust the camera image settings in the Easyfield® program settings so that the movements of the eye are displayed in the convenient way (mirrored or not mirrored).

11.1.7 Measuring the Pupil

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

➔ Move the mouse pointer to the left edge of the pupil on the monitoring image.

➔ 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 Starting the examination

➔ Now instruct the patient to press the hand-held button every time a light spot is seen flashing.

➔ Explain to the patient the examination can be interrupted at any time by pressing and holding down the hand-held button. The examination is automatically resumed when the patient lets go of the hand-held button.

➔ Click on the button [Start Exam.].

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

The following dialog appears so that you can check the data that you have entered:

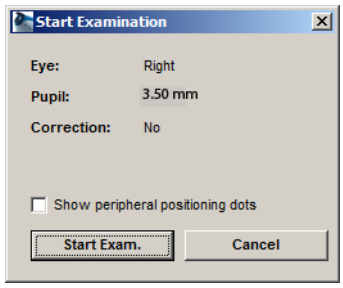


Fig. 11-8: Display of the general data

Recommendation:

➔ Activate the checkbox [Show peripheral positioning lights].

This function helps the self-positioning of the patient. The lighting LEDs form a luminous ring, if this ring is uniformly perceived, the positioning is correct.

➔ 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 [Start Exam.] button.

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

Fig. 11-9: Display of the measured threshold value

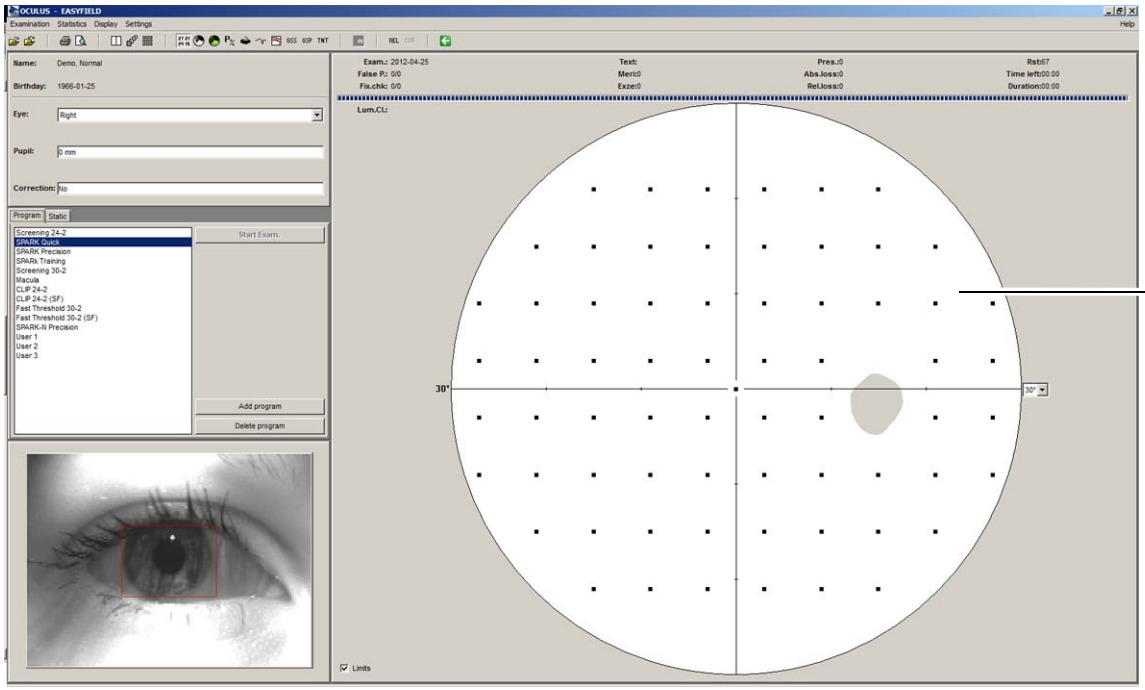
➔ If the measured threshold deviates considerably from the normal threshold for the age group, press the [Repeat] button.

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

The examination program that you selected will now start to run.

11.3 Interrupting the Examination

If you would like to interrupt the examination: the cursor must be located in the main frame of the Easyfield® program window.



1 Main frame of the Easyfield® program window

Fig. 11-10: Easyfield® program window

➔ Press the right mouse button.

The following dialog is displayed:

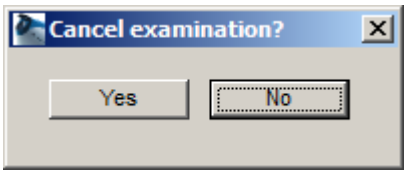


Fig. 11-11: Interrupting the examination

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

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

11.4 Ending the Examination

At the end of an examination, the following dialog box appears:

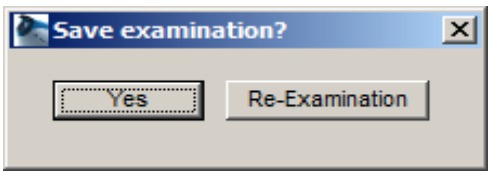


Fig. 11-12: Save the examination results

- ➔ Now decide how you want to proceed, based on the examination results.
- ➔ Tell the patient that the examination has been stopped and that the patient can relax.
- ➔ Disinfect the forehead and chin rest after each examination, *sec. 13.2, page 41*.
- ➔ Disinfect the hand held button after each examination, *sec. 13.2, page 41*.

11.4.1 Saving the Examination Data

If you are content with the findings, or you have already performed the desired re-examination, you can now save the examination results. To do this:

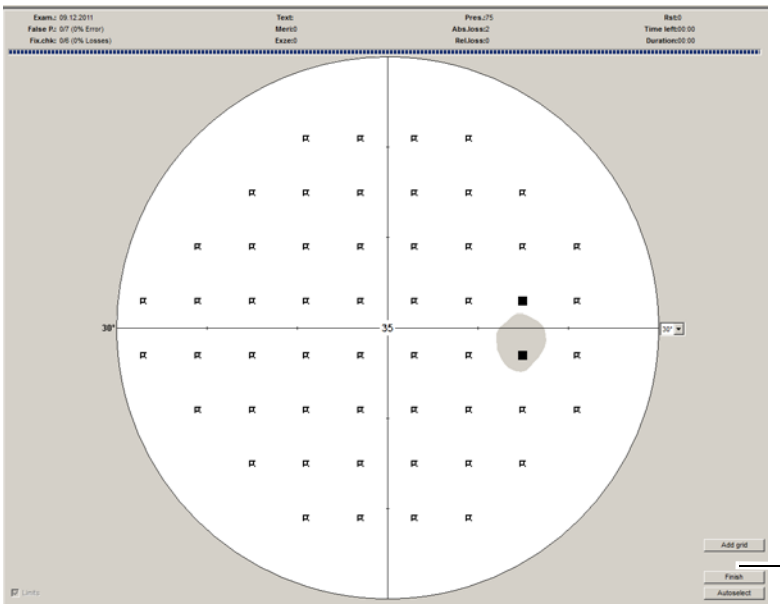
- ➔ Press the [Yes] button.

  The examination data are saved and can be reloaded again later via the Easyfield® program.

11.5 Performing a re-examination

If you want to check peculiar test points, you can conduct a re-examination. Proceed as follows:

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



1 Additional buttons
Fig. 11-13: Additional buttons for a re-examination

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

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

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

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

➔ Then click in the test point grid to define the additional test points.

➔ Press the [Add grid] button to add a predefined grid of test points.
In this case, an additional dialog appears in which you can select the test point grid:

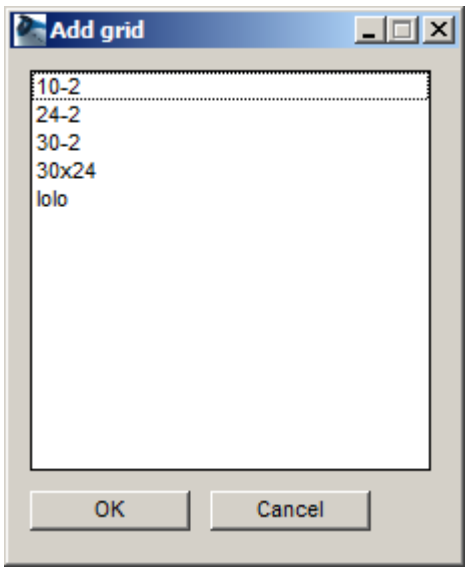


Fig. 11-14: Selection of the grid that is to be added for re-examination purposes

➔ 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 will be displayed:

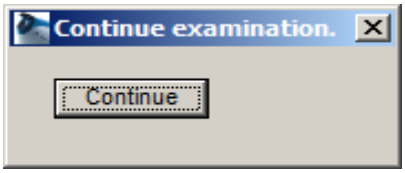


Fig. 11-15: Dialog "Continue examination"

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

After finishing the re-examination, a dialog box appears, asking whether you want to save the examination results *(fig. 11-12, page 32)*.

12 Working with the Patient Data Management system

This section describes how to work with the Patient Data Management system

- Rename it, *sec. 12.1, page 35*
- Export it, *sec. 12.2, page 35*
- Import it, *sec. 12.3, page 36*
- Save it, *sec. 12.4, page 38*

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

12.1 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.

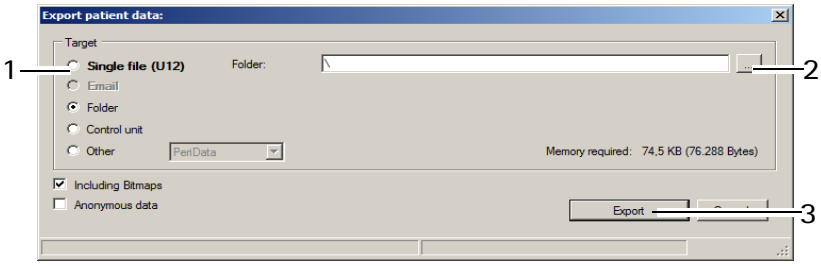
➔ Press the [Save] button.

12.2 Exporting Patient Data

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

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

➔ Press the [Export] button below the patients list. The following dialog will be displayed.



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

Fig. 12-1: "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 (e.g. 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) to select a folder.

➔ In the dialog that appears, select the folder or the file to which the patient data should be exported, e.g. B. TOPO.DAT for data and TOPO.BMP for the pictures.

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

➔ To export the data, press the [Export] button (3).

12.3 Importing Patient Data

In case you keep patient data on a USB stick, you can import this data. The patient data must be saved with a version of the Patient Data Management system which can be read by the version of the Patient Data Management system running on your device. This means that the version of Patient Data Management system on your device must be at the same status or later than the version used to save the patient data on the USB stick.

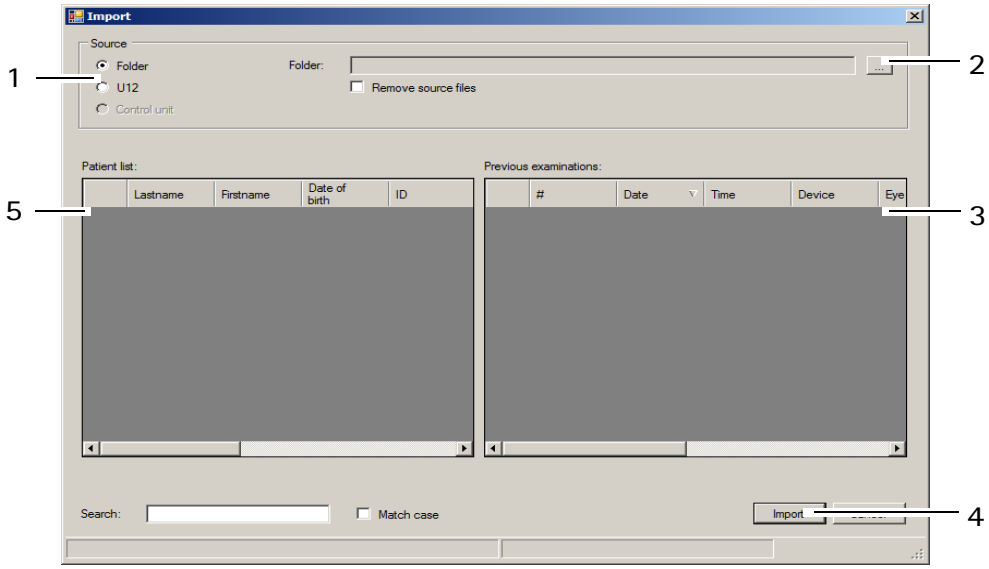
Note

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. 12-2: "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.

12.4 Data Backup

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

Note

Risk of loss of data due to computer viruses

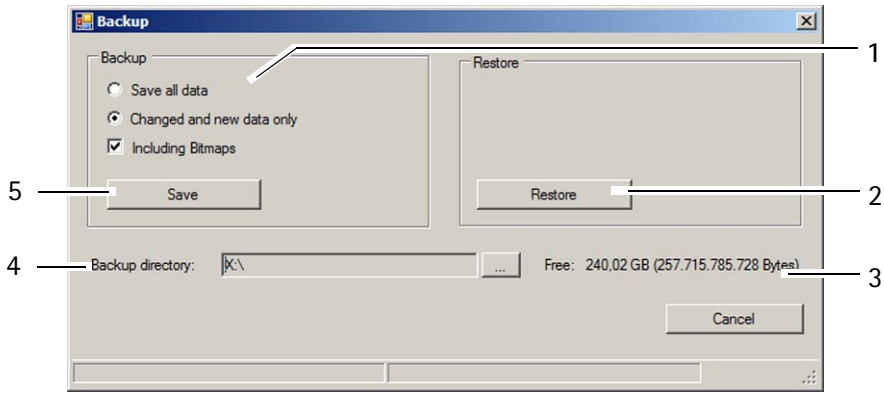
Computer viruses can cause loss of data.

➔ Run a virus check before making a backup to a USB flash drive.

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

12.4.1 Backup Data

➔ Press the [Backup] button at the top right of the Patient Data Management system. The following dialog is displayed:



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

Fig. 12-3: "Backup" dialog

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

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

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

- ➔ Press the [...] button to the right of the "Backup directory" box (4).
- ➔ In the dialog that appears, select the folder to which the data should be backed up.
- ➔ Confirm your selection with [OK].
- ➔ To back up the data, press the [Save] button (5). The previously selected data will then be backed up to the corresponding folder.

12.4.2 Reconstructing Data

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

- ➔ Press the [...] button.
- ➔ In the dialog that appears, select the folder which contains the backup data.
- ➔ Confirm your selection with [OK].
- ➔ To import the data, press the [Restore] button (2). All data in the appropriate directory are copied to the Patient Data Management system.

12.4.3 Automatic Backup

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

13 Cleaning, disinfection and maintenance

This section describes how to clean and disinfect the Easyfield®.

Sterilization is not required.

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

Warning

Risk or personal injury during service or maintenance works

If you use the device during service or maintenance works (cleaning, disinfection and maintenance) personal injury may occur.

➔ Do not use the device during service or maintenance works.

13.1 Cleaning

Caution

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

➔ Turn the Easyfield® off, *sec. 8.2, page 19*.

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

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

Required materials:

- Anti-static cleaner for plastic surfaces
- Cleaner for painted surfaces: mixture of equal parts mineral spirits and distilled water, with a few drops of household detergent if needed
- Soft cloth or lens brush
- Alcohol or lens cleaner

Cleaning inervalls

➔ Clean the chin support and forehead rest after each examination; clean the housing as needed.

➔ Clean the hand held button after each examination.

Cleaning

- ➔ Switch off the Easyfield®, *sec. 8.2, page 19*.
- ➔ Disconnect the power plug.
- ➔ When cleaning, use a damp cloth and make sure that no liquid enters the Easyfield®.
- ➔ Clean the plastic surfaces with the appropriate cleaner.
- ➔ Clean the painted surfaces with the cleaner for painted surfaces.
- ➔ Clean the lenses in the perimeter cone with a soft cloth or lens brush. Use alcohol or a lens cleaner if needed.

13.2 Disinfection

Caution

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

- ➔ Turn the Easyfield® off, *sec. 8.2, page 19*.
- ➔ Pull the power plug before cleaning. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

Required materials (recommended) or an equivalent:

Pursept®-A Xpress disinfectant cloths,
Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt I Deutschland
Telefon: +49 40 52100-0
Telefax: +49 40 52100-318
E-Mail: info@schuelke.com
https://www.schuelke.com/de-de/index.php

- ➔ Disinfect the forehead and chin rest after each examination; disinfect the housing as needed.
- ➔ Disinfect the hand held button after each examination.
- ➔ Disinfect the eyepatch after each use.

13.3 Maintenance

To ensure safe and reliable operation, we recommend the following:

➔ Have the Easyfield® checked every two years by our service department or an authorized dealer.

Note

Damaged equipment will result in erroneous examinations

If you use a damaged unit, the examination result may be incorrect.

If an error occurs that you cannot correct:

➔ Identify a damaged Easyfield® as being out of service.

➔ Report the damage to OCULUS Service department or to your authorized dealer.

➔ Only use an undamaged Easyfield®.

14 Troubleshooting

Caution

Personal injury or equipment damage due to improper troubleshooting.

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

Equipment damage due to improper operation

➔ Never connect or disconnect cables or plug-in when the PC or the Easyfield® is switched on. This can cause destruction of connected equipment.

Fault	Possible Cause	Remedy
No function when the power switch is pressed or the pilot lamp on the power switch does not light up.	The Easyfield® perimeter is not connected to the power supply. Power failure or power outlet is not active	Plug the power cable into the power outlet, or the inlet connector into the jack at the Easyfield® perimeter. Inform the in-house electrician.
No function when the power switch is pressed but the pilot lamp on the power switch lights up.	USB- or serial cable to the PC is not connected properly. The unit has been switched off and back on again too quickly.	Check that the connector is plugged in properly. Wait approx. 5 seconds before turning the unit back on again.
Hand-held button does not respond 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)*.
Background illumination not active.	Unit is in standby mode	Move the mouse, or press any key.

15 Transport and storage

The Easyfield®must be properly dismounted and packed before being transported or stored.

15.1 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, *sec. 8.2, page 19*.
- ➔ Disconnect the connections to the hand-held button, to the netbook/PC/laptop.

  When disconnecting, pull on the respective plug and not on the cable itself.
- ➔ Pack up the Easyfield® in the original packing.

15.2 Transport and Storage Information

Storage

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

Transport

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

After transport and/or storage

➔ Wait approx. 3-4 hours after transport before putting the Easyfield® into initial operation. Extreme temperature changes from cold areas to warm rooms can cause condensation on the optical components.

Note

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

➔ Avoid shocks, vibrations, and contamination.

➔ Avoid high temperatures and humidity.

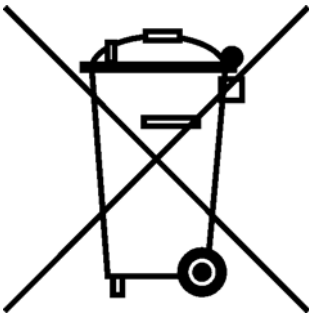
➔ Transport the Easyfield® in an appropriate manner.

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

➔ Do not store the unit near heating elements or moisture.

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

16 Disposal



In accordance with Directive 2012/19/EC of the European Parliament and the 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® in an appropriate manner.

17 Terms of Warranty and Servicing

17.1 Terms of warranty

The Easyfield® 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 Easyfield® carries a warranty to which you are entitled in accordance with the legal provisions.
- If any unauthorized persons interfere with the Easyfield®, 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.

17.2 Assumption of liability for functions and damage

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

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

- There are no user-serviceable parts either on or inside the Easyfield® . OCULUS shall not assume any liability if assembly, extensions, adjustments, changes or repairs are carried out by unauthorized personnel, if the Easyfield® 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.

17.3 Manufacturer's address and service department:

Our service department or authorized representatives will provide you with additional information. Address of the manufacturer and service department:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar
GERMANY
Tel.: +49 641 2005-0
Fax: +49 641 2005-295
E-mail: export@oculus.de
www.oculus.de

USA:

OCULUS, Inc.
17721 59th Avenue NE
Arlington
WA 98223
Tel. +1 425 670 9977
Fax +1 425 670 0742
E-mail: sales@oculususa.com
www.oculususa.com

18 Technical Data

Measuring equipment

Weight	
■ Easyfield® S	4.6 kg (10.2 lb
■ Easyfield® C (mit Kinnstütze)	7.4 kg (16.3 lbs)
Dimensions (W x D x H)	
■ Easyfield® S	274 x 370 – 470 x 314 – 429 mm (10.8 x 14.6 – 18.5 x 12.4 – 16.9 in)
■ Easyfield® C (with chinrest)	316 x 506 – 540 x 320 – 435 mm (12.4 x 19.9 –21.3 x 12.6 – 17.1 in)
Interface	USB, RS232
Perimeter bowl radius	300 mm
Meridian	Adjustable from 0°-360°
Max. eccentricity	30°
Max. power consumption	25 W
Life expectancy	10 years

Measuring parameters

Stimulus	
■ Stimulus size	Goldmann III
■ Stimulus colour	white
■ Stimulus duration	200 ms/user-defined (0,2 s/0,5 s/0,8 s/adaptive)
■ Stimulus luminance range L_s/increments	0 – 3180 cd/m² (0 – 10 000 asb)/1 dB
■ Examination speed	adaptive / fast / normal / slow / user-defined
Background	
■ Luminance	10 cd/m² (31,4 asb)
■ Colour	white
■ LEDs	12, WU-7-730SWC, 2800 mcd, 20 mA

Power adapter

Power adapter	GSM40B12-P1J (05150805)
Mains connection	80 – 264 V AC 1 — 0,5 A
Frequency	47 – 63 Hz
Max. power consumption	46 W
DC output	12 V 3,34 A 40 W max.
Fuses	integrated over current shut-off

Classification per DIN EN ISO 60601 - 1 (VDE 0750)

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

Storage requirements

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

Transport requirements

Ambient temperature	-40°C to +70°C
Relative humidity, including condensation	10% to 95%
Air pressure	500 hPa to1060 hPa

Computer

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

Recommended computer specifications	Windows 7 Pro, Intel® Core™ i5, 4 GB memory; 500 GB HDD , Intel® HD Graphics 520

CE in accordance with directive 93 / 42 / EWG for Medical Devices

The unit is a Class I product.

CE

Conformity assessment: Directive 93/42 / EEC: annex VII

19 Annex

19.1 Electromagnetic Compatibility

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

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

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

Minimal performance quality and essential performance criteria

- A slightly disturbance of the analog camera of the Easyfield® (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 Easyfield® 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 Easyfield®.

➔ 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 Easyfield® 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 Easyfield®.

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	
15000	OCULUS-Easyfield® C	
15005	OCULUS-Easyfield® S	
05200320	Cable with connector plug, EU standard	2.5m
05200210 (110 Volt)	Cable with connector plug, US standard	2.5m
015692000010	USB FS Med isolator	
05150805	Power supply GSM40B12-P1J	see *"Power adapter" page 49*

19.2 Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions and Immunity for the Easyfield®

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2, 5.2.2.1, table 1		
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.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Easyfield® 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	

Guidance and manufacturer´s declaration electromagentic immunity, IEC 60601-1-2, 5.2.2.1, table 2

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidlines
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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%.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV kine(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40 % U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 s	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40 % U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Easyfield® requires continued operation during power mains interruptions, it is recommended that the Easyfield® be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer´s declaration electromagentic immunity,
IEC 60601-1-2, 5.2.2.2, table 4

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – Guidelines
			Portable and mobile RF communications equipment should be used no closer to any part of Easyfield®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 Mhz	V_{rms}= 3 V	$d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E = 3 V/m	$d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 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). Interface may occur in the vicinity of equipment marked with the following symbol: 

Note 1:	At 80 Hz and 800 MHz, the higher frequency range applies.
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Easyfield® is used exceeds the applicable RF compliance level above, 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 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 Easyfield®, IEC 60601-1-2, 5.2.2.2, table 6

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

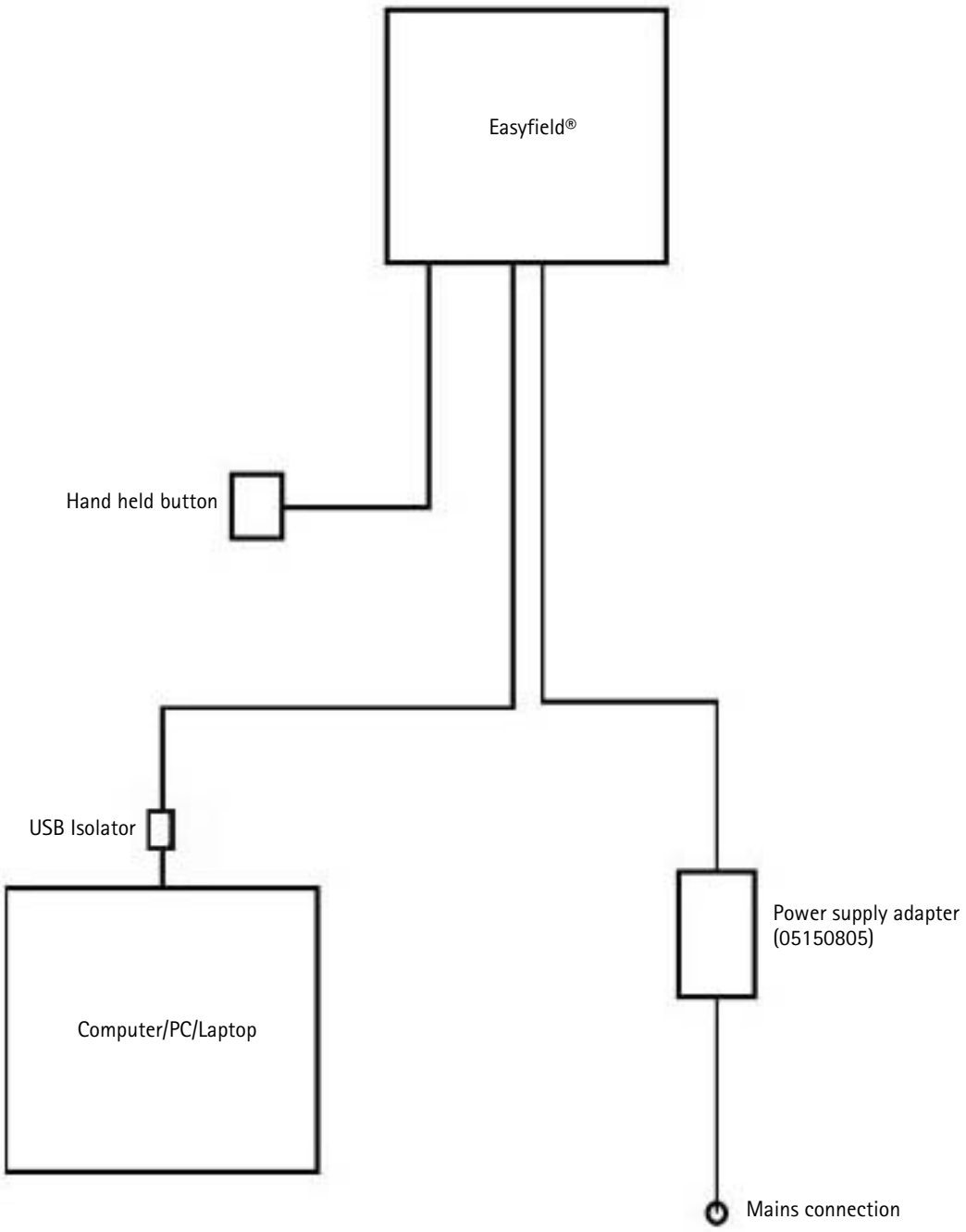
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

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

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

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

19.3 Description of the Connection



19.4 Data Sheet GSM40B12-P1J (05150805)

MEAN WELL 40W AC-DC High Reliability Medical Adaptor **GSM40B series**

(Ⅴ for 5~9V)

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 <50uA
- No load power consumption<0.1W
- Energy efficiency level VI(Except 5~9V for Level V)
- 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

GSM40B is a highly reliable, 40W 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 5VDC 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 (<50 uA), 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 0.1W, GSM40B 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. GSM40B is approved with the international medical safety certificates.

Model Encoding

GSM40 B 05 - P1J

- P1J: DC plug type — P1J: Plug for standard model,2.1ψ x5.5ψ x11mm,c+,tuning fork type; Optional plug type available by customer requested
- 05: Output voltage
- B: IEC320-C8 AC inlet
- 40: Output wattage
- GSM: Series name

File Name:GSM40B-SPEC 2016-03-16

MEAN WELL 40W AC-DC High Reliability Medical Adaptor **GSM40B series**

SPECIFICATION

ORDER NO.		GSM40B05-P1J	GSM40B07-P1J	GSM40B09-P1J	GSM40B12-P1J	GSM40B15-P1J	GSM40B18-P1J	GSM40B24-P1J	GSM40B48-P1J
OUTPUT	SAFETY MODEL NO.	GSM40B05	GSM40B07	GSM40B09	GSM40B12	GSM40B15	GSM40B18	GSM40B24	GSM40B48
	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 ~ 5A	0 ~ 5.34A	0 ~ 4.45A	0 ~ 3.34A	0 ~ 2.67A	0 ~ 2.22A	0 ~ 1.67A	0 ~ 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.6	1000ms, 30ms / 230VAC 1500ms, 30ms / 115VAC at full load							
	HOLD UP TIME (Typ.)	50ms / 230VAC 15ms / 115VAC at full load							
INPUT	VOLTAGE RANGE Note.7	80 ~ 264VAC 113 ~ 370VDC							
	FREQUENCY RANGE	47 ~ 63Hz							
	EFFICIENCY (Typ.)	81%	85.5%	86%	88%	88.5%	89%	90%	91%
	AC CURRENT (Typ.)	1A / 115VAC 0.5A / 230VAC							
	INRUSH CURRENT (Typ.)	30A / 115VAC 65A / 230VAC							
	LEAKAGE CURRENT(max.)	Touch current < 50μA/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. 8)	SAFETY STANDARDS	ANSI/AAMI ES60601-1 / ES60601-1-11, TUV EN60601-1 / 60601-1-11 approved							
	ISOLATION LEVEL	Primary-Secondary: 2xMOPP							
	WITHSTAND VOLTAGE	I/P-O/P:4KVAC O/P-FG:SHORT							
	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	740K hrs min. MIL-HDBK-217F(25℃)							
	DIMENSION	125*50*31.5mm (L*W*H)							
	PACKING	0.29Kg; 40pcs/12.6Kg/1.05CUFT							
CONNECTOR	PLUG	See page 3 ; Other type available by customer requested							
	CABLE	See page 3 ; Other type available by customer requested							

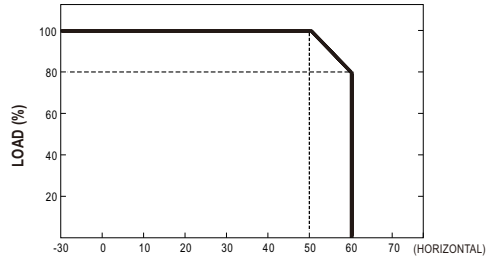
NOTE

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 voltages. Pleas 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)

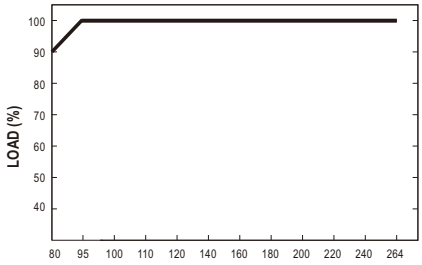
File Name:GSM40B-SPEC 2016-03-16

MEAN WELL 40W AC-DC High Reliability Medical Adaptor **GSM40B series**

■ Derating Curve

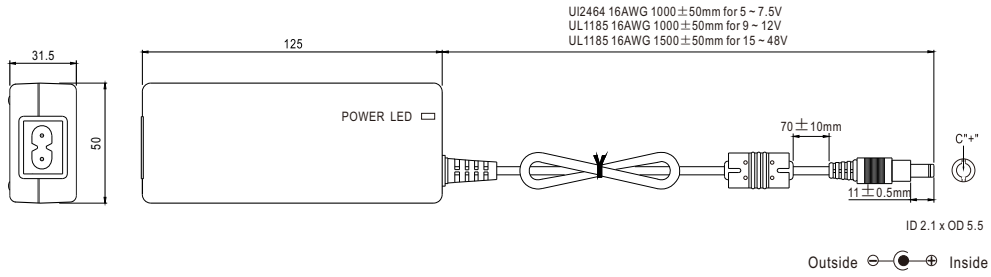


■ Static Characteristics



■ Mechanical Specification

Case No. GSM60B Unit:mm



■ Plug Assignment

Standard plug: P1J

P1J	
P/N	OUTPUT
CENTER	+

Optional lock type plug: P2S

SWITCHCRAFT S761K plug equivalent

■ Installation Manual

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

File Name:GSM40B-SPEC 2016-03-16

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