OCULUS Smartfield

INSTRUCTION MANUAL

Examination of the Central Visual Field up to 60° Eccentricity

OCULUS®

Notes on this instruction manual

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

The Smartfield Perimeter instruction manual will provide you with extensive information, especially about the evaluation programs and display of the examination results.

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

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

OCULUS Optikgeräte GmbH

OCULUS is certified according to DIN EN 13485, setting high standards of quality for the development, manufacture, quality assurance and service of the entire range of products.

Table of Contents

1 Delivery and Packing List

Product and accessories	Order Number
OCULUS Smartfield	14000
■ Instruction Manual	G/14000/XXXX/EN 1219 Rev01
■ Software Installation	SI/50000/xxxx/en
Accessories consisting of	
■ Dust protection cover	02150001101
■ Network cable	05200315
■ Lens holder	081500007000
■ Trial lenses	55903
■ Power supply unit GSM40B12-P1J	05150805
■ Cable with plug, EU Standard	05200320
■ Cable with plug, US Standard	05200210
■ Cable with plug, GB Standard	05200211
■ Cable with plug, Australia Standard	05200212
Optional accessories	
■ Compact Laptop Stand	37499

- If transport damage is discovered from the shipment, please file a complaint with the shipping company immediately.
- Have the damage confirmed on the bill of lading so that an orderly handling of the complaint for damages is possible.
- Keep the packaging for any subsequent transport, for example in case of repairs.

Note

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

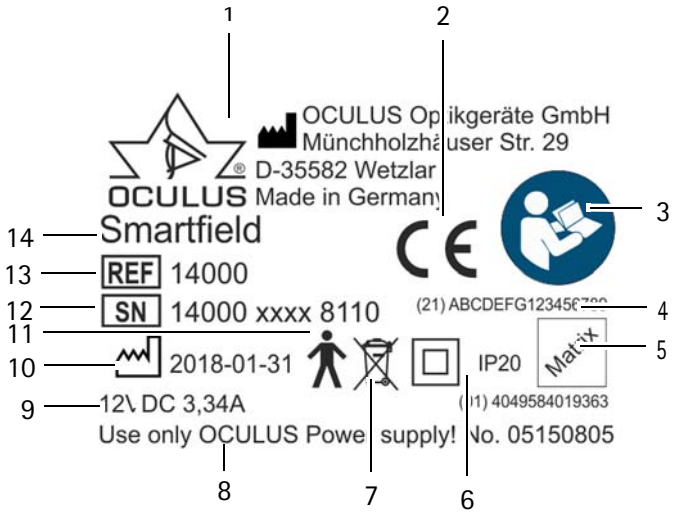
1.1 Software Version

This Instruction Manual describes the following Smartfield software versions and the Patient Data Management system:

- Smartfield software: from version 3.19r1477
- Patient Data Management: from version 6.08

- The Patient Data Management software version is shown on the "Settings" screen" **within the Patient Data Management** program.
- The software version of the Smartfield program is shown on the "Change Settings" screen within the Smartfield program.

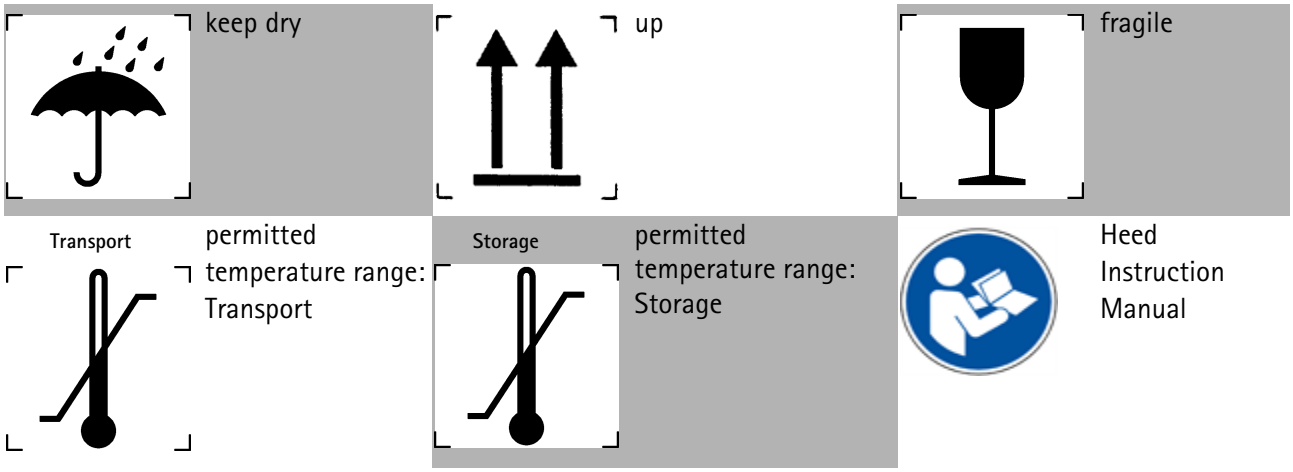
2 Graphic Symbols on the Equipment



1	*Manufacturer*	8	*Power supply unit number*
2	*CE Conformité Européenne*	9	*Power supply unit voltage*
3	*Heed Instruction Manual*	10	*Date of manufacture*
4	*Matrix to identify the device*	11	*Type B unit*
5	*UDI number*	12	*Serial number of the device*
6	*Protection class and degree of protection*	13	*Reference number*
7	*Disposal in household trash is prohibited*	14	*Name of device*

Fig. 2-1: Symbols Smartfield

Symbols on packaging



3 Structure of the Documentation

A folder containing a set of documentation is supplied with your Smartfield Perimeter:

- **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 Smartfield Perimeter.

Caution

All safety-related instructions for use of the Smartfield 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 Smartfield Perimeter.

4 Safety Instructions

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

4.1 About this Manual

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

4.1.1 Used Graphic Symbols

Warning

Identifies a potentially dangerous situation which may cause serious bodily injuries.

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 use, which require special attention.

> This symbol denotes menu paths and screen shots. Example: Call up a new patient:

➔ Smartfield > Examination> New Patient

which means:

➔ Open the Smartfield program.

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

➔ Click on "New Patient".

4.2 Safety Instructions for Use

Caution

Risk of personal injury or property damage due to improper operation

➔ Observe the following safety instructions.

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

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

Warning

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

Changes or modifications may be made to this device only by OCULUS or an authorized dealer.

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

Instructions for operating personnel

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

Transport and storage instructions

Refer to the notes in *sect. 15, page 36*.

Instructions for setup and connection

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

- Do not use or store the Smartfield in rooms that are humid.
- Keep the Smartfield away from water that may drip, surge or splash on it, and make sure that no liquids can enter the Smartfield. Do not place any containers with liquid either close to or on the Smartfield.
- Only operate the Smartfield in rooms used for medical purposes after they have been set up according to the VDE Regulations 0100-710.
- Do not operate the equipment included in the packing list in explosive environments, in the presence of combustible anesthetics, or volatile solvents such as alcohol, benzene, etc.
- Only use a power cord which meets the requirements of the standards IEC 60227-1, Type 53, min. 0,75 m^2 and IEC 60320-1.
- Set up the Smartfield 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 use excessive force when connecting the electrical plug. If a connection is not possible, check whether the plug fits the jack. If you find damage to the plug connector, have the damage corrected by our service department.

Patient environment information

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

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.

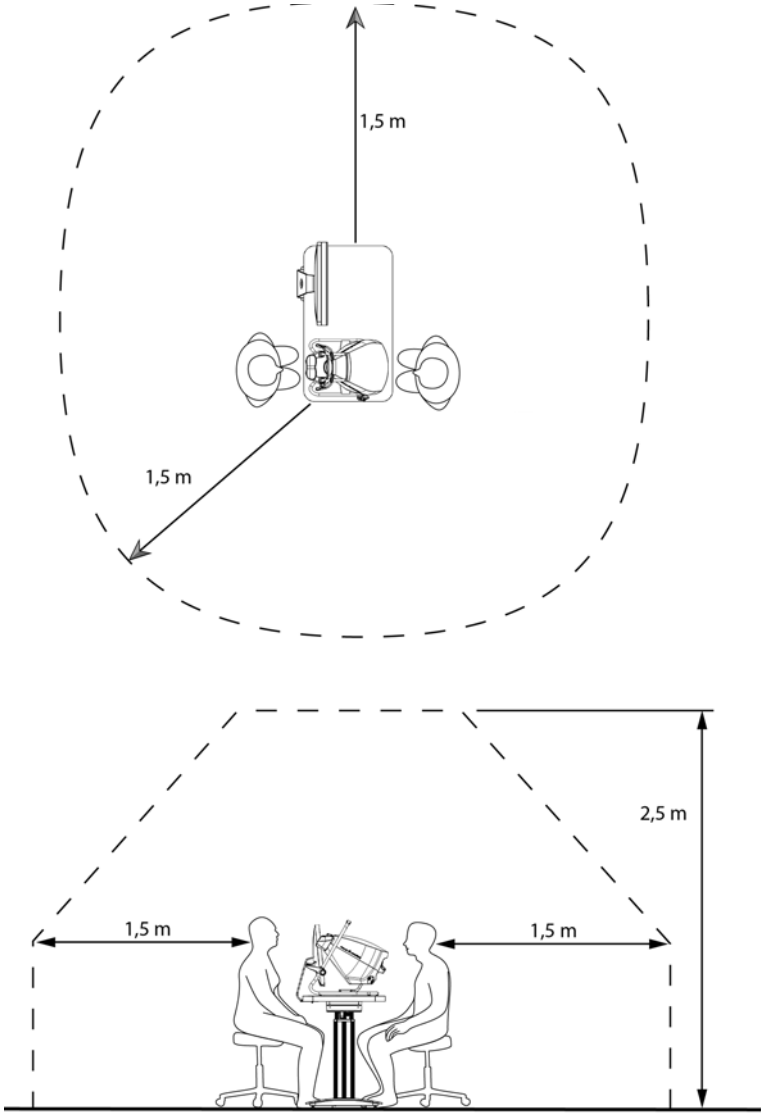


Fig. 4-1: Patient environment

Information about the operation of an ME system

The Smartfield 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

➔ Never put a damaged Smartfield into operation.

➔ Only operate the Smartfield using original accessory parts supplied by us, and when the device is in technically perfect working order. Only use the power supply unit listed in the packing list.

- ➔ Before initial operation: Let OCULUS or an authorized dealer train you in the operation of the Smartfield.
- ➔ Do not touch the patient and the device simultaneously.
- ➔ Make sure that the device cannot tip over, e.g. if it is leaned against or sat on.
- ➔ Only operate the equipment after your have read and understood the Instruction Manual.

Instructions for maintenance

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

Instructions for disassembly and disposal

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

Note on electrical safety

Caution

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

Connecting the Smartfield with non-medical electrical equipment (e.g. data processing equipment) to form 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 supply unit listed in the packing list.
- ➔ Use only a computer that meets the specifications given in this Instruction Manual, *sect. 18, page 40*.

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 Smartfield to the power supply, you must heed the following information:

- ➔ Use a multiple socket extension cord that complies with the requirements of DIN EN ISO 60601-1:2005 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 Smartfield 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 cord it has to be supplied via an isolation transformer.
If you are using a new computer for the Smartfield, 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, *sect. 19, page 43*.

- ➔ 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 Smartfield functions correctly.

Cybersecurity

Do not use the Smartfield 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 "Smartfield).
- ➔ 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 Proper Use

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

The Smartfield offers pre-programmed combinations for often needed examination routines. For example: SPARK, Macula 10-2, Neuro 30x24, Screening 30x24, Periphery 60°. 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 Smartfield Perimeter. Only operate the device using original accessory parts supplied by us, with the power supply unit listed in this manual and when the device is in technically perfect working order.

➔ Make certain that the following connection types are used for the power supply:

Contraindication

None known

6 Device Description

1 *Handle*
2 *Forehead rest*
3 *Viewer with receptacle for corrective lens holder*
4 *Smartfield occluder*
5 *Hand-held pushbutton*
6 *Chin rest*
7 *Chin rest adjustment knob*
8 *On/Off switch*
9 *Port for external power supply*
10 *Connector for hand-held pushbutton*
11 *RJ45 connector for network*

Fig. 6-1: Equipment overview Smartfield

6.1 Operation of the Smartfield

The Oculus Smartfield has been designed for combined use as a screening unit with all perimetrical 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 Smartfield offers pre-programmed combinations for often needed examination routines. For example: SPARK, Macula 10-2, Neuro 30x24, Screening 30x24, Periphery 60°. You can also combine your own routines and then save them as a program.

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

Viewer: Due to the enclosed viewer it is not necessary to darken the room.

Chin rest: The adjustable chin rest ensures 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 Smartfield 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.
- Smartfield 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

Data misuse

OCULUS Optikgeräte GmbH shall not be liable in any form for further use of the data recorded with the Smartfield or for any calculations based thereon.

7 Preliminary Steps

Before the Smartfield is operated for the first time, you must complete the following actions:

- Install the software, *sect. 7.1, page 14*
- Set up the Smartfield, *sect. 7.2, page 14*
- Connect the Smartfield, *sect. 7.3, page 15*
- Ensure operational readiness, *sect. 7.4, page 16*

Caution

Risk of incorrect measurements/equipment damage due to improper set-up

➔ Before first use, make sure the installation and connection of the Smartfield are completed by our service or by a professional authorized by OCULUS.

7.1 Software Installation

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

- Patient Data Management
- Smartfield program
- TNT program

➔ Proceed as described in the *Software Installation*.

➔ After installing the software, shut down the PC or the laptop.

7.2 Setup

The ambient conditions for operation are given in *"Ambient conditions" on page 41*.

➔ Remove the Smartfield from the packaging.

➔ Place the Smartfield on a level surface.

7.3 Connecting

You must connect the Smartfield to the power grid and, depending on the version, to the netbook, the laptop, or the PC. Connection and set-up will be demonstrated using the example of a netbook connection.

Warning

Electrical safety hazard

➔ In order to avoid the risk of electric shock, this device may only be connected to a power supply with a protective earth conductor.

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 Smartfield immediately adjacent to other devices and do not stack it with other devices.

➔ Only use the power supply unit listed in the packing list, *sect. 18, page 40*.

➔ If you use a multiple socket extension cord to connect the Smartfield: Use a multiple socket extension cord that complies with the requirements of DIN EN ISO 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 Smartfield and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

➔ Use a power socket that has a flawless earth conductor connection.

Note

Risk of equipment damage due to incorrect connection

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

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

➔ Please pay attention to the specifications on the nameplate.

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

➔ Connect the hand-held pushbutton (3).

➔ Connect the netbook (1).

1 RJ45 connector for network
2 Connector for external power supply
3 Connector for the hand-held pushbutton

Fig. 7-1: Connecting with the netbook

➔ Connect the device to the mains (2).

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

If you are working with a netbook, you can skip the following steps. Proceed as described in *sect. 8, page 17*.

7.4 Setup Jobs for Initial Start-Up

When you connect the Smartfield to a PC for the first time, you will have to perform several alignment steps.

➔ Proceed as described in the *Software Installation*.

8 Daily Start-Up

8.1 Switching on Smartfield

- ➔ Switch on the netbook, PC or laptop.
- ➔ Wait until the operating system has booted up fully and the Patient Data Management screen appears.
- ➔ Switch on the Smartfield at the On / Off switch.
  When you hear a beep, the unit is ready for operation.

8.2 Switching off Smartfield

- ➔ Close the Smartfield program and Patient Data Management.
- ➔ Shut down the Windows operating system.
- ➔ Turn off the Smartfield with the On / Off switch.
- ➔ After the exam, cover the unit with the provided dust cover.

9 Patient Data Management

You can enter patient data in the Patient Data Management system and then use it.

Additional functions of the Patient Data Management system are found in *sect. 12, page 30*.

The control unit has its own patient management system. If you have a control unit, you can use it to enter or retrieve patient data.

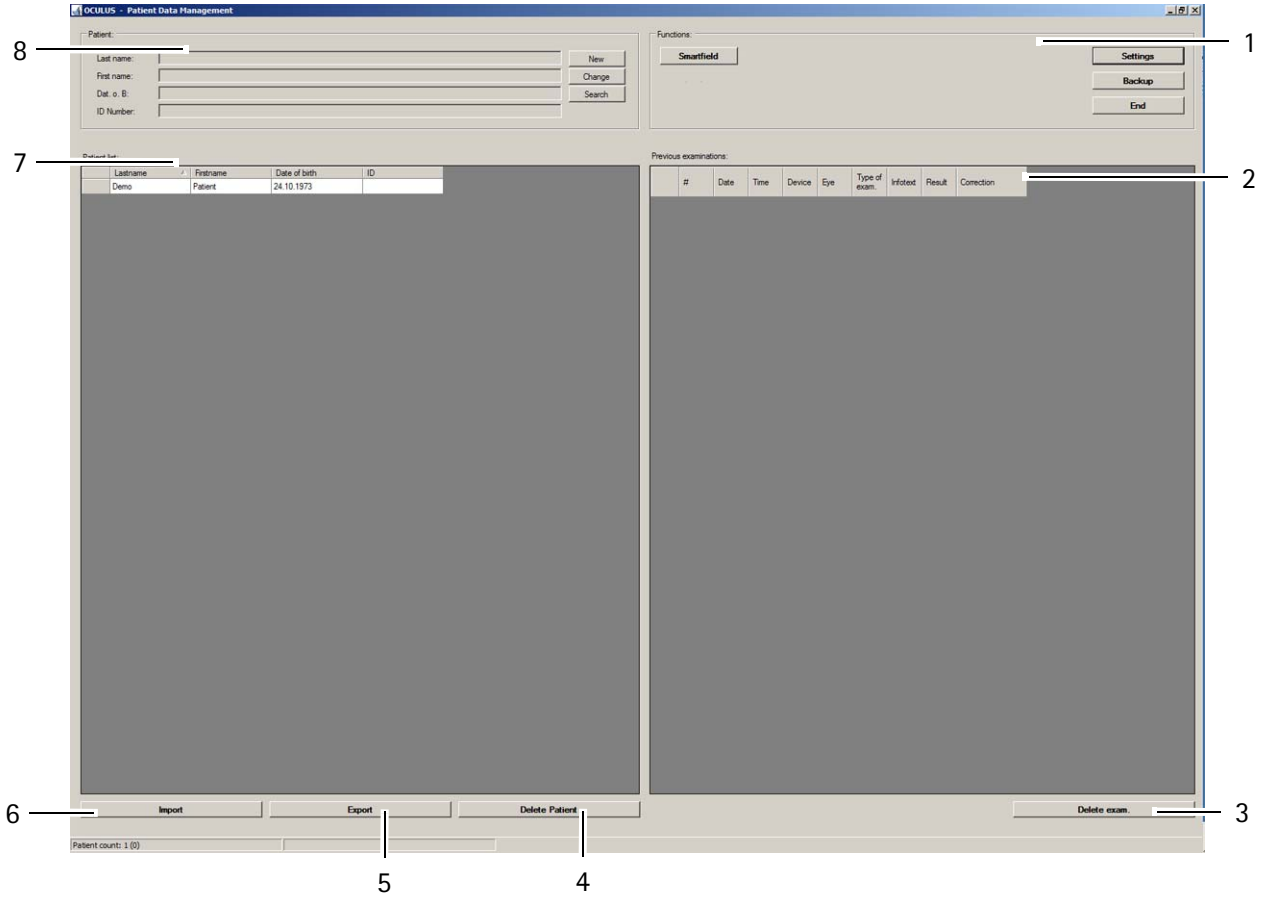
➔ Proceed as described in *sect. 13, page 33*.

9.1 Starting the Patient Data Management

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

➔ If necessary, click on the Smartfield icon: .

The user interface for the Patient Data Management system appears.



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

To get to the Smartfield program, you must first enter a new patient (8) or select an existing patient from the patient list (7).

If the [Smartfield (16 bit)] button is displayed in the "Functions" group box, you can refer back to exams with the previous software of the Smartfield.

9.1.1 Entering a New Patient

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

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

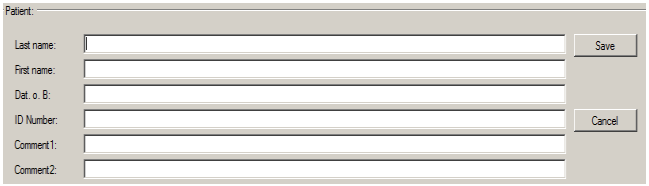


Fig. 9-2: Entering patients

Optionally you can enter an ID number for the patient.

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

➔ Select this new patient from the patient list and start the Smartfield program.

9.1.2 Selecting an Existing Patient

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

➔ 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.

Alternatively, you can search for the patient using an ID number, assuming that one was assigned when the patient was first recorded.

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

Extended patient search: [Extended] checkbox

➔ Click on the [Extended] checkbox.

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

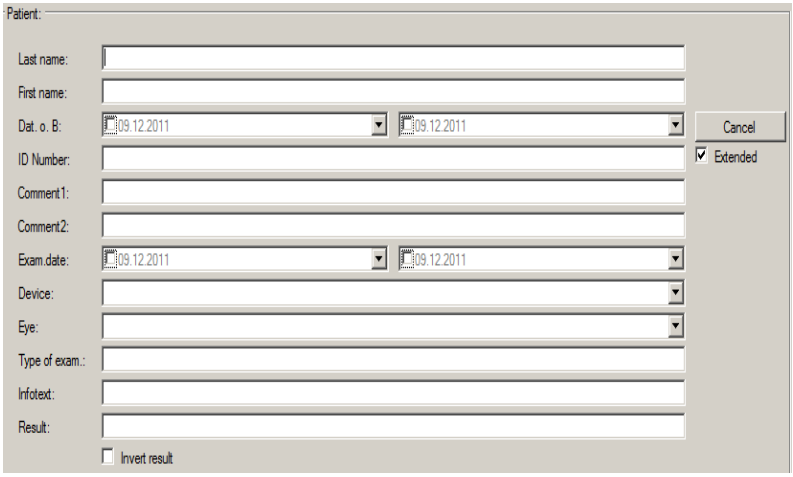


Fig. 9-3: Advanced search

9.2 Starting the Smartfield Program

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

Fig. 9-4: Start the Smartfield program

or

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

10 The Smartfield Program

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

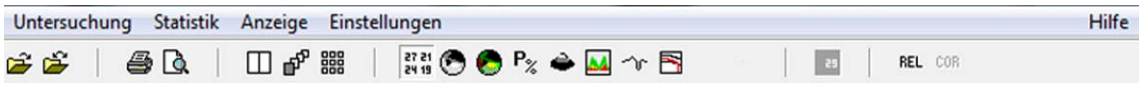


Fig. 10-1: Menu list Smartfield program

Loading previous examinations

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

➔ Select the desired examination by clicking on it.

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

11 Measuring Procedure

Caution

Risk of incorrect measurement due to incorrect use

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

11.1 Examination Preparations

11.1.1 Selecting the Examination Program

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

A description of how to write your own examination programs can be found in the *User Guide* for the Smartfield Perimeter.

11.1.2 Determining the Required Correction

The test stimuli of the Smartfield Perimeter are shown in the distance. Use corrective lenses for distance correction to correct any defects.

11.1.3 Inserting the Corrective Lens

- ➔ Place the required trial lens with the previously determined corrective power into the holder included in the scope of delivery.
- ➔ Place the lens holder included in the scope of delivery for the unit into the viewer of the Smartfield Perimeter.

Fig. 11-1: Inserting the corrective lens holder with corrective lens

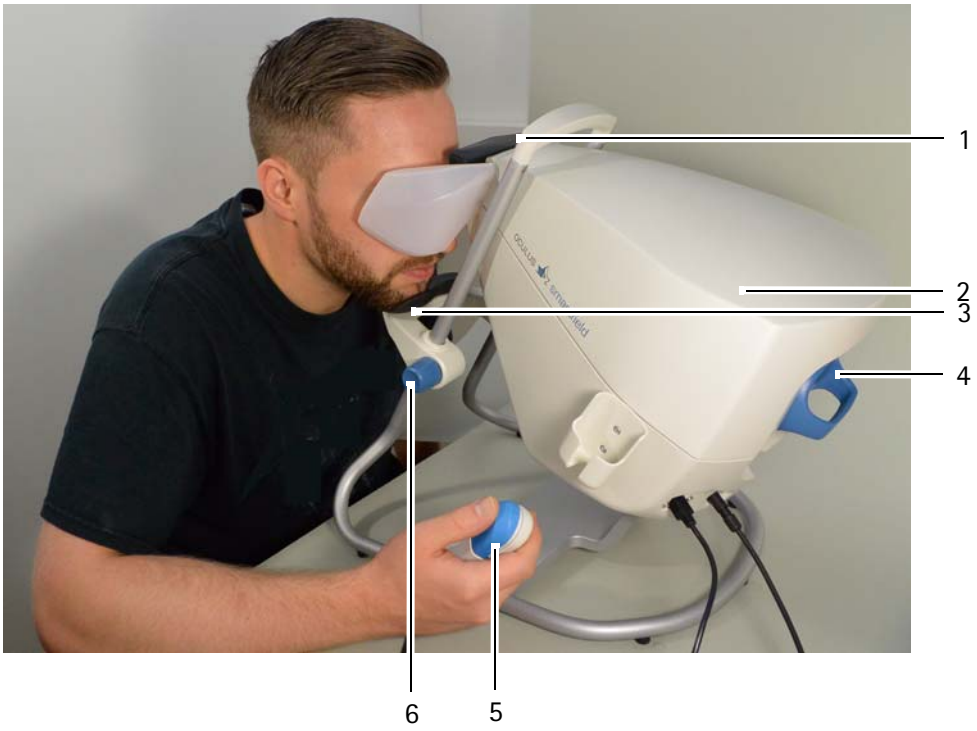
11.1.4 Preparing the Patient

- ➔ Check that the chin rest and the forehead rest and also the hand-held pushbutton have been disinfected 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 pushbutton for the unit and ask him to hold it in one hand.
- ➔ Ask the patient to take a seat and make himself comfortable in front of the unit. He should sit as upright as possible.

The Smartfield occluders allow the examination to be performed without an eye patch.

11.1.5 Positioning the Patient

➔ Do not touch the patient and the device simultaneously.



1 Forehead rest
2 Chin rest
3 Gauge head
4 Gauge head adjuster
5 Hand-held pushbutton
6 Adjusting knobs on the chin rest

Fig. 11-2: Patient positioning

➔ Ask the patient to place his chin on the chin rest (2).

➔ Adjust the movable gauge head (3) with the gauge head adjuster (4) and the press the adjusting knobs on the chin rest (6) for optimal positioning.

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

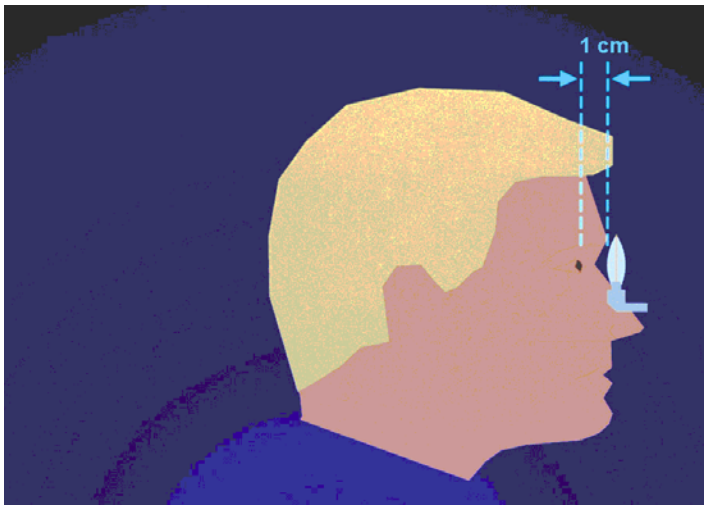


Fig. 11-3: Distance between eye and corrective lens

➔ Ask the patient to rest his forehead against the forehead rest (1) so that he sees the fixation marks (four red dots) in the center of the perimeter

bowl with the eye that is to be examined. The patient is sitting in the correct position when the patient's pupil lies within the red rectangle on the video monitor frame.

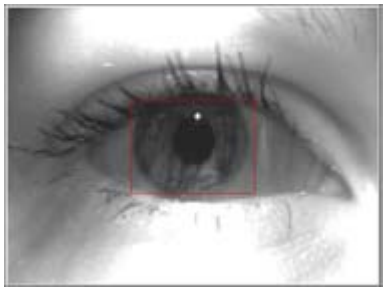


Fig. 11-4: Correct position: Patient's eye in the video monitor frame

➔ 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 top area could be caused by improper positioning of the patient. If the distance from the eye to the permimeter is too big (because the patient is not positioned properly), the patient may not have a full view into the unit.

11.1.6 Positioning the Pupil

➔ Ask the patient to fix his gaze on the middle of the four red points.

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

➔ If necessary, adjust the camera image settings in the Smartfield program settings, so that the movements of the eye are conveniently displayed (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 in the image shown.
- ➔ 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 pushbutton every time he sees a spot of light.
- ➔ Explain to him that he can interrupt the examination at any time by pressing and holding down the hand-held pushbutton. The examination is automatically resumed when he lets go of the hand-held pushbutton again.
- ➔ Click on the button [Start Exam.].

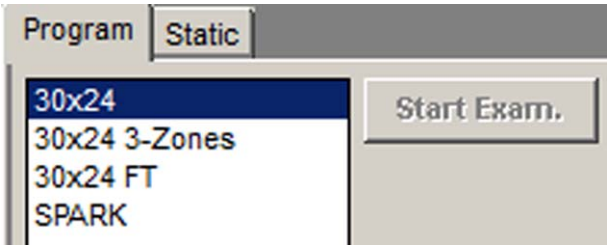


Fig. 11-5: [Start Exam.] button

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

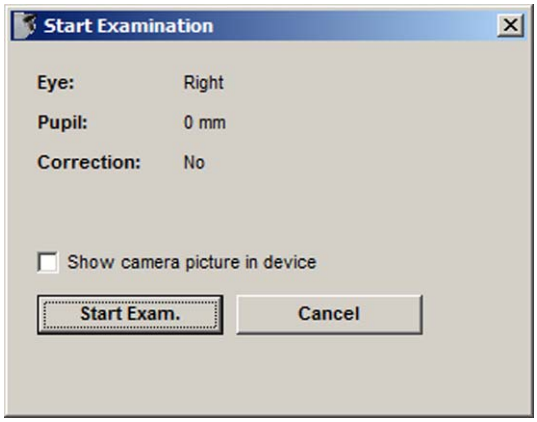


Fig. 11-6: Display of the general data

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

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

➔ Press the button [Start Exam.].

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

Fig. 11-7: Display of the measured threshold value

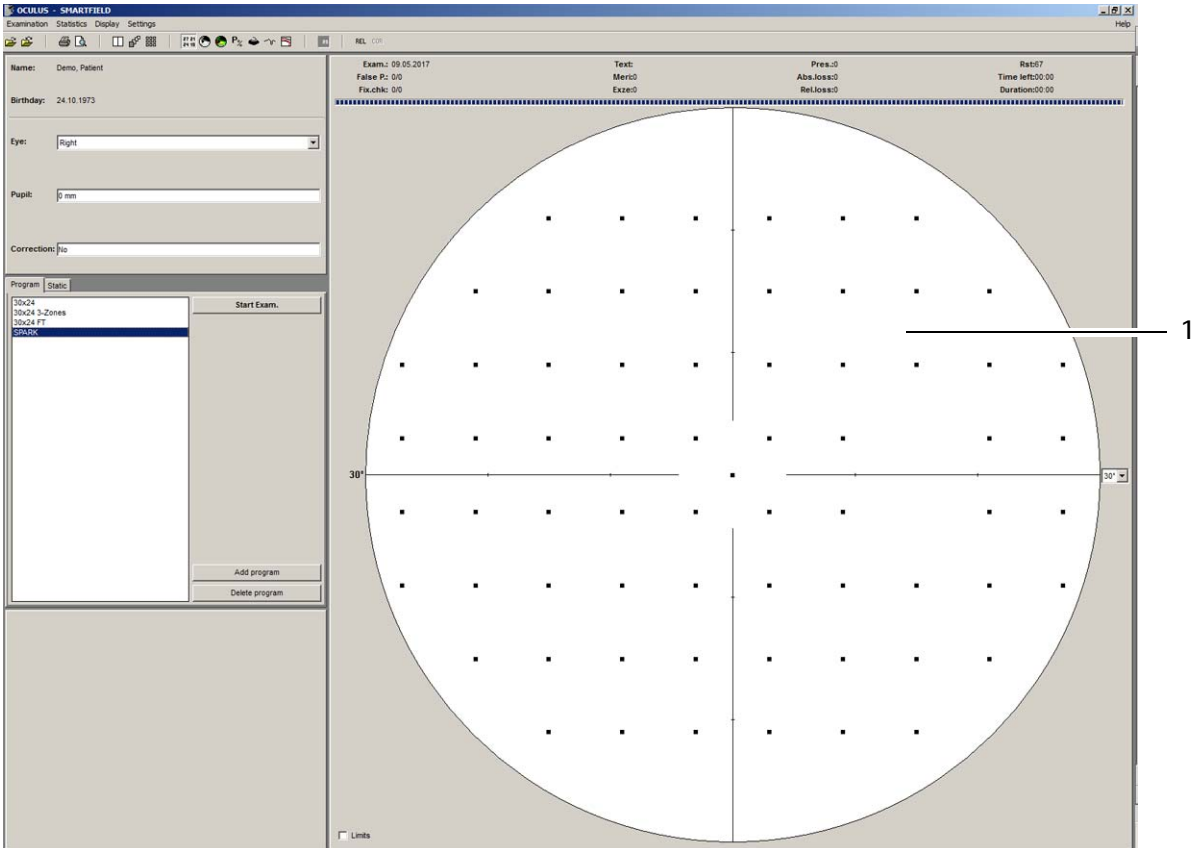
➔ If the measured threshold deviates considerably from the normal threshold for that age group, press the [Repeat] button.

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

The examination program that you selected now starts 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 Smartfield program.



1 Main frame of the Smartfield program

Fig. 11-8: Screen of the Smartfield program

➔ Press the right mouse button.

The following dialog is displayed:

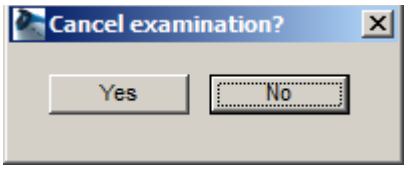


Fig. 11-9: Interrupting the Examination

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

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

11.4 Ending the Examination

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

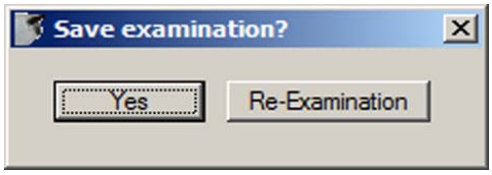


Fig. 11-10: Save the examination results

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

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

➔ Disinfect the chin rest and the forehead rest after each exam.

➔ Disinfect the hand-held pushbutton after each exam.

11.5 Saving the Examination Data

If all examined test points were without pathological findings, or you have 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 Smartfield program.

12 Working with the Patient Data Management

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

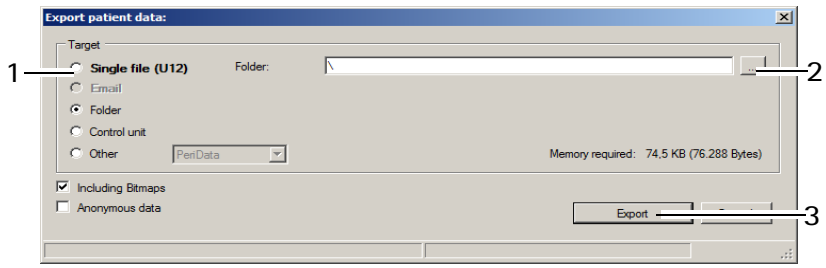
- Forwarding of patient data and examination results
- Backup data
- Change settings

12.1 Forward Exam Results

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

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

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



1 Saving destination selection
2 [...] button for destination selection
3 [Cancel] and [Export] buttons
Fig. 12-1: "Export patient data" dialog

Normally, you enter your preferred data import and export options just once, in the "Settings" area *(Fig. 9-1, page 18)*. You then do not have to perform some of the following steps (for example, selecting the destination).

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

➔ Select the "Target" (1) where you would like to export the data to.

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

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

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

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

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

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

12.1.1 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 the 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.

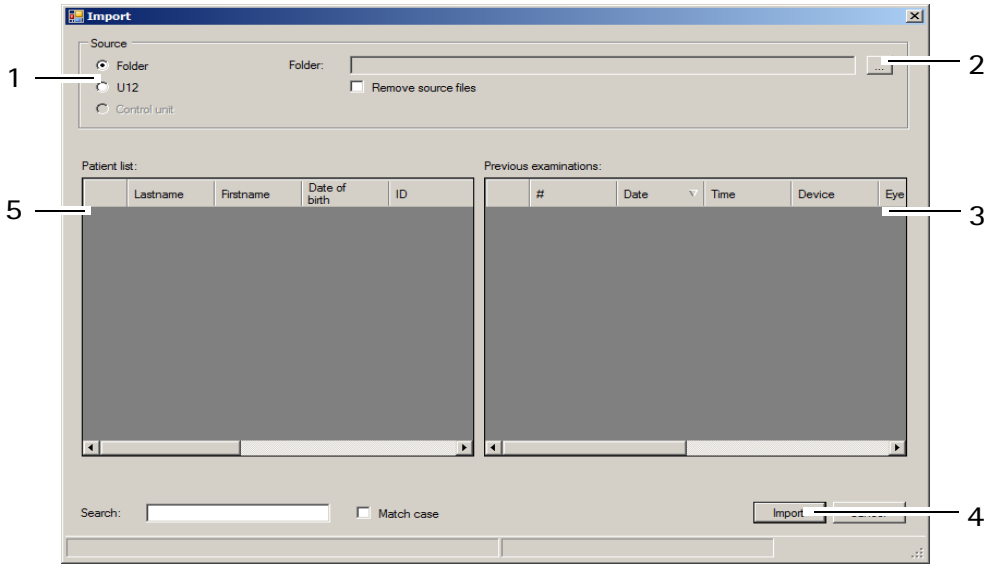
Note

Risk of loss of data due to computer viruses

Computer viruses can cause loss of data.

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

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



1 Select data source
2 [...] button for selecting a folder
3 Examination list
4 [Import] button
5 Patient list

Fig. 12-2: Import" dialog"

The default options for import and export of data are configured in the "Settings" field. See also *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 option (1) where the source data are contained ("Folder" or "U12 (single file)").

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

➔ Press the [...] button (2).

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

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

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

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

The data is then available in the user interface for "Patient Data Management".

13 Cleaning, Disinfection and Maintenance

This chapter describes how to clean and disinfect the Smartfield, and how to replace the forehead rest and the fuses.

No sterilization is required.

➔ Always heed the product descriptions and directions for use of products you use to care for, clean, and disinfect the unit and/or its accessories.

13.1 Cleaning

Caution

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

➔ Switch off the Smartfield, *sect. 8.2, page 17*.

➔ Unplug the power cord before cleaning and maintenance. Pull on the respective plug and not on the cable itself.

➔ Do not clean the Smartfield with aggressive, chlorinated, abrasive or sharp cleaning agents.

Required materials

- Cleaner for plastic surfaces with anti-static effect
- Cleaner for painted surfaces: Mixture of equal parts of alcohol and distilled water, possibly with a few drops of commercial detergent
- Soft cloth or lens brush
- Alcohol or lens cleaner

Cleaning intervals

➔ Clean the chin rest and forehead rest after each examination; clean the housing at least once per month, or as needed.

➔ Clean the hand-held pushbutton after each examination.

Cleaning

➔ Switch off the Smartfield, *sect. 8.2, page 17*.

➔ Unplug the power cord.

➔ When cleaning, use a damp cloth and make sure that no liquid enters the Smartfield.

➔ Clean the plastic surfaces and the occluder with the appropriate cleaner.

➔ Clean the painted surfaces with the cleaner for painted surfaces.

➔ Clean the lenses in the viewer with a soft cloth or a lens brush. If necessary, use alcohol or lens cleaner.

13.2 Disinfection

➔ Recommendation: Use disinfectant wipes suitable for medical devices, e. g.:

Pursept®-A Xpress disinfectant wipes,
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

Note

Equipment damage caused by disinfectant solution

The disinfectant solution may damage the finish if it is sprayed directly onto it.

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

➔ Disinfect after each examination:
- Chin rest
- Forehead rest
- Hand-held pushbutton
- Smartfield occluder

➔ Disinfect the housing as needed.

13.3 Care and Maintenance

To ensure satisfactory and reliable operation, we recommend:

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

Note

Faulty examinations due to damaged equipment

Damaged equipment could result in erroneous examinations.

If an error occurs that you cannot resolve

➔ Label the damaged Smartfield as "out of order".

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

➔ Use only undamaged Smartfield devices.

14 Troubleshooting

Caution

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

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

Equipment damage due to improper operation

➔ Never connect or disconnect cables or plug in or unplug the equipment when the PC or the Smartfield 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 is not lighting up.	The Smartfield Perimeter is not connected to the power supply.	Plug the power cable into the power outlet, or the device connector into the jack at the Smartfield Perimeter.
	Power failure or power socket is not active	Inform the in-house electrician.
No function when the power switch is pressed, but the pilot lamp on the power switch is lit.	PC or control unit not connected properly.	Check that the connector is plugged in properly.
	The unit has been switched off and back on again too quickly.	Wait approx. 5 seconds before turning the unit back on again.
Hand-held pushbutton is not reacting when pressed.	The hand-held pushbutton 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.	Device is in standby mode	Move the mouse, or press any key.

15 Transport and Storage

The Smartfield must be properly dismantled 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 netbook/PC/laptop.

➔ Switch off the device, *sect. 8.2, page 17*.

➔ Disconnect the power plug from the power socket.

Disconnect the connections to the hand-held pushbutton and to the netbook/PC/laptop.

When disconnecting, pull on the respective plug and not on the cable itself.

➔ Pack up the Smartfield in its original packaging.

15.2 Transport and Storage Instructions

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

➔ Wait approx. 3-4 hours after transport before putting the Smartfield into initial operation. In the event of extreme temperature changes from cold areas to warm rooms, the optical components can become fogged.

Note

Equipment damage due to improper transport and storage

➔ Avoid shocks, vibration and dust.

➔ Avoid high temperatures and moisture.

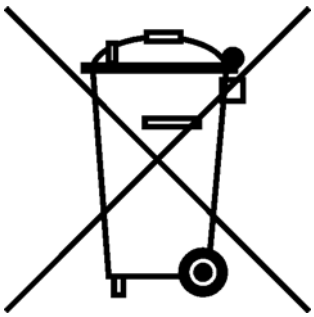
➔ Transport the Smartfield in a compliant manner.

➔ Store the Smartfield in accordance with the storage conditions.

➔ Keep away from heating elements and moisture.

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

16 Disposal



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

➔ Transport the Smartfield in a compliant manner.

17 Terms of Warranty and Service

17.1 Terms of Warranty

The Smartfield has been carefully manufactured using quality materials and modern production methods. If software is included in the scope of delivery, it has been tested by us and meets the technical standards. Please note the following guarantee provisions:

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

17.2 Assumption of Liability for Functions and Damage

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

➔ Use the device in accordance with these instructions and the accompanying User Guide.

- There are no user-serviceable parts either on or inside the Smartfield. If assembly work, modifications, adjustments, repairs, changes or service are performed by unauthorized personnel, or if the Smartfield is improperly maintained or handled, then any liability by OCULUS is voided.
- If the above-referenced work is performed by authorized persons, then a certification of the work shall be requested from this service technician which shall state any changes to factory defaults or to operating ranges. This certification must contain the date of performance and statement of the performing firm, with signature.
- If requested, OCULUS will provide to the service technician a list of spare parts and additional descriptive material for this purpose.

➔ Make certain that only original OCULUS parts are used.

17.3 Manufacturer and Service Address

Supplemental information is available from our Service Department or from our authorized representatives. Manufacturer and service address:

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 Smartfield	7.6 kg (16.8 lbs)
Dimensions (W x D x H)	332 x 418 to 477 x 402 mm (13.1 x 16.5 to 18.8 x 15.9 in)
Interface	RJ45
Max. eccentricity	30°/25° – 60°/50° (with fixation shift)
Max. power consumption	25 W
Power supply	12 V DC; 3.34 A
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	0,8 – 3180 cd/m² (2.5 – 10 000 asb)
■ Examination speed	adaptive/fast/normal/slow/user defined
■ Stimulus viewing distance	infinity (in the distance)
Background	
■ Luminance	10 cd/m² (31,4 asb)
■ Colour	white

Power supply unit

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	integrierter Überstromschutz

Classification according to IEC 60601 - 1 (VDE 0750)

Type of protection against electric shock	Protection class 2
Degree of protection against electric shock	Type B
Level of protection against harmful penetration of water	IP 20

Ambient conditions

Temperature	+10°C to +35°C
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

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

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

CE in accordance with EC Directive 93/42/EEC for Medical Devices

The unit is a Class I product.

CE

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

19 Appendix

19.1 Electromagnetic Compatibility

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

No particular measures are required for OCULUS equipment and systems.

Portable and mobile HF communications devices can affect medical, electrical equipment.

Definition of the minimum operational quality or essential performance characteristics

- A slight disturbance of the analog camera of the device (slight 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 device during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short interruption of the network connection during the examination is permissible because it will not affect the diagnosis, treatment and observation.

Caution

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

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

The use of OCULUS-specified accessories, converters and cable with any devices other than the Smartfield can result in increased emissions or a reduced interference immunity of the other devices.

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

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

Order Number	Description	
14000	OCULUS Smartfield	
05200320	Cable with plug, EU Standard	2.5m
05200210	Cable with plug, US Standard	2.5m
05200211	Cable with plug, GB Standard	2.5m
05200212	Cable with plug, Australia Standard	2.5m
05150805	Power supply unit GSM40B12-P1J	See *"Power supply unit" on page 41*

19.2 Guidelines and Manufacturer's Statement Electromagentic Emmissions and Immunity

Electromagentic emmissions, IEC 60601-1-2, 5.2.2.1, table 1		
The OCULUS Smartfield is intended for operation in the electromagnetic environment specified below. The user of the Smartfield should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – Guidelines**
HF emissions per CISPR 11	Group 1	The equipment uses high-frequency energy exclusively for its internal operation. Therefore, its HF emissions are very low and it is unlikely that neighboring electronic equipment will be affected.
HF emissions per CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker per IEC 61000-3-3	Are met	

Electromagentic immunity, IEC 60601-1-2, 5.2.2.1, table 2			
Immunity test	**DIN EN 60601 – Test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Static electricity discharge (ESD) per IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV ± 8 kV	Floor should be of wood or concrete or be covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electric interference / bursts per IEC61000-4-4	± 2 kV for power lines ± 1 kV for input and output cables	± 2 kV ---------- ± 1 kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surges per IEC 6100-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV ± 2 kV	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations per IEC 61000-4-11	<5% U_τ (>95% dip in of U_τ) for ½ period 40% U_τ (60% dip in of U_τ) for 5 periods 70% U_τ (30% dip in of U_τ) for 25 periods <5% U_τ (> 95% dip in of U_τ) for 5 s	<5% U_τ (>95% dip in of U_τ) for ½ period 40% U_τ (60% dip in of U_τ) for 5 periods 70% U_τ (30% dip in of U_τ) for 25 periods <5% U_τ (> 95% dip in of U_τ) for 5 s	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the Smartfield requires proper operation even after a power failure, then it is recommended that you power the Smartfield from an uninterruptible power supply or from a battery.
Magnetic field at power frequency of (50/60 Hz) per IEC61000-4-8	3 A/m	3 A/m	Magnetic fields at the power frequency should correspond to typical values similar to those in a business and hospital environment.
Note: U_τ is the mains alternating voltage before application of the test level			

Electromagentic immunity, IEC 60601-1-2, 5.2.2.2, table 4

Interference immunity tests	DIN EN ISO 60601 test level	Compliance level	Electromagnetic environment – Guidelines
			Portable and mobile radio equipment, including the cables, should not be used any closer to the Smartfield than the recommended separation distance calculated according to the applicable equation for the transmission frequency. Recommended separation distance:
Conducted HF interference per IEC 61000-4-6	3 V_{eff} 150 KHz to 80 Mhz	V_{eff} = 3 V	$d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$
Emitted HF interference per 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). Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1:	At 80 Hz and 800 MHz the greater frequency range applies.
Note 2:	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and humans.

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

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

Recommended separation distances between portable and mobile RF communications equipment and the Smartfield, IEC 60601-1-2, 5.2.2.2, table 6

The Smartfield is intended for operation in an electromagnetic environment in which the HF interference parameters are controlled. The user of the Smartfield can help to avoid electromagnetic interference by maintaining the minimum distance between portable and mobile HF-telecommunications equipment (transmitters) and the device - depending on the output power of the communications equipment, as specified below.

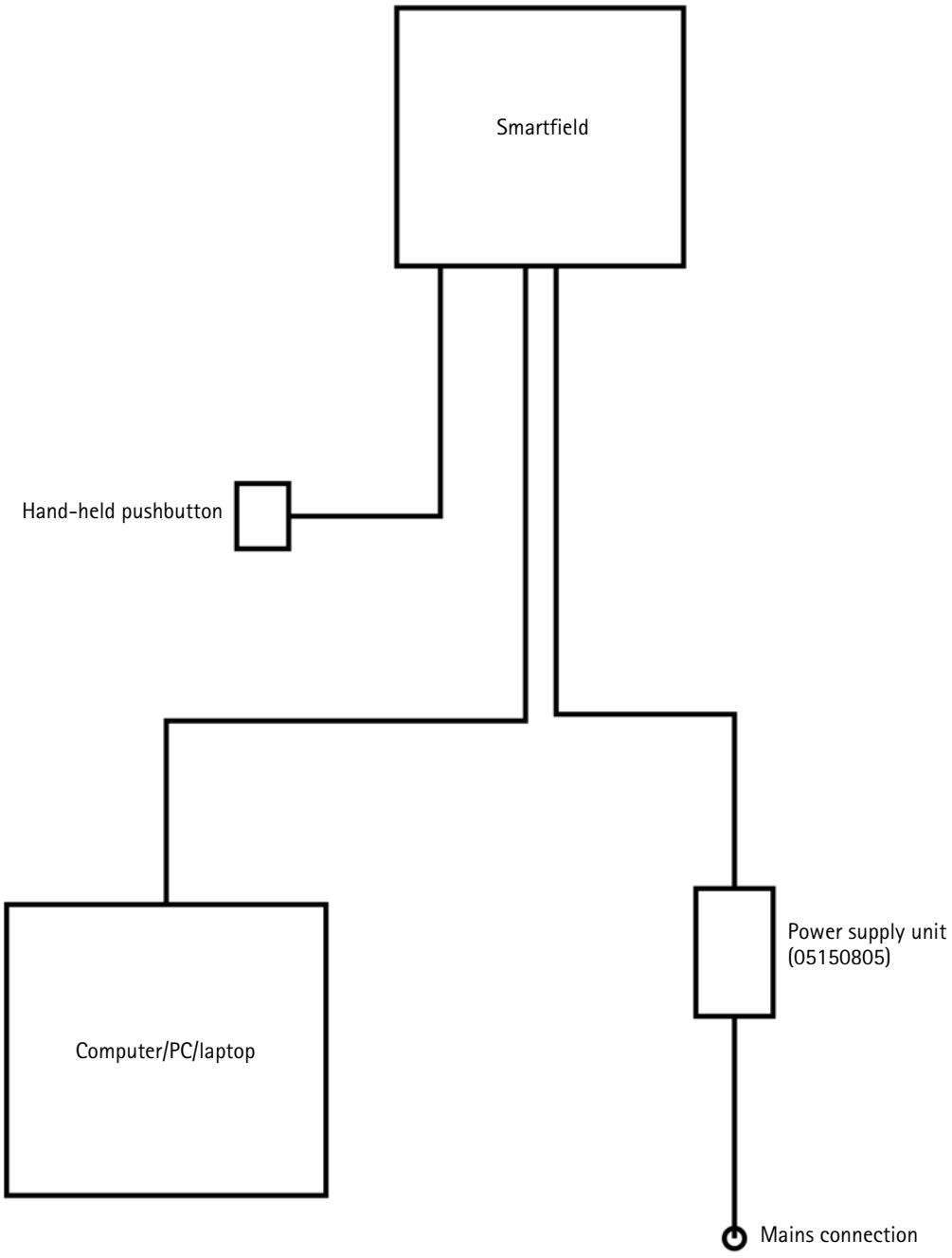
	Separation distance depending on transmitter frequency in m		
Power rating of the transmitter W	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

For transmitters whose maximum rated power is not stated in the above table, the recommended separation distance d in metres (m) can be determined by use of the equation belonging to the particular column, wherein P is the maximum rated power of the transmitter in Watts (W) according to information by the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz the greater frequency range applies.

Note 2: These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and humans.

19.3 Description of the Connection



19.4 Data Sheet Power Supply GSM40B12-P1J (05150805)

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

(Ⅵ 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

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

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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)

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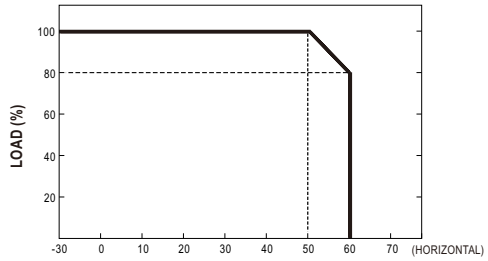
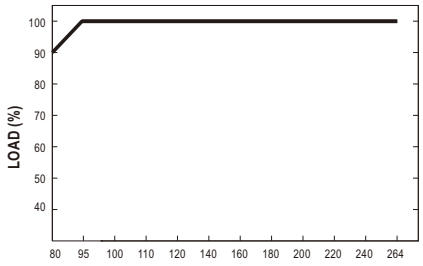
■ Derating Curve

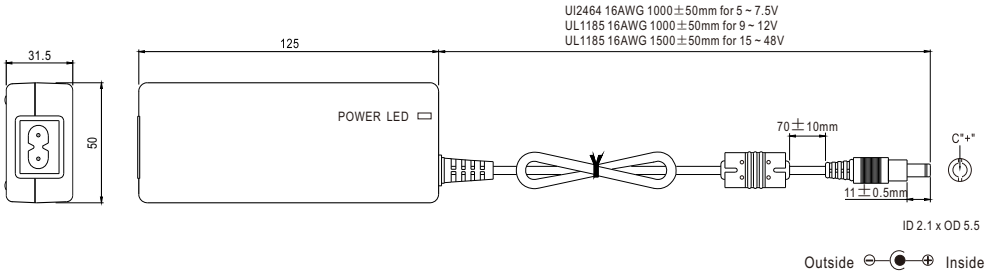


■ Static Characteristics



■ 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

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