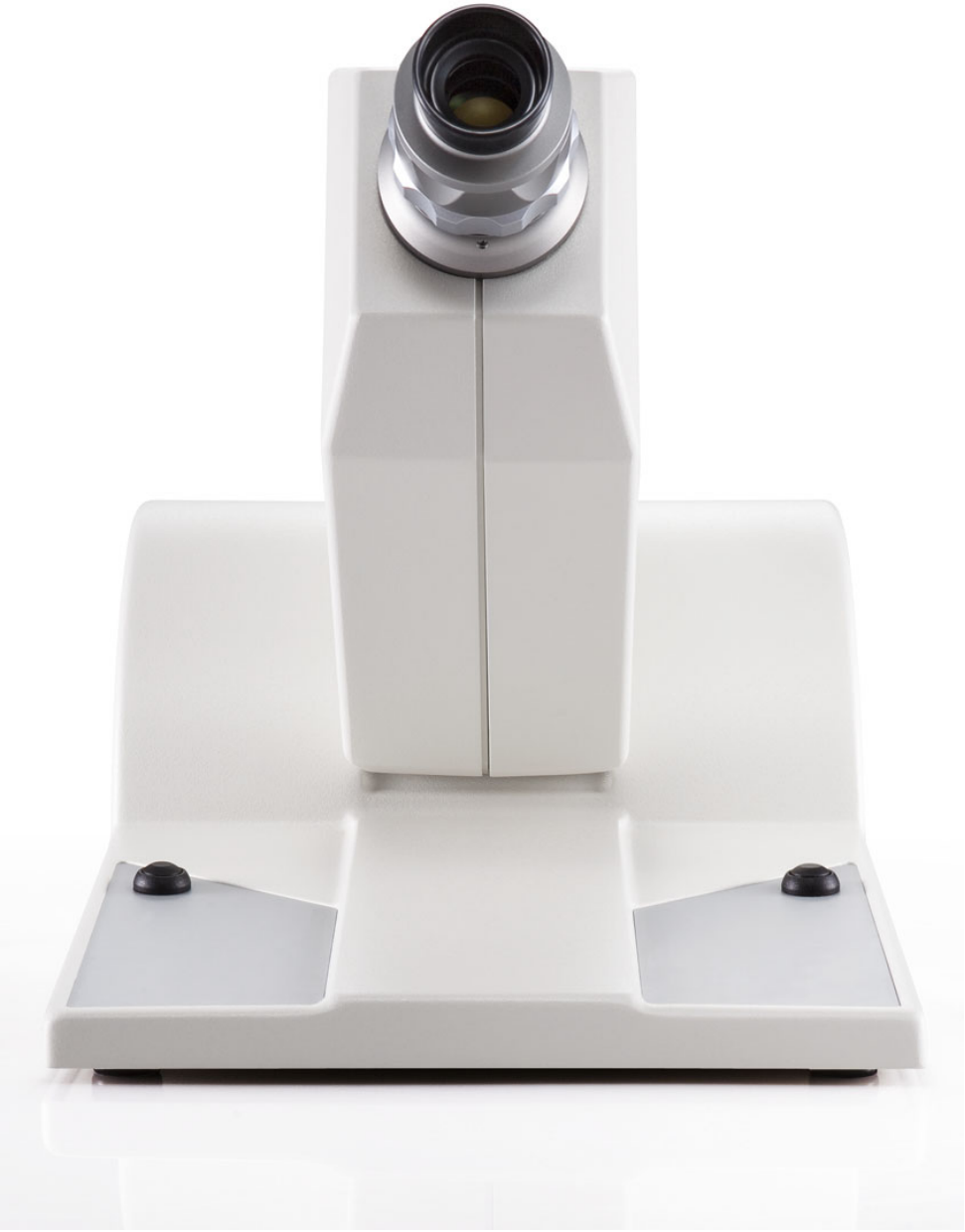
OCULUS

C-Quant



INSTRUCTION MANUAL

OCULUS®

Preface

Thank you for your purchase and the trust you have placed in this OCULUS product. The C-Quant has been manufactured and tested according to strict quality criteria. You have selected a modern and well-engineered product.

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

- We cooperate with many clinics and practicing physicians and develop performance specifications for new instruments in close consultation with them.
- The C-Quant was developed in cooperation with Dr. Tom van den Berg PhD from the Netherland Ophthalmic Research Institute of the Royal Academy (NORI, in 2005 merged into the netherlands institute for Neuroscience, www.nin.nl), in Amsterdam.

Dr. Tom van den Berg began his research on light scatter in the human eye in the mid - 1980s. It was only recently, some 20 years later, that he found in OCULUS a partner for putting his ideas into practice.

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

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

OCULUS Optikgeräte GmbH

Article No.: G/80000/EN
Revision: 02
Release: 14.02.2024

Table of Contents

1 Scope of Delivery 9
1.1 Software version 9
2 Symbols 10
2.1 On the device / Name Plate 10
2.2 Additional Symbols and abbreviations on power adapter 10
2.3 On the packaging 11
3 Structure of the Documentation 12
4 Safety Instructions 13
4.1 Pictograms Used in this Manual 13
4.2 Safety Instructions for Use 13
4.2.1 Instructions for Operating Personnel 14
4.2.2 Transport and Storage Instructions 14
4.2.3 Instructions for Setup and Connection 14
4.2.4 Instructions for Operation 15
4.2.5 Instructions for Maintenance 16
4.2.6 Instructions for Disassembly and Disposal 16
4.3 Cyber-Secutity 17
4.3.1 Data responsibility 17
4.3.2 Device Security 18
4.3.3 User Responsibility 18
4.3.4 Reporting Device Security or Privacy Breaches 18
4.3.5 Recovering from Compromised Accounts or Devices 18
4.3.6 Unavailable Service 18
4.3.7 Precautions 18
4.3.8 Precautions for access control of the computer 19
4.3.9 Precautions if the computer is connected to a LAN or internet network 19
4.4 Patient environment information 20
4.5 Instructions for the operation of a ME system 20
5 Intended Use 22
5.1 Intended Purpose 22
5.2 Medical Indication 22
5.3 Contraindications 22
5.4 Side Effects 22
5.5 User Group 23
5.6 Patient Group 23
6 Device Description 24
6.1 Overview of Device Components 24
6.2 Applied Parts 25
6.3 Mode of Operation of the C-Quant 25
7 Set up and Connection 26
7.1 Electrical Connection 26

7.2 Installation of the Software ... 27
7.3 Setup the software ... 27
8 Operation ... 28
8.1 First-time Operation ... 28
8.1.1 Switching On ... 28
8.1.2 Switching Off ... 28
9 Patient Data Management ... 29
9.1 Starting Patient Data Management ... 29
9.1.1 Entering a New Patient ... 30
9.1.2 Selecting an Existing Patient ... 30
9.1.3 Extended Patient Search: [Extended] Checkbox ... 31
9.1.4 "Invert result" ... 31
9.1.5 Rename Patient Data ... 31
9.1.6 Exporting Patient Data ... 31
9.1.7 Importing Patient Data ... 33
9.2 Data Backup ... 34
9.2.1 Backup Data ... 35
9.2.2 Reconstruct Data ... 35
9.2.3 Automatic Backup ... 36
9.3 Change settings ... 36
9.3.1 "Main" tab ... 37
9.3.2 "Devices" tab ... 39
9.3.3 "Import/Export" tab ... 40
9.4 "Import / Export" group box ... 41
9.5 "Email" tab ... 42
9.6 "Interface" tab ... 43
9.7 "Smartcardreader" tab ... 44
9.8 "Misc" tab ... 45
9.9 "Hecht" tab ... 45
10 Preparing For Messurement ... 46
10.1 Starting the C-Quant Program ... 46
10.2 Overview C-Quant Program Menu ... 46
10.3 Information Boxes (C-Quant Program) ... 47
10.3.1 Common data ... 47
10.3.2 Examination specific data ... 47
10.3.3 Instruction phase ... 48
10.3.4 Start ... 48
10.4 Result fields ... 49
10.4.1 Numerica ... 49
10.4.2 Examination fields ... 50
10.4.3 Examination response chart ... 51
11 How the C-Quant works ... 52
11.1 The measurement principle ... 52
11.2 On-phase ... 52
11.3 Off-phase ... 53
11.4 On-phase ... 54

11.5 Off-phase 54
11.6 Compensation comparison method 54
11.6.1 Seven stimuli for the compensated field are shown: 55
11.7 The psychometric function 57
11.8 Strategy details 57
11.9 Examination phases 58
11.9.1 Instruction phase 58
11.9.2 Dark phase 58
11.9.3 Light phase 58
12 Quick Guide - Performing an examination 59
12.1 Before the examination 59
12.2 Starting an examination 59
12.3 Printout 60
12.3.1 Overview printout (example) 60
13 Practical Guide for operating the C-Quant 61
13.1 Ambient operating requirements 61
13.2 Measuring procedure 61
13.2.1 Eye 61
13.2.2 Correction 62
13.2.3 Range 62
13.3 Patient instruction 62
13.3.1 Eye position 62
13.3.2 Task during the test 63
13.3.3 During the measurement 64
13.3.4 After the measurement 64
13.3.5 When to choose a different "Range" setting? 65
13.4 Measurement - Examples 66
13.4.1 Example 1: esd ≤ 08 and Q ≥ 1 66
13.4.2 Example 2: 0.08 < esd ≤ 0.12 67
13.4.3 Example 3a: esd > 0.12 in “G” range 67
13.4.4 Example 3b: esd > 0.12 in “G” range 69
13.4.5 Example 3c: esd > 0.12 in “G” range 70
13.4.6 Example 4: "Range" setting too high 71
13.4.7 Example 5: "Range" setting too low 72
13.4.8 Example 6: unreliable measurement at low "Range" setting 73
13.4.9 Example 7: reliable measurement at high "Range" setting 74
14 Inserting corrective lenses 75
15 Cleaning and Disinfetion 76
15.1 Cleaning 76
15.2 Dust protection 76
15.2.1 Cleaning enameled surfaces 77
15.2.2 Cleaning the lens 77
15.3 Disinfection 78
15.4 Maintenance 79
16 Troubleshooting 80
17 Dismantling, Transport and Storage 81

17.1 Transport and Storage Conditions 81
17.2 Disassembly 81
17.3 Transport and Storage 81
18 Disposal 83
19 Terms of Warranty and Servicing 84
19.1 Terms of Warranty 84
19.2 Assumption of Liability for Functions and Damage 84
20 Technical Data 86
20.1 Measuring Parameters 86
20.2 Technical specifications 86
20.3 Electrical Specifications power supply 86
20.4 Minimum Computer Requirements 87
20.5 Classification according to IEC 60601 - 1 87
21 Bibliography 88
21.1 Additional information 88
22 Annex 89
22.1 Electromagnetic Compatibility 89
22.2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions for the C-Quant90
22.3 Instructions for integration into an IT-Network 93
22.4 Data Sheet GSM 40B 96

1 Scope of Delivery

Component	Order number
C-Quant	80000
Power supply GSM40B12-P1J	05150805
Mains cable (EU/USA)	05200905 or 05200910
Dust cover	026010005001
Paper roll (3 rolls)	65311
Anti-reflex-coated lenses	80003
Instruction Manual	G/80000
USB FS MED-Isolator	015692000010
USB cabel 1m	10009355
Setup-CD	018000000002

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

➔ When checking the delivery, if you discover transport damages, immediately make your claim with the transport company.

➔ Have the damage confirmed on the bill of lading, so that a proper claim settlement is possible.

➔ Keep the packing material.

Note

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

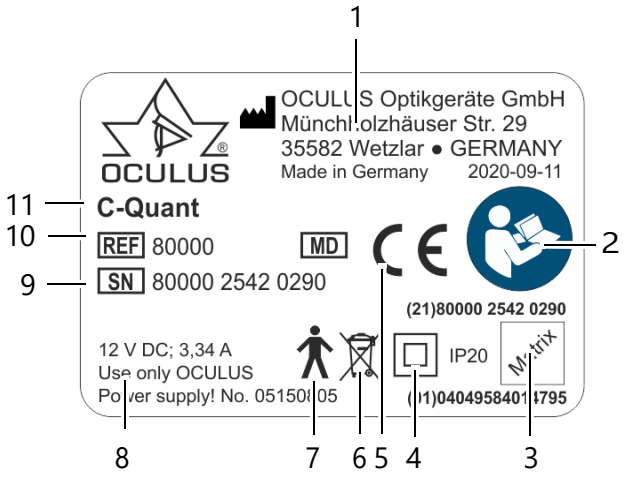
1.1 Software version

The current reference manual describes the following versions of the
C-Quantsoftware as well as the patient data management interface.

- C-Quant Software: 1.11X
- Patient data management: 6.0X

2 Symbols

2.1 On the device / Name Plate



1	Company logo + address	7	Application part of type B
2	Read the operating instructions	8	Power supply, fuse rating
3	Matrix	9	Serial number
4	Protection class	10	Reference number
5	CE	11	Device Name
6	Disposal with household waste is prohibited		

Fig. 2-1: Type plate: Gauge head and device interior

2.2 Additional Symbols and abbreviations on power adapter

Attention

Dangerous voltage

Indoor use only

Conform to US and Canadian standards

polarity of DC connector

Certificated by

2.3 On the packaging

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

3 Structure of the Documentation

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 C-Quant.

Warning

All safety-related instructions for use of the C-Quant are given in the Instruction Manual for the unit. It is imperative that you read and understand the whole Instruction Manual before you use the C-Quant.

4 Safety Instructions

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

4.1 Pictograms Used in this Manual

Warning

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.

Precaution

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

4.2 Safety Instructions for Use

Warning

Personal injury or property damage due to improper operation

- ➔ Observe the following safety instructions.

Personal injury or property damage due to equipment modifications that could jeopardize safety

- ➔ No modifications may be made to this device without the permission of the manufacturer.

4.2.1 Instructions for Operating Personnel

Refer to the notes in 5.5 User Group on page 22

4.2.2 Transport and Storage Instructions

Refer to the notes in 17 Dismantling, Transport and Storage on page 80.

4.2.3 Instructions for Setup and Connection

Note

If the main plug is pulled, all poles are disconnected. The phases are interrupted simultaneously to ensure a safe disconnection.

This is important to ensure that all electrical connections in the device or system are deactivated.

- ➔ Do not use or store the C-Quant in rooms that are humid.
- ➔ Keep the C-Quant away from water that may drip, splash or spray on it, and make sure that no liquids can get into the C-Quant. Do not place any containers holding liquids in the vicinity of the C-Quant.
- ➔ Only operate the C-Quant in rooms used for medical purposes after they have been set up according to the VDE Regulation 0100-710.
- ➔ Do not operate the devices included in the delivery in areas where explosions may occur, or in proximity to flammable anesthetics or volatile substances such as alcohol, benzine or similar products.
- ➔ Do not use excessive force when connecting the electrical plug.

  If a connection is not possible, check whether the plug fits the socket.

  If you find damage to the plug connector, have the damage corrected by our service department, by an OCULUS trained person or by our authorized distributor.
- ➔ Set up the C-Quant 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.
- ➔ Use only OCULUS USB FS MED isolator (no. 01 56920 00 010) for a USB connection. Note that an output voltage of maximum 5 V DC is supplied by a device connected via USB.
- ➔ Use only a mains cable that meets the requirements of IEC 60227-1, Type 53, min. 0.75 m^2 and of IEC 60320-1.

Caution

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

If you use a multiple socket extension cord to connect the C-Quant to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the C-Quant 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 C-Quant, you must have the electrical safety checked. Call OCULUS Service for this purpose.

4.2.4 Instructions for Operation

- ➔ Never operate a damaged C-Quant.
- ➔ Only operate the C-Quant with the original accessories supplied by us and only when the unit is in technically perfect condition.
- ➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the C-Quant.
- ➔ Do not cover the ventilation openings.
- ➔ Only operate the device if you have understood the operating instructions.
- ➔ Do not place heavy objects or the device itself onto the connection cable.
- ➔ Make sure that the power chord has no contact with hot surfaces (for example heater).

4.2.5 Instructions for Maintenance

To ensure satisfactory and reliable operation, we recommend that you have the C-Quant checked every two years by our service department or an authorized dealer. If an error occurs which you cannot correct, label the C-Quant as being "out-of-order" and contact our service department or by our authorized distributor.

4.2.6 Instructions for Disassembly and Disposal

- ➔ When disconnecting electrical connections, pull on the respective plug and not on the cable itself.
- ➔ Dispose of the device according to legal regulations.

4.3 Cyber-Secutity

Warning

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

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

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ Only use the power adapter listed in the packing list.
- ➔ If you use a power strip to connect the C-Quant: Use a power strip that complies with the requirements of IEC60601-1.

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 22 Annex on page 87.

- ➔ Do not use portable and mobile RF communications equipment, which generates strong electric or electromagnetic fields, near the C-Quant.
- ➔ Recommendation is to keep a minimum distance of 4 m. If the distance is shorter, verify the correct operation of the C-Quant.

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

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

4.3.1 Data responsibility

The device itself is not designed to connect with the internet, but only with a computer. It does not require Internet access for regular use.

Do not connect with the internet while using the device. It is considered misuse.
If you elect to connect the computer to the internet for other purposes you are responsible for ensuring data security.

4.3.2 Device Security

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

4.3.3 User Responsibility

User names or passwords must not be shared with colleagues or others, even if they are permitted by law and provider policy to view the same type of information (e.g. two operators reviewing the same patient samples).
Operators have access to patients' ePHI and must not take snap-shots, screenshots or pictures (e.g. using another device) of any information viewed through the device.
Operators should not enter identifying data into the device. All the data on the device should be de-identified and relate to the sample id and not to the patient.

4.3.4 Reporting Device Security or Privacy Breaches

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

4.3.5 Recovering from Compromised Accounts or Devices

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

4.3.6 Unavailable Service

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

4.3.7 Precautions

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

4.3.8 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 “Mesotest”).
- Change the password regularly.
- Do not note the password in an accessible location.
- Use different passwords for different users.
- Enable the screen saver and use the option for the necessity of reentering the password when exit the screen saver.
- Choose an adequate time setting for starting the screen saver if software session is inactive (e.g. 10 minutes).
  Adequate time setting should consider duration of examination, number of patients, time between examinations, use of other devices in the examination room, several user, etc.
- Lock the computer if you are leaving the workstation (shortcut: ‘windows logo key’ + ‘L’).

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

- If you elect to connect the computer to the LAN or internet, you are responsible for ensuring data security.
- Prefer wired connections of the computer to the network.
- If you are using Wi-Fi connections nevertheless, please ensure the usage of adequate security methods (for example WPA2/AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- The usage of a firewall (software or hardware) is recommended.
- Heed the instructions for integration into an IT-Network *(20 Technical Data on page 84).*

Always use a wired connection to transfer examination data from the unit to the PC. Do not use wireless technologies.

4.4 Patient environment information

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

➔ Only use devices that are compliant with IEC 60601-1 in the patient environment.

Caution

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

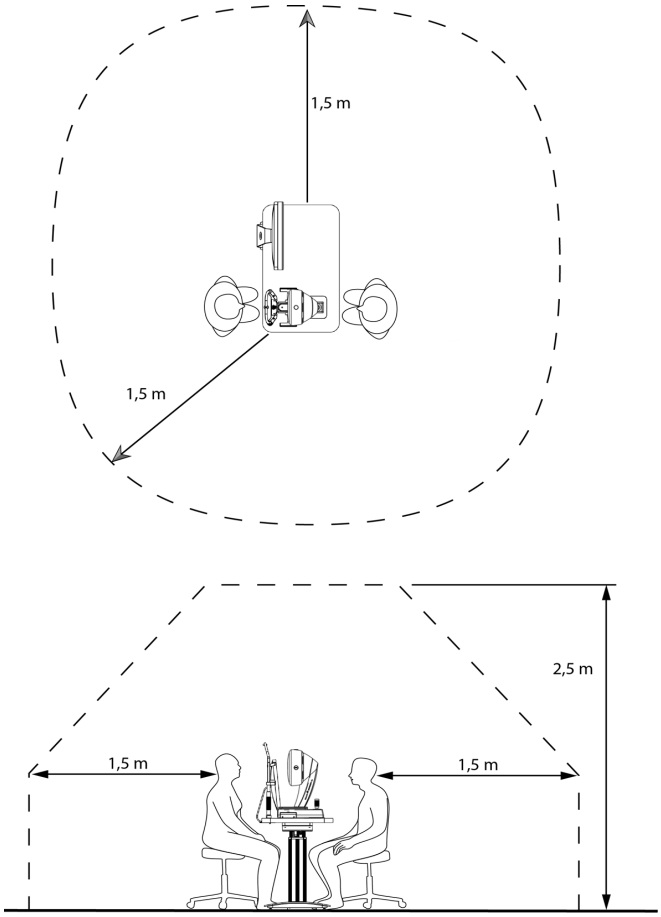


Fig. 4-1: Patient environment

4.5 Instructions for the operation of a ME system

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

All devices of the ME system must comply with the requirements of IEC 60601-1.

5 Intended Use

5.1 Intended Purpose

This unit may be used only for the purposes described in this Instruction Manual. It is designed for tests of the retinal straylight of the human eye.

The unit may be used only by persons whose proper use of the unit is ensured by their training and practical experience.

Use the unit only with original parts and accessories delivered by us and in a technically flawless condition.

With the computer controlling the C-Quant it is not permitted to run other software parallel to the examination software in the foreground (such as screen saver, user programs, etc.). Modes to save energy (BIOS or Windows) should be deactivated.

Use the unit only with an electric supply system whose supply voltage is within the range given on the type plate.

Please take care to observe the safety precautions given above.

5.2 Medical Indication

The device is indicated as an aid to compare the visual functions to an age-related normal examination time. The C-Quant allows a monofocal rapid measurement of straylight and thus calculates the differences in age and expected stray light value.

5.3 Contraindications

-none known-

5.4 Side Effects

-none known-

5.5 User Group

The OCULUS C-Quant is intended exclusively for use in:

- Eye specialists practices
- Clinics
- At opticians or optometrists

The OCULUS C-Quant is intended for use by trained staff:

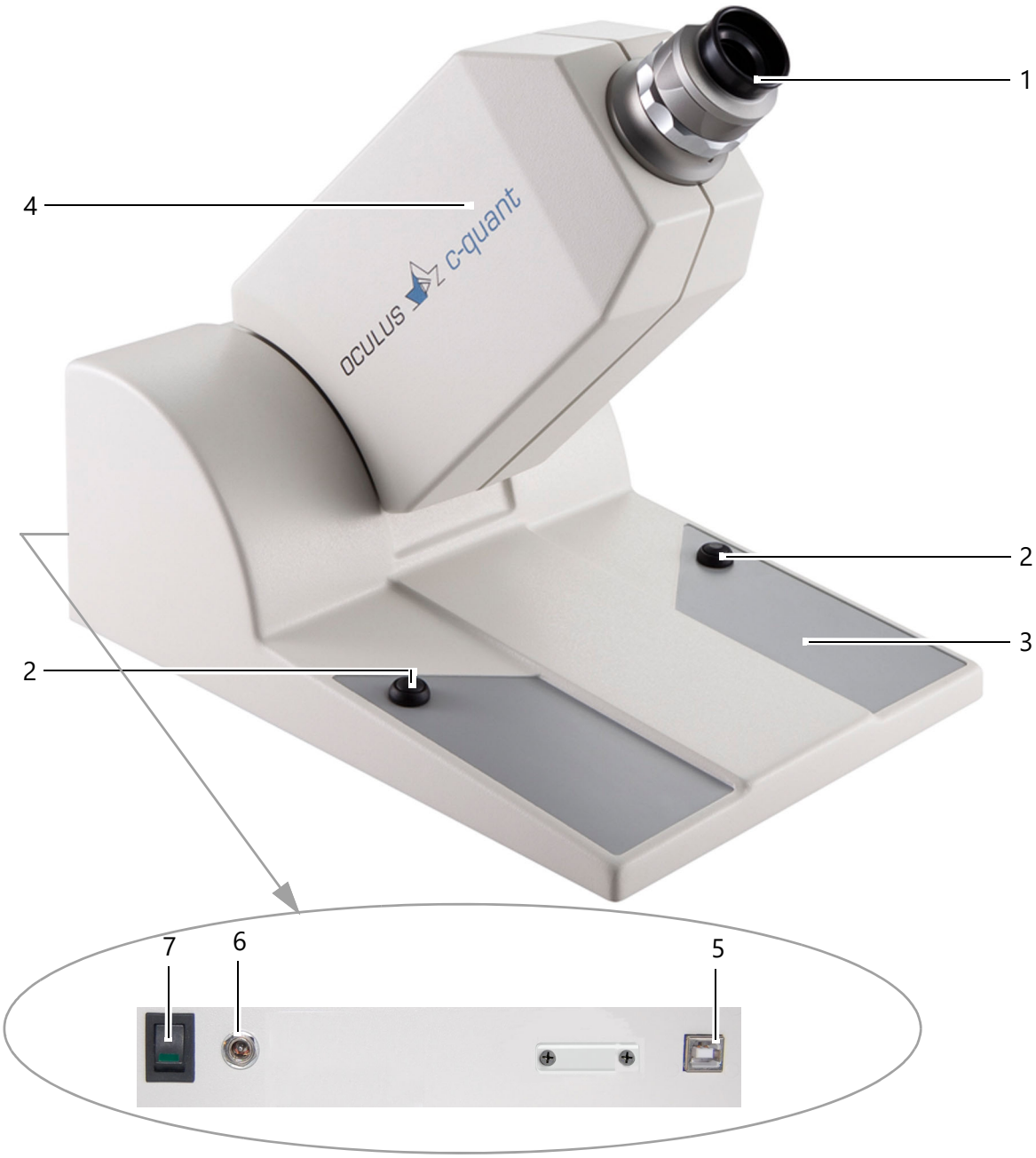
- Who, based on their knowledge, training and practical experience, can ensure professional handling.
- Who have been instructed by OCULUS personnel or an authorized dealer prior to putting the device into operation.

5.6 Patient Group

From 3 years up to not limited. No restrictions on weight and health status. The patient must be awake and able to be seated and to follow instructions.

6 Device Description

6.1 Overview of Device Components



1 Lensholder with eyepiece cup
2 Patient´s response buttons
3 Base plate
4 Adjustable View
5 USB port
6 Main connection
7 On/Off switch

Fig. 6-1: C-Quant: Side view

6.2 Applied Parts

1 Lensholder with eyepiece cup
2 Patient´s response buttons
3 Base plate

6.3 Mode of Operation of the C-Quant

The C-Quant measures, in an accurate and objective way, the amount of straylight on the retina caused by light scattering in a patient´s eye. In an ideal eye there would be no light scattering at all, but because the eye media are not optically ideal, there will always be some light scattering; which degrades the image projected on the retina, thus the quality of vision.

The effect of increased straylight can be compared to what would be seen through very dirty glasses. In short, more straylight means worse vision.

Straylight may be significantly increased above normal values because of cataract, corneal distrophies, refractive surgery or other pathologies.

It is designed for computer-controlled operation via USB interface.

7 Set up and Connection

Warning

Risk of incorrect measurements/equipment damage due to improper setup

➔ Before first use, make sure the installation and connection of the "C-Quant" examination station are completed by our service or by a professional authorized by OCULUS.

Note

➔ Do not expose the C-Quant to any vibrations, shocks, contaminants, moisture, or high temperatures.

➔ Handle the optical device with care.

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

➔ Place the OCULUS-C-Quant on a level surface.

7.1 Electrical Connection

Warning

Electrical safety hazard

➔ Do not use the C-Quant adjacent to or stacked with other equipment.

➔ If you have to use the C-Quant adjacent to or stacked with other equipment, verify the correct operation of the C-Quant.

➔ Only use the power adapter listed in the list, 22.1 Electromagnetic Compatibility on page 87.

➔ If you use a power strip to connect the C-Quant: Use a power strip that complies with the requirements of IEC 60601-1.

The electrical connectors are on the backside of the device, *Fig. 6-1: C-Quant: Side view on page 23*.

➔ Link up the C-Quant with the PC via the or the USB-cable.

- ➔ Connect the low-voltage socket of the supplied desktop power supply to DC input connector.
- ➔ Connect the AC power cable to the desktop power supply.
- ➔ Connect the power plugs C-Quant power supply to a power outlet, see 22.1 Electromagnetic Compatibility on page 87.

Note

Risk of equipment damage due to incorrect connection

If you do not connect the C-Quant 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.

7.2 Installation of the Software

Warning

- ➔ The computer must comply the requirements of IEC 62368-1.
- ➔ First install the software before connecting the device to the PC.

7.3 Setup the software

- ➔ Insert the Setup CD C-Quant (01800000002) into CD-ROM.
- ➔ The CD starts automatically. Follow the on-screen installation instructions.
- ➔ If the CD does not start automatically, run setup.exe from CD-ROM.

8 Operation

Warning

To keep electrical safety

➔ Do not touch the C-Quant (including accessories) and the patient simultaneously.

8.1 First-time Operation

➔ Wait approx. 3-4 hours after transport before operating the C-Quant for the first time. Extreme temperature changes from cold areas to warm rooms can cause condensation on the optical components.

8.1.1 Switching On

➔ Turn on the C-Quant with the on/off switch (position ON), see *Fig. 6-1: C-Quant: Side view on page 23*. The LED on the switch lights up green.

8.1.2 Switching Off

➔ End the current session.

➔ Turn the C-Quant off with the on/off switch (OFF position), see *Fig. 6-1: C-Quant: Side view on page 23*.

9 Patient Data Management

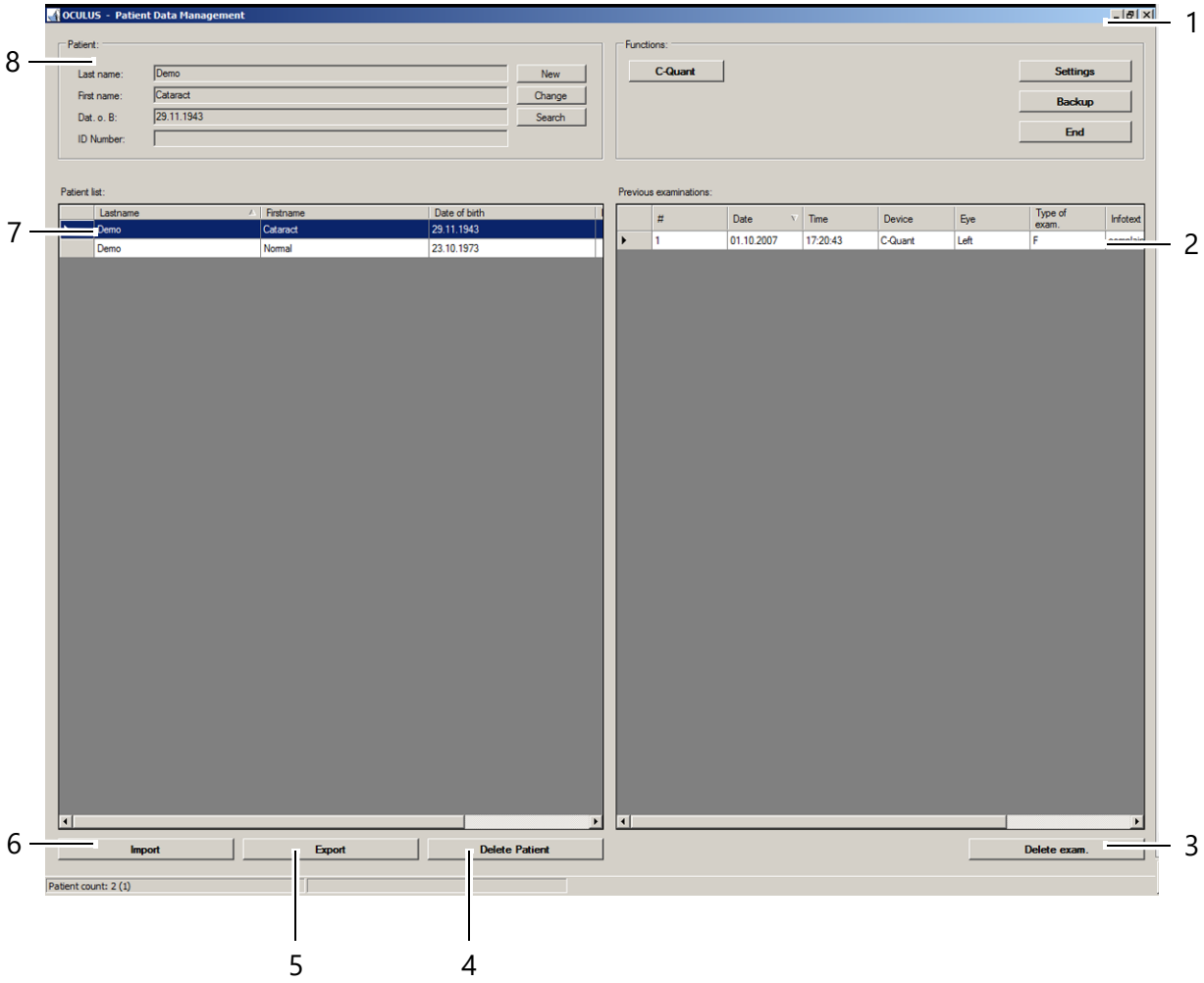
9.1 Starting Patient Data Management

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

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

➔ If necessary, click on the C-Quant icon:  .

The user interface for the Patient Data Management appears.



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

Fig. 9-1: Patient Data Management user interface

If the Windows desktop appears, you have to start the Patient Data Management program from there.

To get to the C-Quant program, you must first enter a new patient (8) or select an existing patient from the examination list (2).

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.

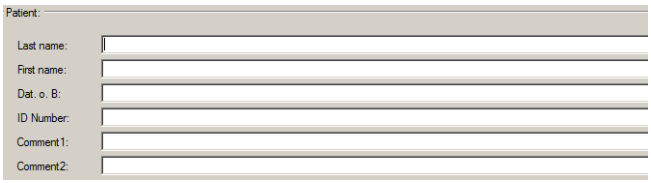


Fig. 9-2: Entering patients

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.

9.1.2 Selecting an Existing Patient

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

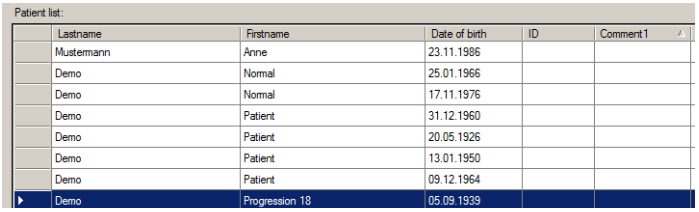


Fig. 9-3: Patient list

➔ 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.

Alternatively, you can search for the patient using an ID number, first name or date of birth, 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 any previous examinations for that patient in the examination window (bottom right side).

9.1.3 Extended Patient Search: [Extended] Checkbox

➔ Click on the [Extended] checkbox.

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

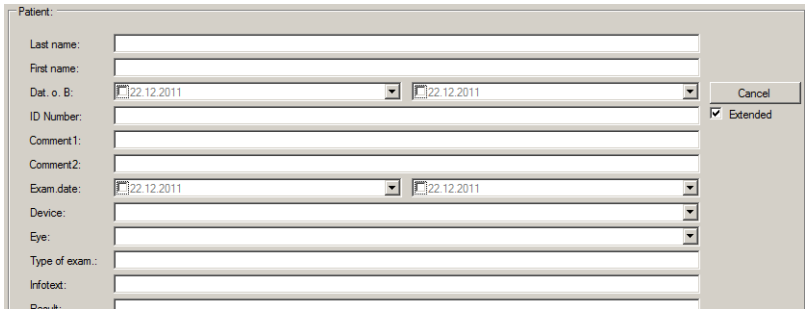


Fig. 9-4: Advanced search

9.1.4 "Invert result"

If this option is activated, all data that do not meet the selected search criteria are displayed.

- When the [Search] button is activated, all other buttons are deactivated (greyed out).

➔ To exit search mode, you must press the [Quit Search] button. The other buttons are then reactivated.

9.1.5 Rename Patient Data

Patient data can be changed retroactively after it has been added.

➔ Press the [Change] button.

The entry boxes for patient data are now free; the cursor jumps to the "Last name" field.

➔ Change the entries in the individual boxes.

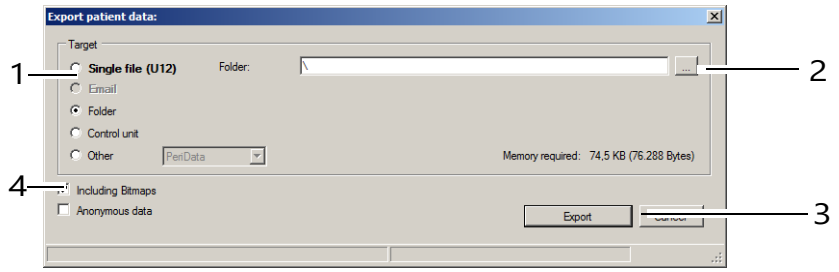
➔ Press the [Save] button.

9.1.6 Exporting Patient Data

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 is displayed:



1 Saving destination selection
2 [...] button for the destination selection
3 [Cancel] and [Export] buttons
4 [Include Bitmaps] checkbox

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

Normally, you enter your preferred data import and export options once in the "Settings" area *(Fig. 9-1: Patient Data Management user interface on page 28)*. Carrying out the following steps will then be partially omitted (for example, selecting the destination).

➔ Select the "Target" (1) you would like for the exported data.

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

➔ Activate the checkbox [Including Bitmaps] (4), if it is presently deactivated.
➔ Press the [...] button. (2).
- 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).

9.1.7 Importing Patient Data

If you keep patient data on a USB stick, you can import this data. Generally speaking, the various software versions are compatible with each other, so that you can still import data, even if they have been exported from a newer or an older version of the Patient Data Management system.

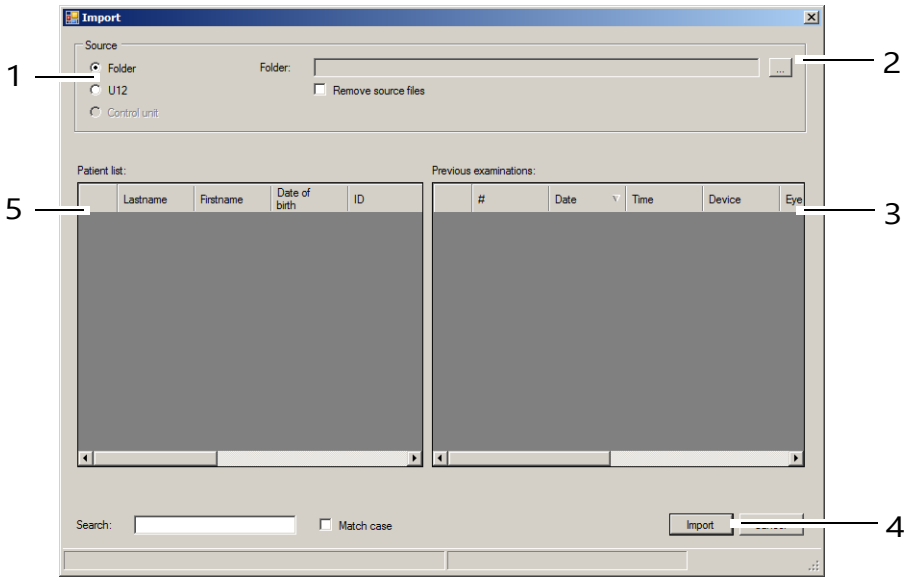
Note

Loss of data due to computer virus

Computer viruses can cause loss of data.

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

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



1 Select the source of the data
2 [...] button
3 Previous examinations
4 [Import] button
5 Patient list

Fig. 9-6: "Import" dialog

The options for import and export of data are set as defaults in the "settings" field, see also *9.3.3 "Import/Export" tab on page 39*.

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 "Single file (U12)" option.

- ➔ Press the [...] button (2).
- ➔ In the dialog box, select the directory or the file where the patient data is 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.

9.2 Data Backup

You should carry out a backup of patient and examination data at regular intervals. In case of a 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 for a while.

Note

Loss of data due to computer viruses

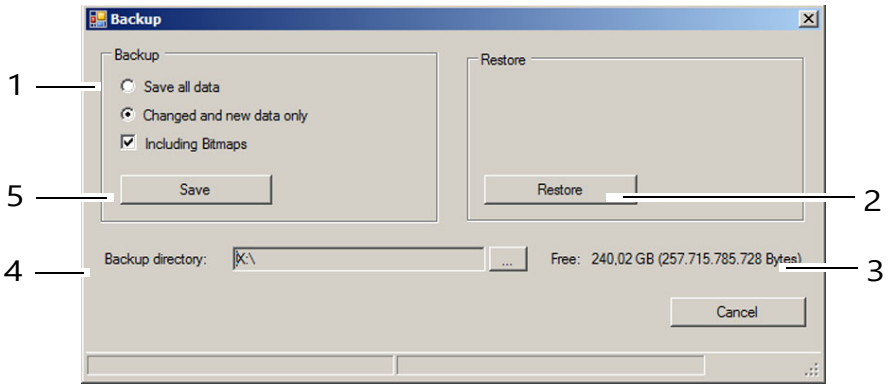
Computer viruses can cause loss of data.

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

The general rules for the creation of backup copies apply to backing up data with the help of the patient data management user interface. Storage of backup files should always be done on a separate system (e.g. on a USB stick with adequate capacity).

9.2.1 Backup Data

➔ Press the [Backup] button in the "functions" field. The following dialog is displayed:



1 Backup data selection
2 [Restore] button
3 Display free storage space
4 Backup folder and button [...] to select a folder
5 [Save] button

Fig. 9-7: "Backup" dialog

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

The patient data management function tags all saved data records internally.

Selecting the option "Changed and new data only" only backs up those data records which were not saved during a previous backup.

➔ Press the [...] button to the right next to 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.

9.2.2 Reconstruct Data

If a loss of data occurs, the data from a previous backup can be imported again into the patient data management user interface.

➔ 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 corresponding folder will be written into the patient data management function.

9.2.3 Automatic Backup

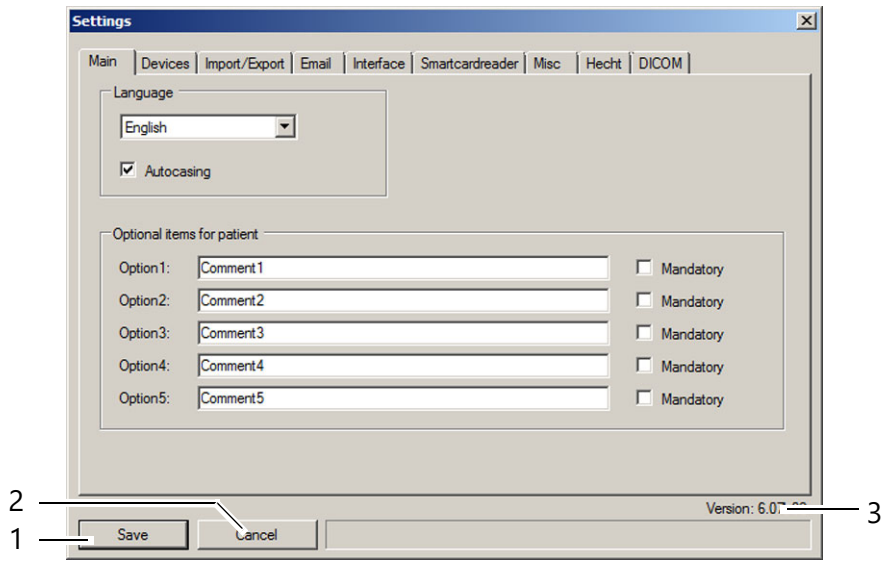
Besides the manually executed backup, there is also the option to carry out a backup when the patient data management user interface is closed. The settings required for this can be found in the "Settings" area, see *9.3.3 "Import/Export" tab on page 39*.

9.3 Change settings

Basic specifications for working with the Patient Data Management user interface can be made in the "Settings" area.

➔ Press the [Settings] button in the upper right portion of the Patient Data Management user interface.

The "Settings" menu page will be displayed. The "Main" tab will appear in the foreground.



1 [Save] button

2 [Cancel] button

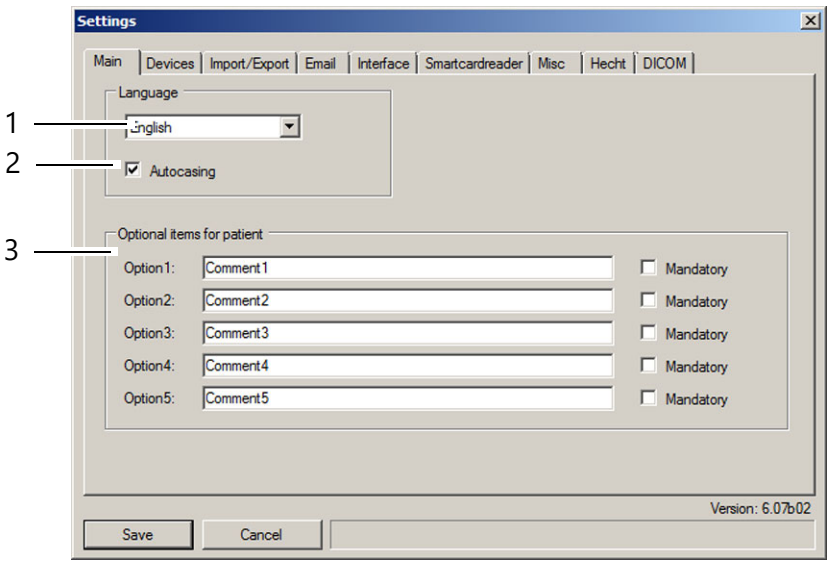
3 Program version of Patient Data Management

Fig. 9-8: "Settings" screen

The following information and buttons are available to you on all tabs:

- The version of the Patient Data Management program appears on the lower right (3).
- There are two buttons below and to the left for saving (1) or discarding (2) the changes that have been made. **All** changes are always saved or discarded, and then the screen is closed.

9.3.1 "Main" tab



1 "Language selection" drop-down list
2 Checkbox [automatic upper case /lower case]
3 Optional patient entries

Fig. 9-9: "Settings" screen, "Main" tab

"Language" box

➔ Select the language to be used to display the Patient Data Management user interface from the "Language" drop-down list (1).

➔ Enable the [Autocasing] checkbox (2) as required. If the checkbox is active, the first letter of a patient's first and last name are **always** converted to capital letters.

"Optional items for patient" box

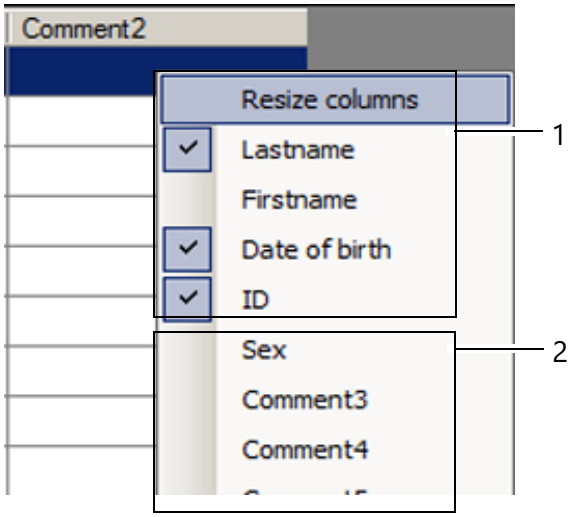
Besides the five standard attributes of first name, last name, date of birth, gender, and ID, up to five additional attributes can be freely defined.

➔ Enter the identifiers for the attributes in the fields Option 1 to 5, for example, "Comments".

To be able to carry out entries for the newly defined attributes, proceed as follows:

➔ Click with the right mouse button on the patient list and open the associated context menu.

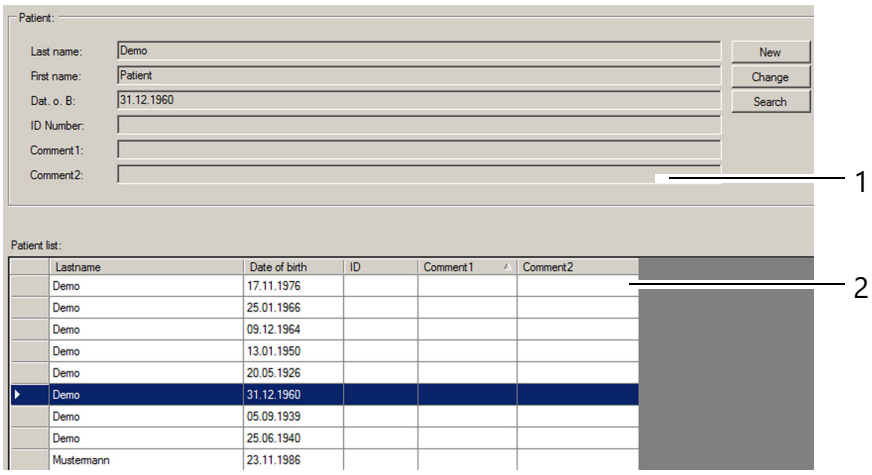
➔ Select the desired attribute, e.g. "Comment2" [2].



1 Previously enabled attributes
2 New attribute selected

Fig. 9-10: New attribute enabled

The context menu will close, and the attribute "Comment2" will be displayed in the upper section of the entry fields for patient data (1) as well as in the patient list (2).

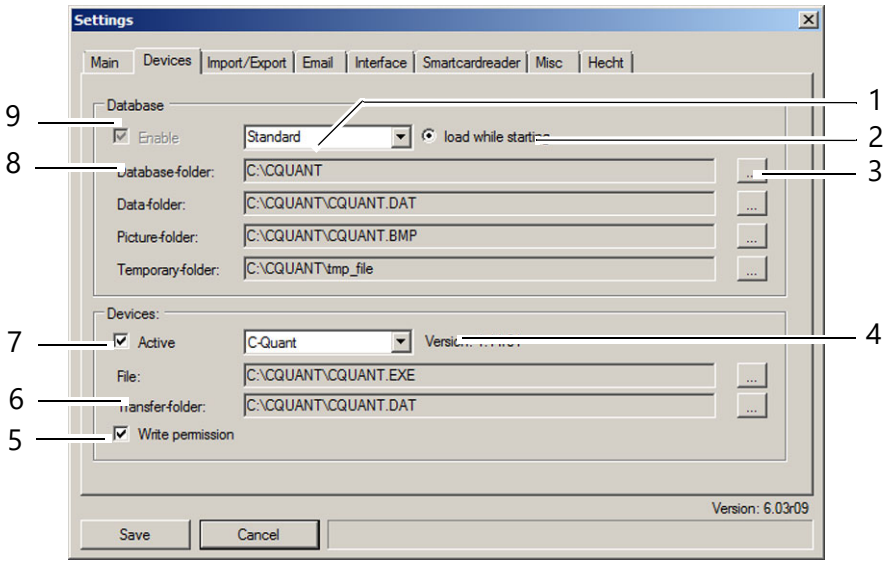


1 Attribute "Comment2" as an input field
2 Attribute "Comment2" in the patient list

Fig. 9-11: Custom attribute "Comment"

The selection of attributes in the context menu is done in the same manner. The currently selected attributes are marked with a check.

9.3.2 "Devices" tab



1 Drop-down list for selecting a database
2 "Load while starting" radio button
3 Folder selection
4 Drop-down list for selecting a device
5 [Write permission] checkbox
6 Path for the currently selected device
7 Checkbox for activating a device
8 Path for the database
9 Checkbox for activating a database

Fig. 9-12: "Devices" tab

"Database" box

Different users can be set up for different databases.

➔ In the drop-down list for selecting a database (1), choose the entry (User) that you would like to edit.

➔ Choose the corresponding path for the database, data, and images using the individual buttons for folder selection (3).

Normally, two different folders are created for data and images during installation, as shown here (8).

- **For data:** Name of the device plus the .DAT identifier
- **For images:** Name of the device plus the .BMP identifier

➔ For each user, enable whether the associated database should be enabled or not (9).

If more than one database is enabled, an additional drop-down list appears on the main page of the Patient Data Management user interface. You can enable a user (or the assigned database) in this list. The patient list and the associated examinations are updated when the active user is changed.

➔ You can also select the "load while starting" option (2) for exactly one user. The associated database is loaded by default when the Patient Data Management user interface is started, and is selected accordingly.

"Devices" box

Make settings for the connected devices in this box.

- ➔ In the drop-down list, select the desired device (4).
- ➔ If the device is in fact connected, then mark the checkbox [Active] (7).
- ➔ Choose the path to the associated device's application file using the folder selection button.

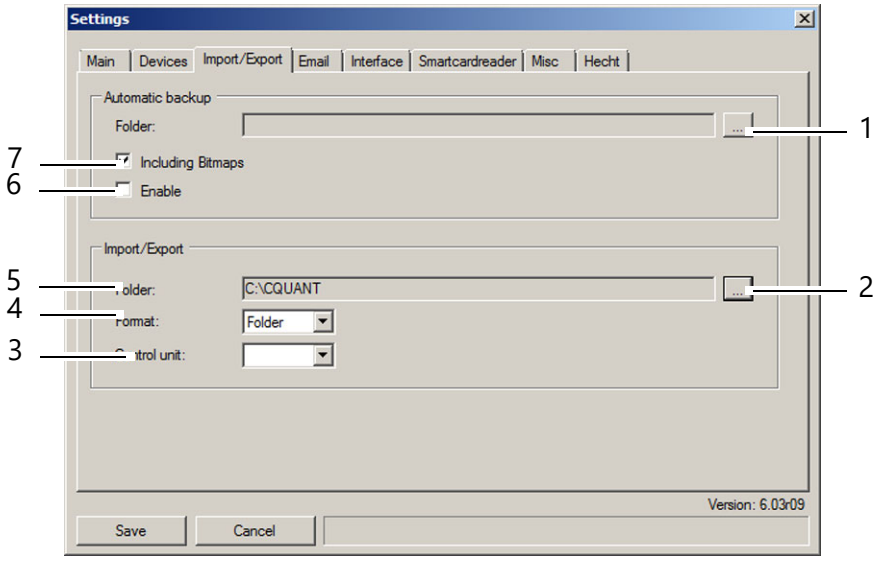
When you save patient and examination data in the database, it is initially placed in the so-called "Transfer folder". This folder is always created locally on the PC.

- ➔ Choose the transfer folder using the folder selection button. This should correspond with the name of the device and the .DAT extension.

You can also specify settings for devices which are not connected to the PC.

- ➔ Enable the checkbox [Write permission] for the devices that are in fact connected to the PC.

9.3.3 "Import/Export" tab



1 Automatic backup folder
2 Select import/export folder
3 [Remove source files] checkbox
4 Interface for manual operating unit
5 Standard format for import and export
6 [Active] checkbox
7 [Including bitmaps] checkbox

Fig. 9-13: "Import/Export" tab

"Automatic backup" box

In addition to the manually executed backup (*9.3.3 "Import/ Export" tab on page 39*), there is also the option to perform a backup when the Patient Data Management user interface is closed. The settings required for this can be specified in the group box.

- ➔ Select the folder where the data should be saved during an automatic backup using the folder selection button (1).
- ➔ Select the check box [Including Bitmaps] (7) if camera images should also be backed up.
- ➔ If the automatic backup should be executed with the specified settings, enable the [Enable] check box (6).

9.4 "Import / Export" group box

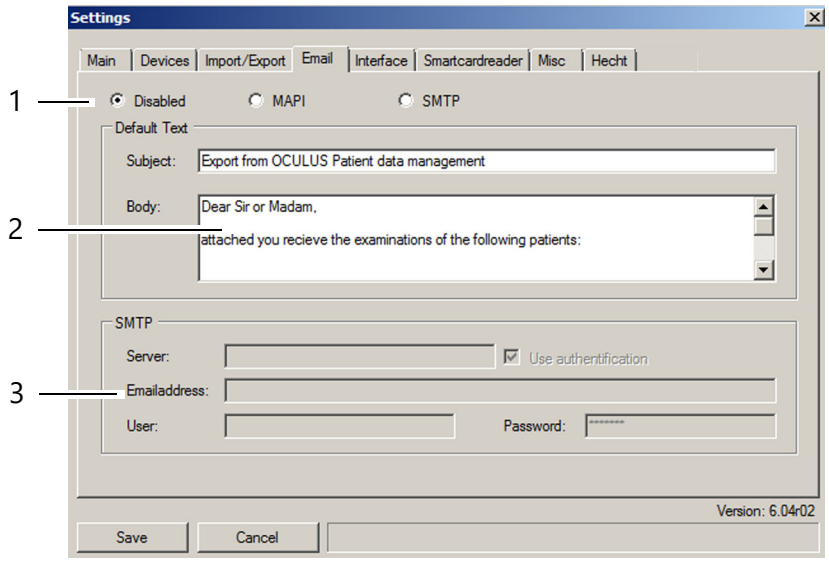
You can enter settings in this box to import and export Patient Data Management data.

Note

The settings specified in this tab for import and export of data can be overwritten. These are only default values.

- ➔ Select the folder using the folder selection button (1) which should normally be used as the default for import or export.
- ➔ In the "Format" drop-down list (5), select whether the default import or export should be done for a folder or a single file (U12).
- ➔ Keep the checkbox [Remove source files] (3) enabled, so that the data import does not cause any data loss.

9.5 "Email" tab



1 Select e-mail connection
2 Standard text for subject and body text
3 SMTP connection selection

Fig. 9-14: "Email" tab

With the three radio buttons in the upper part of the tab (1), you can determine whether the email connection is active, and if it is, how the transfer of data should take place.

➔ Enable the option "MAPI" if an email program (e.g. Microsoft Outlook) is installed on your PC and if data should be sent using this program.

➔ Enable the option "SMTP" if **no** email program is installed on your PC but you would still like to send the databy email. In this case, additional entries in the "SMTP" box are necessary.

"Default text" group box

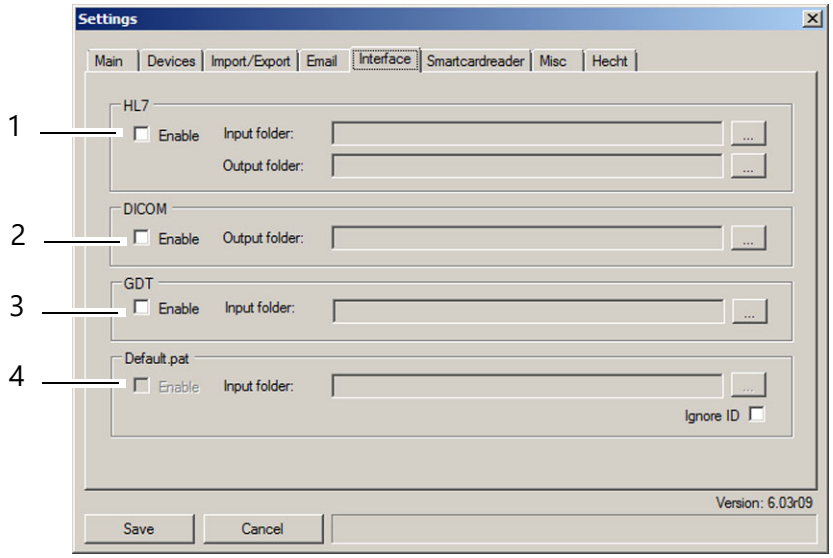
➔ Enter the default text for sending emails in the "Subject" and "Body" (2) boxes. You can adjust this text before email is actually sent (e.g. particular to patients or examinations).

"SMTP" group box

If no email program is installed on the computer, several additional entries must be made here to be able to send emails.

➔ Contact your system administrator if you have questions about the individual entries.

9.6 "Interface" tab



1 Settings for HL7
2 Settings for DICOM
3 Settings for GDT
4 Settings for Default.pat

Fig. 9-15: "Interface" tab

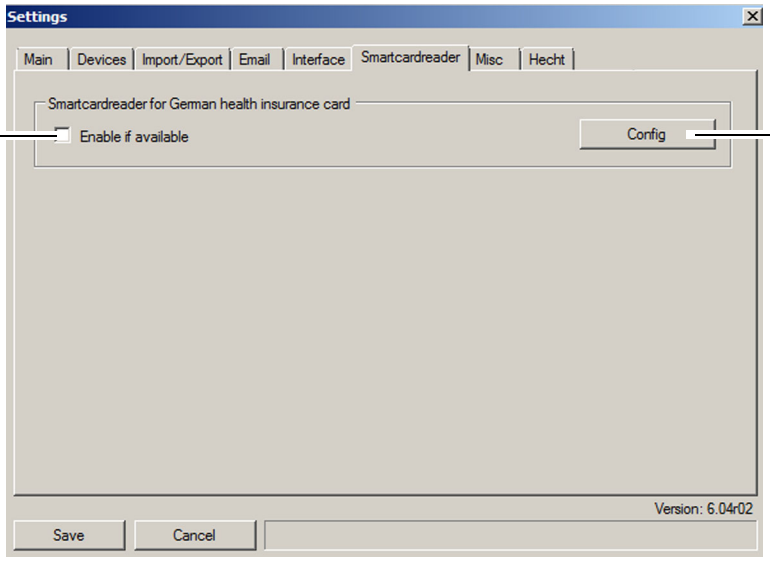
Use this tab to enter the folder for different interface types and to enable or disable them.

The interface "Default.pat" (3) is used if the Patient Data Management user interface is launched by a third-party program.

➔ Add the interface "Default.pat" to the directory of the other program.

➔ Select the third-party program's folder as the "in" folder.

9.7 "Smartcardreader" tab



1 [Config] button 2 [Active] checkbox

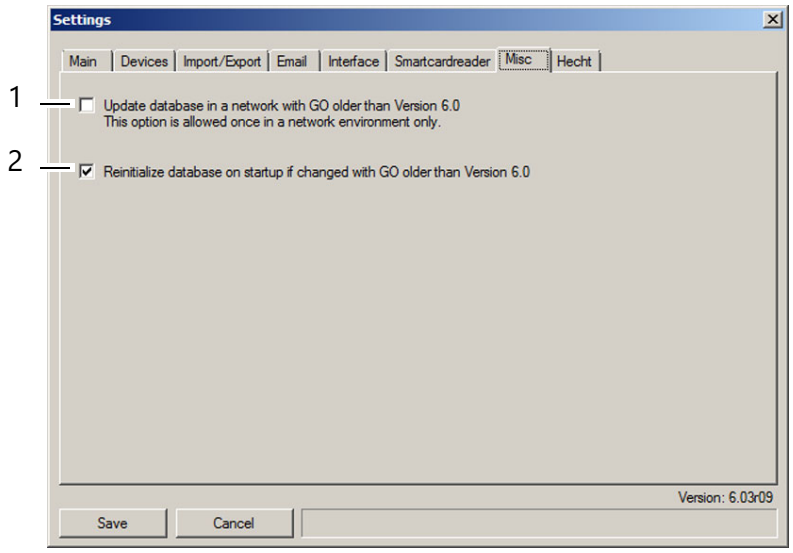
Fig. 9-16: "Smartcardreader" tab

You can configure a smartcard reader on this tab to be able to directly import patient data from the patient's insurance card into the Patient Data Management user interface. First, you have to configure the smartcard reader (usually only once).

➔ Press the [Config] button (2). A page appears for you to select the type of smartcard reader you are using.

➔ Select the [Enable if available] checkbox (1) to enable the smartcard reader.

9.8 "Misc" tab



1 Checkbox to manage the database

2 Check box to import a database

Fig. 9-17: "Misc" tab

The Patient Data Management user interface is available in two different versions: V2.x and V6.x. In principle, implementing both versions on the same network should be avoided. In any case, if it is unavoidable due to the higher technical requirements of the new version V6.x, then the corresponding settings must be set on this tab.

- ➔ Enable the checkbox on this tab (1) on **exactly one PC** that has version V6.x installed.
- ➔ Make sure that this checkbox is **not** enabled on any other PC which has version V6.x of the Patient Data Management user interface installed.
- ➔ Enable Checkbox (2) so that data from the database will be read in again after the next start.

This ensures that the database is automatically updated when a patient is created on a PC with the older Patient Data Management V2.x.

The "IPad Report" field is currently disabled.

9.9 "Hecht" tab

"Hecht" tabs iscurrently disabled.

10 Preparing For Messurement

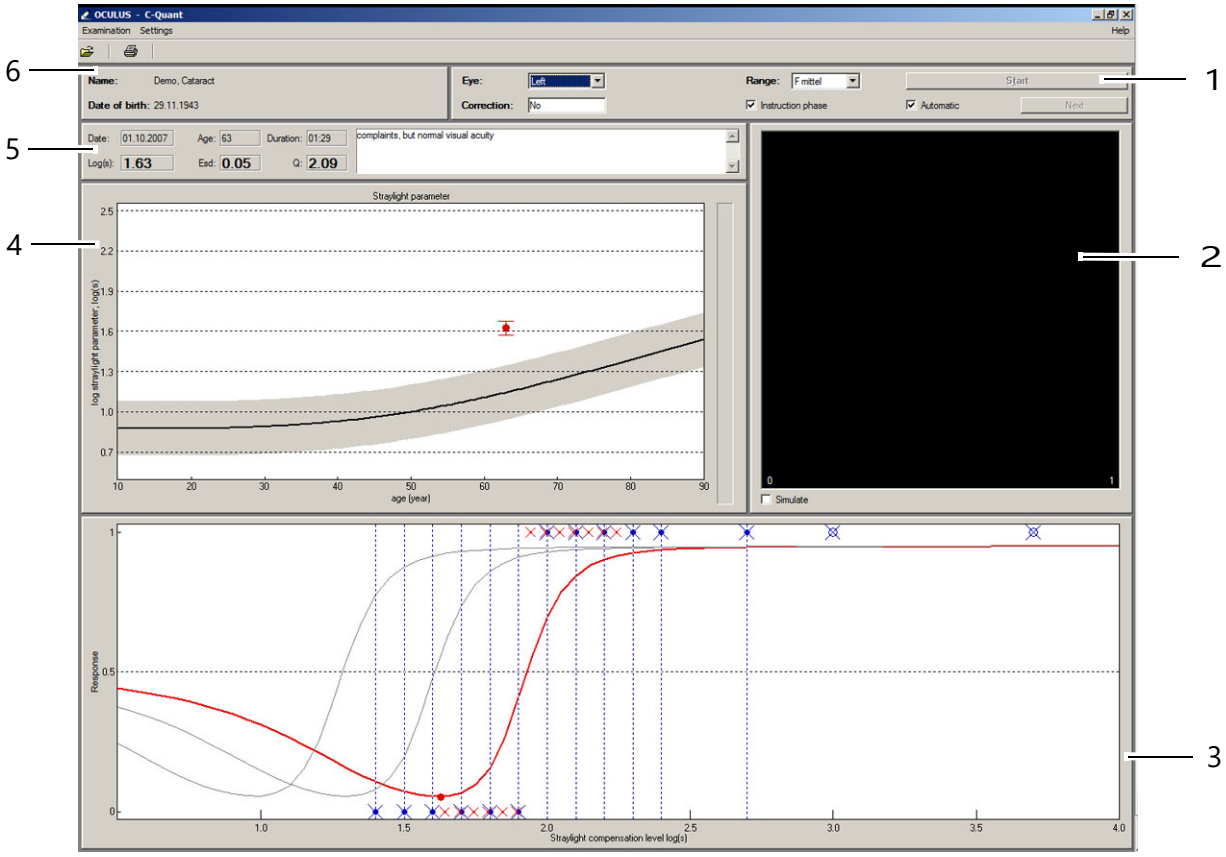
10.1 Starting the C-Quant Program

Switching from Patient Data Management to the Examination program:

➔ After you have selected a patient *(9.1 Starting Patient Data Management on page 28)* start the Examination program by clicking [C-Quant].

➔ Alternately, you can start the program by double clicking the patient you have selected.

10.2 Overview C-Quant Program Menu



1 [Start] button
2 Examination field
3 Examination response chart
4 Graphical result fields
5 Numerical result fields
6 Common data and examination specific data

Fig. 10-1: C-Quant program menu

The menu bar contains the following main items:

- Examination

  Loads an existing examination, prints the most recent examination results and exits the examination software via the menu item "New patient / Exit" (returns to patient data management).
- Settings

  Here you can adjust user-specific settings (language and date format) as well as system settings.

10.3 Information Boxes (C-Quant Program)

The main window is subdivided into a number of fields.

10.3.1 Common data

The patients name and date of birth are displayed in the upper left corner of the main window.

Fig. 10-2: Common data

10.3.2 Examination specific data.

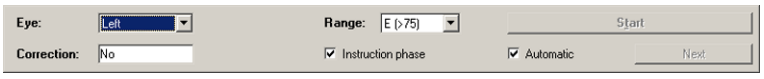


Fig. 10-3: Relevant data to the examination

This is where to enter all data relevant to the examination:

Eye:

Select the eye to be examined.

"Range" **field**

The measurement range can be chosen to fit the kind of patient.

For many eyes the E range (default) is efficient.

Very young and healthy eyes are more effectively studied with a lower range setting.

Very old patients or high straylight eyes are more effectively studied with a higher range setting *(see 13 Practical Guide for operating the C-Quant on page 60)*.

Correction

➔ Click on the "Correction" button.

The following dialog boxappears:

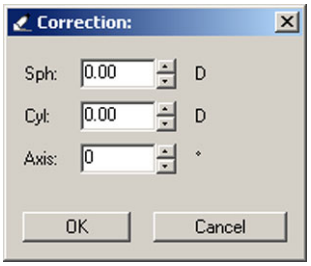


Fig. 10-4: Correction of sight

➔ Enter the spherical power, cylinder power and axis if any are used *(see 13.1 Ambient operating requirements on page 60)*.

➔ Click [OK] to confirm the selected corrective lens.

10.3.3 Instruction phase

When this checkbox is activated the examination starts with the presentation of five test stimuli to familiarize the patient with the procedure.

The response in all five cases should be "1". If the patient responds otherwise the program issues a warning.

➔ The third test stimulus is difficulty for many patients.

➔ Click [Continue anyway] if the patient shows proper understanding.

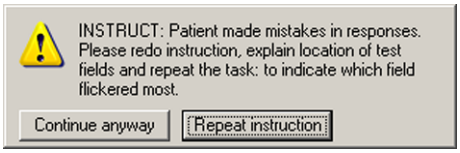


Fig. 10-5: Warning: mistakes in responses

The responses to these stimuli have no influence on the examination outcome.

To see time the instruction phase can be switched off depending on patient understanding.

It is automatically switched off after the first measurement.

10.3.4 Start

➔ Click on the [Start] button to start the examination.
Alternatively you can use the keyboard shortcut [Alt]-t.

Automatic

When this option is activated (default setting) the next stimulus is shown automatically as soon as the patient has responded to the one before.

When this option is deactivated the next stimulus can be called up by clicking on [Next].

10.4 Result fields

Note

In the following sections a sub-opitmal measurement is chosen as example. *See 13.4 Measurement - Examples on page 65, example 4.*

10.4.1 Numerica

Fig. 10-6: Results shown numerically

Here the result of (Log(s) = patient's straylight value) of the current examination is shown numerically. In addition the field shows the examination date, the patient's age at the time of examination, the examination duration and the quality parameters Esd and Q.

- Esd is the expected standard deviation of the individual measurement value in case of repeated measurements.

  The smaller Esd is, the more reliable the result.
- Q is a further quality criterion. In this case the result is the more reliable the higher the value is.
- If Esd < 0.08 and Q > 1, the reliability of the result is considered to be good.

  If Esd < 0.08 and Q > 0.5, the reliability is considered to be acceptable.

  A warning is given if Esd > 0.08 or Q < 0.5.

[On the right is a field for entering comments on the examination performed].

Graphic (straylight parameter)

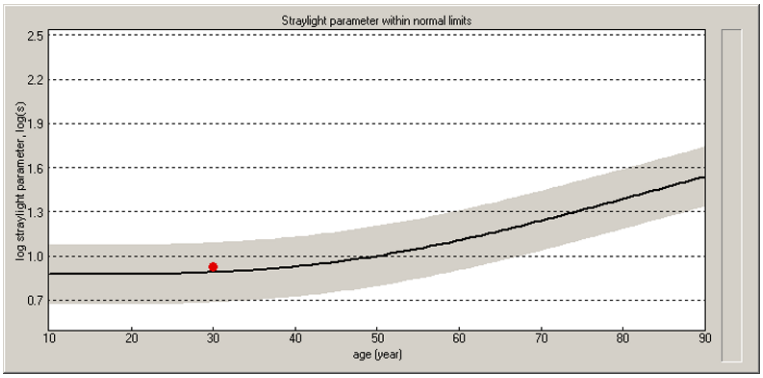


Fig. 10-7: Graphic: measured straylight value

- The measured straylight value (log(s)) is entered in the normal age curve (red dot). The black line is the average curve, while the gray area gives the range of normal variation. If the red dot is outside the gray area, this signifies a conspicuous finding.

10.4.2 Examination fields

Stimulus field view

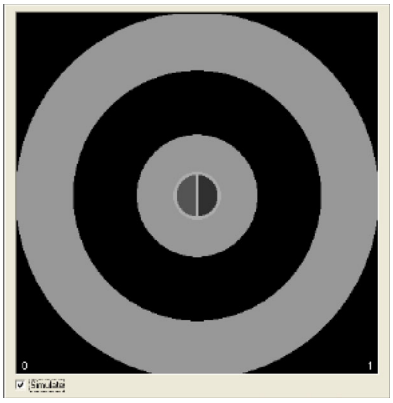


Fig. 10-8: Stimulus field

This is the diagram presented to the patient.

The "0" and "1" at the bottom indicate with which key the patient can produce the responses "0" or "1" in the examination response chart.

If you want to first explain the examination procedure to the patient, activate "Simulate".

10.4.3 Examination response chart

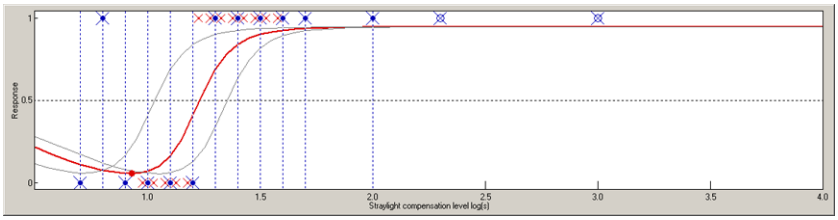


Fig. 10-9: Responses given in the course of an examination

This diagram shows all the responses given in the course of an examination.

Responses can only take on either of the values "0" or "1".

In the course of an examination the compensation light is presented at random either onthe left or on the right.

"1" signifies that the patient pressed the key on the side where the compensation light was presented.

The outcome values in the diagram are represented by different symbols depending on the phase currently being examined.

- instruction phase 
- dark phase 
- light phase 

Extensive studies have shown that the results follow a specific curve, referred to as the"psychometric function".

The red curve shows the location of the psychometric function obtained from the current measurement results (sect. 10.3, page 31).

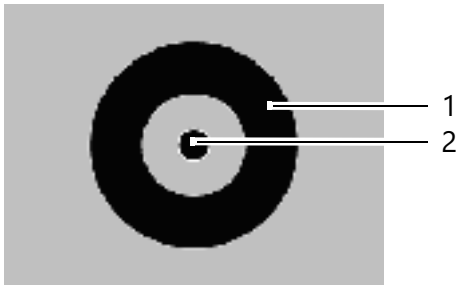
Its minimum, marked with a red dot, gives the patient's straylight value log(s).

The gray curves delimit the area considered normal for the age of the patient.

11 How the C-Quant works

11.1 The measurement principle

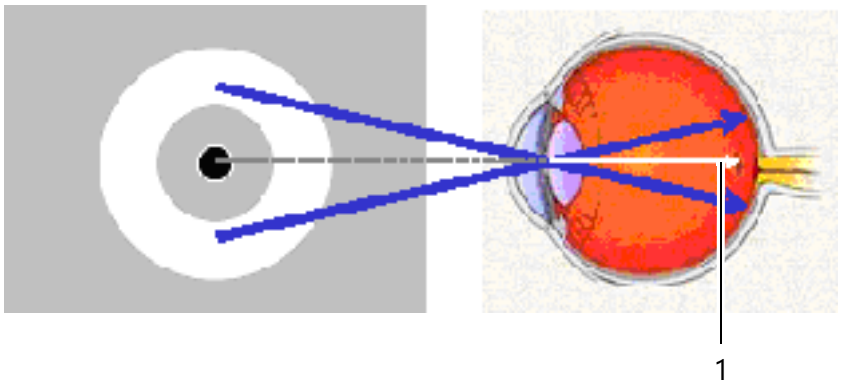
To understand the measurement principle it is helpful to reduce the stimulus field to two fields: the central test field and the outer ring (straylight source).
These two fields are shown in black in the diagram below.



1 Straylight source (outer ring) 2 Central test field
Fig. 11-1: Two fields

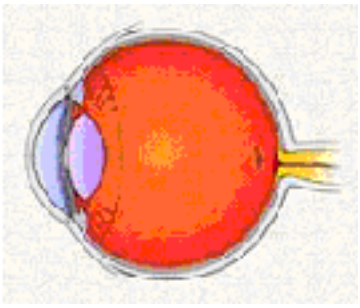
Now the outer ring starts to flicker.
The phase when the ring is on is referred to as the "on-phase" and the phase when it isoff is referred to as the "off-phase".
In the on-phase the ring of the straylight source is projected onto the retina.
However, some of the light is scattered by the lens and other parts of the eye and is thusprojected on the part of the retina onto which the test field projects (fovea).

11.2 On-phase



1 Straylight

11.3 Off-phase

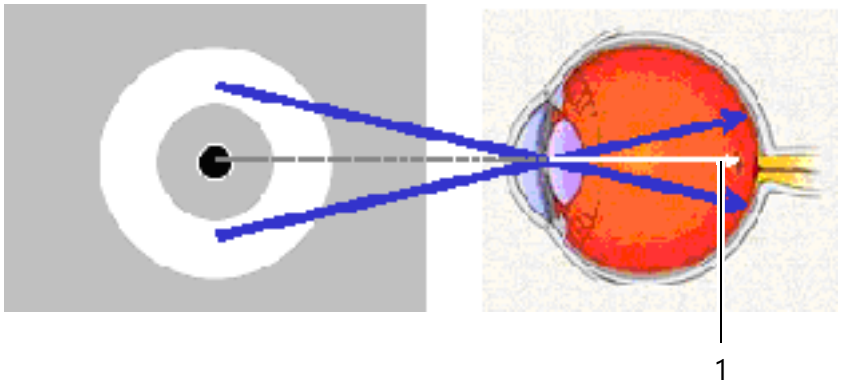


As a result of the light scatter the patient thus sees the test field flicker synchronously with the straylight source even though it is actually dark.

Since only a small fraction of the light emitted by the straylight source is actually scattered the test field appears to flicker gray.

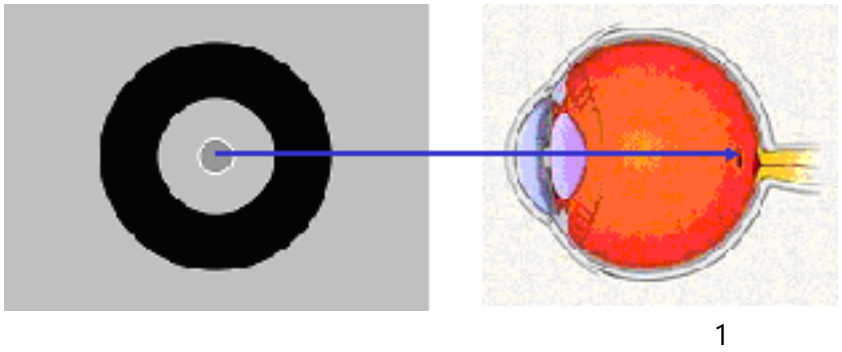
To determine the amount of light that is scattered by the patient's eye the test field is nowmade to flicker itself, but counter-phase to the straylight source: When the straylightsource is off the test field is on and vice versa.Now the test field appears gray both in the on-phase and in the off-phase.

11.4 On-phase



1 Straylight

11.5 Off-phase



1 Compensation light

Now the brightness of the test field is adjusted until the patient no longer sees any flicker.This yields his or her straylight value.

11.6 Compensation comparison method

Determining the exact straylight value by means of direct compensation has proven difficult in practice because many patients are unable to tell when the test field no longer flickers.

For this reason the compensation comparison method was developed.

The stimulus field with this method is similar to that used with the direct compensationmethod, except that the test field is divided in two.

1 Straylight source (outer ring) 2 Central test field

Fig. 11-2: Compensation comparison

During the examination a number of short stimuli are presented to the patient and he is then asked to decide which of the two test fields flickers more intensely.

The following example illustrates the underlying idea.

The left test field is off all the time.

In the right test field compensation light appears counter-phase to the straylight source at varying intensity.

We will assume that patient has a straylight value of 10. The dimensional unit of straylight is disregarded in this example because it has no significance for understanding the measurement principle.

11.6.1 Seven stimuli for the compensated field are shown:

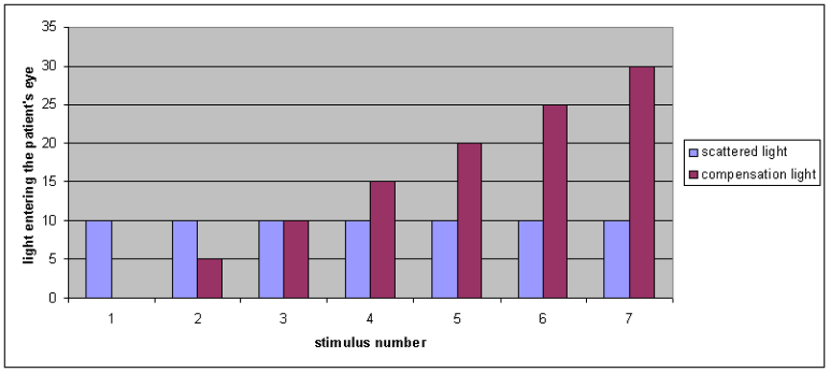


Fig. 11-3: Seven stimuli

The left test field corresponds to stimulus numbher 3 all the time.

If the patient states that the left test field flickers more intensely, this is counted as "0".

If he sees the right test field flicker more intensely, this gives "1".

- For the individual stimuli this has the following consequences:

1 Here no compensation light is presented, so that the two test fields appear the same.

Given sufficient test repetition the patient will choose right just as often as left, givingan average value of 0.5.

2 The right test field shows compensation light at intensity level 5. This means that the left test field has a flicker intensity of 10, while the right field has a flicker intensity of 10 -5 = 5. The response will most often be "0". If the stimulus is repeated sufficiently often he will sometimes give "1". Ultimately the outcome will tend towards 0.1.

3 This stimulus is referred to as direct compensation. The straylight is of equal intensity as the compensation light, so that the patient will not see any flicker in the right test field and will therefore answer with "0".

4 Here the difference in flicker intensity between the right and left test field is 5 again. As with stimulus 2 the flicker intensity of the left test field is greater. The average response value will be 0.1.

5 The compensation light is precisely twice as intense as the scattered light, meaning that the flicker intensity is 20-10=10, equal to that in the other test field. The patient will therefore find that the two

6 Here the compensation light is 2.5 times as intense as the scattered light, and the patient will give an average response of 0.85.

7 The compensation light is 3 times as intense as the scattered light and clearly produces greater flicker. The patient will give 1 on average.

Plotting the results in a chart gives the following picture (two measurement points have been added to extend the curve):

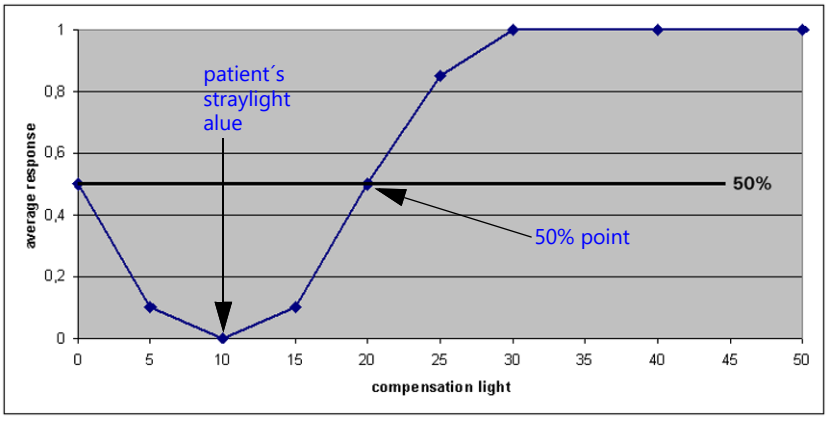


Fig. 11-4: Plotting the results in a chart

11.7 The psychometric function

The curve in Fig. 10-3 represents a rough approximation of what is known as the "psychometric function".

This concept is widely applicable to human sensory functions and is used to describe phenomena of hearing, smelling, pain perception and vision.

In our case the curve will shift over the abscissa (x-axis) to a greater or lesser degree, depending on the patient's straylight value.

The psychometric function can be used to determine a person's straylight value with great precision on the basis of only a few stimuli responses.

Rather than by determining the straylight value "directly" this is done by finding the point on the curve where the response value becomes 0.5.

In our example this happens at two points: one where both test fields are switched off and one where the compensation light is precisely twice a intense as the scattered light.

At the second point the curve shows a very steep slope.

The goal is to locate this point, also referred to as the 50 % value.

The patient responses will normally change quickly in the proximity of the 50 % value resulting in the steep slope at this point.

From here the patient's straylight value can easily be calculated.

Results obtained in this way have shown to be very precise and reproducible.

11.8 Strategy details

In practice the examination procedure is a little more complicated.

Stimuli are presented left and right at random to prevent the patient's anticipation from influencing the outcome.

Also, to prevent the patient from confusing differences in flicker intensity with differences in brightness, the instrument continually adjusts the test fields so that they have equal average brightness at each presentation.

The abscissa of the examination response chart has a logarithmic scale, termed "straylight compensation level log(s)".

The "straylight compensation level" is determined by the ratio between the compensation light (in one half of the central test field) and the intensity of the straylight source. It is given in the same measurement units as the straylight parameter "s".

In this way the responses given by the patient can be assessed directly in terms of his straylight value.

With a logarithmic scale the response pattern (probabilities according to the psychometric function) takes on a constant shape when depicted graphically.

To determine the patient's straylight value the psychometric curve is shifted horizontally until it most closely fits with the response pattern.

The patient's 50 % value is exactly twice as high as his straylight value.

11.9 Examination phases

11.9.1 Instruction phase

This phase is available as an option to familiarize the patient with the examination procedure.

It consists of five stimuli which do not contribute to the examination outcome.

The first three stimuli are presented without the straylight source, i.e. the flicker is produced only by the two test fields.

For the last two stimuli the straylight source is switched on as well, as in the actual examination.

However, the compensation light is turned so high that patients will always see the compensationlight flickering more intensely, regardless of his straylight value.

11.9.2 Dark phase

In this phase the compensation light is kept constant while the intensity of the straylight source is continually increased.

This will make the patient's decision more and more difficult, up to the point where the straylight source reaches its full intensity.

The measurement principle with this procedure remains the same.

This phase simulates the increasing glare experienced by motorists from oncoming vehicles.

11.9.3 Light phase

The result of the dark phase gives a reasonably good approximation of the patient's straylight value.

To determine it with greater precision he is now shown 13 stimuli in the light phase which are grouped around the initially determined value.

In this phase the straylight source has a constant intensity of 300 cd/m2, and the stimuli are presented in random order.

12 Quick Guide - Performing an examination

12.1 Before the examination

Before starting an examination you need to specify the eye, correction lens and range *(10.3 Information Boxes (C-Quant Program) on page 46)*.

Please observe the following points:

- The eye not being examined should be covered.
- The corrective lenses should be clean and free of scratches, since this would affect the measurements.
- The patient must hold the eye to be examined close to the viewing hole, without pressing against it *(see 13.1 Ambient operating requirements on page 60)*.
- The patient should open his eye as wide as possible to prevent light scatter by hiseyelashes.
- The examination should preferably be performed in a dimly lit room.

➔ Instruct the patient as follows:

"Decide which field shows more flicker and press the corresponding key on the instrument."

12.2 Starting an examination

➔ To start an examination click on the [Start] button *(see 10.1 Starting the C-Quant Program on page 45)*.

During the examination the responses given by the patient and the momentarily best fitting psychometric curve are shown in the chart below *(10.4.3 Examination response chart on page 50)* and the values in the result fields *(10.4 Result fields on page 48)* are continuously adjusted.

When the examination has been completed the result fields show the final values.

If during the examination the patient fails to respond to a stimulus within two seconds the following warning appears:

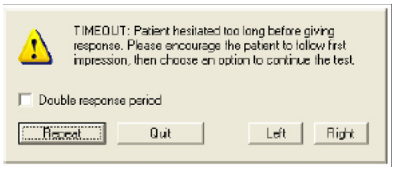


Fig. 12-1: Patient instruction

The patient can now no longer respond and you have to decide whether to continue or break off the examination.

If the patient frequently gets this message after a stimulus and can't decide, encourage him to press a key even if the test fields look the same.
Alternatively you can increase the response time by a factor of two and continue, or enter a response yourself.

Note

The following practical guide *(13 Practical Guide for operating the C-Quant on page 60)* contains more detailed information on the measurement with the OCULUS C-Quant.

12.3 Printout

12.3.1 Overview printout (example)

OCULUS C-Quant	Name:	Demo, Patient	
Version: 1.00	Date of birth:	1973/10/23	ID:

Date of exam.: 2004/10/05
Correction: No

Right eye (OD):
Time: 16:37:27 Age category: A Log(s): 0.93 Q: 1.39 Esd: 0.05 Comment:

Left eye (OS):
Time: 16:48:41 Age category: F Log(s): 1.63 Q: 2.09 Esd: 0.05 Comment:

You can either make a screenshot printout or an overview printout. The overview printout contains no graphics. You can only make an overview printout of examinations that were performed on the same day. To print out all examinations you need to load the relevant examination data and print them out separately.

13 Practical Guide for operating the C-Quant

This chapter gives some examples of possible measurement outcomes, which can be useful to interpret your own results, especially when measurement reliability is not optimal.

It is assumed that you are already familiar with basic operation of the C-Quant.

Please start to familiarize yourself with the measurement by testing your own eye.

Play with different range settings (including "G") and (erroneous) corrective lenses up till errors of + and - 4D.

Study the response patterns (lower graph of the C-Quant screen) obtained and compare them with the examples in this document.

13.1 Ambient operating requirements

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

13.2 Measuring procedure

Warning

A scratched or soiled lens will lead to wrong measurements.

➔ Before measuring: Make sure that the lens is clean, see 15.2.2 Cleaning the lens on page 76.

Three settings need to be made on the screen *(sect. 9.1, page 23)* before a measurement can be started.

13.2.1 Eye

If both eyes are to be measured, start with the better/dominant eye.

The other eye should be occluded with an eye patch or something similar.

13.2.2 Correction

The refractive correction is not critical for the C-Quant measurement.

A deviation of the best corrected value of up to 2 diopters can easily be tolerated.

Cylindrical errors of up to 3 diopters may be corrected with the spherical equivalent.

It is recommended to use only one trial lens for refractive correction, unless the cylindrical correction is more than 3 diopters.

➔ For visual acuities down to 0.2, it should still be possible to perform the test.
For visual acuities of 0.1 or lower, the test will be very difficult to perform.

13.2.3 Range

The default "Range" setting is “E moderate”. This will be a proper setting in many cases, if straylight increase is mild.

If high straylight values are expected (e.g. with cataract or corneal turbidities), settings “F medium log(s)” or “G high log(s)” must be used.

“G” can also be used if you want an easy (first) test. The response pattern obtained will guide you how to proceed.

➔ The chosen "Range" setting might turn out to be not optimal for the actual patient.
Depending on the circumstances, it might be necessary to repeat the measurement with a different "Range" setting in order to obtain a (more) reliable measurement (see “After the measurement” below).

13.3 Patient instruction

13.3.1 Eye position

➔ Position the eye close to the eyepiece, keeping a minimal distance (figure a).
A slight touch is good, but not firmly against it. If the eye is tightly against the eyepiece, condensation may form on the

lens of the C-Quant, which will influence the measurement outcome (figure b).

Also, if the eye is too far from the eyepiece, this will give a wrong test result (figure c).

Keep your eye normally open and do not squeeze, as this may also influence the measurement outcome (figure d).

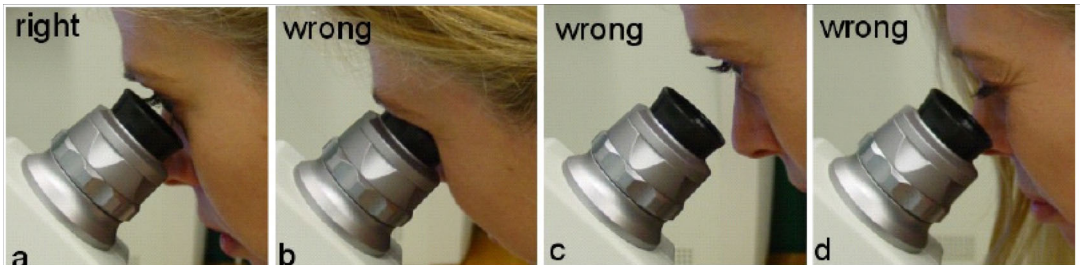


Fig. 13-1: Eye position

13.3.2 Task during the test

- ➔ Only concentrate on the two half fields in the center of the field; ignore the flickering ring.
- ➔ Pay attention to flicker in the two half fields, decide which one flickers more clearly/strongly, and press the corresponding button on the C-Quant (left button if the left test field flickers stronger, right button if the right test field flickers stronger).

  This procedure will be repeated for a series of stimulus presentations, until the test is finished.
- ➔ React by first impression and react promptly.

  Do not try to think about a presentation, but guess which side flickers more strongly.

  The buttons can be pressed as soon as flicker appears, shortly after the beep.
- ➔ For several presentations, it will be hard to tell the difference between the two half fields (they seem to be flickering equally strong).

  This is normal, and also here you must make a choice following your first impulse.
- ➔ Optional information (only if the patients ask): one measurement consists of about 25 presentations and usually takes 1.5 to 2 minutes.
- ➔ Make sure the patient is seated comfortably and the measurement takes place in a quiet environment with a minimum of background noise and other people around.

  The measurement requires full attention from the patient.
- ➔ Start the measurement by clicking the [Start] button.

  A "Start Examination" dialog appears where you can check if you entered the correct "Eye" and "Correction" settings.

➔ This information must be correct, as it can not be altered afterwards.
The settings can be altered in the dialog box.
➔ Click the [OK] button to start the actual measurement.

13.3.3 During the measurement

If the patient is too hesitant to choose between the two half fields and/or refuses to press a button, you can enter responses yourself with the arrow keys on the computer/laptop.
If you need to generate a random answer (in case the patient is undecisive with respect to the left/right choice), it is best to always press the same key (e.g. the left arrow key).
Use this option cautiously.

In case the response time has expired the option to enter a response yourself is given in a dialog box *(12.2 Starting an examination on page 58)*.

13.3.4 After the measurement

- When the measurement is finished, reliability is automatically verified. The measurement is considered reliable when esd ≤ 0.08 and Q ≥ 0.5.
  In this case, both numbers are shown in black (Example 1).

Note that esd is the (estimated) uncertainty in the log(s) value. As illustrated in the graph, the log(s) uncertainty may be different in upward and downward direction. The numerical value of esd given above the graph is the average of the plus esd and the minus esd.

- When esd > 0.08 and/or Q < 0.5, these values are shown in red, and the message "Reliability not optimal. Consider to repeat the measurement" appears. What to do in such a case?
  This depends on the actual value of esd. The reliability requirements employed in the C-Quant are rather strict. In most clinical cases, measurements with esd ≤ 0.1 or even esd ≤ 0.12 are sufficiently reliable, even ignoring the Q value (Example 2).
  To really get the best out of the measurement, you could consider to repeat the measurement in order to obtain a measurement with esd ≤ 0.08.
  Before repeating the measurement, you should verify if a correct "Range" setting was chosen (see below).

- If esd > 0.12, the measurement should be considered not reliable (but see below).

  The measurement should be repeated to obtain a measurement with esd ≤ 0.12.

  Again, you should first verify if a correct "Range" setting was chosen (see below).
- If reliability does not improve, the test may be too difficult for the patient (e.g. because of very low visual acuity).

  In this case, the "G" setting for "Range" may help. The "G" setting is the easiest for everybody, and should be used for difficult cases.
- If esd > 0.12 using a high "Range" setting (e.g. "G"), the result might still contain valuable information. For many clinical applications, it is not necessary to know the exact straylight value, but only whether or not the value is increased.

  In some cases, this information can be deduced from a measurement, even if esd > 0.12 (Examples 3a, 3b, and 3c).
- When it is desirable to know the exact straylight value (e.g. for follow-up measurements) after performing the test with the "G" range, another attempt could be made to obtain a reliable measurement at the patient's proper "Range" setting (the patient might have improved his performance after performing the test with the "G" range).

13.3.5 When to choose a different "Range" setting?

- The "Range" setting might be too high if the straylight value of the patient is low.

  In this case, there are too many 1 responses and not enough 0 responses (Example 4).
- The "Range" setting might be too low if the straylight value of the patient is much increased.

  In this case, there are too many 0 responses and not enough 1 responses (Example 5).
- In both cases, repeating the measurement with the same "Range" setting will not yield a lower esd value.

  You can only improve reliability by choosing a different "Range" setting.

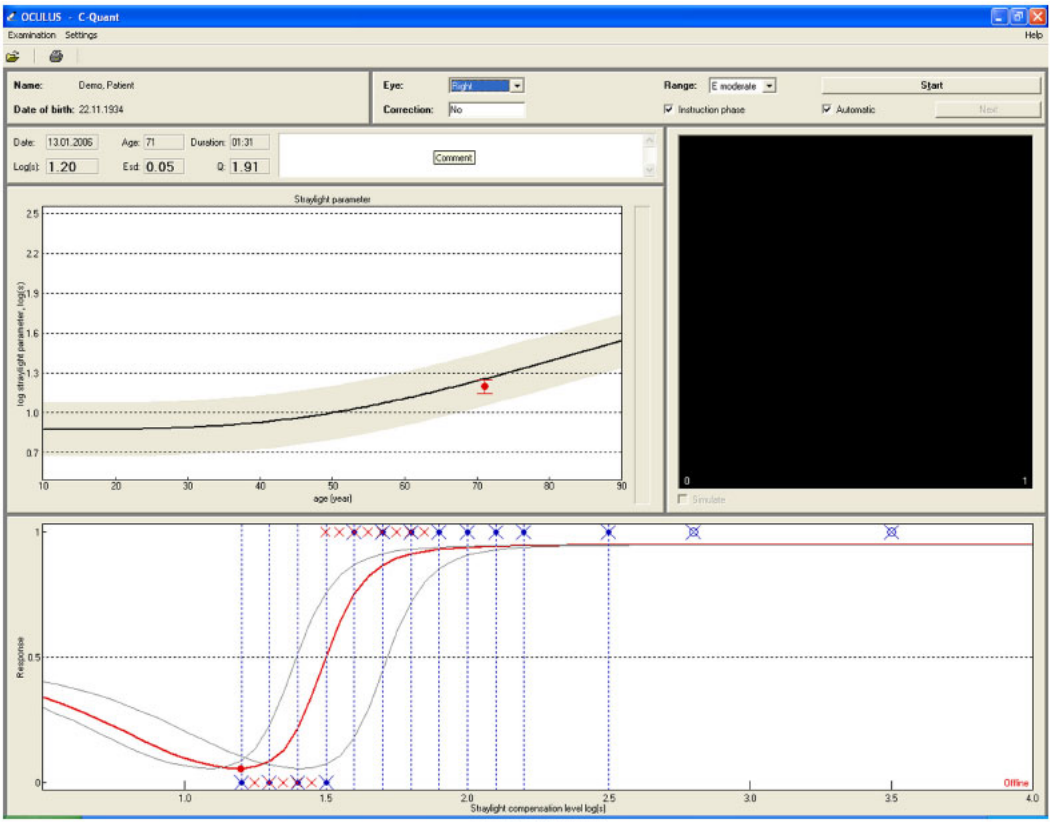
It is not always clear if the chosen range was too low (Example 6). In such a case it is anyway a good idea to choose a higher "Range" setting, because the test will be easier to perform then.

- (Example 7) shows that the patient from Example 6 is perfectly able to do the measurement.
  The chosen range in Example 6 was apparently too low.

13.4 Measurement - Examples

13.4.1 Example 1: esd ≤ 08 and Q ≥ 1

- This is a reliable measurement.
  Note that there is almost no overlap between the 0 and 1 responses.
  More overlap means a less reliable measurement.

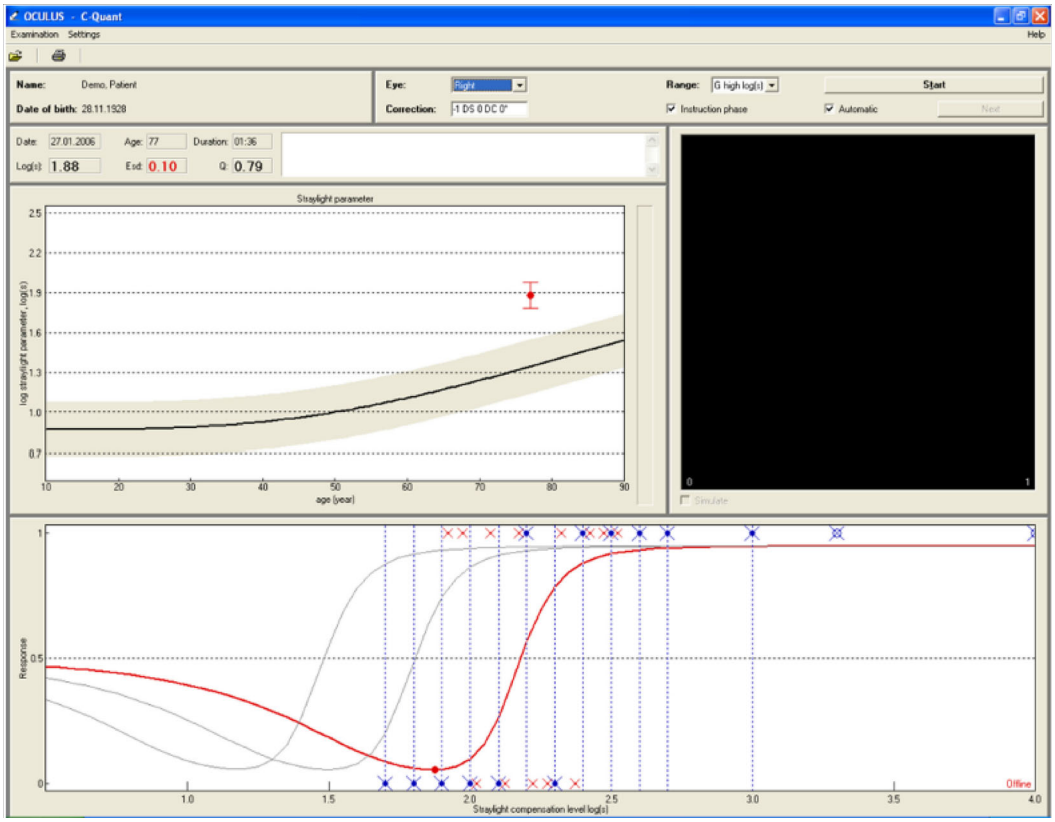


13.4.2 Example 2: 0.08 < esd ≤ 0.12.

- Although reliability is not optimal, this measurement may be accepted as a good measurement in most cases.

  However, if time allows, it is recommended to repeat the measurement in order to obtain a better reliability.

  Note that there is quite some overlap between the 0 and 1 responses.

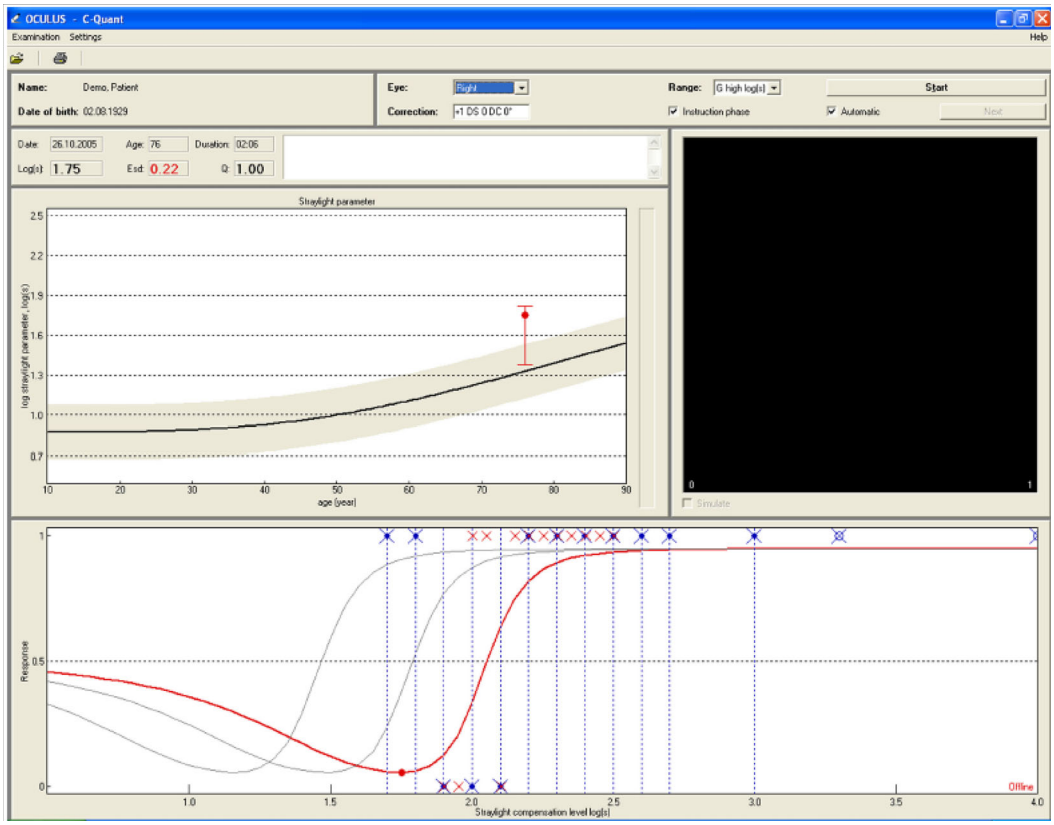


13.4.3 Example 3a: esd > 0.12 in “G” range

- If there is no time to repeat the measurement, this measurement can be used to estimate an upper limit for the straylight value.

  Because there is a consistent row of 1 responses in the right part of the graph, it is quite certain that the patient does not

have a straylight value higher than the outcome of the measurement.
If you need a more reliable straylight value, just repeat the measurement.

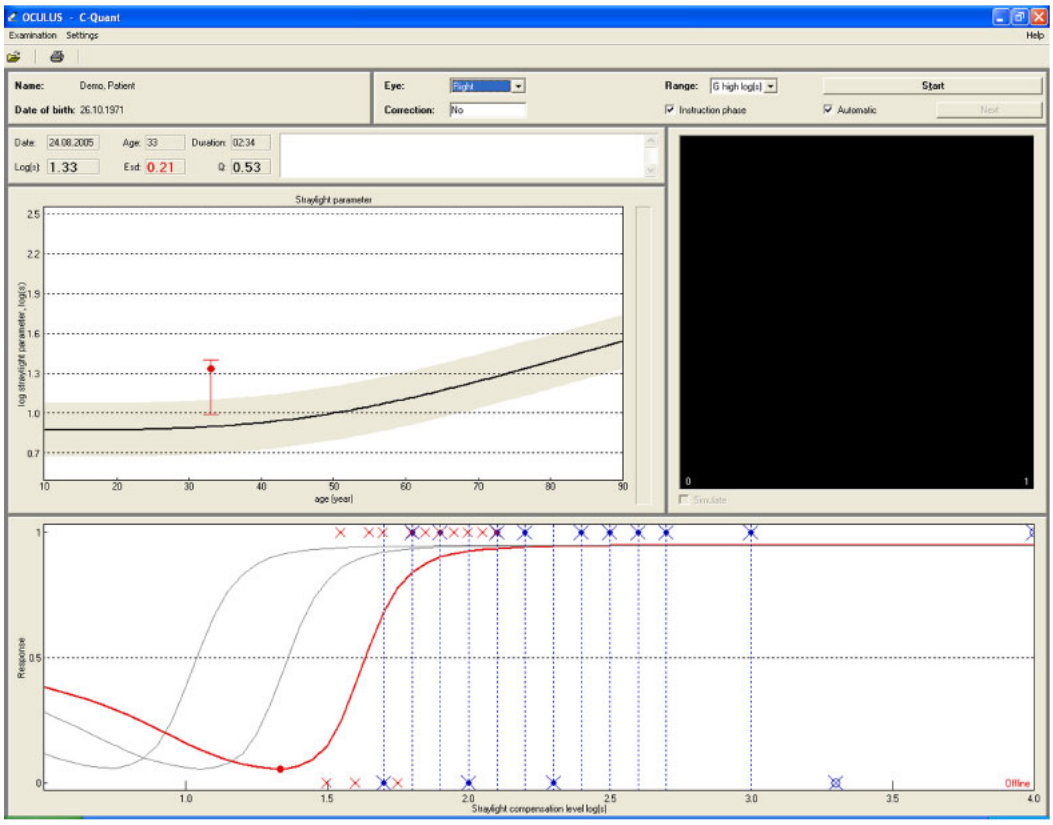


13.4.4 Example 3b: esd > 0.12 in “G” range

- This example is similar to Example 3a: if there is no time to repeat the measurement, the outcome of this measurement can be used to estimate an upper limit for the straylight value.

  If you decide to repeat the measurement, the surplus of 1 responses would suggest choosing a lower "Range" setting (as in Example 6), but the presence of some erroneous points (blue points at 2.0, 2.3 and 3.3) indicates that this patient has difficulties to perform the test.

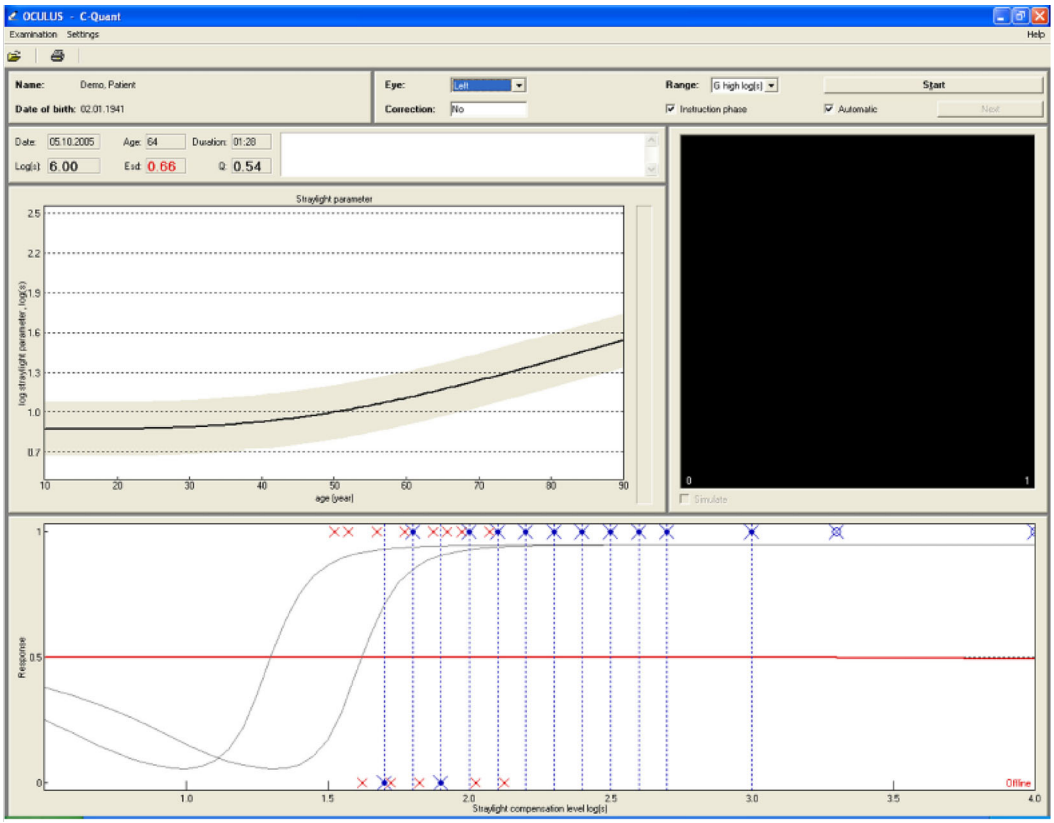
  Note that the same "Range" setting (“G”) is the easiest for the patient.



13.4.5 Example 3c: esd > 0.12 in “G” range

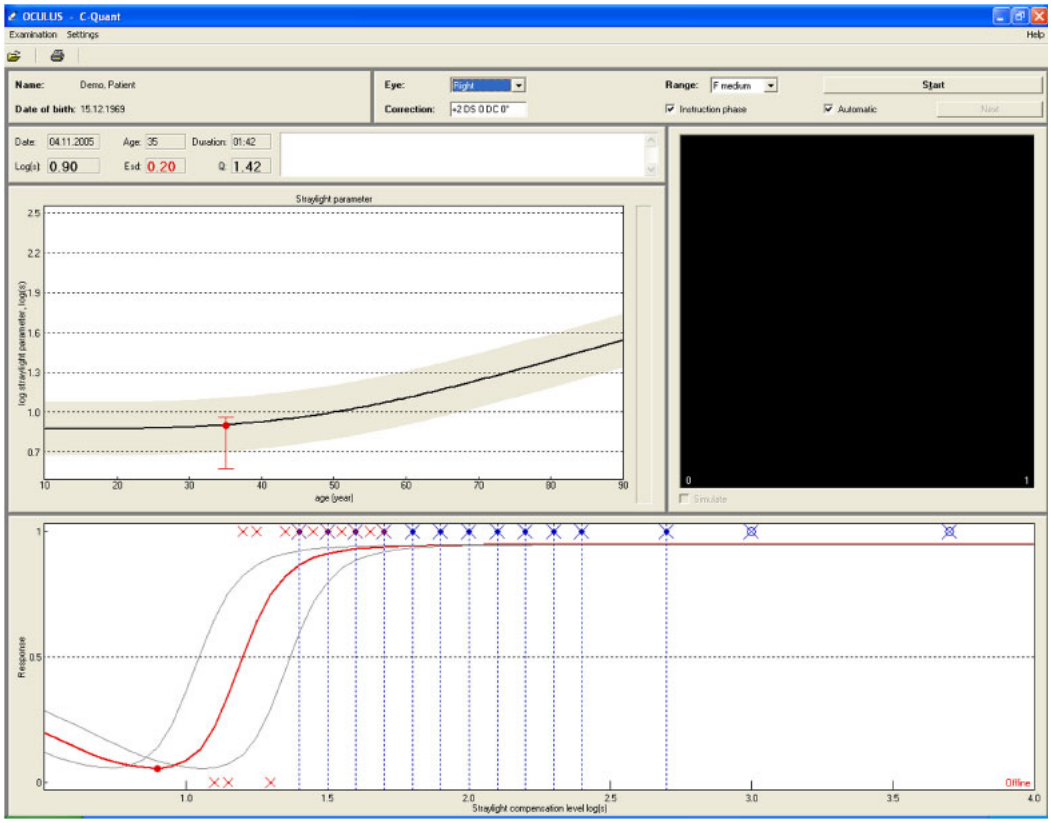
- This example is similar to Examples 3a and 3b, only esd is so high that no estimation for the straylight value could be calculated (log(s)=6.00 is a meaningless value).

  However, you can make this estimation yourself by looking at the 1 and 0 responses: the 50%-point of the curve will probably be not higher than 1.8, corresponding to a straylight value of 1.5, a moderately increased value.



13.4.6 Example 4: "Range" setting too high

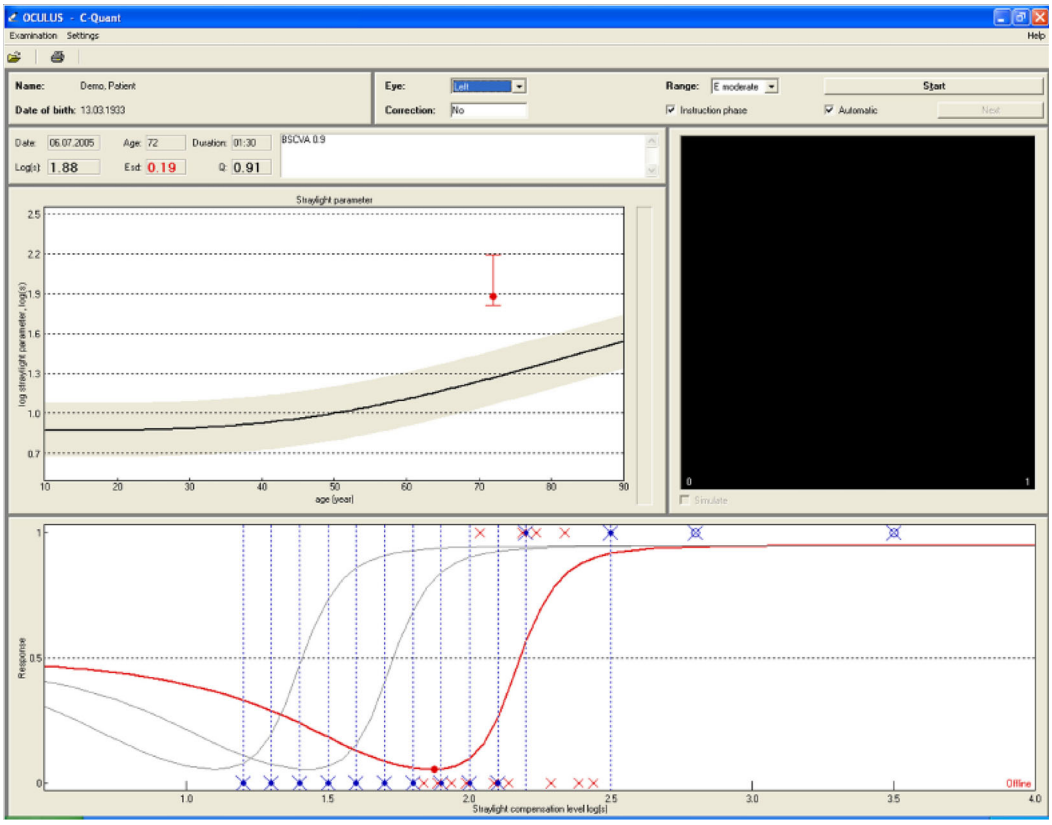
- This measurement went very well, only there are too many 1 responses and not enough 0 responses for a reliable estimation of the straylight value.
  Reliability can be improved by repeating the measurement at a lower "Range" setting.



13.4.7 Example 5: "Range" setting too low

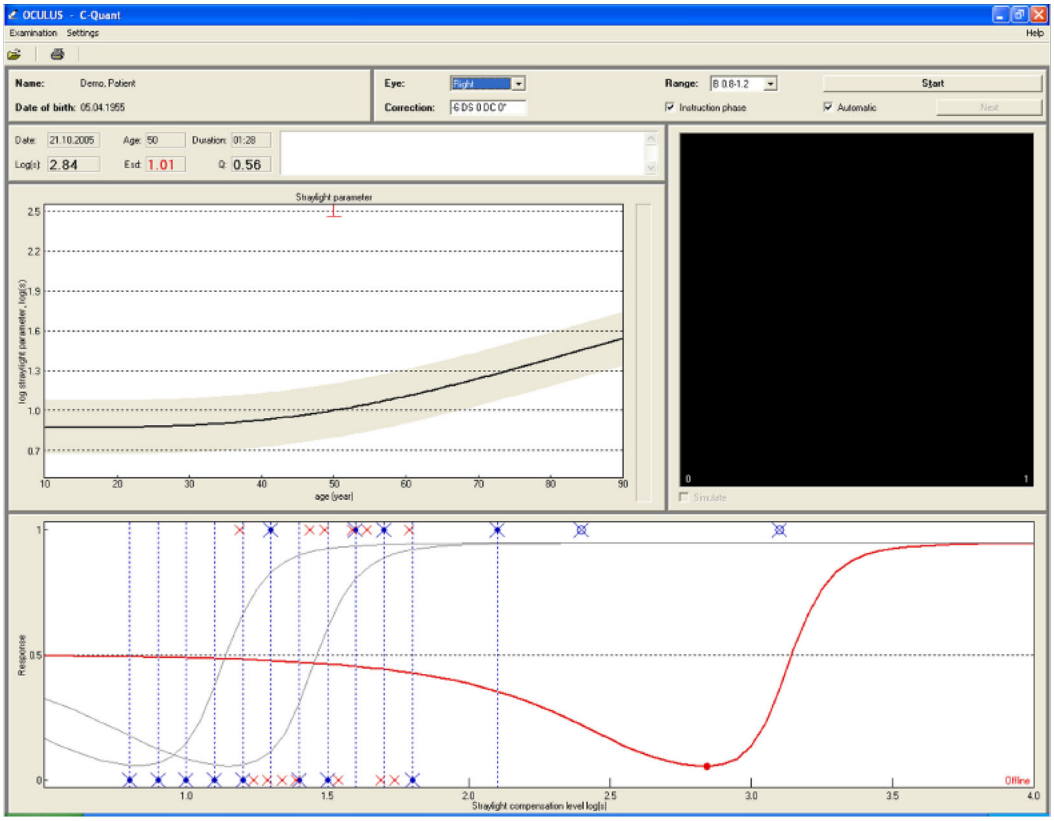
- There are too many 0 and not enough 1 responses for a reliable estimation of the straylight value.

  The measurement reliability can be improved by repeating the measurement at a higher "Range" setting (which will be “G” in this case).



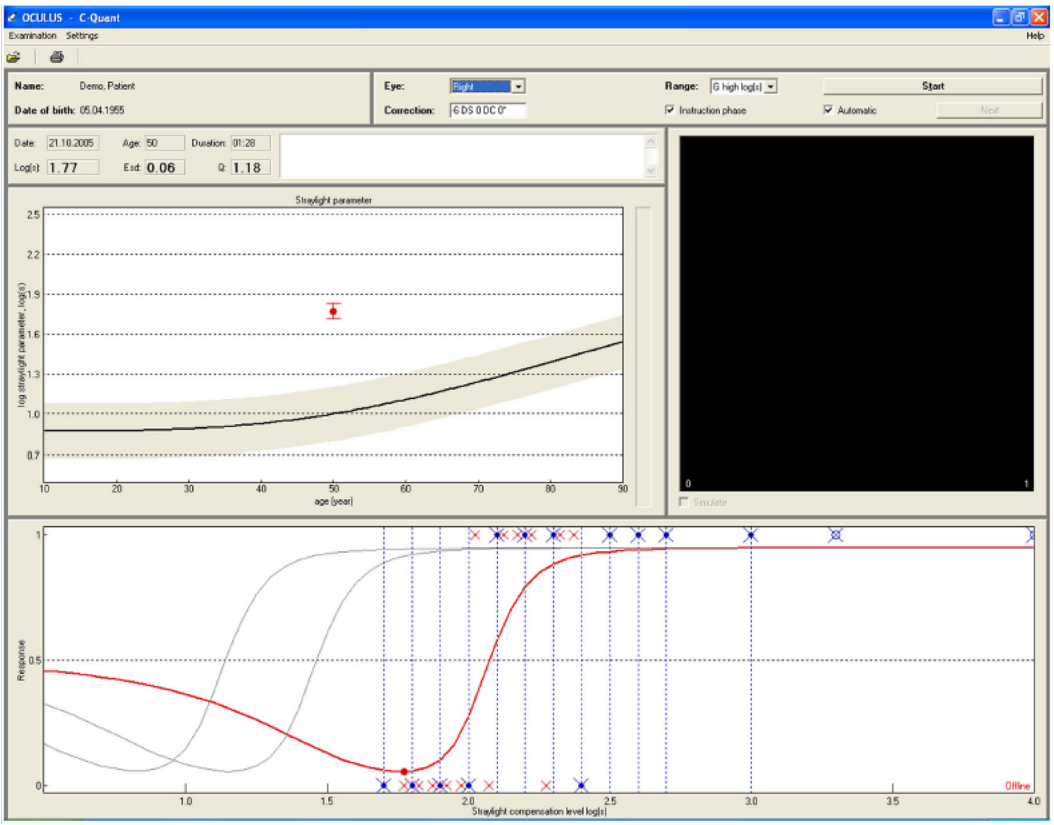
13.4.8 Example 6: unreliable measurement at low "Range" setting

- From this result you can not tell if the "Range" setting was chosen too low, or if the test is too difficult for the patient.
  In both cases it is wise to repeat the measurement at a higher "Range" setting, in this case the “G” setting (see Example 7).



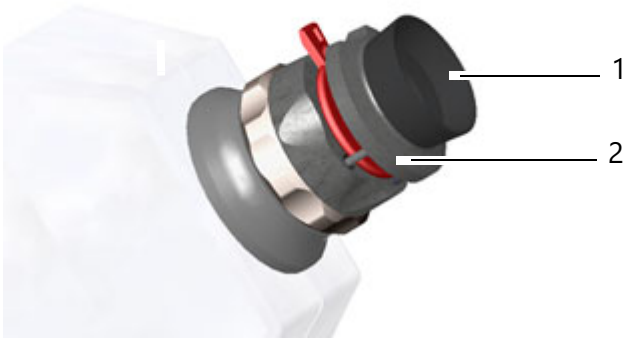
13.4.9 Example 7: reliable measurement at high "Range" setting

- The same patient as in Example 6, but measured with the "G" setting.
  This is a reliable measurement (esd ≤ 0.08 and Q ≥ 1). The chosen range in Example 6 was apparently too low.



14 Inserting corrective lenses

➔ Pull out the clamping device of the lens holder and insert a lens in the opening.



1 Eyepiece cup 2 Lens holder

Fig. 14-1: Inserting lenses

15 Cleaning and Disinfetion

Warning

➔ Always disconnect the power supply before cleaning or disinfecting the unit, 17.2 Disassembly on page 80.

15.1 Cleaning

Precaution

➔ Do not clean the C-Quant with aggressive, chlorinated, abrasive or harsh cleansers.

➔ Always take care to observe the product descriptions and instruction manuals of agents and equipment which you use for the care, cleaning and disinfection of the unit or its accessories.

Required materials:

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

15.2 Dust protection

➔ To prevent dust from entering the viewing hole always keep the instrument in the dust cover included in the delivery when the instrument is not in use.

15.2.1 Cleaning enameled surfaces

➔ Take care not to let cleansers enter the instrument.

We generally recommend using an antistatic cleanser for plastic surfaces (to inhibit recontamination).

Otherwise you can simply use a damp cloth to clean the outer enameled surfaces.

Use a mixture containing equal parts of spirit and distilled water to remove any residues.

You can also add a few drops of a commercial detergent to this mixture.

The lens of the viewing hole can be cleaned with a soft cloth or lens brush using alcohol or an optical cleanser.

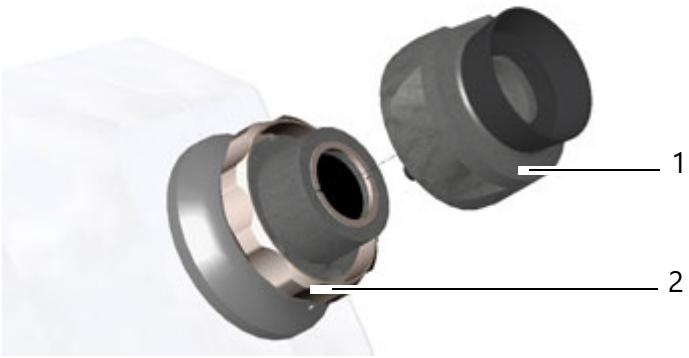
15.2.2 Cleaning the lens

Warning

A scratched or soiled lens will lead to wrong measurements.

➔ For this reason try to avoid to come into contact with the lens and use the dustcover which has been delivered together with the lens, when the device is not in use.

➔ To clean a soiled lens, turn the ring nut clockwise until you can remove the eyepiece.
Clean the lens with a soft cloth.



1 Eyepiece 2 Ring nut
Fig. 15-1: Cleaning lenses

15.3 Disinfection

Required material:

- Mikrozid sensitive wipes premium
  Fa. Schülke & Mayr
  Softpack 48 pieces
  Art.Nr. 165711
  Schülke & Mayr GmbH
  Telefon: +4940521000
  Telefax: +494052100318
  mail@schuelke.com
  www.schuelke.com

Note

Equipment damage caused by disinfectant solution

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

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

➔ OCULUS recommends for disinfection of all surfaces except those of Plexiglass.

➔ After every use disinfect eyepiece, hand rests, keys and other surfaces which have been in contact with the patient.

15.4 Maintenance

The C-Quant is designed so that no special maintenance is necessary. For safety reasons, we recommend that the illumination and electrical values be checked every two years.

➔ Please contact OCULUS Service for this.

Precaution

Additional measures are not required during preventive maintenance.

16 Troubleshooting

Warning

Risk of personal injury or equipment damage due to improper troubleshooting

- ➔ Do not plug in or pull out any cables while the C-Quant is switched on.
- ➔ 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.

Error	Possible Cause	Remedy
No function when the On/ Off switch is pressed, the On/Off switch does not light up	The C-Quant is not connected to the power supply.	Plug the power cable into the power outlet, or into the port at the C-Quant.
	Power failure or power outlet is not active.	Inform the in-house electrician.
		Check that the connector is plugged in properly.
	The unit was turned off and immediately on again.	Wait 5 seconds between turning the unit off and on again.
The printer is not printing	The connection cable of the printer/ PC is not correctly plugged in.	Connect the plug again.
	The ink/toner cartridge is empty.	Replace the cartridge.

17 Dismantling, Transport and Storage

The C-Quant, must be properly dismantled and packed before being transported or stored.

17.1 Transport and Storage Conditions

The following values apply for a period of 15 weeks at most in the shipping container.

Storage	
Ambient temperature:	-10°C to +55°C
Relative humidity, including condensation:	10% to 95%,
Air pressure:	500 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

17.2 Disassembly

- ➔ End the current session.
- ➔ Switch off the C-Quant with the On/Off Switch.
- ➔ Unplug the power cord.

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

17.3 Transport and Storage

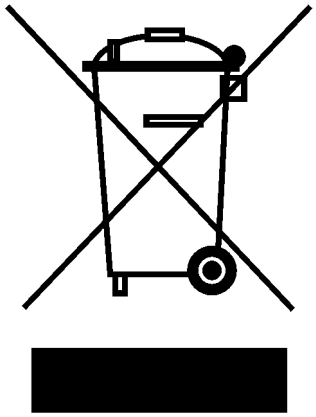
Warning

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

- ➔ Avoid shocks, vibrations, and contamination.
- ➔ Avoid high temperatures and humidity.

- ➔ Transport the C-Quant carefully.
- ➔ Store the C-Quant in compliance with the storage conditions.
- ➔ Avoid placing near heaters and moisture.

18 Disposal



In accordance with Directive 2002/96/EC of the European Parliament and the Council of 04 July 2003, and in accordance with German law governing the marketing, return and environmentally compatible disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste.

➔ Dispose the C-Quant in a compliant manner.

19 Terms of Warranty and Servicing

19.1 Terms of Warranty

Please note the following warranty provisions:

- Prior to and while operating the device it is important that you heed the instruction manual and safety instructions.
- In accordance with legal regulations, you are entitled to a warranty for the C-Quant.
- If modifications are made to the C-Quant 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 supplied computer hardware and software.
- 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 on the date of purchase apply.

19.2 Assumption of Liability for Functions and Damage

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

- Only use the equipment in conformance with this instruction manual.
- There are no parts either on or inside the C-Quant that require maintenance or repair by the user. If assembly work, modifications, adjustments, repairs, changes or service are performed by unauthorized personnel, or if the C-Quant is improperly maintained or handled, then any liability by OCULUS is voided.
- If the above-referenced work is performed by authorized persons,
  request a certification of the scope and type of repair, and, if necessary, the changes to the standard values or to the operating range from the service technician. This certification must contain the date of performance and statement of the performing firm, with signature.

- If requested, OCULUS will provide the service technician with a list of spare parts and additional descriptive material for this purpose.
- Make certain that only original OCULUS parts are used.

20 Technical Data

20.1 Measuring Parameters

Light source	White LED
Maximum LED brightness	300 cd/m²
Size of the test field	14°

20.2 Technical specifications

Dimensions height x width x depth	380 x 250 x 325 mm (15.0 x 9.8 x 12.8 in)
Weight	4.3 kg (9.5 lbs)
Interface	USB 1.1, Typ B 5 V
CE marking	CE 0123
Contraindications	None Noted

20.3 Electrical Specifications power supply

Mains connection	100 - 240V AC, 50 Hz - 60 Hz
Output voltage	12 V DC
Output power, max.	40 VA

20.4 Minimum Computer Requirements

The computer must comply with the requirements of IEC 62368-1

CPU	Intel® Core™ i5
Operating system	Windows® 11
RAM	8 GB
Interface	USB

20.5 Classification according to IEC 60601 - 1

Type of protection against electric shock	Protection class 2
Level of protection against electric shock	Type B
Level of protection against harmful penetration of water	IP20

21 Bibliography

- Van den Berg TJTP. Analysis of intraocular straylight, especially in relation to age. Optom Vis Sci, 72:52-59; 1995.
- Van den Berg TJTP, Coppens JE, Franssen L. New approach for retinal straylight assessment: Compensation Comparison. Invest Ophthalmol Vis Sci 46:ARVO E abstract 4315; 2005.
- Van den Berg TJTP, Hagenouw MPJ, Coppens JE. The ciliary corona: physical model and simulation of the fine needles seen radiating from point light sources. Invest Ophthalmol Vis Sci 46:2627-2632; 2005.
- Van den Berg TJTP, van Rijn LJ, et al. Relevance of glare sensitivity and impairment of visual function among European drivers. EC report 2005. www.glare.eu
- Franssen L, Coppens JE, van den Berg TJTP. Compensation comparison for assessment of retinal straylight. Invest Ophthalmol Vis Sci 47:768-776; 2006.
- Coppens JE, Franssen L, van Rijn LJ, van den Berg TJTP. Reliability of the compensation comparison stray-light measurement method. J Biomed Opt, 11:34027; 2006.
- Van den Berg TJTP, van Rijn LJ, Michael R, Heine C, Coeckelbergh T, Nischler C, Wilhelm H, Grabner G, Emesz M, Barraquer RI, Coppens JE, Franssen L. Straylight effects with aging and lens extraction. Am J Ophthalmol, 144:358-363; 2007.

21.1 Additional information

More information about the working principles of the C-Quant can be found in the separate document "Compensation Comparison in the Oculus C-Quant straylight meter".

More information about retinal straylight in general and its relation to other measures of visual function can be found in the separate document "Introduction to retinal straylight".

More thorough references related to these subjects can be found in the separate document "C-Quant literature overview".

For additional information, please contact:

Tom van den Berg

Ocular Signal Transduction group (www.nin.nl)

The Netherlands Institute for Neuroscience (NIN)

Amsterdam, The Netherlands

Phone: +31-20-5665185

Email: t.j.vandenberg@nin.knaw.nl

22 Annex

22.1 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 C-Quant (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 C-Quant 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.

Warning

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 C-Quant.

➔ 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 C-Quant 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 C-Quant.

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

Order number	Description	
80000	C-Quant	
05200905	Cable with connector plug, EU standard	2.5 m (98.4 in)
05200910 (110 Volt)	Cable with connector plug, US standard	2.5 m (98.4 in)
05150805	Power supply GSM40B12-P1J	12 V, 3.34 A
10009355	USB mini cable	1 m (39.4 in)

22.2 Guidance and Manufacturer's Declaration - Electromagnetic Emissions for the C-Quant

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2		
The OCULUS C-Quant is intended for operation in the electromagnetic environment specified below. The user of the C-Quant should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The C-Quant uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF-emissions CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

Electromagentic immunity, IEC 60601-1-2			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV 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 61000-4-5	± 1 kV line(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	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the C-Quant requires continued operation during power mains interruptions, it is recommended that the C-Quant be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagentic immunity, IEC 60601-1-2			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Conducted RF IEC 61000-4-6	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz	V_{eff} = 3 V	Portable and mobile RF communications equipment should be used no closer to any part of C-Quant, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interferences may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz		
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 C-Quant is used exceeds the applicable RF compliance level above, the C-Quant should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the C-Quant.
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 C-Quant, IEC 60601-1-2			
The C-Quant in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the C-Quant can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the C-Quant 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.			

22.3 Instructions for integration into an IT-Network

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

It is essential that you follow the 4.5 Instructions for the operation of a ME system on page 20 in the device instruction manual.

Please note the following information for implementing an integration of the PEMS into an IT-Network:

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

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

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

- Prefer wired LAN connection

- IPv4 network
- Fast-Ethernet (100 Mbit/s minimum)

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

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

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

- Refer to the section 4.3 Cyber-Secutity on page 17.
- Refer to the “Floating License Key - License management for software options” instruction manual (if applicable)
- Refer to device specific DICOM interface description (if applicable)

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

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

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

- Loss of data
- unsuitable data exchange
- Data corruption
- unsuitable temporal data allocation
- unexpected data reception
- unauthorized access to data

Connection of the PEMS to an IT-Network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.
The responsible organization should identify, analyze, evaluate and control these risks.
Subsequent changes to the IT-Network could introduce new risks and require additional analysis.

Changes to the IT-Network include:

- changes in IT-Network configuration
- connection of additional items to the IT-Network
- disconnecting items from the IT-Network
- upgrade and update of equipment connected to the IT-Network

22.4 Data Sheet GSM 40B

MEAN WELL

40W AC-DC Single Output Medical Adaptor **GSM40B series**

■ Features

- Universal AC input / Full range
- 2 pole AC inlet IEC320-C8
- High efficiency up to 91%
- Low leakage current <50μA
- Protections: Short circuit / Overload / Over voltage
- Fully enclosed plastic case
- Medical safety approved (2×MOPP between primary to secondary)
- Class II power (without earth pin)
- LED indicator for power on
- No load power consumption<0.1W
- ErP step2 compliant (level V)
- Meet EISA 2007 (Energy Independence and Security Act)
- 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 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 (<50μA), 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, the design of GSM40B observes the latest energy regulation (Level V); 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
- 05: Output voltage
- B: IEC320-C8 AC inlet
- 40: Output wattage
- GSM: Series name

File Name:GSM40B-SPEC 2014-04-08

MEAN WELL 40W AC-DC Single Output 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	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							
	OVER TEMPERATURE	Shut down o/p voltage, re-power on to recover							
ENVIRONMENT	WORKING TEMP.	-30 ~ +60℃ (Refer to "Derating Curve")							
	WORKING HUMIDITY	20% ~ 90% RH non-condensing							
	STORAGE TEMP., HUMIDITY	-40 ~ +85℃, 10 ~ 95% RH							
	TEMP. COEFFICIENT	±0.03% / ℃ (0 ~ 50℃)							
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes							
SAFETY & EMC (Note. 7)	SAFETY STANDARDS	ANSI/AAMI ES60601-1 / ES60601-1-11, TUV EN60601-1 / 60601-1-11 approved							
	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							
	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	Standard type P1J: 2.1φ * 5.5φ * 11mm, tuning fork type, center positive for stock ; Other type available by customer requested							
	CABLE	See page 2 ; Other type available by customer requested							

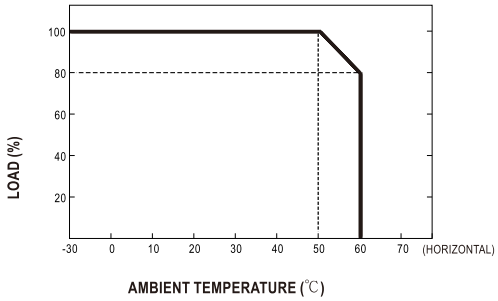
NOTE

1. All parameters are specified at 230VAC input, rated load, 25℃ 70% RH ambient.
2. DC voltage: The output voltage set at point measure by plug terminal & 50% load.
3. Ripple & noise are measured at 20MHz by using a 12" twisted pair terminated with a 0.1uf & 47uf capacitor.
4. Tolerance: includes set up tolerance, line regulation, load regulation.
5. Line regulation is measured from low line to high line at rated load.
6. 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. 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)

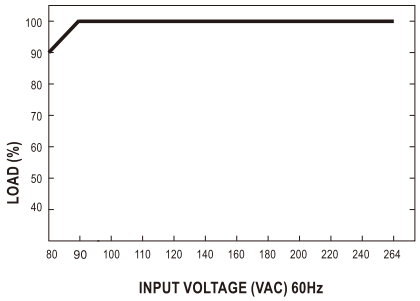
File Name:GSM40B-SPEC 2014-04-08

MEAN WELL 40W AC-DC Single Output Medical Adaptor **GSM40B series**

■ Derating Curve

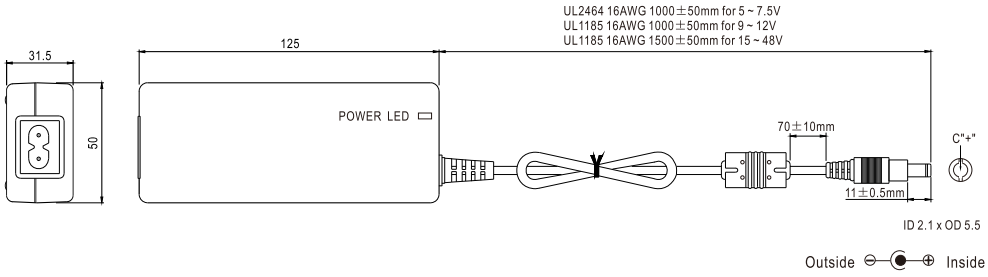


■ Static Characteristics



■ Mechanical Specification

Case No. GSM60B Unit:mm



■ Plug Assignment

Standard plug: P1M

P1M	
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 2014-04-08

WWW.OCULUS.DE

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

G/80000/EN
Lot:

OCULUS®