MESOGRAPH®

for eyemate®-IO

Instruction for use

Version 1.0 / 2019-07

CE 0344

Manufacturer	**Implandata Ophthalmic Products GmbH** Kokenstrasse 5, 30159 D - Hanover Phone: +49 511 2204 258-0 info@implandata.com www.implandata.com
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Valid from hardware version of the device	2.0
Valid from firmware version of the device	2.13/2.05
PC software	2.0

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Table of contents

1 General Information

1.1 About this instruction for use

These operating instructions describe the handling of the **Mesograph** product, part of the **-eyemate**® product family**.** The instructions for use are only valid for the product version mentioned and only for the original initial equipment delivery of the product.

These instructions for use are an integral part of the **Mesograph** and must be available at all times.

The exact observance of these operating instructions is the prerequisite for the intended and safe operation of the **Mesograph**.

This instructions for use is intended for medical specialists; the patient receives a specific instructions for use.

This instructions for use can be downloaded on the website www.implandata.com.

1.2 Symbols used in this instruction for use

HAZARD!

Failure to observe this warning will result in serious injury or personal injury.

WARNING!

Failure to observe this warning may result in serious injury or personal injury.

CAUTION!

Failure to observe this warning may result in minor personal injury or damage to the product.

Tip

A tip contains valuable additional information or suggests measures with which the operation of the product can be made more efficient and simpler.

1.3 Abbreviations used in these instructions for use

STK	Safety check
IOP	Intraocular pressure
implandata	Implandata Ophthalmic Products GmbH

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2 Safety and security

2.1 General safety instructions

Observe legal regulations	Observe the relevant legal and official regulations as well as the corresponding guidelines and specifications of your local facility when handling this device. The operator is responsible for compliance.
Training	The **Mesograph** may only be operated by trained personnel! It is the responsibility of the equipment operator to train and instruct the operating personnel.
Application	A briefing is required to use the **Mesograph.** See chapter 4.2 for training measures. Do not drop the unit under any circumstances. Do not operate the device outdoors. Observe the environmental conditions in chapter 11 Technical data. The device is not suitable for environments enriched with oxygen or where there is a risk of explosion. Explosion hazard exists, for example, in the immediate vicinity of flammable anaesthetics. Do not place the device in the immediate vicinity of devices with high electromagnetic radiation. The Mesograph must not be in the immediate vicinity of pacemakers or active implanted medical devices. A minimum distance of 20cm must be maintained to pacemakers!
Visual and functional check on the device	Before each use, check the device, the accessories and the buttons for damage. In case of damage, do not operate the device any further and contact Implandata.
Electrical protection	The **Mesograph** is powered by a battery. Only type 2CR5 batteries may be used. The use of rechargeable batteries is not permitted.
Electromagnetic compatibility (EMC)	The **Mesograph** was tested according to the current EMC regulations. In order to avoid EMC interference, the **Mesograph** may only be put into operation as described in this document. Use of the device may affect other medical electrical devices. The effects of radio signals on medical devices depend on various factors and are therefore unpredictable. Use of accessories other than those specified in this document may result in increased electromagnetic emissions or reduced noise immunity of the equipment or system.
Modifications to the device	Changes or modifications to the device without the express permission of the manufacturer are not permitted. These may result in electrical or mechanical hazards, increased electromagnetic emissions, or reduced noise immunity of the equipment or system, and thus affect the - electromagnetic compatibility of the **Mesograph** or other equipment.

Combination with other devices	The **Mesograph** may only be connected to a PC via the USB interface by trained personnel.
Accessories	The manufacturer only assumes warranty for operation with approved accessories. See Chapter 10.
Cleaning	Do not allow any liquid to enter the interior of the device. Do not continue to use the device after liquid has penetrated and contact Implandata.
Storage	Observe the information in chapter 11 "Technical data".
Disposal	See Chapter 9.

2.2 Symbols

2.2.1 Device

Symbols for user information can be found at relevant points on the device as well as on the label located on the back of the device.

Figure 1: Label Mesograph

Symbols	Significance
Symbol on the device	
SN	Serial number of the device
REF	Order number
	Manufacturer
	Application part of type BF
	Protect from moisture!
	The device must not be disposed of with normal hospital waste. For more information on disposal, please contact your authorized dealer or the manufacturer.
CE 0344	CE mark with identification number of the notified body. The product complies with the Essential Requirements of the Council Directive 90/385/EEC on Medical Devices.
	Follow the instructions for use!

2.2.2 Device packaging

The packaging label is located on the outside of the Mesograph's device packaging.

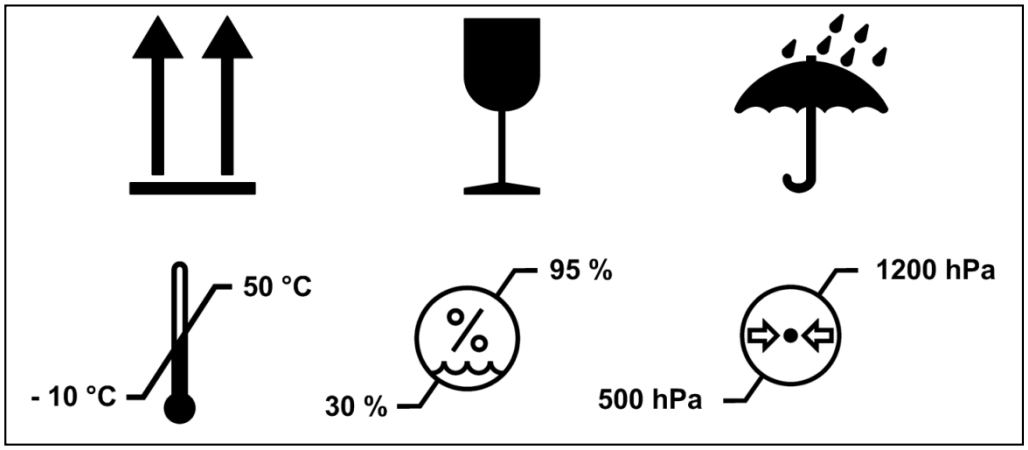
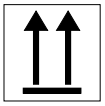
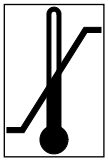
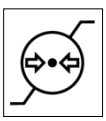


Figure 2: Packaging label Mesograph

Symbols	Significance
Symbols on the packaging	
	Top
	Fragile
	Protect from moisture
	Permissible temperature range
	Permissible humidity range
	Permissible ambient pressure range

3 Device description

3.1 System description and function

The **eyemate® system** for telemetric measurement of intraocular pressure consists of the implantable, biocompatible **eyemate-IO** microsensor, which remains permanently implanted in the patient's eye, and the hand-held Mesograph for power supply and data readout of the eyemate-IO microsensor.

The measurement of the intraocular pressure by the eyemate-IO microsensor is initiated by the Mesograph. The Mesograph activates the eyemate-IO microsensor by means of a low level magnetic field. The sensor then measures intraocular pressure and sends the measured intraocular pressure values to the Mesograph. The pressure value is displayed and the measurement data is stored.

In the Figure 3 the functional principle of the **eyemate®** system is shown graphically.

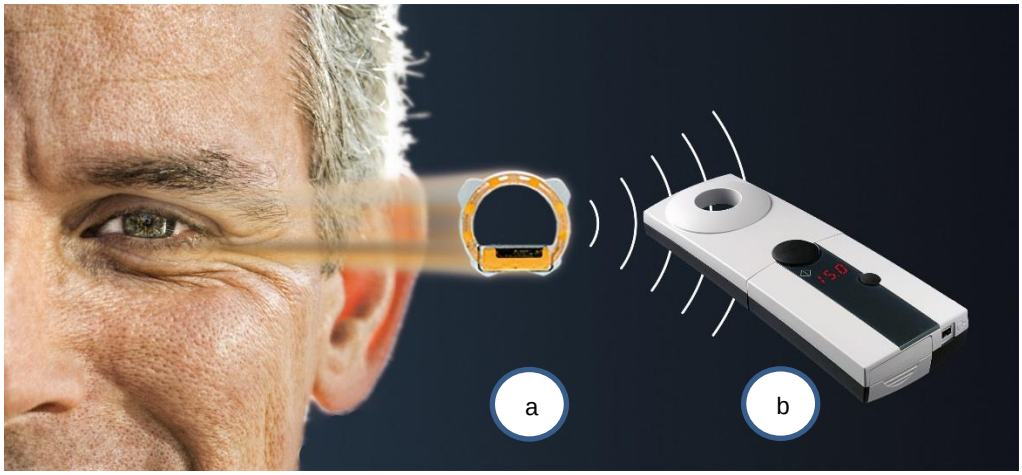


Figure 3: Operating principle

a. eyemate-IO (implant)
b. Mesograph

3.2 Intended use

The **Mesograph** is a readout device for measuring intraocular pressure in the human eye.

The handheld device can only determine the intraocular pressure together with the **eyemate-IO** sensor (see Figure 3).

The device has the following functions: Real-time recording, registration, display, storage and export of biophysiological measurement data.

The reader is used under non-sterile conditions.

The device is intended for use in ophthalmological practice/clinic as well as at home.

3.3 User group

WARNING!

Patients with pacemakers or active implanted medical devices should always consult their physician before use and use the device under increased precautions.
The Mesograph must not be in the immediate vicinity of pacemakers or active implanted medical devices.

The user group is:

- Medical-technical personnel (e.g. doctor or nurse)
- Patient
- Patient assistance.

3.4 Contraindication

A contraindication is the presence of an active implant in the head/neck region.

3.5 Device components

3.5.1 Mesograph

WARNING!

The device must not be dismantled by the user into its individual components (antenna and handset). This is the responsibility of Implandata's service.

WARNING!

Keep the device and its components (especially the battery cover) away from small children, as small components can be swallowed.

Structure Mesograph:

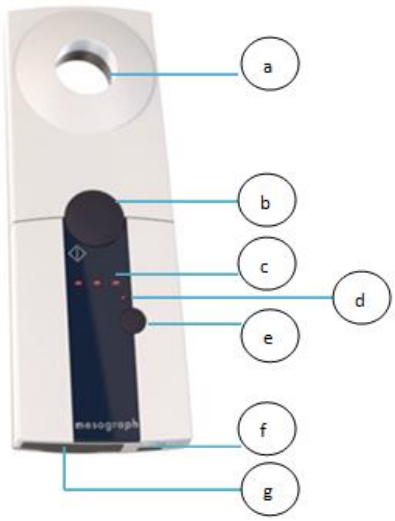


Figure 4: Structure of the Mesograph

	Device component	Description/ Function
a	Measuring site	Generation of a magnetic field, which thereby supplies the implant with energy; reading of the IOP values
b	Start button	Activating a manual measurement
c	Display	Display of status and determined IOP values (in mmHg)
d	LED indicator	Indicator of the active state from standby mode.
e	Stop button	Abort measuring process
f	Plug connection	Connection point between Mesograph and telemetric Multiline plug through the connector cable
g	Battery cover	Access to the battery compartment; The instrument is powered by a 2CR5 lithium battery, see chapter 10.

Acoustic signals

The following acoustic signals may sound during the operation of the Mesograph:

Sound	Significance
2 x short *(total approx. 1 sec.)*	Device switches from standby mode to active mode
6-7 x fast like "clock ticking"	Measuring process
1 x double *(approx. 4 sec.)*	End of successful measurement
1 x long *(approx. 4 sec.)*	Error during measurement

Display indication

The Mesograph does not display past measured values.
The displayed measured value is always the measured value of the measurement just performed.

The measured values of the intraocular pressure are displayed in mmHg and in 0.1 mmHg steps. The displayed measured values lie in the range from -2 to +70 mmHg.

The device does not evaluate the measured eye pressure values and does not provide any corresponding information, e.g. at high eye pressures.
The device does not compare measured values with previously acquired measurements.

The LED display uses predefined symbols to indicate the device status and any malfunctions.

Display indication	Significance
	Display in standby mode
	Display when the active mode is activated (<1 sec. pressing of the start button) and during the measuring process.
	Display when measuring mode is activated (>1 sec. pressing of the start button)

Display indication	Significance
	Example of a display of the determined IOP value, after successful completion of the measurement.
	Display of an "Error", e.g. due to an operating error during the measurement process or a full measurement data storage.
	"Battery low" indicator Replace the battery, see Chapter 5.2 "Battery replacement".

3.5.2 eyemate-IO

Without the eyemate-IO microsensor, the Mesograph has no function, as the reader communicates with the microsensor and in this way determines the intraocular pressure.

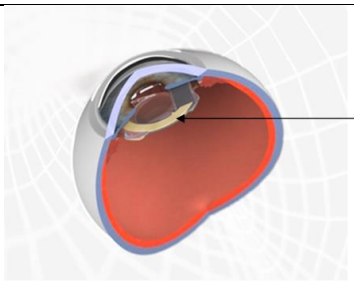


Figure 5: Exemplary representation of the implanted eyemate-IO microsensor in the eye

3.5.3 Mesograph Software

Chapter 5.3.1 explains the settings and functions of the **Mesograph software.**

This software is installed on your system by a representative of the manufacturer. Please contact the manufacturer.

4 Operation of the Mesograph

4.1 General information on the operation of the device

WARNING!

The device may only be put into operation and used in accordance with the information in this operating instruction.

WARNING!

Strong direct light irradiation into the eye can lead to incorrect measurements and should be avoided.

Avoid eye movements and strain on the eye (rub/pressure on eye) during and before performing a measurement.

The device can be re-used. It is not a -single use product.

4.2 Trainings

WARNING!

Before commissioning, training is required for the user group. In particular, the patient must be instructed in the device by the attending physician.

Before using the eyemate-system, medical personnel are trained by the manufacturer on how to use it and receive a training certificate. Only with this training certificate medical personnel can instruct colleagues, patients or patient assistants in the handling of the Mesograph.

4.3 Handling conditions

WARNING!

The user is not allowed to remove the antenna of the Mesograph. This is the responsibility of the Implandata service employee.

WARNING!

Patients with pacemakers or active implanted medical devices should always consult their physician before use and use the device under increased precaution.
The Mesograph must not be in the immediate vicinity of pacemakers or active implanted medical devices.

WARNING!

The Mesograph should not be used in the immediate vicinity of other electromagnetic devices.

4.4 Scope of delivery

The reader is delivered in a ready-to-measure condition.

The Mesograph is sent to the doctor's surgery or clinic in a surgical kit with the following components (**SET010001-DEU**):

- 2 x Reader (Mesograph),
- 2 x Battery,
- 1 x Instruction for use for medical personnel
- 1 x Instruction for use for patients and patient assistance
- 2 x eyemate-IO Implant with diameter 11.3mm
- 2 x eyemate-IO Implant with diameter 11.7 mm
- 2 x eyemate-IO Implant with diameter 12.1 mm
- 1 x Instruction for use for eyemate-IO
- 2x Medicel ACCUJECT Injector EM-IO 1.11x Instruction for use for Medicel ACCUJECT Injector EM-IO 1.1

All components of the surgical kit are shipped and transported together in a large outer package. The Mesograph is additionally protected in a leather case and a single sturdy transport package.

Please return all unneeded OP-Kit components to Implandata. Use the transport packaging for the return shipment.

4.5 Before the first operation of the Mesograph

Verification of the zero adjustment before implantation of the eyemate-IO sensor

Prior to shipping the surgical kit, the manufacturer performed a zero adjustment between the supplied eyemate-IO implants and the Mesograph reader. This zero adjustment must be checked with the hand-held Mesograph before implanting the eyemate-IO implant of the selected size. For this purpose a measurement as described in paragraph 5.1 is performed, whereby the selected eyemate-IO implant must remain in its packaging. The measurement must result in a value between -2 mmHg and +2 mmHg.

If the measured value is outside this range, this eyemate-IO sensor cannot be implanted. In this case, check the zero adjustment on the second eyemate-IO implant of the same size. If the measured value is between -2 mmHg and +2 mmHg, the eyemate-IO sensor can be implanted. If a value outside this range is also determined for this eyemate-IO sensor, this sensor cannot be implanted either. In this case the manufacturer must be contacted.

The check of the zero adjustment should be performed on the day of implantation, but does not necessarily have to be performed immediately prior to surgery.

5 Operation

WARNING!

Check the unit for completeness and integrity before each use.

WARNING!

Never place the reader in or near a MRI.

WARNING!

Patients with pacemakers or active implanted medical devices should always consult their physician before use and use the device under increased precautions.
The Mesograph must not be in the immediate vicinity of pacemakers or active implanted medical devices.

WARNING!

Do not use the device in the following environments:

- humid / wet environment (the permissible ambient conditions can be found in chapter 11).
- oxygen-enriched environment.

An environment is considered enriched with oxygen if the concentration of oxygen is

a) is more than 25 % at ambient pressures up to 110 kPa, or
b) at ambient pressures above 110 kPa, the partial pressure of oxygen is greater than 27.5 kPa.

5.1 Execution of the measurement

WARNING!

The device must not be used in the event of known damage to the Mesograph reader itself or to the eyemate-IO implant.

WARNING!

The electromagnetic field is emitted with the start of the measurement (Press the start button for >1 sec.).
No electromagnetic field is emitted in standby and active modes.

WARNING!

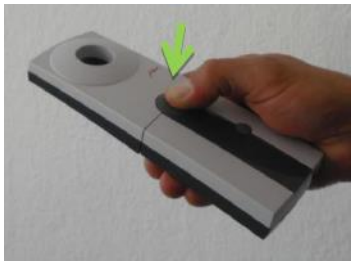
No therapeutic decisions may be made solely on the basis of the measurement results of the device. An adequate alternative diagnostic procedure (e.g. Goldmann standard) should always be used for this purpose.

If there is any doubt about the validity of a measured value, perform the measurement again.
If the measured value determined deviates greatly from the expected measured value, you should also repeat the measurement for your own safety.

Do not carry out measurements under direct incident light.

With the operating steps below, the measurement of the intraocular pressure in the human eye is carried out.

#	Operating step	Photo
1	Take the **Mesograph** in your hand (hand of your choice).	
	Hint: For the now following measurement, the patient must be relaxed and calm.	

#	Operating step	Photo
2	Press the start button on the **Mesograph continuously and with little effort** for 1 second. Two short beeps will sound to indicate the measuring mode. **Hint:** – In order to avoid influences on the intraocular pressure, the patient should look relaxed and straight ahead into the distance, avoiding eye movement. The outer eye muscles should be relaxed, the eyelid open. – The patient should move as little as possible during the measurement procedure. – Until the measurement is completed, the display shows three red lines. After the measurement, the measured value is displayed at this point.	
3	Immediately (within 2 seconds) after pressing the start button, hold the **Mesograph** approx. < 5 cm in front of the eye at which the intraocular pressure is to be measured. It must be ensured that the device does not touch the eyeball and does not exert any mechanical force on the eye surface, as this would falsify the physiological intraocular pressure. Glasses must not be worn during the measurement. **Hint:** – Observe the prescribed distance between eye and reader. It is intended that the patient looks through the circular opening during the measurement. The eyelid should be relaxed, the eyes should not be twisted or moved. If the distance of < 5 cm between the eye and the Mesograph handheld device is not maintained or if the device is held at an incorrect angle, an error will be caused because the eyemate-IO cannot be activated because the distance is too great (display EEE and acoustic signal, see Chapter 3.5.1). – The correct handling can be seen in the illustration on the right. – In the event of an incorrect measurement, the measurement must be repeated taking into account the distance of < 5 cm between the eye and the Mesograph handheld device.	

#	Operating step	Photo
	– See chapter 3.4.1 for an explanation of the displays and beeps in the event of a measurement error.	

#	operating step	photo
4	If the measurement is carried out correctly, the measurement process is started. **The duration of a single measurement process is max. 2 seconds.** **Hint:** During the measurement approx. 6 fast ticker noises (like clock ticking) can be heard. This ticking, which lasts approx. 4-5 seconds, indicates the active measurement process and confirms that the measurement has been carried out correctly. At the end of the measurement, two beeps sound.	
5	The measured value determined (intraocular pressure) is shown on the display in red when the measurement is complete. At the same time, the determined value and the exact time (time/date) of the measurement are stored by the handset.	

Approx. 5 seconds after completion of a measurement, the instrument automatically switches to a power-saving "stand-by mode" and does not have to be switched off. The instrument can be reactivated for a new measurement at any time as described above.

5.2 Battery replacement

WARNING!

Only use the intended battery type 2CR5 lithium battery, see chapter 10.

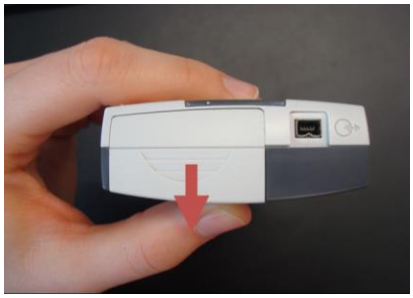
WARNING!

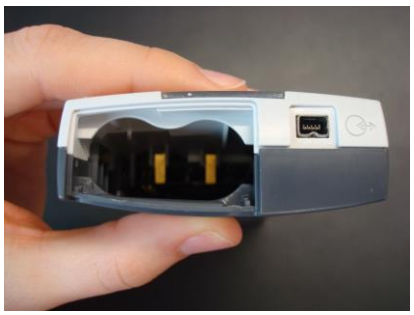
Incorrect insertion of the battery can lead to health impairment/disorders! Therefore, observe the operating steps described in this instruction for use.

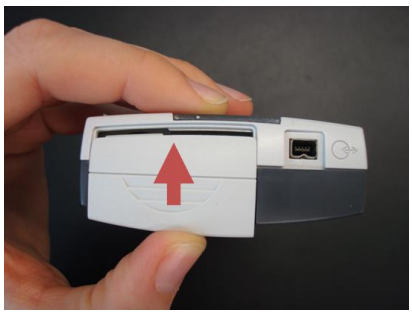
If the display does not show the empty battery symbol (see 3.5.1), the battery has sufficient capacity and there is no need to change the battery.

The battery life is designed for approx. 3,000 measurements.

If the Mesograph display shows the empty battery symbol (see 3.4.1), replace the battery as described below:

Operating step	**Photo**
Take the M**esograph** in your hand.	
Open the battery compartment by pressing lightly on the ribbed surface of the battery compartment cover and simultaneously sliding the cover in the direction of the arrow. See 3.4.1 for battery compartment location.	

Operating step	Photo
	
The cover of the battery compartment is now removed.	
Remove the battery from the battery compartment.	
The battery compartment is now empty.	
Insert the appropriate battery (see chapter 10) into the device. The "+/ -" symbols on the battery must point into the battery compartment of the unit.	

Operating step	Photo
The housing is form-coded so that the battery can never be inserted incorrectly.	
Then close the battery cover again to protect and secure the battery. Close the cover of the battery compartment in the direction of the arrow until the cover clicks into place visibly and audibly.	
The battery compartment is now closed.	

5.3 Data download and Goldmann comparison

WARNING!

Only use the connection cable provided by the Implandata to connect the reader to the PC.

WARNING!

Perform 5 eyemate-IO measurements and note the respective readings displayed by the Mesograph along with the time. Then, as indicated, download the measurement data from the Mesograph and verify the measurement data (last 5 measurements) together with the time. If there is a match (no tolerance in the measured values, 1 minute tolerance in the time), the file can be accepted as valid.

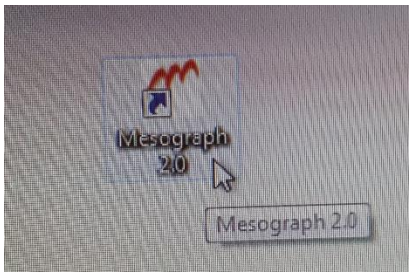
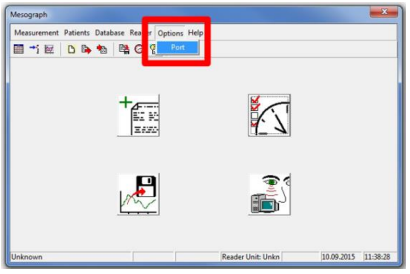
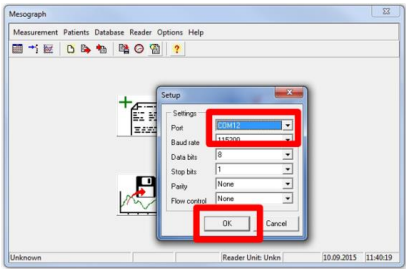
5.3.1 Download measurement data

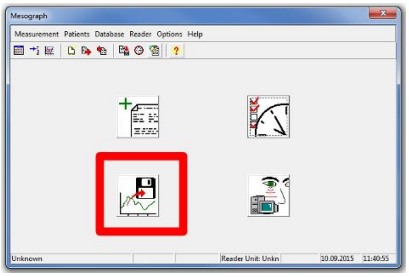
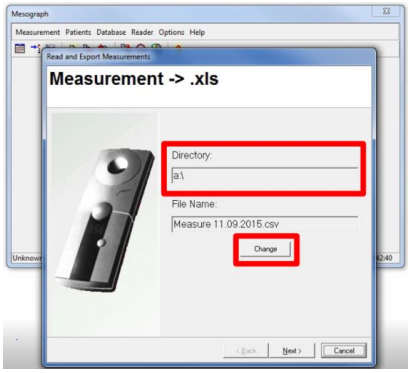
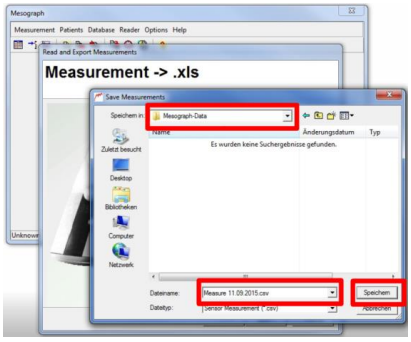
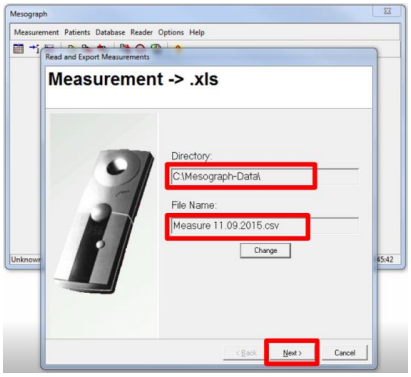
The measured values can be stored on a PC via the connector cable.

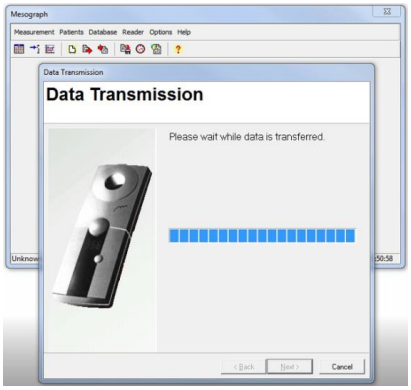
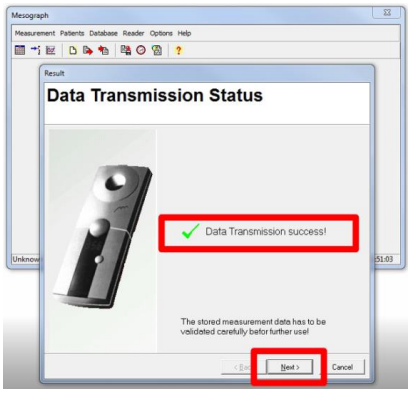
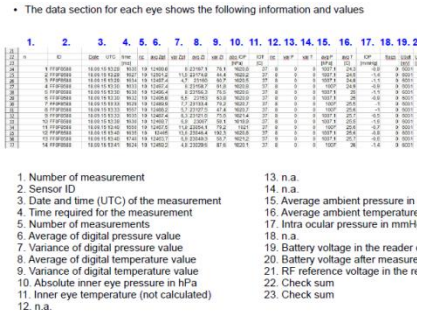
The stored values for the intraocular pressure (IOP) contain all corrections (ambient pressure, zero adjustment, Goldmann offset).

The procedure described here deletes all measurement data from the reader, i.e. the measurement data storage memory is released for new measurements. In the case of a full measurement data storage memory (up to 3000 measurements) no further measurements are possible and the message "EEE" is displayed. For this reason, the procedure described here should be carried out at least once a year in order to enable continuous functionality.

Follow the steps below to transfer the reader data to the external PC:

#	Operating step	Photo
1	Connect the connector cable to the Mesograph and to the PC.	
2	Start the Mesograph software on the PC.	
3 Should the software be used for the first time or if the serial port number has changed: An error message appears: "Serial Port cannot be opened! Delete this message by clicking "OK". Select "Options" and "Port" from the menu bar. Enter the correct serial port number of the connection cable.	 

#	Operating step	Photo
4	Select "Measurement Data Download from Reader Unit" in the main window.	
5	The default directory must be changed. Change the file name if necessary. Click "Change" to continue.	
6	Select a folder or create a new one. Example: *C:\Mesograph-Data* The file name is assigned by the program and contains the date of the download. You can change the file name if necessary. The file name must end with **".csv".** Click "Save" to continue.	
7	The changes are listed here (see markings). Click "Next" to continue.	

#	Operating step	Photo
8	The software now downloads the data from the device. The file is saved in the selected folder under the selected name. The data on the device is deleted.	
9	Click "Next" when the transfer is complete.	
10	The "Time" window appears. Finish the process by clicking "Finish". Open the csv file with MS Excel or Open Office.	
11	Information contained in the csv file. See example in appendix, chapter 14.	

5.3.2 Adjustment with the Goldmann Applanation Tonometer (GAT)

WARNING!

Adjustment with the Goldmann Applanation Tonometer (GAT) should only be considered if the IOP measured with the GAT is below 21 mmHg.

The adjustment with the Goldmann Applanation Tonometer (GAT) must be carried out with the utmost care, especially with regard to the correct execution of the GAT measurement and taking into account the limitations of the GAT underlying method.

Note: GAT is the recommended reference measurement method for eyemate-IO measurements. However, due to the different measurement methods, different measurement results can be expected as eyemate-IO measures the IOP directly (direct manometry) on the one hand and GAT approximates the IOP based on secondary size measurements on the other hand. Larger GAT errors are expected especially in IOP > 21 mmHg, and in eyes with deviations from the anatomical average.

WARNING!

To ensure a permanent comparability of the eyemate® system with the Goldmann applanation tonometer, it is recommended to perform a comparative measurement at least once a year.

WARNING!

After implantation, and also after every operation on the eye, the correct function of the eyemate-IO must be checked using Goldmann applanation tonometry (GAT) and corrected if necessary.

If the difference between the measurement methods exceeds 5 mmHg, or if no valid measurement result can be obtained, please contact the manufacturer.

WARNING!

Make sure that the Goldmann tonometer used is within the prescribed calibration interval.

WARNING!

Immediately after the Goldmann adjustment has been carried out, check whether it has been carried out successfully. For this purpose, an eyemate-IO measurement is performed, the result of which must not differ by more than 2 mmHg from the underlying Goldmann value. If this is not the case repeatedly, please contact the manufacturer.

The measurement with the tonometer must under no circumstances take place at the same time as the measurement with the reader, since a mutual influence of the measurements cannot be ruled out.

	In order to carry out the control measurement, the measurement should first be carried out with the reader in order to rule out any influence on the intraocular pressure by the mechanical action of the Goldmann tonometer.

	**The control measurement may only be carried out with a Goldmann applanation tonometer (GAT).**

	The eyemate-IO sensor measures the actual pressure in the eye (primary size). GAT is known to derive intraocular pressure from a secondary size. Comparative measurements show a correspondence between the two measuring methods, but absolutely identical measured values are not to be expected due to the different measuring methods.

Follow the steps below to perform a control measurement:

#	Operating step	Photos
1	Have the patient perform a measurement as described in section 5.1. It is important that the patient has already taken his place at the slit lamp, sits comfortably and is calm. The correct execution of this measurement is crucial for the continued accurate measurement of intraocular pressure.	
2	Then carry out a Goldmann measurement. To avoid the danger of an investigator bias, the investigator should not know the eyemate-IO value. Since intraocular pressure is a dynamic variable and even the slightest movements of the eye can lead to pressure changes, the Goldmann measurement should be performed directly after the eyemate-IO measurement. The patient should not move more than necessary in the meantime.	
3	Connect the connector cable to the Mesograph and to the PC.	
4	Start the Mesograph software on the PC.	

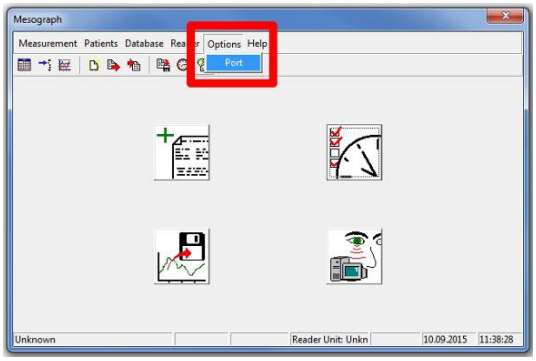
5

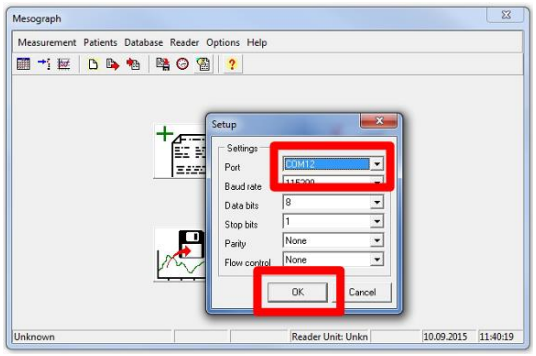
Should the software be used for the first time or if the serial port number has changed:

An error message appears: "Serial Port cannot be opened!

Delete this message by clicking "OK".

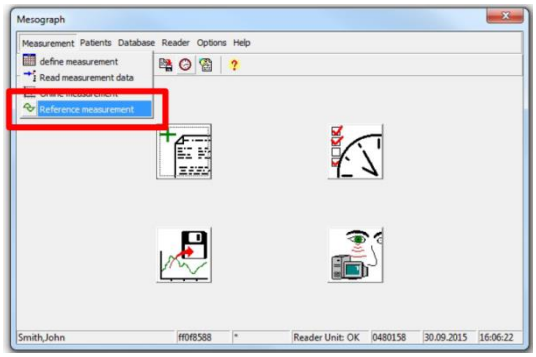
Select "Options" and "Port" from the menu bar. Enter the correct serial port number of the connection cable.





6

Select "Reference Measurement" from the Measurement drop-down menu.



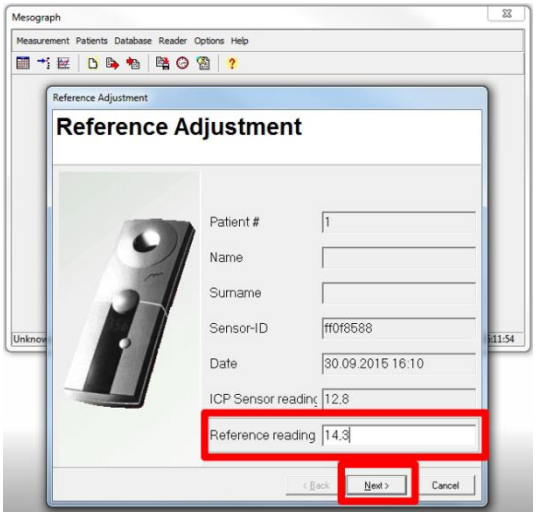
7

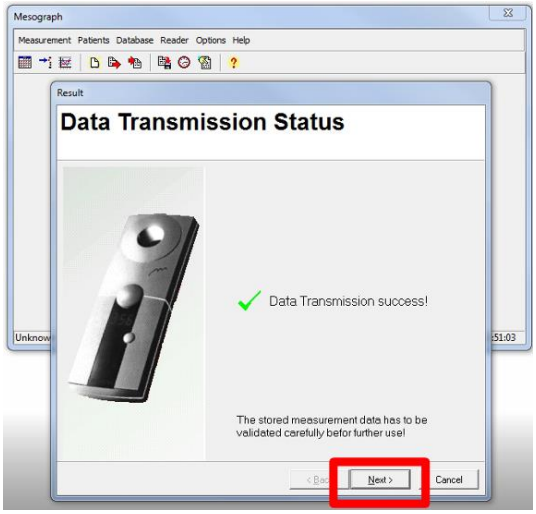
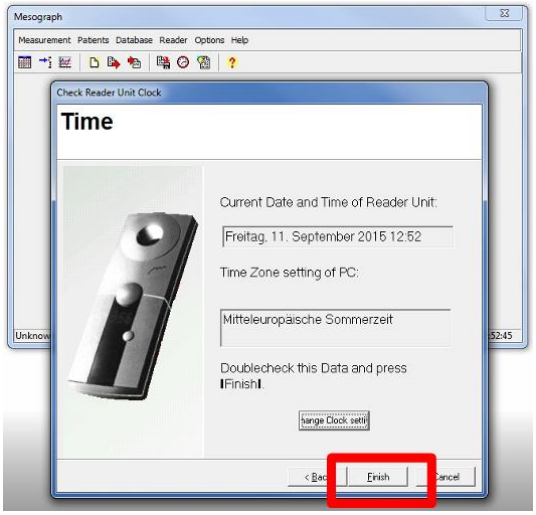
The software now connects to the device.

The PC software reads the data set of the last measurement performed as well as the calibration data of the corresponding transponder from the reader.

Enter the value of the reference measurement.

The reader will automatically correct the measured values for the reference value.



	Click "Next" to continue.	
8	Click "Next" when the transfer is complete.	
9	The "Time" window appears. Compare the actual time with the time in the Mesograph. Finish the process by clicking "Finish".	

6 Hygiene measures

HAZARD!

Do not allow any liquids to enter the interior of the device!

Immediately contact Service (see Chapter 7) if liquid enters the interior of the unit.

6.1 Cleaning the housing surface

Cleaning cycle: wipe with a damp cloth as required
Cleaning agent: mild, biodegradable cleaning agent

Wipe the housing surface of the device with a slightly moistened soft cloth.

6.2 Disinfection of the housing surface

Disinfection cycle: as needed
Disinfectant: alcohol-based

The housing surface of the Mesograph can be disinfected.

Derived from the biocompatibility test, wipe disinfection with disinfectant wipes is recommended for the Mesograph.

For example, the following disinfectants are recommended:

- Bacillol 30 Tissues (Bode Chemie GmbH)
- Mikrobac tissue (Bode Chemie GmbH)

7 Service/ Maintenance

HAZARD!

Do not carry out any independent repair or service work on the device.
Contact Implandata in case of malfunctions/problems with the device.

Besides changing the battery, the Mesograph is maintenance-free.

A regular safety check (STK) according to the Medical Device Directive is not required.

A regular metrological check (MTK) according to the German MPBetreibV is not necessary, as the measuring function of the device is regularly checked by means of calibration with the Goldmann tonometer.

If you have any questions about the product, please contact us:

Implandata Ophthalmic Products GmbH
Kokenstrasse 5,
30159 Hanover/ Germany
www.implandata.com
Phone: +49 511 2204 258-0
Email: service@implandata.com

Return
Only after consultation with Implandata faulty devices can be returned to Implandata for repair. In case of return please use the original transport packaging.

8 Troubleshooting and debugging

8.1 System failures

The following overview shows possible causes and remedial measures in the event of an error.

In the event of an error, check whether you can use the "Remedy" column to correct any errors that occur. Only then should you contact Implandata Service, see Chapter 7.

Error	Cause	Remedy
No display after completed measuring process	No sufficient operating voltage at the device Measured value display switched off Display defective	Replace the battery. Otherwise contact the device service.
No reaction of the device to operating inputs	Internal device error	Contact the device service.
No reaction after pressing the start button	Internal device error	Contact the device service.
"EEE" display after measurement	Inaccurate measurement, eyemate-IO implant is out of reach of the Mesograph handheld: - Too large distance between Mesograph measuring device and eye (> 5cm) - Mesograph measuring device is not placed frontally to the eye (tilted). - Mesograph Measuring device is moved during the measuring process. Internal device error Ambient conditions (air pressure, temperature, ...) are outside the device specification. Measured value memory is full	Repeat the measurement. Otherwise contact the device service.

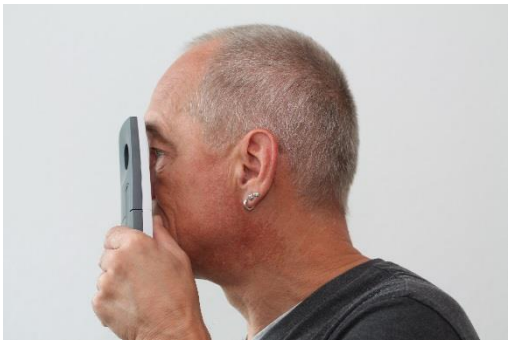
flaw	cause	remedy
No connection between Mesograph and PC software	Connector cable defective Internal device error	Check the connector cable. Otherwise contact the device service Restart Software Connect the cable again, then start the software.
Connection aborted during the measuring process	Inaccurate measurement; internal device error	Check the position of the reader and correct it if necessary. Repeat the measurement. Otherwise contact the device service
Unforeseen device behavior and/or incorrect or invalid measured or displayed values		Repeat the measurement under adequate conditions. Otherwise contact the device service
Mesograph not prepared for use with a specific eyemate-IO		Each Mesograph is assigned to an eyemate-IO before implantation. The Mesograph will only work with this implant. Please make sure that you are using the correct Mesograph.

8.2 Incorrect operation

Note that the patient is relaxed during the measurement, holds his eye still and look straight forward without tension during the measurement.

The error mode can occur, among other things, due to incorrect handling of the Mesograph.

The following table compares the incorrect with the correct handling.

Incorrect handling	Correct handling
	
	

9 Disposal

Please send the device to Implandata for disposal.

Address:

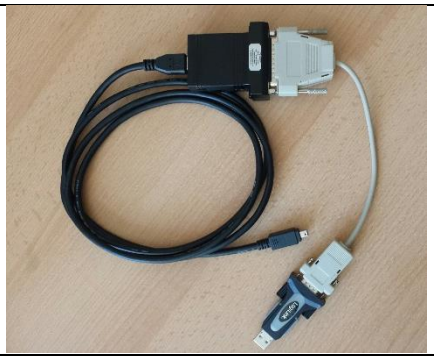
Implandata Ophthalmic Products GmbH

Kokenstrasse 5

D-30159 Hanover/ Germany

10 Spare parts list

All accessory components are listed below.

Components	Item number	Article photo
2CR5 (lithium battery)	**REA100104**	
Connector cable	**REA100103**	

11 Technical data

Classifications	
Degree of protection	BF
Protection class	IP 30
Medical device class	Accessories for AIMD
Minimum product life	2 years
Physical data	
Size (WxHxD), including accessories	180 mm x 66 mm x 26 mm
Weight	Mesograph: approx. 180 g PC adapter: approx. 45 g Fire Wire cable (length 1.8 m): approx. 100 g Modem cable (length 0.25 m): approx. 45 g
Power supply	Integrated 6V lithium battery, Type 2CR5
Power	6 Volt – 1,600 mAh
Fuse	Fuse on the printed circuit board (1A F) - only to be changed by service personnel
Data transmission interface	proprietary
Transmission frequency (carrier frequency)	13.56 MHz
Transmission power (Transmission power)	Variable, max. 0.5 W
Maximum distance of electromagnetic field (MdF)	30 mm
Environmental conditions	
Operation	
Temperature	+10° C to +40° C
Air humidity	30 % to 90 %, non-condensing
Air pressure	800 hPa to 1,150 hPa
Max. operating height	1700 m
Storage and transport	
Temperature	-10° C to +50° C
Air humidity	30 % to 95 %, non-condensing
Air pressure	500 hPa to 1,200 hPa
Display indications and functions	
Display indication	Visual display of: Measured value, error measurement, empty battery, status
Admission	
CE-Mark	CE_{0344}
	The **eyemate®** complies with EC Directive 90/385/EEC on active implantable medical devices and its national implementation in the form of the German Medical Devices Act (MPG).
Standards	EN 60601-1:2012 EN 60601-1-2:2007

12 Electromagnetic compatibility

The **Mesograph** is intended only for use with original accessories in the electromagnetic environment specified below.
The user of the **Mesograph** should ensure that the instrument is operated in such an environment.

Tab.1: Guidelines and manufacturer's declaration - Electromagnetic emissions

Interference emission measurements	Compliance	Electromagnetic Environment Guide
Radio interference field strength in the frequency range from 30 Mhz - 1000 Mhz to EN 55011	Matches	
	passed	no special requirements
radiated interference in the frequency range from 30 Mhz - 1000 Mhz	EMC Report, EPA, Annex 10	
RFI field strength in the frequency range from 9 khz - 30 Mhz according to EN 55011	Matches	
	passed	no special requirements
radiated interference in the frequency range from 9 khz - 30 Mhz	EMC Report, EPA, Annex 11	
Permissible range of operating frequencies according to ETSI EN 300 330-2	Matches	
	passed	no special requirements
permitted range of operating frequencies	EMC report, EPB, Appendix 1	
Limit values for field strength and carrier frequency in the range from 9 kHz to 30 MHz according to ETSI EN 300 330-2	Matches	
	passed	no special requirements
limits for field strength and RF carrier in the range from 9 kHz to 30 MHz	EMC report, EPB, Appendix 2	
Limit values for the permissible range of the modulation bandwidth according to ETSI EN 300 330-2	Matches	
	passed	no special requirements
limits for the permitted range of modulation bandwith	EMC report, EPB, Appendix 3	
Sender Secondary broadcast to ETSI EN 300 330-2	Matches	
	passed	no special requirements
transmitter spurious and out-of-band emissions	EMC report, EPB, Appendix 4	
Receiver secondary transmission according to ETSI EN 300 330-2	Matches	
	passed	no special requirements
receiver spurious emissions	EMC report, EPB, Appendix 4	

The **Mesograph** is intended only for use with original accessories in the electromagnetic environment specified below:
The user of the **Mesograph** should ensure that the instrument is operated in such an environment.

Tab.2: Guidelines and manufacturer's declaration - Electromagnetic immunity; Part 1

Immunity tests	IEC 60601 test level	Tuning level	Electromagnetic environment - Guidelines
Discharge of static electricity (ESD) according to IEC 61000-4-2: Immunity to Electrostatic Discharge	± 6 kV Contact discharge ± 8 kV Air discharge	Matches *passed* EMC Report, EPA, Annex 1	Floors should be made of wood, concrete or ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8: *Power frequency magnetic field immunity test*	3 A/m	Matches *passed* EMC Report, EPA, Annex 6	Magnetic fields at the mains frequency should correspond to the typical values found in business and hospital environments.

Tab.3: Guidelines and manufacturer's declaration - Electromagnetic immunity; Part 2

Immunity tests	IEC 60601 test level	Tuning level	Electromagnetic environment - Guidelines
Radiated RF disturbances according to IEC 61000-4-3: *Immunity to Radiated Electromagnetic Fields*	3 V/m 80MHz to 2.5 GHz	Matches *passed* E1] V/m EMC Report, EPA, Annex 2	Portable and mobile radios should not be used at a distance from the **Mesograph** less than the recommended protective distance calculated from the equation applicable to the transmission frequency. **Recommended protective distance:** $d = \left\lfloor \frac{3,5}{E1} \right\rfloor \sqrt{P}$ $d = \left\lfloor \frac{3,5}{E1} \right\rfloor \sqrt{P}$ for 80 MHz to 800 MHz $d = \left\lfloor \frac{7}{E1} \right\rfloor \sqrt{P}$ for 800 MHz to 2.5 GHz With P as rated power of transmitter in watts (W) according to transmitter manufacturer and d as recommended protective distance in meters (m) The field strength of stationary radio transmitters should be less than the compliance level at all frequencies according to an on-site study [a] [b]. Interference may occur in the vicinity of equipment bearing the following symbol. 

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

Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is caused by absorption and reflections of buildings, and people.

a The field strength of stationary transmitters, e.g. base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters can theoretically not be predicted exactly.
To determine the electromagnetic environment with respect to the stationary transmitters, a study of the site should be considered. If the measured field strength at the location where the **Mesograph** is used exceeds the above compliance levels, the **Mesograph** should be observed to demonstrate its intended function. If unusual performance characteristics are observed, additional measures may be required, such as a change in orientation or a different location of the **Mesograph**.

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

The **Mesograph** is designed to operate in an electromagnetic environment where RF disturbances are controlled.

The user of the **Mesograph** can help prevent electromagnetic interference by maintaining the minimum distance between portable and mobile RF telecommunications devices (transmitters) and the Mesograph, depending on the output power of the communications device as indicated below.

Table4: Recommended protective distances between portable and mobile RF telecommunications equipment and the Mesograph

Transmitter rated power W	**Protective distance dependent on transmission frequency m**		
	150 kHz to 80 MHz $d = \left\lfloor \frac{3,5}{E1} \right\rfloor \sqrt{P}$	**80 MHz to 800 MHz** $d = \left\lfloor \frac{3,5}{E1} \right\rfloor \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left\lfloor \frac{7}{E1} \right\rfloor \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not given in the table above, the recommended protective distance d in metres (m) can be determined using the equation associated with the column, where P is the maximum rated power of the transmitter in watts (W) as specified by the transmitter manufacturer.
Note 1: At 80MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is caused by absorption and reflections of buildings, and people.

13 Warranty

The legally prescribed guarantee period of 12 months applies.

The claim to warranty expires with:

- Improper use or handling,
- Operating errors that lead to damage to the device,
- Failure to observe the instructions for use,
- Changes to the device (modifications, alterations, extensions, etc.) may be made without the written consent of the manufacturer,
- Opening of the housing by unauthorized persons,
- Use of non-original accessories or spare parts,
- Force majeure (e.g. lightning strike),
- Transport damage due to improper packaging during return shipment.

If a possible reclamation is unlawful, we shall be entitled to demand reasonable remuneration for the inspection and shipment of the device.

In case of warranty or repair please return the complete device with all accessories only in original packaging.

If a device is not returned in its original packaging, the special packaging must be invoiced separately for the return shipment.

Thank you for your understanding!

Implandata Ophthalmic Products GmbH

Kokenstrasse 5

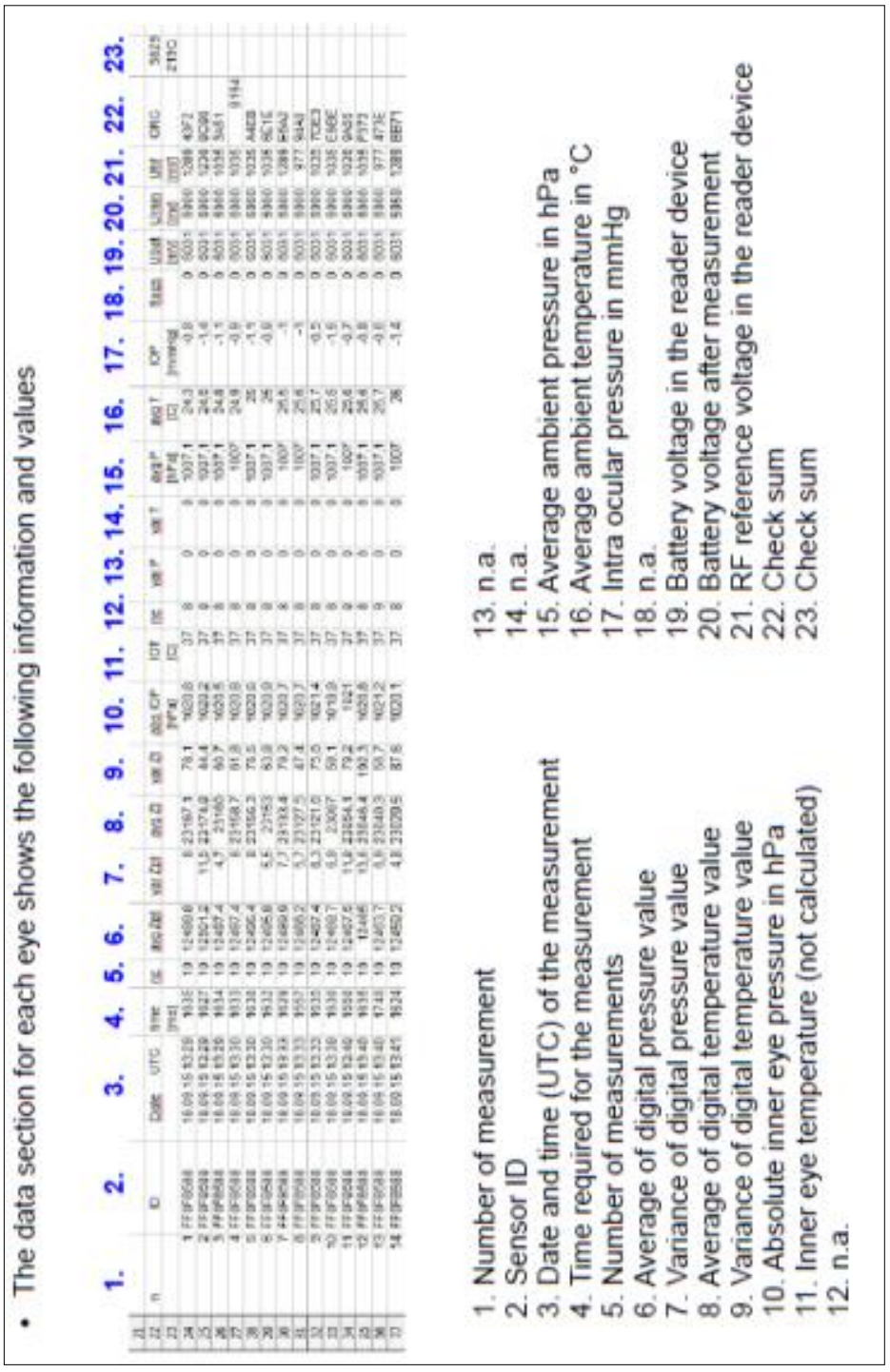
30159 Hanover/ Germany
www.implandata.com

Phone: +49 511 2204 258-0

Email: service@implandata.com

14 Appendix

Figure 6: Information in the csv file[1]



[1] Implandata Ophthalmic Products GmbH