Implandata Ophthalmic Products GmbH

eyemate®-IO(/KP) Implant and Mesograph Reader Device

Instructions for use for patients

Version 1.0 / 2020-01

CE 0344

Manufacturer	**Implandata Ophthalmic Products GmbH** Kokenstrasse 5, 30159 D - Hannover Phone: +49 511 2204 2580 info@implandata.com www.my-eyemate.com
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Valid from firmware version of the device	2.13/2.05

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Table of contents

1 General Information

1.1 About this instructions for use (IFU)

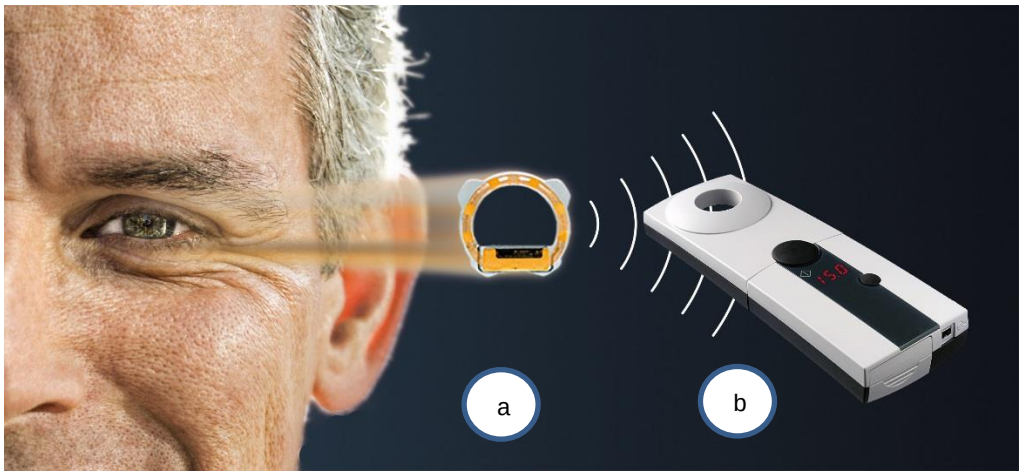
This IFU is intended for patients who are implanted with eyemate®-IO(/KP) pressure sensing devices. The IFU provides information about the eyemate system, comprising the eyemate®-IO(/KP) implant and the Mesograph reader device. It describes the safe use of the Mesograph and provides safety information about the eyemate®-IO(/KP) implant.

Please read this IFU carefully and address any remaining questions to the manufacturer before using the system. Please note, this IFU is only valid for the product versions specified in this document.

This IFU can be downloaded from the manufacturer's website: **www.my-eyemate.com**

1.2 eyemate® system

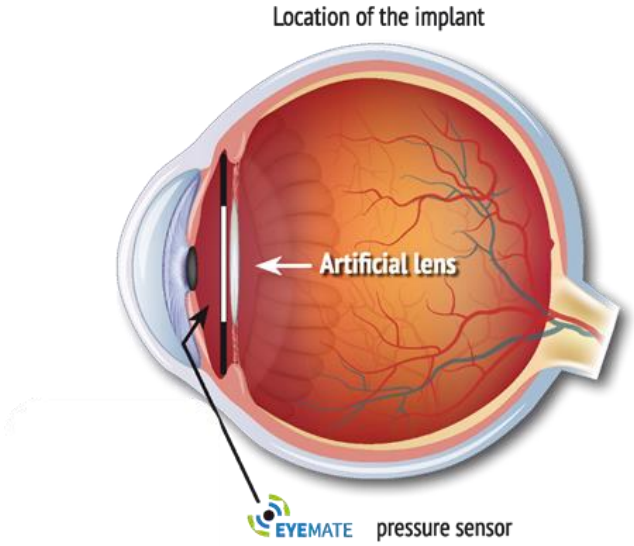
The eyemate® system is intended for direct measurement of the intraocular pressure (IOP) and provides direct and digitized IOP readings in mmHg. The system can be used for frequent daily IOP measurements by you at home, without the need for professional assistance.



The eyemate® system consists of the biocompatible eyemate®-IO(/KP) pressure sensing implant (a), which is a CE-marked (CE 0344, 2017 and 2019) active implantable medical device (AIMD) and permanently remains in the patient's eye, as well as the Mesograph reader device (b), which provides wireless communication with the implant in order to obtain and display IOP measurement values.

The implant is wirelessly powered and operated by briefly holding the Mesograph reader device in front of the eye. The reader device activates the implant via a harmless magnetic field, obtains data from the implant and displays the IOP value in mmHg. The measured IOPs are stored in the reader device.

> *Without the eyemate®-IO(/KP) implant, the Mesograph has no function, as the reader communicates with the implant and in this way determines the intraocular pressure.*



1.3 Intended use

The eyemate®-IO(/KP) intraocular pressure sensor is a CE marked (CE 0344, 2017 and 2019) active implantable medical device (AIMD). Together with the Mesograph reader device, it is intended as a diagnostic system for users to measure the intraocular pressure (IOP).

The Mesograph can only determine the intraocular pressure together with the eyemate®-IO(/KP) implant.

1.4 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's assistant.

1.5 Symbols used in this IFU

HAZARD!

Failure to observe this warning will result in serious injury.

WARNING!

Failure to observe this warning may result in serious injury.

Tip

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

1.6 Abbreviations used in this IFU

IFU	Instructions for use
IOP	Intraocular pressure
AIMD	Active implantable medical device
EMC	Electromagnetic compatibility
MRI	Magnetic resonance imaging

2 Indications

The **eyemate®-IO** intraocular pressure sensor is an AIMD to be permanently implanted in the ciliary sulcus of patients with primary open angle glaucoma (POAG) and indicated cataract surgery with capsular bag IOL.

The **eyemate®-IO/KP** intraocular pressure sensor is an AIMD to be permanently implanted in the posterior chamber of an aphakic or pseudophakic eye in patients indicated for the Boston-Keratoprosthesis Type I (BI-KPro) implantation.

The reader device is to be used by the patients implanted with eyemate®-IO(/KP) intraocular pressure sensor.

3 Contraindications

WARNING!

Observe the contraindications.

- AIMDs in the head/neck region.
- Patients with other AIMDs must consult their physician. Non-compliance may result in serious injury.

4 ⚠General safety information

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	Before initial operation, the user must be instructed in the device by the attending physician.
Application	An instruction is required to use the Mesograph. See chapter 10.2 for training measures. Do not drop the unit under any circumstances. Do not operate the device outdoors. Observe the environmental conditions in chapter 17.2. The system is calibrated to an absolute pressure range of 800-1150 hPa. Therefore, at altitudes above 1700 meters, measurements will be voided by the system. However, in order to prevent damage to the implant, you should avoid activities such as scuba-diving. Absolute pressure beyond 2000 hPa (10 meters underwater) will permanently damage the implant. 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 14 and 19.
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 17.2.
Disposal	See chapter 16.

5 ⚠When/whom to notify about the implant

WARNING!

Following any ocular procedure, the correct function of the eyemate®-IO(/KP) implant must be confirmed by an experienced and qualified specialist. Please contact your treating ophthalmologist.

- **Pacemakers and other Active Implantable Medical Devices (AIMDs):** Use of Mesograph reader by patients with AIMDs in head and neck region is prohibited. Patients with other AIMDs must consult their physician before using the Mesograph device. Non-compliance may result in serious injury.
- **Glaucoma drainage devices:** notify your treating physician of the eyemate®-IO(/KP) implant. Glaucoma drainage devices (GDD) are unlikely to interfere with the eyemate®-IO(/KP) implant if they are placed such that there is no physical contact between the two devices.
- **Ocular surgeries and other therapies:** Notify your treating physician if you need to undergo ocular surgery or other medical treatments. In order to avoid physical damage to the eyemate®-IO(/KP) implant, avoid:
  - high energy ultrasound in the vicinity of the implant.
  - diathermy in the vicinity of the implant.
  - therapeutic ionizing radiation in the vicinity of the implant.
  - implant exposure to direct laser energy.
  - hyperbaric therapy (beyond 2000 hPa absolute pressure).
- **At the airport:** The eyemate®-IO(/KP) implant contains metals and could trigger safety scanning equipment. Please notify the airport security personnel and provide your *Implant Card/Implant Pass*
- **MRI:** notify your treating physician/radiologist of the eyemate®-IO(/KP) implant and provide them with the MRI safety information described below.

6 MRI safety

WARNING!

While the implant does not prevent you from getting MRI scans, it is very important to not take the Mesograph reader device near an MRI scanner.

Non-clinical testing demonstrated that eyemate®-IO(/KP) is MR Conditional. A patient with this device can be scanned safely immediately after implantation under the following conditions:

Static Magnetic Field

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the eyemate®-IO(/KP) produced the following temperature rise during MRI performed for 15 min of scanning (i.e., per pulse sequence) in 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change: +1.6˚C

Therefore, the MRI-related heating experiments for the eyemate®-IO(/KP) at 3 Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6˚C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the eyemate®-IO(/KP). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5 mm relative to the size and shape of the eyemate®-IO(/KP).

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	103mm^2	24mm^2	140mm^2	38mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

7 Complications and adverse events

Similar to any ocular surgery complications may occur following implantation of the eyemate®-IO(/KP). In most cases, however, the complications are expected to be temporary and manageable by medication. Please contact your treating ophthalmologist in case you experience discomfort or adverse events.

8 Explantation

It is not necessary to explant an eyemate®-IO(/KP) implant which is either non-functional or is known to function incorrectly. The malfunctioning device may safely remain in the eye. However, if medically indicated, the eyemate®-IO(/KP) can be explanted at any time.

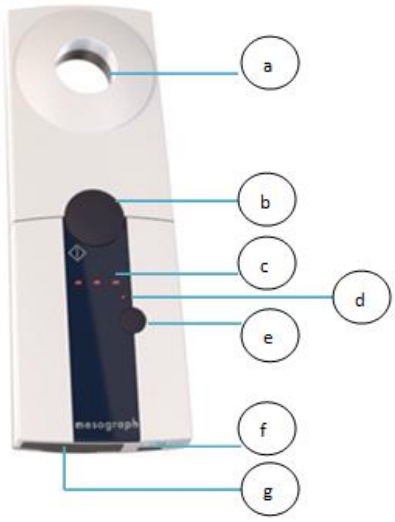
9 Mesograph reader device components

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.



	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; Mesograph is powered by a 2CR5 lithium battery, see chapter 14.

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 indication	Significance
	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)
	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 11.2 "Battery replacement".

10 Handling of the Mesograph reader device

10.1 General information

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 used several times. It is not a one-time product.

10.2 Trainings

WARNING!

Before commissioning, the user must be instructed in the device by the attending physician.

10.3 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.

11 Operation of the Mesograph reader device

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 17.2).
- 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.

11.1 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(/KP) 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.

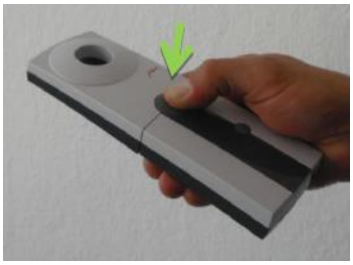
WARNING!

Do not attempt to adjust your glaucoma medication based on the eyemate® measurement data. Contact your ophthalmologist if you have any concerns regarding your IOP measurement values.

If there is any doubt about the validity of a measured value, perform the measurement again. Contact your ophthalmologist if you have any concerns regarding your IOP measurement values.

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).	
	Tip: For the now following measurement, you must be relaxed and calm.	
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. **Tip:** – In order to avoid influences on the intraocular pressure, you should look relaxed and straight ahead into the distance, avoiding eye	

#	Operating step	Photo
	movement. The outer eye muscles should be relaxed, the eyelid open. – You 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. **Tip:** – Observe the prescribed distance between eye and reader. It is intended that you look 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(/KP) cannot be activated because the distance is too great (display EEE and acoustic signal, see Chapter 9). – 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. – See chapter 9 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.** **Tip:** 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.

If you have any questions or unusual pressure values, please contact your ophthalmologist.

11.2 Battery replacement

WARNING!

Only use the intended battery type 2CR5 lithium battery, see chapter 14.

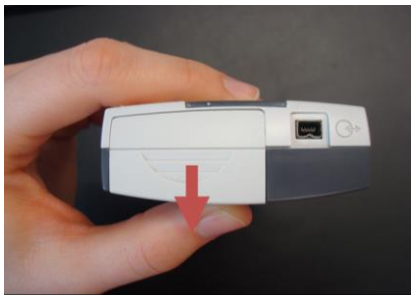
WARNING!

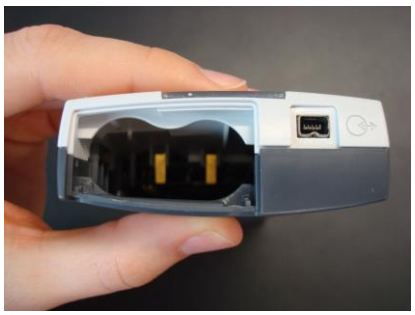
Incorrect insertion of the battery can lead to health impairment/disorders! Therefore, observe the operating steps described in this instruction for use.

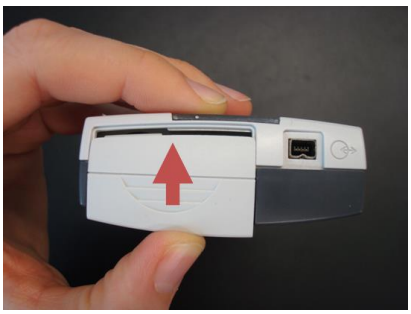
If the display does not show the empty battery symbol (see section 9), the battery has sufficient capacity and there is no need to change the battery.

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

If the Mesograph display shows the empty battery symbol (see section 9), replace the battery as described below:

Operating step	Photo
Take the Mesograph 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 section 9 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 14) 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.	

12 Hygiene measures

HAZARD!

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

Immediately contact Service (chapter 15.3) if liquid enters the interior of the unit.

The Mesograph reader is used under non-sterile conditions.

12.1 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.

12.2 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)

13 Service/ Maintenance

HAZARD!

Do not carry out any independent repair or service work on 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 Medical Device Directive is not necessary, as the measuring function of the device is regularly checked by means of calibration with the Goldmann tonometer or finger palpation.

14 Spare parts list

All accessory components are listed below.

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

15 Troubleshooting and debugging

15.1 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 15.3.

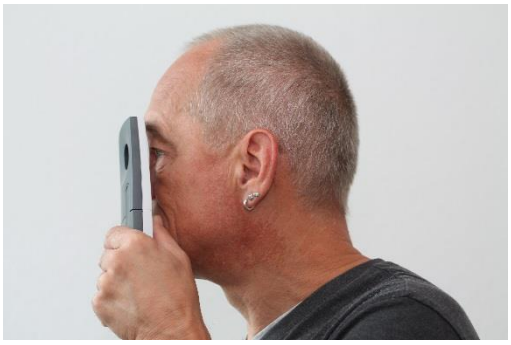
Error	Cause	Remedy
No display after completed measuring process	No sufficient operating voltage at the device Measured value display switched off Display defective	Replace the battery. Otherwise contact the device service.
No reaction of the device to operating inputs	Internal device error	Contact the device service.
No reaction after pressing the start button	Internal device error	Contact the device service.
"EEE" display after measurement	Inaccurate measurement, eyemate®-IO(/KP) 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
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(/KP)		Each Mesograph is assigned to an eyemate®-IO(/KP) before implantation. The Mesograph will only work with this implant. Please make sure that you are using the correct Mesograph.

15.2 Incorrect operation

Please relax, hold your eyes still and look straight ahead 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
	
	

15.3 Device service and return shipment

Should you not be able to fix an obvious device error with the actions described above, please contact the manufacturer:

Implandata Ophthalmic Products GmbH
Kokenstrasse 5,
30159 Hannover, Germany

Phone: +49 511 2204 2580
info@implandata.com
www.my-eyemate.com

Faulty devices can be returned to the manufacturer for repair after consultation with the device service.

In the case of a return, please use the original transport packaging and the return note. This is enclosed with the original packaging.

16 Device disposal

Please send the device to Implandata for disposal. Please use the return form enclosed in the original packaging.

Address:

Implandata Ophthalmic Products GmbH

Kokenstrasse 5

D-30159 Hanover/ Germany

17 Device specifications and labels

17.1 Labels and symbols

17.1.1 Device labels and symbols

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.

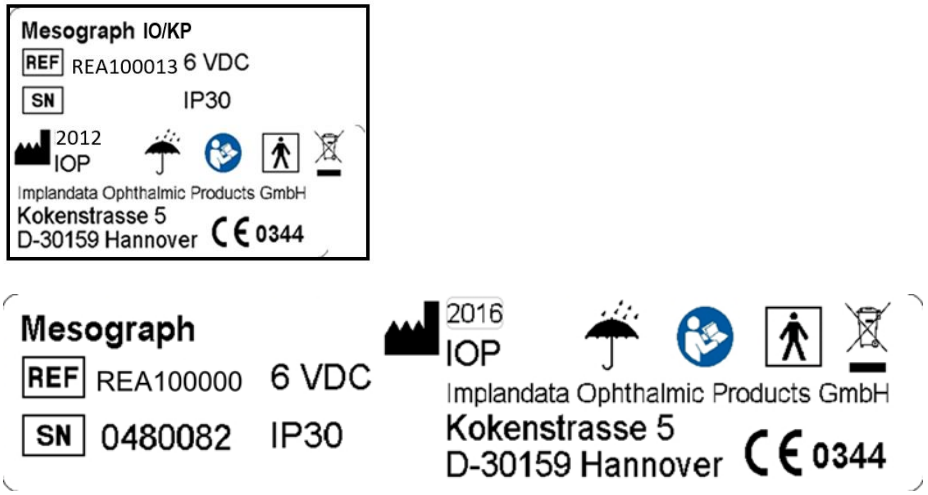


Figure 1: Mesograph label

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!

17.1.2 Device packaging labels and symbols

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

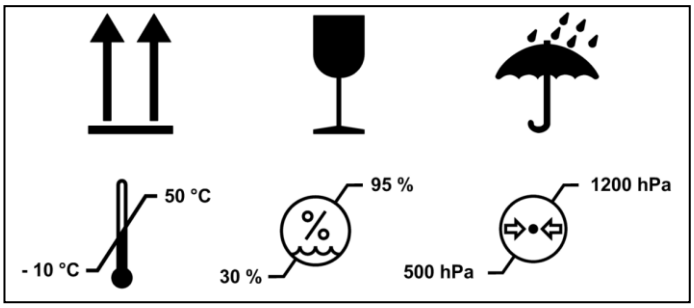


Figure 2: Packaging label Mesograph

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

17.2 Specifications table and environmental conditions

Classifications	
eyemate®-IO(/KP) Implant	AIMD
Mesograph	
Degree of protection	BF
Protection class	IP 30
Medical device class	Accessories for AIMD
Minimum product life	
eyemate®-IO(/KP) Implant	10 years
Mesograph	2 years
Physical data	
eyemate®-IO(/KP) Implant	
Available sizes	∅ 11.3 mm (IMP010001) ∅ 11.7 mm (IMP010002) ∅ 12.1 mm (IMP010003)
Implant thickness	0.5-0.9mm (all implant sizes)
Weight (11.3mm, 11.7mm and 12.1mm implants)	52 mg, 55mg and 63mg
Mesograph	
Size (WxHxD), including accessories	180 mm x 66 mm x 26 mm
Weight	approx. 180 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

18 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 bandwidth	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	

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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.

19 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!

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