

# **MESOGRAPH for eyemate<sup>®</sup>-IO/KP**

Instruction for use for patients

Version 1.0 / 2019-09





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## Table of contents

<b>1</b>	<b>General Information .....</b>	<b>1</b>
1.1	About this instruction for use .....	1
1.2	Symbols used in this instruction for use .....	1
1.3	Abbreviations used in these instructions for use.....	1
<b>2</b>	<b>Safety and security .....</b>	<b>3</b>
2.1	General safety instructions .....	3
2.2	Symbols .....	5
2.2.1	Device .....	5
2.2.2	Device packaging .....	6
<b>3</b>	<b>Device description .....</b>	<b>7</b>
3.1	System description and function.....	7
3.2	Intended use.....	7
3.3	User group.....	8
3.4	Contraindication.....	8
3.5	Device components.....	8
3.5.1	<b>Mesograph</b> .....	8
3.5.2	<b>eyemate<sup>®</sup>-IO</b> .....	12
<b>4</b>	<b>Operation of the Mesograph .....</b>	<b>13</b>
4.1	General information on the operation of the device.....	13
4.2	Trainings .....	13
4.3	Handling conditions.....	13
<b>5</b>	<b>Operation.....</b>	<b>14</b>
5.1	Execution of the measurement.....	14
5.2	Battery replacement .....	18
<b>6</b>	<b>Hygiene measures .....</b>	<b>21</b>
6.1	Cleaning the housing surface .....	21
6.2	Disinfection of the housing surface.....	21
<b>7</b>	<b>Service/ Maintenance.....</b>	<b>22</b>
<b>8</b>	<b>Troubleshooting and debugging.....</b>	<b>23</b>
8.1	System failures .....	23
8.2	Incorrect operation .....	24
8.3	Device service and return shipment .....	25

<b>9</b>	<b>Disposal.....</b>	<b>26</b>
<b>10</b>	<b>Spare parts list.....</b>	<b>27</b>
<b>11</b>	<b>Technical data .....</b>	<b>28</b>
<b>12</b>	<b>Electromagnetic compatibility .....</b>	<b>29</b>
<b>13</b>	<b>Warranty.....</b>	<b>33</b>

# 1 General Information

## 1.1 About this instruction for use

These operating instructions describe the handling of the **Mesograph** product, part of the **eyemate**<sup>®</sup> 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.

## 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

<b>STK</b>	Safety check
<b>IOP</b>	Intraocular pressure
<b>implandata</b>	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	Before initial operation, the user must be instructed in the device by the attending physician.
Application	<p>An instruction is required to use the <b>Mesograph</b>. See chapter 4.2 for training measures.</p> <p>Do not drop the unit under any circumstances.</p> <p>Do not operate the device outdoors. Observe the environmental conditions in chapter 11 Technical data.</p> <p>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.</p> <p>Do not place the device in the immediate vicinity of devices with high electromagnetic radiation.</p> <p>The <b>Mesograph</b> must not be in the immediate vicinity of pacemakers or active implanted medical devices. A minimum distance of 20cm must be maintained to pacemakers!</p>
Visual and functional check on the device	<p>Before each use, check the device, the accessories and the buttons for damage.</p> <p>In case of damage, do not operate the device any further and contact Implandata.</p>
Electrical protection	<p>The <b>Mesograph</b> is powered by a battery.</p> <p>Only type 2CR5 batteries may be used. The use of rechargeable batteries is not permitted.</p>
Electromagnetic compatibility (EMC)	<p>The <b>Mesograph</b> was tested according to the current EMC regulations.</p> <p>In order to avoid EMC interference, the <b>Mesograph</b> may only be put into operation as described in this document.</p> <p>Use of the device may affect other medical electrical devices.</p> <p>The effects of radio signals on medical devices depend on various factors and are therefore unpredictable.</p> <p>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.</p>
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 <b>Mesograph</b> or other equipment.

Combination with other devices	The <b>Mesograph</b> 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 Implants.
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
<b>Symbol on the device</b>	
	Serial number of the device
	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 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.

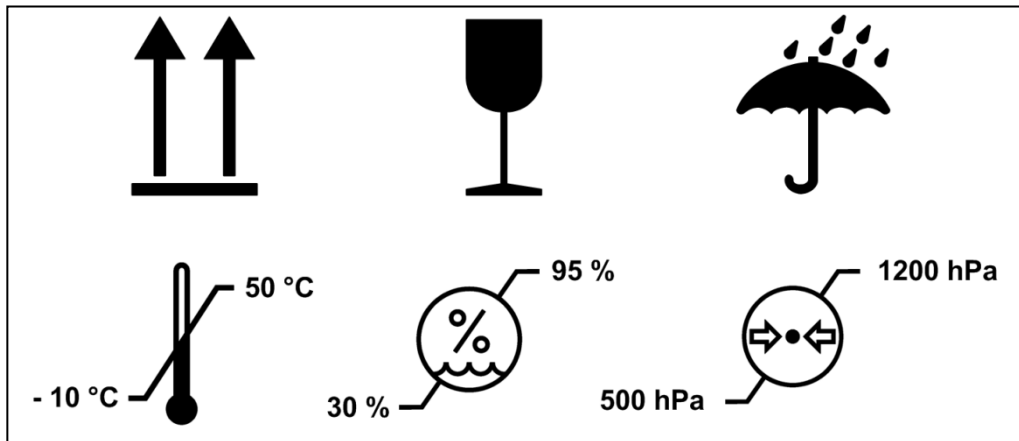
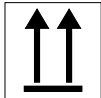


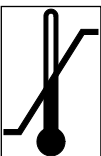

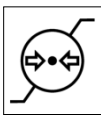


Figure 2: Packaging label Mesograph

Symbols	Significance
<b>Symbols on the packaging</b>	
	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/KP** microsensor, which remains permanently in the patient's eye, and the hand-held **Mesograph** for power supply and data readout of the **eyemate®-IO/KP** microsensor.

The measurement of the intraocular pressure by the **eyemate®-IO/KP** microsensor is initiated through the **Mesograph**. The **Mesograph** activates the **eyemate®-IO/KP** microsensor by means of a harmless 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.

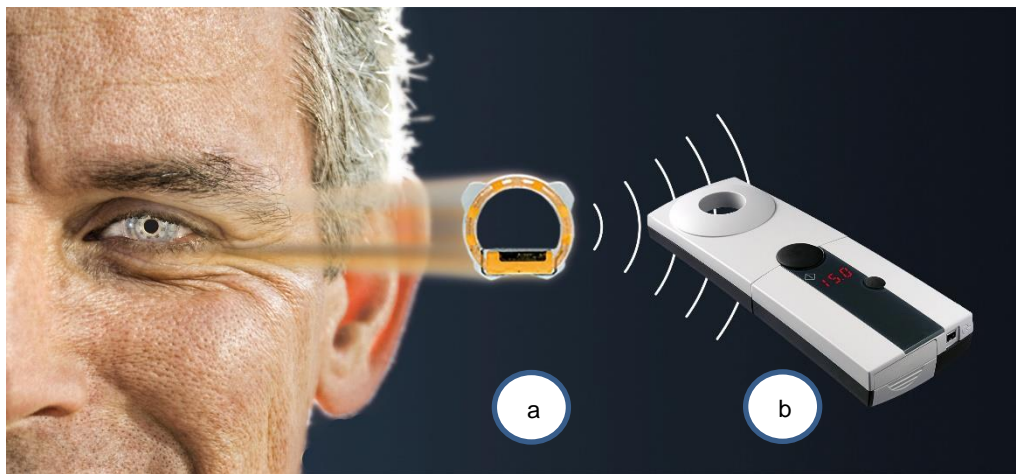


Figure 3: Operating principle

- a. **eyemate®-IO/KP** (implant)
- b. Mesograph

### 3.2 Intended use

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


The handheld device can only determine the intraocular pressure together with the **eyemate®-IO/KP** 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

	<p><b>WARNING!</b></p> <p>Patients with pacemakers or active implanted medical devices should always consult their physician before use and use the device under increased precautions.</p> <p>The <b>Mesograph</b> must not be in the immediate vicinity of pacemakers or active implanted medical devices.</p>
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The user group is:


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


### 3.4 Contraindication

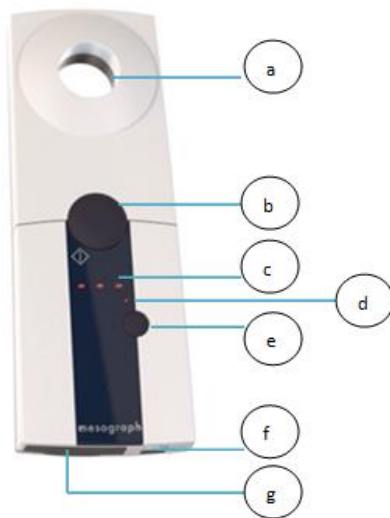
A contraindication is the presence of an active implant in the head/neck region.

### 3.5 Device components

#### 3.5.1 Mesograph

	<p><b>WARNING!</b></p> <p>The device must not be dismantled by the user into its individual components (antenna and handset). This is the responsibility of Implantservice's service.</p>
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	<p><b>WARNING!</b></p> <p>Keep the device and its components (especially the battery cover) away from small children, as small components can be swallowed.</p>
---	---

**Structure Mesograph:****Figure 4: Structure of the Mesograph**

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


**Acoustic signals**


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


<b>Sound</b>	<b>Significance</b>
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".

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### 3.5.2 eyemate®-IO



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

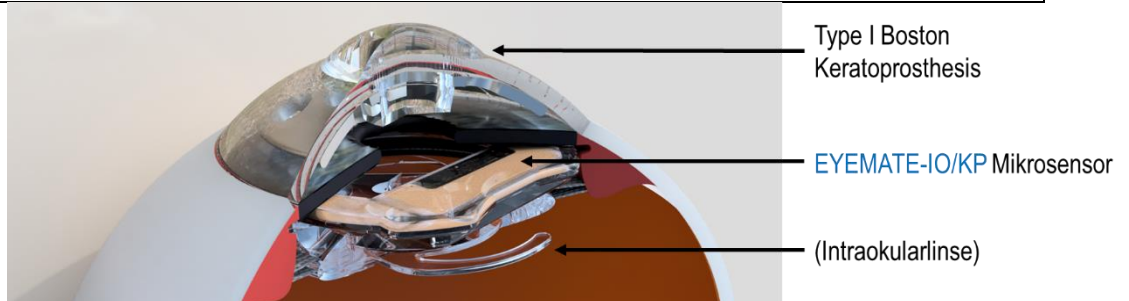


Figure 5: Exemplary representation of the implanted eyemate®-IO/KP microsensor in the eye

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

### 4.2 Trainings

**WARNING!**

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

### 4.3 Handling conditions

**WARNING!**

The user is not allowed to remove the antenna of the **Mesograph**. This is the responsibility of the Implantservice 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.


## 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<sup>®</sup>-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.

 *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 <b>Mesograph</b> in your hand (hand of your choice).	
	<p> <b>Hint:</b></p> <p>For the now following measurement, you must be relaxed and calm.</p>	
2	<p>Press the start button on the <b>Mesograph continuously and with little effort</b> for 1 second.</p> <p>Two short beeps will sound to indicate the measuring mode.</p> <p> <b>Hint:</b></p> <ul style="list-style-type: none"> <li>- In order to avoid influences on the intraocular pressure, you should look relaxed and straight ahead into the distance, avoiding eye movement. The outer eye muscles should be relaxed, the eyelid open.</li> </ul>	

#	Operating step	Photo
	<ul style="list-style-type: none"> <li>- You should move as little as possible during the measurement procedure.</li> <li>- Until the measurement is completed, the display shows three red lines. After the measurement, the measured value is displayed at this point.</li> </ul>	





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:**


- 3
- 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 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.
  - See chapter 3.4.1 for an explanation of the displays and beeps in the event of a measurement error.





#	operating step	photo
	<p>If the measurement is carried out correctly, the measurement process is started.</p> <p><b>The duration of a single measurement process is max. 2 seconds.</b></p>	
4	<p> <b>Hint:</b></p> <p>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.</p> <p>At the end of the measurement, two beeps sound.</p>	
5	<p>The measured value determined (intraocular pressure) is shown on the display in red when the measurement is complete.</p> <p>At the same time, the determined value and the exact time (time/date) of the measurement are stored by the handset.</p>	
	<p>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.</p>	
	<p> If you have any questions or unusual pressure values, please contact your ophthalmologist.</p>	



## 5.2 Battery replacement




	<p><b>WARNING!</b></p> <p>Only use the intended battery type 2CR5 lithium battery, see chapter 10.</p>
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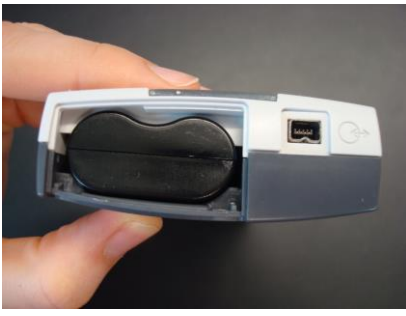

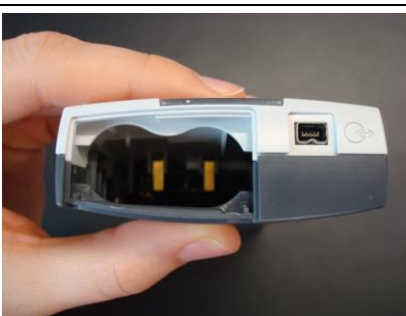


	<p><b>WARNING!</b></p> <p>Incorrect insertion of the battery can lead to health impairment/disorders! Therefore, observe the operating steps described in this instruction for use.</p>
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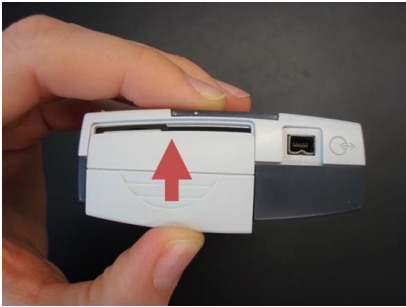

	<p>If the display does not show the empty battery symbol (see 3.5.1), the battery has sufficient capacity and there is no need to change the battery.</p>
---	---

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
<p>Take the <b>Mesograph</b> in your hand.</p>	
<p>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.</p>	
<p>See 3.4.1 for battery compartment location.</p>	

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

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

## 6 Hygiene measures

	<p><b>HAZARD!</b></p> <p>Do not allow any liquids to enter the interior of the device!</p> <p>Immediately contact Service (see Chapter 7) if liquid enters the interior of the unit.</p>
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### 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.



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.

## 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 Implantservice, 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, <b>eyemate®-IO/KP</b> implant is out of reach of the Mesograph handheld: - Too large distance between <b>Mesograph</b> measuring device and eye (> 5cm) - <b>Mesograph</b> measuring device is not placed frontally to the eye (tilted). - <b>Mesograph</b> 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 <b>eyemate®-IO/KP</b>		Each <b>Mesograph</b> is assigned to an <b>eyemate®-IO/KP</b> before implantation. The <b>Mesograph</b> will only work with this implant. Please make sure that you are using the correct Mesograph.

## 8.2 Incorrect operation



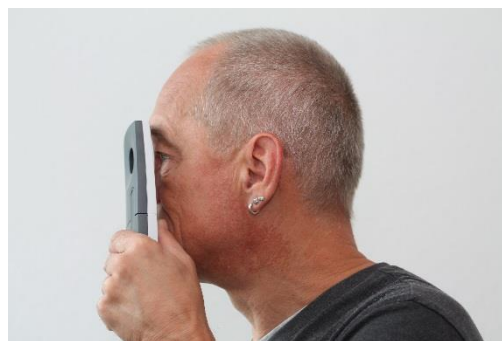
*Note that you are relaxed during the measurement, hold your eye still and look straight forward without tension during the measurement.*

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**



**8.3 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 258-0  
[info@implandata.com](mailto:info@implandata.com)  
[www.implandata.com](http://www.implandata.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.



## 9 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

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## 10 Spare parts list

All accessory components are listed below.

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

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## 11 Technical data

<b>Classifications</b>	
Degree of protection	BF
Protection class	IP 30
Medical device class	Accessories for AIMD
Minimum product life	2 years
<b>Physical data</b>	
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
<b>Environmental conditions</b>	
<b>Operation</b>	
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
<b>Storage and transport</b>	
Temperature	-10° C to +50° C
Air humidity	30 % to 95 %, non-condensing
Air pressure	500 hPa to 1,200 hPa
<b>Display indications and functions</b>	
Display indication	Visual display of: Measured value, error measurement, empty battery, status
<b>Admission</b>	
CE-Mark	CE <sub>0344</sub>
	The <b>eyemate</b> <sup>®</sup> 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 <i>passed</i>	no special requirements
<i>radiated interference in the frequency range from 30 Mhz - 1000 Mhz</i>	EMC Report, EPA, Annex 10	
RFI field strength in the frequency range from 9 khz - 30 Mhz according to EN 55011	Matches <i>passed</i>	no special requirements
<i>radiated interference in the frequency range from 9 khz - 30 Mhz</i>	EMC Report, EPA, Annex 11	
Permissible range of operating frequencies according to ETSI EN 300 330-2	Matches <i>passed</i>	no special requirements
<i>permitted range of operating frequencies</i>	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 <i>passed</i>	no special requirements
<i>limits for field strength and RF carrier in the range from 9 kHz to 30 MHz</i>	EMC report, EPB, Appendix 2	
Limit values for the permissible range of the modulation bandwidth according to ETSI EN 300 330-2	Matches <i>passed</i>	no special requirements
<i>limits for the permitted range of modulation bandwidth</i>	EMC report, EPB, Appendix 3	
Sender Secondary broadcast to ETSI EN 300 330-2	Matches <i>passed</i>	no special requirements
<i>transmitter spurious and out-of-band emissions</i>	EMC report, EPB, Appendix 4	
Receiver secondary transmission according to ETSI EN 300 330-2	Matches <i>passed</i>	no special requirements
<i>receiver spurious emissions</i>	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	$\pm 6$ kV Contact discharge $\pm 8$ kV Air discharge	Matches  <i>passed</i>  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:  <i>Power frequency magnetic field immunity test</i>	3 A/m	Matches  <i>passed</i>  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:  <i>Immunity to Radiated Electromagnetic Fields</i>	3 V/m 80MHz to 2.5 GHz	Matches  <i>passed</i>  E1] V/m  EMC Report, EPA, Annex 2	<p>Portable and mobile radios should not be used at a distance from the <b>Mesograph</b> less than the recommended protective distance calculated from the equation applicable to the transmission frequency.</p> <p><b>Recommended protective distance:</b></p> $d = \left[ \frac{3,5}{E1} \right] \sqrt{P}$ $d = \left[ \frac{3,5}{E1} \right] \sqrt{P} \text{ for 80 MHz to 800 MHz}$ $d = \left[ \frac{7}{E1} \right] \sqrt{P} \text{ for 800 MHz to 2.5 GHz}$ <p>With P as rated power of transmitter in watts (W) according to transmitter manufacturer and d as recommended protective distance in meters (m)</p> <p>The field strength of stationary radio transmitters should be less than the compliance level at all frequencies according to an on-site study <sup>a,b</sup>. Interference may occur in the vicinity of equipment bearing the following symbol.</p> <div style="text-align: center;">  </div>
<p>Note 1: At 80MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not be applicable in all cases. The spread of electromagnetic quantities is caused by absorption and reflections of buildings, _____ of _____ and people.</p> <p>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 <b>Mesograph</b> is used exceeds the above compliance levels, the <b>Mesograph</b> 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 <b>Mesograph</b>.</p> <p>b Over the frequency range from 150kHz to 80MHz, the field strength should be less than 3 V/m.</p>			

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 $d = \left\lceil \frac{3,5}{E1} \right\rceil \sqrt{P}$	80 MHz to 800 MHz $d = \left\lceil \frac{3,5}{E1} \right\rceil \sqrt{P}$	800 MHz to 2.5 GHz $d = \left\lceil \frac{7}{E1} \right\rceil \sqrt{P}$
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**

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# Instructions for Use (IFU)

## Mesograph for eyemate-IO/KP for Patients

### Approval

	Name / Function	date	signature
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Reviewed by:	T. Schneider/Head of M&S	11.09.2019	
Reviewed by:	S. Meyer / Head of R&D	11.09.19	
Approved by:	M. Ostermeier / General Manager	11.09.2019	
Released by:	H. Sun / Head of QA&RA	11.09.2019	

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### History

version	release date DD. Month YYYY	Description of Change	reason of change	author
A	See above	Initial English version based on the German version 1.0	Initial version	M. Grammenos