eyemate®-Reader

Instructions for use for medical professionals

Version 2024-06 (en)

CE 0344

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This instructions for use (IFU) can be downloaded from the manufacturer's website: http://infocenter.my-eyemate.com/

The summary of safety and clinical performance (SSCP) for eyemate®-Reader is included in the SSCPs of the eyemate® implants. These are available in the European database on medical devices (EUDAMED) https://ec.europa.eu/tools/eudamed and are linked to the following basic UDI-DIs:

426064817IMP217F for eyemate®-SC
426064817IMP107A for eyemate®-IO
426064817IMP137G for eyemate®-IO/KP

Device Regulation: EU MDR 2017/745, Class III (eyemate®-Reader is an accessory to AIMD)

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1 General Information

The eyemate®-Reader (REA320100) is a CE marked (CE 0344, 2021) accessory to the eyemate® intraocular pressure sensing implants and provides wireless communication with the eyemate® implant in order to obtain and display IOP measurement values.

1.1 About this instruction for use

This IFU is intended for medical professionals who treat patients implanted with eyemate®-IO, eyemate®-IO/KP and eyemate®-SC devices. It describes the use of the eyemate®-Reader device (CE 0344, 2021) and its accessories: the eyemate®-Key and the battery charger.

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.

Please also refer to the enclosed *eyemate®-IO/KP adjustment IFU* for the case of the eyemate®-IO/KP patients.

Upon IFU download: Ensure that the IFUs are obtained from the manufacturer's website: http://infocenter.my-eyemate.com/

WARNING!

Read this IFU carefully and follow the instructions!

1.2 Symbols used in this instruction for use

WARNING!

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

TIP

Tips provide valuable information to facilitate the device use and improve efficiency.

1.3 Acronyms used in these instructions for use

AIMD	Active Implantable Medical Device
EMC	Electromagnetic compatibility
GAT	Goldmann applanation tonometry
IFU	Instructions for use
IOP	Intraocular pressure
MRI	Magnetic Resonance Imaging

2 Indications, contraindications, warnings and safety information

2.1 Indications and target population

The eyemate®-Reader is to be used by patients implanted with an eyemate® intraocular pressure sensor, and medical professionals who treat these patients.

The **eyemate®-IO** intraocular pressure sensor (IMP010001, IMP010002 and IMP010003) is an AIMD, which is permanently implanted in the ciliary sulcus of patients with primary open angle glaucoma who have undergone cataract surgery with capsular bag intraocular lens (IOL).

The **eyemate®-IO/KP** intraocular pressure sensor (IMP130001, IMP130002 and IMP130003) is an AIMD, which is permanently implanted in the posterior chamber of an aphakic or pseudophakic eye in patients who have undergone Boston-Keratoprosthesis Type I (BI-KPro) implantation.

The **eyemate®-SC** intraocular pressure sensor (IMP210001) is an AIMD, which is permanently implanted in suprachoroidal space of the eye in patients indicated for non-penetrating glaucoma surgery.

2.2 Contraindications

WARNING!

Observe the contraindications!

- Usage of eyemate®-Reader by patients with AIMDs in head and neck region is prohibited.
- Patients with AIMDs must consult their physician before using the eyemate®-Reader device. Noncompliance may result in serious injury. For the case of pacemakers, it is important to maintain a minimum distance of 20 cm when the eyemate®-Reader is activated.

2.3 ⚠ Warnings and safety information

⚠ General

- Any serious incident that occurs in relation to the system should be reported to the manufacturer and the relevant competent authority in your country. Serious incident means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat. To report the serious incident to the manufacturer please email: complaint@implandata.com.
- The device operator is responsible for compliance with relevant laws and regulations.
- Only operate the eyemate®-Reader device and its accessories in accordance with the instructions described in this IFU.
- Keep the eyemate®-Reader device and accessories out of reach of children.

⚠ Intended user and training

- Training is required before operating the eyemate®-Reader device and its accessories. Training of the medical professionals is provided by the manufacturer's representatives. Patient training must be provided by the medical professional (please refer to **section 2.4** for details).
- The eyemate®-Key is only intended for use by ophthalmic professionals in the ophthalmic practice/clinic setting. The use of the eyemate®-Key by the patient is prohibited.

⚠ Electromagnetic emission and interactions with other devices

- Use of eyemate®-Reader by patients with AIMDs in head and neck region is prohibited.
- Do not operate the reader device near a pacemaker or other AIMDs. This includes patients implanted with eyemate® devices as well as any persons with an AIMD who are in close proximity of the eyemate®-Reader. Patients with AIMDs must consult their physician before using the eyemate®-Reader device. Non-compliance may result in serious injury. For the case of pacemakers, it is important to maintain a minimum distance of 20 cm.
- When the main button of the eyemate®-Reader is pressed for 1 second in "manual measurement mode", the device is activated and emits an electromagnetic field. The device remains active for several seconds (typically 5s) while the communication with the implant is in progress. There is no electromagnetic radiation in standby mode.
- Do not take the eyemate®-Reader near an MRI scanner.
- Do not place the eyemate®-Reader in the immediate vicinity of devices with high electromagnetic radiation.
- Use of the eyemate®-Reader device may affect other electrical medical devices. The effects of wireless signals on medical devices depend on various factors and are therefore unpredictable. To avoid electromagnetic interference, the eyemate®-Reader must only be operated as described in this document.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the eyemate®-Reader, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Do not attempt to dismantle, repair or modify the eyemate®-Reader. Doing so may result in electrical hazards, mechanical hazards, hazardous level of electromagnetic emission, or lower immunity to electromagnetic interference with other devices.
- Do not use accessories other than those specified in this document. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Please refer to electromagnetic compatibility data in **section 11**.

⚠ Environmental conditions

- Do not place the eyemate®-Reader device in the immediate vicinity of combustible agents.
- Do not place the eyemate®-Reader in environments with high humidity or water exposure. In case of liquid penetration inside the eyemate®-Reader, immediately discontinue use.
- Do not perform IOP measurement in bright light conditions.
- Observe the ambient environmental conditions (**section 10.1**).

- The eyemate® system operates correctly within the absolute pressure range of 800-1150 hPa. Therefore, at altitudes above 1700 meters reliable measurements cannot be obtained.
- Absolute pressure beyond 2000 hPa (e.g., 10 meters underwater) will permanently damage the implant. Therefore, activities such as scuba-diving must be avoided.

⚠ Device performance, calibration and IOP data

- Do not implant an eyemate® pressure sensing device if the pre-implantation check has not been successfully performed. Please return the eyemate® implant to the manufacturer.
- The IOP measurements obtained by the eyemate® system is providing complementary information to other diagnostic measures performed in glaucoma patients. Therapeutic decisions should be made only in the context with the performance of other glaucoma measures.
- Following implantation, following any ocular procedure and at least once a year the correct function of the eyemate® system must be confirmed by an experienced and qualified specialist. Goldmann applanation tonometry (GAT) is the recommended reference method for eyemate®-IO and eyemate®-SC measurements. However, since the eyemate® system measures the IOP directly whereas GAT is an indirect technique affected by many factors, in most cases there will be some deviation between the IOP values obtained using the two methods. Therefore, calibrating eyemate® based on GAT must be performed with utmost care, taking into account the limitations of the GAT method. In particular, larger GAT errors are expected for IOPs above 21 mmHg. Consequently, GAT adjustment should only be considered if the IOP measured with the GAT is below 21 mmHg.
- Ensure that the Goldmann tonometer is within its calibration period before using it for reference measurements. The Goldmann tonometer must be maintained in accordance with its IFU, and its correct function must be checked once a month. If the Goldmann tonometer does not pass this check, please contact its manufacturer for service.
- To avoid measurement artifacts caused by manipulation of the implanted eye, the GAT measurement must always be performed AFTER the eyemate® measurement.

⚠ Device damage and disposal

- Do not drop the eyemate®-Reader.
- Check the eyemate®-Reader device for any signs of wear or damage before each use. In case of any damage, do not continue to operate the device and contact the manufacturer.
- Do not dispose of the eyemate®-Reader device or accessories. Please return the damaged or nonfunctional device to the manufacturer.

2.4 ⚠ Patient training information

The patient shall be briefed by the healthcare provider on the following topics:

- **Patient IFU**

  The patient is instructed to consult their IFU. Particular attention is to be given to the warning messages, contraindications and activities/medical procedures to be avoided.

- **When/whom to inform about the implant**
  - The patient is instructed to inform their healthcare providers about the implant BEFORE any medical procedure or MRI scan, and provide their implant card.
  - At the airport security.

- **Device operation**

  The patient is first shown the IOP measurement procedure and then is asked to repeat the measurement in the presence of the medical professional to ensure the instructions are correctly followed.

- **Device calibration and repair**
  - The patient is instructed to contact their treating ophthalmologist if there are concerns regarding the measured IOP values. The patient must not attempt to adjust their medication.
  - The patient is instructed to consult their treating ophthalmologists about any recent medical procedures, in case the eyemate® system needs to be calibrated.
  - The patient is instructed to contact the manufacturer for technical problems if troubleshooting instructions provided in the IFU do not resolve the issue.

3 Device description

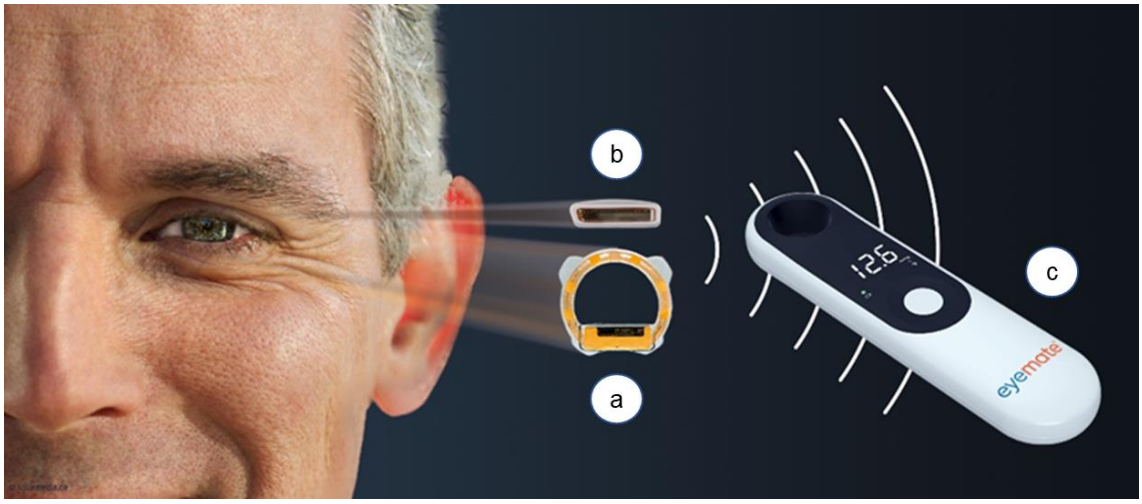
3.1 eyemate® system

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

The eyemate® system consists of a biocompatible eyemate® pressure sensing implant, which permanently remains in the patient's eye, as well as the eyemate®-Reader device (c).

In eyemate®-IO(/KP) patients the implant (a) is located in the ciliary sulcus of the eye. In eyemate®-SC patients the implant (b) is located in the suprachoroidal space.

The implant is wirelessly powered and operated by activating and holding the eyemate®-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 on the eyemate®-Reader.



The accessories of the eyemate®-Reader include the eyemate®-Key, the eyemate®-Cable Antenna (available separately) and a battery charger.

3.2 Operational modes of the eyemate®-Reader device

Manual IOP measurements (using eyemate®-Reader):

The patient or their treating medical professional can perform a single IOP measurement by activating and holding the eyemate®-Reader in front of the eye, as described in **section 6**. The measurements can be repeated as often as desired, typically several times per day. The measured IOP value is displayed on the reader device in mmHg and is stored.

Automated continual IOP monitoring (using eyemate®-Reader and eyemate®-Cable Antenna):

Using the eyemate®-Cable Antenna (optional accessory), which is secured around the eye, the IOP measurements are performed periodically (e.g., every 5 minutes) for up to 24 hours, in order to give a more detailed overview of the circadian IOP profile. The continual measurements can be performed at medical facilities or by the patient at home setting.

Please refer to **section 9** for details on how to place an order.

Adjustment of the eyemate® system based on GAT (using eyemate®-Reader and eyemate®-Key):

The performance of the eyemate® system is verified by comparing the measured IOP values to those obtained with GAT. Please refer to **section 5** for details.

Pre-implantation procedure (using eyemate®-Reader and eyemate®-Key):

Before implanting the eyemate® implants, it is necessary to perform a pre-implantation check to confirm the correct functionality of the implant using the eyemate®-Reader and the eyemate®-Key. Please refer to **section 6** for instructions on how to perform the pre-implantation procedure.

3.3 Intended use

The eyemate® intraocular pressure sensing implants are CE marked (CE 0344, 2021) active implantable medical devices (AIMDs). Together with the eyemate®-Reader device, they are intended as a diagnostic system for users to measure the intraocular pressure (IOP).

eyemate®-Reader: The eyemate®-Reader is an accessory to the eyemate® implant and is exclusively designed to operate with this implant. To provide power to the implant and initiate data communication, the eyemate®-Reader device must be activated in close proximity of the implant. It is a reusable device and is used under non-sterile conditions.

eyemate®-Key: The eyemate®-Key is only intended for use in the ophthalmic practice / clinic for the purpose of pre-implantation check and GAT adjustment, as described in this IFU. It is a reusable device and is used in non-sterile conditions.

eyemate®-Cable Antenna: The eyemate®-Cable Antenna (an optional accessory which is available separately) used in combination with the eyemate®-Reader, is intended for automated continual monitoring of the intraocular pressure for up to 24 hours, in the ophthalmic practice / clinic as well as by the patient at home setting. It is a single-use device and is used under non-sterile conditions.

WARNING!

The IOP measurements obtained by the eyemate® system is intended as only one of the inputs used for IOP monitoring in glaucoma patients. IOP readings must be validated using standard tonometry such as GAT

3.4 Intended user and use environments

The eyemate®-Reader is intended for *Professional Healthcare Facility Environment* as well as *Home Healthcare Environment*.

The eyemate®-Key is only intended for *Professional Healthcare Facility Environment*.

The eyemate®-Reader device is used by the patients who have an eyemate® implant in their eye, as well as the patient's carer, treating ophthalmologist and their medical staff. The eyemate®-Key is only intended for use by ophthalmic professionals in the ophthalmic practice/clinic setting.

WARNING!

The use of the eyemate®-Key by the patient is prohibited.

3.5 Description of eyemate®-Reader system components

The eyemate® system consists of the eyemate® implant and the eyemate®-Reader system. The eyemate®-Reader system consists of the eyemate®-Reader (handheld device) as well as its accessories: the eyemate®-Key, the eyemate®-Cable Antenna (optional accessory) and the battery charger. The device components as well as the displayed messages and the audio signals are described in the following sections.

Components of the eyemate®-Reader system:

	Components	Description
eyemate®-Reader device		
a	Antenna aperture	Generates a magnetic field for powering the eyemate® implant.
b	Main button	Activates the reader device/ initiates an IOP measurement.
c	Display	Three 7 segment LEDs for displaying measured IOP data as well as errors and other messages.
d	Battery LED	Shows the status of the battery.
e	GSM LED	Remains off. Reserved for future internet connectivity options.
f	Micro-USB socket	Used for connecting the charger, the eyemate®-Key and the optional eyemate®-Cable Antenna.
Accessories		
g	eyemate®-Key	The eyemate®-Key is only for professional use and it is provided to the ophthalmic professionals whose patients receive the eyemate® implants. It is plugged into the micro-USB socket for the purpose of pre-implantation check and GAT adjustment.
h	eyemate®-Cable Antenna (available separately)	The cable antenna is an optional accessory, which is available separately and is used for automated continual monitoring mode (see **section 3.2**).
i	Battery charger (not shown)	The charger is provided with the eyemate®-Reader. It is plugged into the micro-USB socket for charging the eyemate®-Reader.

Description of the audio signals:

Audio signal		Description
Start of measurement sound	One long beep (low pitch)	Indicates that the device is activated (start button was pressed long enough) and the measurement is about to start
Ticking sound		The antenna is being powered and the eyemate®-Reader is communicating with the implant.
OK sound	Two short beeps (high pitch)	The procedure is successful.
Error sound	One long beep (high pitch)	Indicates a problem and is generally accompanied by an error message.

Description of the displayed messages during normal operation:

Displayed messages		Description
	"running snake"	Busy sign. Switching to expert mode or battery charging is in progress.
	Steady border	Device successfully switched to expert mode or battery charging process completed.
	"8.8.8"	User presses main button. Start of the measurement.
	Blinking "."	Measurements are in progress.
	IOP value	The measured IOP value is displayed in mmHg.

Description of the battery LED:

LED	Description
Steady red	battery charge is less than 20%
Blinking red	Battery charge is less than 5%
Steady green	If the eyemate®-Reader is **connected to the charger**, a steady green battery LED indicates that the battery is now fully charged. If the eyemate®-Reader is **not connected to the charger**, a steady green battery LED indicates that the battery charge is above 20%.
Blinking green	Charging is in progress.

4 IOP measurement procedure

To obtain an IOP measurement using the eyemate®-Reader device, please follow the steps described below. Refer to **section 3.5** for description of different visual and audio signals.

WARNING!

Training is required before operating the eyemate®-Reader device and its accessories. Training of the medical professionals is provided by the manufacturer's representatives. Patient training is provided by their medical professional (please refer to **section 2.4**).

TIP

eyemate®-Reader does not display past measurements. Past measurements are, however, stored in the device.

TIP

The measurement values are shown in mmHg, with one decimal digit. Only values which are between -2 and +70 mmHg are displayed.

	Description of the steps	Images/displayed messages/buzzer and LED status
1	Please ask the patient to sit in a comfortable position and relax. The patient must take off their glasses. **TIP** To avoid measurement artifacts, please ask the patient to sit still and avoid moving, manipulating, pressing or rubbing of the implanted eye. Hearing aid users: In case of discomfort, the hearing aid is to be removed before performing IOP measurements.	
2	Hold the eyemate®-Reader in your hand and press the main button for 1 second.	Display:  Buzzer: OK sound

	Description of the steps	Images/displayed messages/buzzer and LED status
3	Immediately after pressing the main button, hold the eyemate®-Reader device in front of the implanted eye. Ensure the reader is not pressing against the eyelid. Two seconds following pressing of the main button the measurement begins and the antenna is powered for a maximum duration of 5 seconds. The eyemate®-Reader begins wireless communication with the implant and obtains the IOP value. **TIP** To avoid measurement artifacts, please ask the patient to sit still and avoid moving, manipulating, pressing or rubbing of the implanted eye. Hearing aid users: In case of discomfort, the hearing aid is to be removed before performing IOP measurements.	 Display:  Buzzer: ticking sound
4	The measured IOP value (in mmHg) is displayed for 30 seconds.	Display:  Buzzer: Ok sound
5	The eyemate®-Reader then automatically returns to standby mode.	

5 eyemate® adjustment based on Goldmann applanation tonometry

Following implantation, following any ocular procedure and at least once a year the correct function of the eyemate® system must be confirmed by an experienced and qualified specialist. The correct functionality of the eyemate®-IO and eyemate®-SC implants is verified using Goldmann applanation tonometry (GAT). For the case of the eyemate®-IO/KP implant, the functionality is verified by finger palpation which is described in the enclosed *eyemate®-IO/KP adjustment IFU*.

Please follow the steps described below. The eyemate® system needs calibration if the discrepancy between the IOP measured by the eyemate® system and the one obtained with GAT is ≥ 5 mmHg.

WARNING!

Goldmann applanation tonometry (GAT) is the recommended reference method for eyemate®-IO and eyemate®-SC measurements. However, since the eyemate® system measures the IOP directly whereas GAT is an indirect technique affected by many factors, it is expected that in most cases there will be some deviation between the IOP values obtained using the two methods. Therefore, calibrating eyemate® based on GAT must be performed with utmost care, taking into account the limitations of the GAT method. In particular, larger GAT errors are expected for IOPs above 21 mmHg. Consequently, **GAT adjustment should only be considered if the IOP measured with the GAT is below 21 mmHg**.

WARNING!

Ensure that the Goldmann Tonometer is within its calibration period before using it for reference measurement. The Goldmann tonometer must be maintained in accordance with its IFU, and its correct function must be checked once a month. If the Goldmann tonometer does not pass this check, please contact its manufacturer for service.

	Description of the steps	Images/displayed messages/buzzer and LED status
1	Please connect the eyemate®-Key to the micro-USB socket of the eyemate®-Reader and press the main button. The display shows the busy sign (“running snake”) indicating that the reader is switching to Expert mode, where automatic return to standby mode is prevented.	Display: 
2	If the reader device has successfully switched to Expert mode, a steady border is displayed.	Display:  Buzzer: OK sound

	Description of the steps	Images/displayed messages/buzzer and LED status
3	Please ask the patient to perform an IOP measurement by pressing the main button of the eyemate®-Reader for 1 second and immediately holding it in front of the implanted eye. To avoid operator's bias, the patient must not disclose the IOP value to the medical professional who performs the Goldmann reference measurement.	
4	The measured IOP value is displayed (in mmHg).	Display:  Buzzer: Ok sound
5	At this point, it is necessary to obtain the reference measurement using GAT. Please place the eyemate®-Reader aside for the duration of the GAT measurement. Please ensure the eyemate®-Key remains connected to the eyemate®-Reader until the end of the procedure. The measured IOP value will continue to be displayed on the eyemate®-Reader for the entire duration that the user is obtaining an IOP measurement using the Goldmann tonometer.	
6	Please note down the eyemate® measurement and the GAT value. **In case the discrepancy between the IOPs measured by the eyemate® system and the one obtained with GAT is ≥ 5 mmHg, the eyemate® system needs calibration. Please inform the manufacturer and provide the IOP values.** The procedure is now completed. Please remove the eyemate®-Key to automatically switch back to the manual measurement mode.	
7	Upon receipt of the calibrated reader device from the manufacturer, it is important to perform an IOP measurement in the manual measurement mode to verify that the intended GAT adjustment has been successfully performed. Please note, as the IOP values fluctuate over time, repeating the IOP measurements using the eyemate® system will deliver a slightly different IOP value each time.	

6 Pre-implantation procedure

Before the eyemate® pressure sensing devices can be implanted in the eye, its functionality must be verified by performing a “pre-implantation check”. The procedure is performed while the eyemate® implant is in its original sterile packaging. If the pressure measured during the preimplantation check is equal to or within the range of -2.0 and 2.0 mmHg, the eyemate® implant is functioning as expected and can be implanted. If the value is outside this range, the implant has failed the pre-implantation check and has to be returned to the manufacturer in its original packaging. The implantation check must be performed not later than one week prior to the scheduled implantation. If longer time has elapsed or in case of unexpected adverse events (e.g., suspected damage to the implant during pre-implantation handling), it is recommended to repeat the pre-implantation check.

WARNING!

Do not implant an eyemate® pressure sensing device if the pre-implantation check has not been successfully performed.

	Description of the steps	Images/displayed messages/buzzer and LED status
1	Please connect the eyemate®-Key to the micro-USB socket of the eyemate®-Reader and press the main button. The eyemate®-Reader switches to Expert mode where the pre-implantation check can be performed. The display shows the busy sign (“running snake”) indicating that the reader device is switching to Expert mode.	Display: 
2	If the reader device successfully switched to Expert mode, a steady border is displayed.	Display:  Buzzer: OK sound
3	Perform a pressure measurement. To do that, press the main button for 1 second while holding it near the sterile package containing the eyemate® implant. **TIP** The sterile package contains a protective box in which the implant is located. Hold the eyemate®-Reader such that the box is positioned at the center of the antenna aperture of eyemate®-Reader and is parallel with it. Do not exert force on the package since this increases the relative pressure.	 Buzzer: ticking sound

	Description of the steps	Images/displayed messages/buzzer and LED status
4	The measured pressure value is displayed (in mmHg). Note the displayed value. If the displayed pressure is equal to or within the range of -2.0 and 2.0 mmHg, it indicates that the eyemate® pressure sensing device is behaving as expected and can now be implanted. Do not implant an eyemate® pressure sensing device if the measured pressure value is outside the range of -2.0 to 2.0 mmHg. Please return the eyemate® implant to the manufacturer. Do not attempt to adjust the displayed value.	Display:  Buzzer: Ok sound
5	The pre-implantation check is now completed. Please disconnect the eyemate®-Key.	

7 Device maintenance

7.1 Charging

For charging the eyemate®-Reader device please follow the steps described below:

> **TIP**
>
> It is not possible to take IOP measurements if the eyemate®-Reader is connected to the charger.

	Description of the steps	Images/displayed messages/buzzer and LED status
1	Connect the charger to the micro-USB socket and press the main button. The eyemate®-Reader switches to the charging mode and the busy sign (“running snake”) is displayed for 10 seconds.	Display: 
2	The battery LED shows the charging status.	Dis Battery LED: Blinking green (charging in progress) OR Steady green (fully charged)
3	The display remains off during the charging process unless the user presses the main button.	
	If charging is still in progress, the busy sign (“running snake”) will be displayed for 10 seconds.	Display: 
	If the battery is fully charged, the “steady border” will be shown on display for 10 seconds.	Display: 
4	Disconnecting the reader device from the charger automatically switches the eyemate®-Reader device to the standby mode. The device can now be used for taking IOP measurements.	

7.2 Cleaning and disinfection

WARNING!

Avoid eyemate®-Reader device contact with any liquids. In case of liquid penetration inside the eyemate®-Reader, immediately discontinue use.

WARNING!

If the same eyemate®-Reader device is used on different patients, it must be cleaned and disinfected before use.

Cleaning: For cleaning use a damp cloth.

Disinfection: please use commercial wipes designed for disinfection of sensitive material surfaces and medical devices. Do not use abrasive agents. Do not use liquids or foams.

Compatibility of the following products with eyemate®-Reader have been tested:

- Bacillol® 30 Tissues (BODE Chemie GmbH)*
- Mikrobac® Tissues (BODE Chemie GmbH)**

*Active ingredients: Ethanol 140 mg/g; Propan-2-ol 100 mg/g; Propan-1-ol 60 mg/g; N-Alkyl-Aminopropyl-Glycine 5 mg/g

**Active ingredients: Benzyl C12-18-alkyldimethyl-ammonium chloride 4mg/g; didecyldimethylammonium chloride 4mg/g

8 Troubleshooting and device service

WARNING!

Do not attempt to dismantle, modify or repair the eyemate®-Reader device. Doing so may result in electrical hazards, mechanical hazards, hazardous level of electromagnetic emission, or lower immunity to electromagnetic interference with other devices.

WARNING!

Check the eyemate®-Reader device for any signs of wear or damage before each use. In case the eyemate®-Reader is damaged, immediately discontinue use and contact the manufacturer.

8.1 Description of error messages

For troubleshooting, please refer to the information provided in this section and implement the recommended corrective actions. The following table provides a list of error messages and required corrective actions.

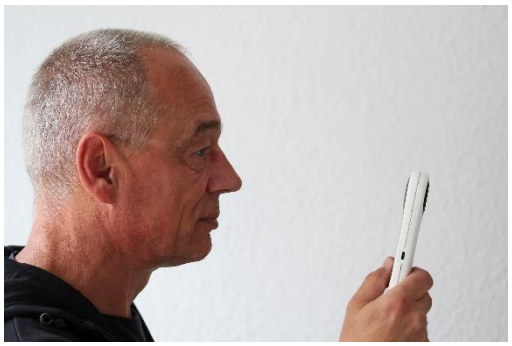
Error message	Cause of error	Corrective action
 Displayed for 30 seconds	eyemate®-Reader is unable to communicate with the eyemate® implant due to system failure or user error, as described below:	
	• **User error** includes incorrect holding or handling of the eyemate®-Reader during the measurement.	Please refer to **section 8.2** for instructions on how to prevent user errors.
	• **System failure** includes damaged reader or implant	Please contact the manufacturer (**section 8.3**).
 Displayed for 30 seconds	Calibration data for the eyemate® implant cannot be used or is not available.	Please contact the manufacturer.
 Blinking for 30 seconds	The measured IOP value is out of range (<-2.0 mmHg). This error may be caused by out of range environmental conditions (ambient pressure outside the range of 800 hPa – 1150 hPa), user error, damaged implant or damaged reader device.	Please ensure the procedure is performed correctly and check the ambient conditions. Avoid manipulation or pressing of the eye. Repeat the IOP measurement.

Error message	Cause of error	Corrective action
 Blinking for 30 seconds	The measured IOP value is out of range (>70.0 mmHg). This error may be caused by out of range environmental conditions (ambient pressure outside the range of 800 hPa – 1150 hPa), user error, damaged implant or damaged reader device.	Please ensure the procedure is performed correctly and check the ambient conditions. Avoid manipulation or pressing of the eye. Repeat the IOP measurement.
 Displayed for 30 seconds when the main button of the eyemate®-Reader is pressed.	It indicates that the battery is lower than 5% and therefore performing an IOP measurement is not possible.	Please recharge the eyemate®-Reader device.

8.2 User errors

Cases of incorrect use of the eyemate®-Reader are described below.

User error	Corrective action
Device does not start the measurement because the main button is not pressed for a sufficiently long duration.	To obtain a measurement press the main button for at least 1 second. 
eyemate®-Reader is not held correctly in front of the eye and therefore a measurement cannot be obtained. 	Hold the reader directly in front of the eye. 

User error	Corrective action
eyemate®-Reader is held too far away from the eye and therefore no wireless commination is established and as a result a measurement cannot be obtained	Hold the eyemate®-Reader close to the implanted eye. (Maximum of 3 cm for the case of eyemate®-SC and maximum of 4 cm for the case of eyemate®-IO(/KP).)
	

8.3 Device return to manufacturer for repair

In case of problems and issues regarding the eyemate®-Reader device, please first refer to the recommendations provided in the troubleshooting section above. If problems persist, contact the manufacturer for consultation. If the manufacturer recommends that the device be returned for service, please send the device along with all accessories in its original packaging to the address below. Please complete the provided return form and include it in the return package.

Contact details of the manufacturer:

Implandata Ophthalmic Products GmbH
Kokenstrasse 5,
30159 Hannover
Germany

Tel.: +49 (0) 511 2204 2580
Fax: +49 (0) 511 2204 2589
Website: www.my-eyemate.com

General inquires: info@implandata.com
Technical issues: service@implandata.com
Reporting complaints/serious incidents: complaint@implandata.com

9 Accessories and replacement parts

To order accessories and replacement parts please include the following part numbers in your order form.

REA320100	eyemate®-Reader device
REA320101	Charger
REA320300	eyemate®-Key
REA320400	eyemate®-Cable Antenna

To place an order, please fill out the provided order form and return it to the manufacturer.

The eyemate®-Reader is provided with a copy of *eyemate®-Reader IFU for patients*, the eyemate®-Key is provided with a copy of *eyemate®-Reader IFU for medical professionals* (this document). The eyemate®-Cable Antenna is provided with its IFU.

The IFUs and the order forms can also be downloaded from the manufacturer's product website:

www.my-eyemate.com

WARNING!

Do not use accessories other than those specified in this document. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

10 eyemate®-Reader device specifications and labels

10.1 Specifications

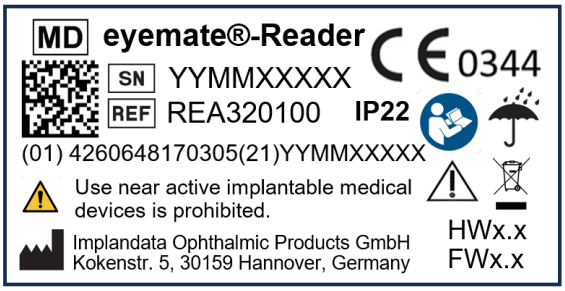
Classification	
Ingress protection level	IP22 (the device housing provides protection against dripping water when tilted at 15°, and it provides protection against solids >12.5mm)
Medical device class	Accessory to AIMD (Class III, MDR 2017/745)
Device lifespan	Minimum of 5 years
Parameters and materials	
Dimensions (WxLxH)	49 x 188 x 23 mm
Weight	115 g
Data transmission	Reserved for future internet connectivity option
Carrier frequency (communication of the reader with the implant)	13.56 MHz
Transmission power	Maximum 0.5 W
Maximum measurement distance (maximum distance between the implant and the reader for effective read-out)	40 mm for eyemate®-IO(/KP) 30 mm for eyemate®-SC
Measurement resolution	1 mmHg
Battery	1.2 Ah Lithium Ion Battery
Display screen	3 digit 7 segment LED display in White
LEDs	2 LEDs, each with green and red light
IOP display units	mmHg
eyemate®-Reader housing material	Polyurethane
Device operation conditions	
Operation temperature in *Professional Healthcare Facility Environment*	-20 °C to +40 °C
Ambient charging temperature	-20 °C to +40 °C
Ambient humidity	non-condensing
Ambient pressure range	800 hPa to 1150 hPa
Maximum altitude	1700 m
Environmental conditions for device transport and storage	
Storage temperature range	0 °C to +45 °C
Transport temperature range	-20 °C to +60 °C
Ambient humidity	non-condensing
Ambient pressure range	500 hPa to 1200 hPa

Regulatory approval	
CE-certification	CE0344 The eyemate® system is certified in accordance with MDR 2017/745
Applied standards	EN 60601-1 EN 60601-1-2 EN 60601-1-6 EN 60601-1-11

10.2 Device and packaging labels

eyemate®-Reader

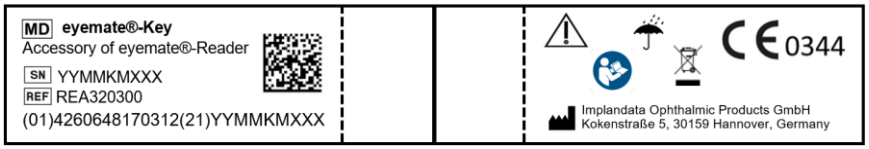
The following label is placed on the eyemate®-Reader device as well as the packaging:



The following label is placed on the eyemate®-Reader packaging:

eyemate®-Key

The following label is located on the eyemate®-Key as well as the packaging:



The following label is placed on the eyemate®-Key packaging:

Description of symbols			
	Atmospheric pressure limitation	REF	Catalogue number
	Caution		Do not dispose of the device in domestic waste. Please return the device to the manufacturer.
	Follow instructions for use.		Handle with care
	Keep dry		Manufacturer
MD	Medical device	SN	Serial number
	Temperature limit	IP_{N1N2}	N1= 2: protected against solid foreign objects of 12 mm and greater. N2= 2: protected from water spray less than 15 degrees from vertical.
CE 0344	This device is in compliance with the requirements of the EU MDR 2017/745 and is CE certified by the Notified Body DEKRA B.V. with identification number 0344.		

11 Electromagnetic compatibility

Testing in accordance with ETSI EN 301 489-1 and 489-3	
Test specifications	ETSI EN 301 489-1 V2.2.3 (2019-11); ETSI EN 301 489-3 V2.1.1 (2019-03)
Classification based on EN 301 489-1	Radio and ancillary equipment for portable use (portable equipment)
Operating frequency	13.56MHz

Results

The equipment under test (EUT) complies with the requirements of the above test specification.

Enclosure Port

Emission

Requirement	**Reference**	**Test Specification**	**Verdict[1]**
Radio Disturbance Electric Field < 1 GHz	EN 55032	30 MHz - 1 GHz (class B) SAC	P
Radio Disturbance Electric Field > 1 GHz	EN 55032	1 GHz - 6 GHz (class B) SAC	P

Immunity

Environmental Phenomena	**Reference**	**Test Specification**	**Performance criterion**	**Verdict[1]**
Radio-frequency electromagnetic field. Amplitude modulated	EN 61000-4-3	3 V/m 0.08 - 1 GHz AM 1 kHz; m = 0.8	Continuous phenomena	P
Radio-frequency electromagnetic field. Amplitude modulated	EN 61000-4-3	3 V/m 1 - 6 GHz AM 1 kHz; m = 0.8	Continuous phenomena	P
Electrostatic discharge (ESD)	EN 61000-4-2	Contact: ±4 kV Air: ±8 kV	Transient phenomena	P

[1] P=Pass

Testing in accordance with IEC 60601-1-2	
Test specifications	IEC 60601-1-2: Edition 4.0, 2014; EN 60601-1-2 Edition 4.0, 2015
Classification	Class B, Group 1
Environment of intended use	*Professional healthcare facility environment* and *home healthcare environment*

Results

The EUT complies with the requirements of the above test specification.

Emission Enclosure Port

Requirement	Reference	Test Specification	Verdict[4]
Radio Disturbance Electric Field < 30 MHz	CISPR 11	150 kHz - 30 MHz [5] SAC	N/A
Radio Disturbance Electric Field > 1 GHz	CISPR 11 CISPR 16-2-3	30 MHz - 1 GHz (class B) SAC	P
Radio Disturbance Electric Field > 1 GHz	CISPR 11 CISPR 16-2-3	1 GHz - 18 GHz [6] (class A / B) SAC	N/A
Radio Disturbance Electric Field	CISPR 25[7]	Limit acc. ECE R-10 and EN 50498[8]	N/A
Radio Disturbance Electric Field	DO160G, sect. 21[9]	100 MHz - 6 GHz Category M	N/A

Immunity Enclosure Port

Environmental Phenomena	Reference	Test Specification	Verdict[4]
Power Frequency Magnetic Field	IEC 61000-4-8	30 A/m [10] 50 Hz or 60 Hz	N/A*
Radio-frequency electromagnetic field. Amplitude modulated	IEC 61000-4-3	80 MHz - 2.7 GHz ☒ Home Healthcare 10 V/m ☒ Prof. Healthcare 3 V/m ☒ 80 % / 1 kHz ☐ other as defined in RMF	P
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380 - 390 MHz 27 V/m; PM 50%; 18 Hz 430 - 470 MHz 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz [11] 704 - 787 MHz 9 V/m; PM 50%; 217 Hz 800 - 960 MHz 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz 9 V/m; PM 50%; 217 Hz	P
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact: ±8 kV Air: ±15 kV	P
RF-Surgery test	IEC 60601-2-x		N/A**

*) Customer states: Equipment has no magnetic sensitive components.
**) Customer states: Equipment is not operated near active RF-surgery.

[4] P (Pass): test object meets the requirement; F (Fail): test object does not meet the requirement; NA:test case doesnot apply to the test object; NR: test case is not requested by the client; NP: test case was not performed

[5] For group 1 equipment, no limits apply in the frequency range 150 kHz to 30 MHz.
[6] For group 1 equipment, no limits apply in the frequency range > 1 GHz. (see CISPR 11 chapter 6.2.2.4 and 6.2.2.5). The limits between 1 GHz and 18 GHz apply only to group 2 equipment operating at frequencies above 400 MHz.

[7] Standards applicable for transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25.

[8] IEC 60601-1-2 has no detailed requirement concerning limit to be used. Therefore the limits of the European Automotive Regulation ECE R10 and Aftermarket electronic equipment in vehicles (EN 50498) is used.

[9] ME EQUIPMENT and ME SYSTEMS intended for use in aircraft shall meet the RF EMISSIONS requirements of ISO 7137. ISO 7137 is identical to RTCA DO-160C:1989 and EUROCAE ED-14C:1989. The latest editions are RTCA DO-160G:2010 and EUROCAE ED-14G:2011. Therefore, use of Section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be considered.

[10] Applies only to ME EQUIPMENT and ME SYSTEMS with magnetically sensitive components or circuitry.

[11] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Testing in accordance with ETSI EN 300 330

Test specifications: ETSI EN 300 330 V2.1.1

Results

The EUT complied with the requirements of the test specifications.

Transmitter Requirements

Test-Spec. [1]	Test Case	Config.	Verdict[1]
Transmitter requirements			
Clause 4.3.1	Permitted range of operating frequencies	-	P
Clause 4.3.2	Operating frequency ranges	EUT2	P
Clause 4.3.3	Modulation bandwidth	EUT2	P
Clause 4.3.4	Transmitter H-field requirements Only for equipment under class 1 and 2	EUT2	P
Clause 4.3.5	Transmitter RF carrier current Only for equipment under class 3	-	NA[2]
Clause 4.3.6	Transmitter radiated E-field Only for equipment under class 4	-	NA[2]
Clause 4.3.7	Transmitter conducted spurious emissions Only for equipment under class 3	-	NA[2]
Clause 4.3.8	Transmitter radiated spurious domain emission limits < 30 MHz	EUT2	P
Clause 4.3.9	Transmitter radiated spurious domain emission limits > 30 MHz For equipment under class 1, 2 and 4	EUT2	P
Clause 4.3.10	Transmitter Frequency stability Only for channelized systems	-	NA[3]

Transmitter and Receiver Requirements

Test-Spec.	Test Case	Config.	Verdict[1]
Receiver requirements			
Clause 4.4.2	Receiver spurious emissions Does only apply to receivers which a not co-located with transmitters	-	NA[4]
Clause 4.4.3	Adjacent channel selectivity Only for channelized systems in the 27 MHz range	-	NA[5]
Clause 4.4.4	Receiver blocking or desensitization; Not for tagging systems	-	NA[5]

[1] P (Pass): test object meets the requirement; F (Fail): test object does not meet the requirement; NA: test case does not apply to the test object; NR: test case is not requested by the client; NP: test case was not performed.

[2] Test case is not applicable since the EUT is product class 1 equipment.

[3] Test case is not applicable since the EUT has no channel definition.

[4] Test case is not applicable since the EUT is a RFID transmitter without receive-only mode.

[5] Test case is not applicable since the EUT is a tagging system (RFID). The test case does not apply to tagging systems (refer to [1], table 7).

[1] ETSI EN 300 330 V2.1.1

Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

12 Device disposal

Please do not dispose of the eyemate®-Reader device and accessories. Please complete the provided return form and send the device to the manufacturer for disposal.

Implandata Ophthalmic Products GmbH
Kokenstrasse 5
30159 Hannover
Germany

13 Warranty

A warranty period of 12 months from the date of delivery applies. This warranty does not cover the following cases:

- Improper use
- Operating errors that cause damage to the device
- Non-compliance with the instructions for use
- Implementation of any changes to the device without the written permission of the manufacturer
- Opening of the device housing by unauthorized persons
- Use of non-original accessories or spare parts
- Force majeure (e.g. lightning strike, flood, theft)
- Damage during transportation due to improper packaging upon return

Please refer to **section 8.3** for instructions on how to return the damaged device to the manufacturer. If a customer complaint is unlawful, IOP GmbH reserves the right to demand an appropriate fee for testing and shipping of the device.