Implandata Ophthalmic Products GmbH

eyemate®-IO/KP adjustment IFU

Supplementary to the eyemate-Reader IFU for medical professionals

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This supplementary 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

1.1 About the eyemate®-IO/KP adjustment instructions for use (IFU)

This is the supplementary IFU of the eyemate®-Reader when used in conjunction with eyemate®-IO/KP. It supplements the GAT-adjustment (Chapter 7) described in the eyemate®-Reader IFU for medical professionals by finger palpation, which is the approved control measurement for 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.

1.2 Symbols used in this IFU

Warning!

Failure to observe the warnings may result in serious personal injury.

Tip

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

1.3 Acronyms used in this IFU

IFU	Instructions for use
IOP	Intraocular pressure
GAT	Goldmann applanation tonometry

2 eyemate® adjustment based on finger palpation

The correct functionality of the eyemate®-IO/KP implant must be verified by means of finger palpation.

In case of discrepancies between the IOP measured by the eyemate® system and the typical eyemate®-IO/KP values for palpation, eyemate® calibration (“GAT adjustment”) can be performed using the eyemate®-Key.

The manufacturer recommends to carry out a comparative measurement at least once a year and, if necessary, to carry out a measurement adjustment (calibration).

At the end of the GAT adjustment a confirmation measurement is to be performed in manual measurement mode to ensure that the calibration has been successful. 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.

The control measurement may only be carried out with finger palpation.

The eyemate®-IO/KP implant measures the actual pressure in the eye (primary size). It is known that finger palpation derives the intraocular pressure from a secondary quantity. Comparative measurements show a correspondence between the two measuring methods, but absolutely identical measured values are not to be expected due to the different measuring methods.

Warning

After the implantation, and also after every operation on the eye, the correct function of the eyemate®-IO/KP must be checked using the finger palpation method and corrected if necessary.

If no valid measurement result can be obtained, please contact the manufacturer.

Warning

In order to ensure continuous comparability of the eyemate®-IO/KP system with the finger palpation values, it is recommended to carry out a comparative measurement at least once a year and, if necessary, to carry out a measurement adjustment (calibration).

Comparison of eyemate®-IO/KP with manometric values during a clinical study showed the following typical pressure ranges:

Pressure levels through palpation	Typical eyemate®-IO/KP value
"soft/hypotonic"	< 12 mmHg
"normal"	12 - 24 mmHg
"borderline"	17 - 27 mmHg
"hypertonic"	> 23 mmHg

If the measured value of the eyemate®-IO/KP read out with the eyemate®-Reader is within the above range during palpation, no adjustment of the eyemate®-IO/KP system is required.

If, however, there is a significant deviation of > 5 mmHg) between the typical eyemate®-IO/KP values for palpation and the actually measured eyemate®-IO/KP values, a calibration is recommended.

Warning

If a hypertonic intraocular pressure is determined by palpation, but this is not confirmed by the eyemate®-IO/KP measured value, a measurement adjustment **must not** be carried out, since the possible wide dispersion of the intraocular pressure values in the hypertonic range will make it impossible to adjust the reader sensibly.

An adjustment may only be carried out if a reduction of the intraocular pressure has been achieved by appropriate measures and if the intraocular pressure has been classified as "soft/hypotonic", "normal" or "borderline" by palpation.

Under no circumstances should the finger palpation measurement be carried out at the same time as the reader measurement, since a mutual influence of the measurements cannot be ruled out.

In order to carry out the control measurement, the reading device should always be used first in order to rule out any influence on the intraocular pressure caused by the mechanical action of finger palpation. To avoid the risk of an examiner bias, the examiner should not know the eyemate®-IO/KP value.

	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
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 reference measurement (finger palpation).	
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 by means of finger palpation. Please place the eyemate®-Reader aside for the duration of the finger palpation 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 for the entire duration that the user determines the pressure level through palpation.	
6	Please note down the eyemate® measurement and the reference measurement values. **In case the discrepancy between the IOPs measured by the eyemate® system and the one obtained with finger palpation 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.	

8	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 eyemate 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.	