

# Reading glasses

## 1. Name of the product

This user manual has been developed for the medical device - reading glasses - manufactured by Blue Iris sp.z o.o. sp. k., which includes the following list of models:

- brilo.eu
- correct+
- visual

## 2. Manufacturer

The reading glasses described in this manual are manufactured by:

Blue Iris sp. z o.o. sp. k., Rymarkiewicza str. 5A, 60-681 Poznań

## 3. Intended use of the device

The described medical device - reading glasses - is intended for short-term use by the patient, in order to temporarily correct minor defects of the human visual system during reading, with a compensation strength ranging from +1.0 to a maximum of +3.50 dioptre. Their use improves the vision quality and allows for correct reading of the text. The use of reading glasses prevents the progress of visual impairments and compensates for refractive errors.

The function of the reading glasses is to correct the eyesight during visual work such as reading. Correction is achieved by using lenses mounted in the glasses. The strength is equal for both lenses in the glasses. The maximum compensation strength of corrective lenses in used Blue Iris reading glasses is +3.50 dioptre. The patient selects the appropriate strength of the lenses as a result of an attempt to read the selected text.

The manufacturer supplies the reading glasses to various commercial points, at which no special instructions from a specialist physician are necessary in order to allow the patient to purchase the product. Although the patient does not require an appointment with an ophthalmologist and/or an optometrist, it is recommended to evaluate the visual impairment with the help of a specialist.

The medical device - reading glasses - meets the requirements of i.e. the following standards:

- PN-EN 14139:2010
- PN EN ISO 14971:2020
- PN-EN 62366-1:2015-07/AC:2018-08
- PN-EN ISO 12870:2018-06
- PN-EN ISO 8624:2021-01

The reading glasses are delivered to commercial points in the form of a ready-to-use medical device. This means that the frame elements and temple ends are already formed, and the lenses mounted in the frames are characterized by a specific compensation strength, indicated on the lenses. As a result, the patient receives information regarding their strength, which allows for correct selection of appropriate glasses. The temple ends of reading glasses are also shaped. Therefore, it is not necessary to visit an optician's shop for the correction of frames and/or lenses. In consequence, the medical device - reading glasses - is a reusable device intended for use by one patient. If the patient notices problems with reading despite using the device, a doctor should be consulted in order to examine the eyesight.

It is recommended to store the described medical device - reading glasses - in a case. Additionally, please remember about proper maintenance – such as cleaning with a soft cloth or washing with water in case of more recalcitrant dirt.

The frequency of use of the product depends on the individual needs of the user. It may be occasional and apply to temporary situations in which the user will use the product or the user may require the corrective effect more often - depending on the frequency of performing vision-related work such as reading.

## 4. Warnings associated with the use of the product

- The use of the device should be consulted with an ophthalmologist.
- Blue Iris reading glasses are only intended for near vision and reading.
- Improper use of the product - medical device - reading glasses - is intended for use by patients who need to correct their eyesight while reading. These are not corrective glasses that are used to correct the eyesight defects during other vision-related works. The maximum strength of the lenses is +3.50 dioptr.
- The reading glasses are not glasses for correcting the eyesight while driving a car or other motor vehicles.
- Discomfort, headaches or other ailments may occur during the use of the device as a result of improperly selected glasses.
- Certain types of frames can cause allergic reactions in case of patients susceptible to allergies.
- If the device does not achieve its intended use - the strength of the lenses is too high or too low to read the text.
- The device should be stored in a case in order to protect it against mechanical damage.
- The device should be maintained and kept clean. The device should be cleaned with a soft cloth. In case of heavy dirt, gently rinse the glasses with water and then let them dry. The cleaned glasses should be stored in a case.
- The device should not be cleaned with strong chemicals, as this may result in damage and cause irritation or allergy to the patient.
- In the event of discoloration and/or damage to the surface of glasses and/or frames caused by improper maintenance of the product, please contact the manufacturer immediately.

## 5. Contraindications regarding the use of the device

- The reading glasses should not be used to protect the eyes from radiation emitted by any type of monitors. The device does not include appropriate filters which provide such protection.
- Mechanical damage of the device is a contraindication to use.
- Sharp edges or protruding elements which may cause injury to the patient who will use the medical device reading glasses are also contraindicated.
- In case of occurrence of skin sensitization or irritation after contact with the device, please consult a physician.
- In the event of loss or damage of the elements of the device, please consult the store to check whether the frames can be repaired.

### **CAUTION:**

In the event of a serious incident while using the medical device - reading glasses - this fact should be immediately reported to the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products:

- e-mail: [incydenty@urpl.gov.pl](mailto:incydenty@urpl.gov.pl)
- registered letter or courier: al. Jerozolimskie str. 181c, 02-222 Warsaw
- fax: 48 22 492 11 29

## 6. Information regarding the shelf life of the product

The product may be used as long as it can still be ensured that it fits properly and it fulfils its function.

## 7. Date of issuing the manual

28.03.2022