



PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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EYEWEAR INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Lead Glasses, Goggles, and fitovers ("Leaded Eyewear") are intended to be worn by persons who are present in the **EXAMINATION** or **OPERATING ROOM** during **RADIOLOGICAL** procedures requiring the use of x-ray/fluoroscopy. They are intended primarily to protect the eyes of the **OPERATOR**.

2. CAUTION

Leaded Eyewear are not rated for impact resistance and the lead lenses should not be used to protect against impact nor in any situation where possibility of an impact exists.

3. COMPLIANCE STANDARDS FOR EYEWEAR: IEC 61331-1:2014 | ASTM 2547-18

- **Lead (Pb) equivalent material (mm Pb) \geq 0.50mm LE at 150kV**

Protection Configuration:

_PL75	=Plano Lens 0.75mm (\pm 0.05) Pb equiv.	_SS	=Lead strip side shield 0.50mm (\pm 0.05) Pb equiv.
_PL50	=Plano Lens 0.50mm (\pm 0.05) Pb equiv.	_SS50	=Lead lens side shield 0.50mm (\pm 0.05) Pb equiv.
_RX75	=Prescription lens 0.75mm (\pm 0.05) Pb equiv.	_SS75	=Lead lens side shield 0.75mm (\pm 0.05) Pb equiv.
_RX50	=Prescription lens 0.50mm (\pm 0.05) Pb equiv.		

4. GENERAL INSTRUCTIONS

PACKAGING & STORAGE

Eyewear should be stored in a protective case in normal room temperature and low humidity conditions when not in use.

CLEANING & DISINFECTING

a. Lenses: Never use ammonia or chlorine-based cleaners. Use of alcohol is permitted for lenses that do not possess an anti-reflective (A/R) coat. Soak lenses in alcohol between 2 and 10 minutes and rinse with water. To clean A/R coat lenses soak in diluted soap and water. **DO NOT** allow water to remain or dry onto the lenses as this can discolor/damage the lens. Wipe and dry using a Protech cleaning cloth or equivalent soft, lint free cloth.

b. Frame: Use any standard eyewear cleaning cloth. Diluted soap and water usually will not discolor or damage the frame.

MAINTENANCE & REPLACEMENT

a. Maintenance: Examine eyewear frequently and before each use. Cease use and replace or repair immediately if the eyewear are chipped, pitted, or damaged. You may tighten screws/hinges if they loosen.

b. Replacement: Use only CE or Protech approved lenses and frames to repair the eyewear or request an RMA (return/repair) through your local representative.

EU TYPE:

Regulation (EU) 2016/425, Module B EU Type Examination Cert #: 523548/1

BTTG Testing & Certification Ltd. (Notified body #0338)

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