



PROTECH LEADED EYEWEAR INC,
DBA PROTECH MEDICAL

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LEAD BARRIERS INSTRUCTIONS FOR USE (IFU)

1. INTENDED USE

Lead Barriers are used by healthcare professionals as a mobile solution to protect them from the harmful effects of x-ray radiation during medical & other procedures requiring the use of x-ray/fluoroscopy. Barriers are usually used in combination with other radiation safety products (such as lead garments) to provide complete protection from x-ray.

2. CAUTION

Always check to ensure your lead barrier is in good, working condition and that the base or window is not pitted, chipped, punctured or damaged. Damage to the protective barrier can compromise protection and use of Lead Barrier should cease immediately until it has been properly repaired or replaced.

3. PROTECTION & COMPLIANCE STANDARDS

EN 61331-1:2014: (EU) Protective devices against Diagnostic Medical X-ray radiation. (Determination of attenuation properties of material)

EN 61331-3:2014: (EU) Protective devices against diagnostic medical X-radiation Part 3: Protective clothing, Eyewear and Protective Patient shields.

ASTM 2547-18: (USA) Standard test method for determining the attenuation properties in a primary x-ray beam of materials used against radiation.

4. GENERAL INFORMATION

STORAGE

When not in use, the mobile barrier should be stored in area free of loose objects that may fall and damage it. Casters should be locked to prevent unintentional movement. Keep mobile barrier out of direct sunlight, high humidity and prolonged exposure to extreme heat. Store at 70-80°F (21-27°C).

MAINTENANCE & REPAIRS

a. Maintenance: Examine barrier before use. If the lead acrylic window or base becomes pitted, chipped or damaged cease use immediately. Basic cleaning maintenance is required to ensure acrylic is clear and keep casters free of debris.

b. Cleaning Barrier Frame: Barrier frame may be cleaned with any non-Ammonia based or non-chlorine based cleaner. Any neutral based disinfecting product may be used for disinfecting if necessary. Never use Ammonia, Bleach or other Acid or Alkali based cleaners.

c. Cleaning Lead Acrylic Window: Use only clear water and mild non-abrasive detergent solution. Avoid any cleaning products with ammonia, ketones, halogens, window cleaners, kitchen scouring compounds, aromatics and solvents such as thinners, acetone, gasoline, benzene and tetrachloride. Any cleaner that is abrasive should be avoided. For disinfection or to remove adhesives, a 70% alcohol solution, followed by rinsing with clear water may be used. Always wipe dry with a soft cloth.

d. Cleaning Lead Glass Window: Never use ammonia or chlorine-based cleaners. Window is made with high lead oxide content glass; the surface is susceptible to scratches and attack by acids and alkalis. Use only water, non-abrasive cleaning agents and always wipe dry with a soft cloth. DO NOT allow water to remain or dry as this can discolor/damage the glass.

e. Repairs: For repairs, please contact Protech or your local representative.

DISPOSAL

This barrier contains lead in the upper and/or lower panels. Users must dispose of Barriers and accessories by complying with local, state and federal (or international) regulations where applicable.

5. EU TYPE EXAMINATION

PPE is in conformity with the provisions of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical specifications, testing based upon IEC 61331- 1:2014 and internal quality management procedures. This is identical to the PPE which is the subject of **EU Module B Type-Examination Certificate 523415/1 issued by BTTG Notified Body 0338**, Manchester M17 1EH whom performed the EU type-examination (Module B), which is now held by **Shirley, Notified Body 2895**, Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI and is subject to the procedure set out in Regulation (EU) 2016/425, Module D under the supervision of the notified body Shirley Technologies (Europe) Limited (Sky Business Centre, Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI), performed at Protech Leaded Eyewear, Inc., 1360 N Killian Dr. Unit 2, Lake Park, Florida 33403.

6. WARRANTY POLICY

Protech's **Lead Barriers** are warranted to be free of defects in materials and workmanship to the original purchaser for **one year**. If a defect appears, a return request must be made with Protech or authorized reseller. Protech will issue an RMA form to be completed and submitted along with the return of merchandise. All returns must be accompanied by an RMA with valid RMA #. All returns will be evaluated and examined.

Protech will either repair or replace the defective item or part without charge to the purchaser. This warranty is void when the product has been tampered with, when repairs or attempted repairs have been made by unauthorized persons, or when the item has been subject to misuse, abuse or damage in transit.