PROTECH LEADED EYEWEAR INC,
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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 and 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. REGULATORY INFORMATION

**For detailed Declaration of Conformity info, scan the QR code.**

### UKCA TYPE EXAMINATION

X-Ray Protection Garments and related accessories ("PPE") described above is in conformity with the provisions of Regulation (EU) 2016/425 as brought into UK Law and amended; the models satisfy the requirements of the manufacturer's technical and quality management specifications with testing based upon IEC 61331-1:2014, IEC 61331-3:2014 and applicable FDA regulations and ASTM testing standards. This is identical to the PPE which BTTG, Approved Body #0338 (6 Wheel Forge Way, Trafford Park, Stretford, Manchester M17 1EH, United Kingdom), performed the EU Module B type-examination on and issued the EU type-examination Certificate #523415. The PPE is subject to the conformity assessment procedure set out in Regulation (EU) 2016/425 as brought into UK Law and amended, Module D (Certificate #54180) under surveillance of the Approved Body BTTG, Aproved Body # 0338, performed at Protech Leaded Eyewear, Inc. DBA Protech Medical, 7960 Central Industrial Drive, Suite 125, West Palm Beach, FL 33404 USA.

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### EU TYPE EXAMINATION

X-Ray Protection Garments and related accessories ("PPE") described above is in conformity with the provisions of Regulation (EU) 2016/425 and the models satisfy the requirements of the manufacturer's technical and quality management specifications with testing based upon IEC 61331-1:2014 and IEC 61331-3:2014. This is identical to the PPE which Shirley Technologies (Europe) Limited, Notified Body 2895 (Port Tunnel Business Park, Office 13 Unit 21, Dublin 17, ROI), performed the EU Module B type-examination on and issued the EU type-examination Certificate #SH00791. The PPE is subject to the conformity assessment procedure set out in Regulation (EU) 2016/425, Module D (Certificate #SH00654) under surveillance of the notified body Shirley Technologies (Europe), Limited, notified body number 2895, performed at Protech Leaded Eyewear, Inc. DBA Protech Medical, 7960 Central Industrial Drive, Suite 125, West Palm Beach, FL 33404 USA.

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## 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.