

# VISUAL INSPECTION RADIO ASSIST

The Visual Inspection Radio Assist (VIRA) is a compact, fully automated visual inspection system for radiopharmaceuticals, designed for seamless integration into our hot cells. It performs reliable visual inspection of small and medium-sized batches, independent of vial type or liquid.

Using controlled vial rotation under multiple lighting conditions, the system automatically performs the entire visual inspection process, including visible particles, cosmetic defects, cap integrity issues and fill level checks, ensuring consistent and reproducible inspection results.

The VIRA combines Von Gahlen's expertise in hot cell manufacturing, radiation shielding and GMP-compliant radiopharmaceutical production with LUO's patented automated visual inspection technology, a proven platform implemented and validated in GMP-regulated environments. Together, these technologies deliver a compact, fully integrated solution that supports the stringent quality requirements of GMP Annex 1, including sterility assurance, inspection, validation, risk management, and quality control.

Designed to optimize workflow and maximize production efficiency, the system performs the entire visual inspection utilizing the latest developments in machine learning and AI, while the vial remains in a fixed position. This minimizes footprint, increases inspection consistency, and enables highly accurate defect detection with a low false reject rate through advanced image analysis software.

| Variants                        | VG-VIRA-X1R |
|---------------------------------|-------------|
| Volume range                    | 1 to 25 mL  |
| Cycle time                      | 30 s        |
| Vial type acc. ISO 8362         | 10R to 25R  |
| Outside dimensions (mm) (W*D*H) | 250*250*520 |
| Floor space                     | 250*250     |





## STANDARD FEATURES

### Radiation protection

- Internal shielding for enhanced durability.
- Designed for Von Gahlen hot cells for optimal work flow and maximum operator safety.

### Sample & product handling

- Automated detection.
- Easy manipulation of vials, using one or two ball tong manipulation units.
- Integration with the Von Gahlen hot cell system
- Vial remains in a fixed position during inspection to minimize footprint.

### Air handling

- Cleanroom class A compliant.
- Designed for laminar downflow without affecting the air quality at critical points.

### Cleaning

- Housing made out of a solid piece of anodized Aluminum.
- Smooth exterior surface finish for easy cleaning.
- Compatible with most common cleaning agents.
- Unit is compatible with 35% hydrogen peroxide vapor decontamination, generator not included.

### Sensors

- Shielded camera.
- Multiple lights, to allow for different lighting conditions.
- Lighting conditions are optimized to detect various defects.

### System operation & control

- User-friendly and intuitive user software.
- Fully automated approval.
- The data of each batch is logged and stored in the database. Batch reports can be printed or paperless.
- Audit Trail logs system events and all data acquisitions, deletions, overwrites, and auditing changes, in line with risk management principles.
- Implementation of software is conformed to SDLC [software development life cycle].
- Development and validation of software according to GAMP and is compliant with Eudralex V4 Annex 11 and 21 CFR Part 11.

### Detection

- Vials contaminated with visible particles or defects are detected.
- Performance is at least as accurate as manual inspection, based on the Knapp-Kushner method.
- The detection software is powered by the latest AI technologies.
- Customizable defect library. Can detect visible defects in the product and on the vial.

## OPTIONAL FEATURES

- Barcode / QR code can be identified for vial recognition system.
- Form parts for various vial sizes possible.
- Grey Zone where the operator has final decision.