

THECLA

SHIELDED ISOLATOR WITH INTEGRATED RADIOPHARMACEUTICAL DISPENSING SYSTEM



COMPACT | VERSATILE | SAFE



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SHIELDED ISOLATOR WITH INTEGRATED RADIOPHARMACEUTICALS DISPENSING SYSTEM

THECLA is a shielded isolator with an integrated dispensing system for syringes, equipped with a laminar flow on the entire main chamber (Class A) and specifically designed for dispensing radiopharmaceuticals under sterile conditions and in accordance with cGMP guidelines.

- Class A dispensing chamber equipped with laminar flow on the entire area
- Class B material introduction chamber (airlock)
- Syringe semi-automatic fractioning system integrated in the main chamber
- $^{68}\text{Ge}/^{68}\text{Ga}$ generator housing compartment
- Dose calibrator up to 2 Ci
- Final product extraction system in shielded container by means of specific compartment

Generator compartment and tray for synthesis module

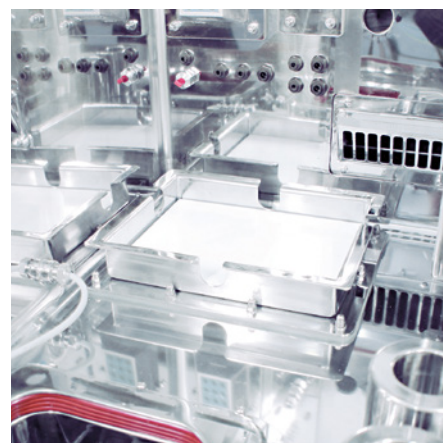
Material inlet compartment

The new shielded THECLA isolator with an integrated dispensing system for radiopharmaceuticals consists of:

- a Class A main chamber featuring a shielded front door with hand access and equipped with a Comecor IBC Dose Calibrator (measuring range up to 2 Ci)
- a Class B material input prechamber, placed beneath the work surface of the main chamber
- an integrated semi-automatic dispensing system for syringes
- a syringe discharge system for the extraction of the final product, directly inside the shielded container.

The shielded THECLA isolator has a compact and essential design, as well as being supplied with standard equipment: this makes the THECLA isolator extremely easy to use and one of the most competitive shielded isolators on the market.

Thanks to its small size, it can be positioned in confined spaces, also against the rear side and with little space on the side: indeed, maintenance is carried out from the front side.



The cell is equipped with a compartment suited to house a $^{68}\text{Ge}/^{68}\text{Ga}$ generator.

The compartment is adequately sized to host a gallium generator and can be closed via a shaped metal sheet suitable for any capillary passage.

The cell is equipped with a removable surface above the generator area to house a small synthesis module.

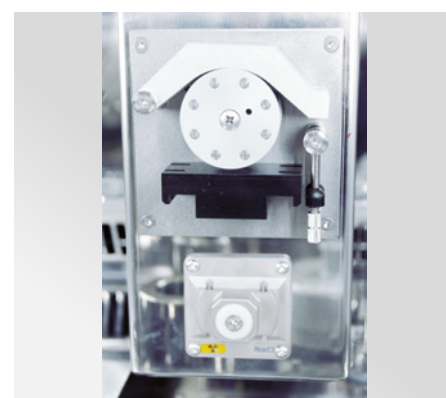


The prechamber is equipped with a sliding tray and a pneumatic lifting device to introduce or extract materials from the work surface.



The IBC Dose Calibrator is a completely digital dose calibrator. The ionisation chamber is connected directly to a PC with Windows. Like all Comecer dose calibrators, each model is used in combination with a completely digital VIK-202 model ionisation chamber.

The IBC software offers a simple and user-friendly interface that supports all functions required for dose calibration when preparing radiopharmaceuticals.



The main chamber is fitted with a fractionator system of radiopharmaceuticals in single-dose syringes of both PET/SPECT isotopes and RADIOMETABOLIC THERAPY.

The single-use kit and the special, patented pierceable septum allow packaging the closed syringes ready for transport to the administration unit, thereby protecting the sterility of the preparation.



The machine is fitted with a syringe unloading system with ventilated duct between chamber and transport container. The system allows you to unload the dispensed syringe directly into the specific shielded container.

GENERAL FEATURES

Main technical features

- Shielded and hinged front door of the main chamber equipped with a shielded window and hand passage doors
- Filtration system to generate laminar flow in the Class A chamber, made with an HEPA H14 absolute filter
- Filtration system for Class B chambers with HEPA H14 absolute filtering cartridge
- Air outlet filtration system made with active carbon filtering cartridge
- An inflatable gasket system, placed on the perimeter of the openings, seals the chambers
- Technical gas supply lines
- Temperature and humidity sensor
- Connection for DOP test (filter sealing test) for absolute filters
- Geiger-Muller probe to detect radioactivity inside the cell and door interlock management*
- Particle-counter sensor in the main chamber*

Technical data

Frame support material		Carbon steel treated with epoxy paints
External covering material		AISI 304 - Scotch-Brite™
Working chamber material		AISI 316L - Mirror-Bright
Lead purity	Title	Pb 98% + Sb 2%
Shielding (Pb)	mm	50
Visual screen measurements	mm	200 x 200 (l x h)
Weight	kg	4400
Internal dimensions of the dispensing chamber	mm	566 x 597 x 599 (l x d x h)
Dimensions of the tray for material introduction (airlock)	mm	138 x 138 x 185 (l x d x h)
External dimensions	mm	800 x 1070 x 2400* (l x d x h)

* The cell requires about 760 mm of front space for maintenance



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