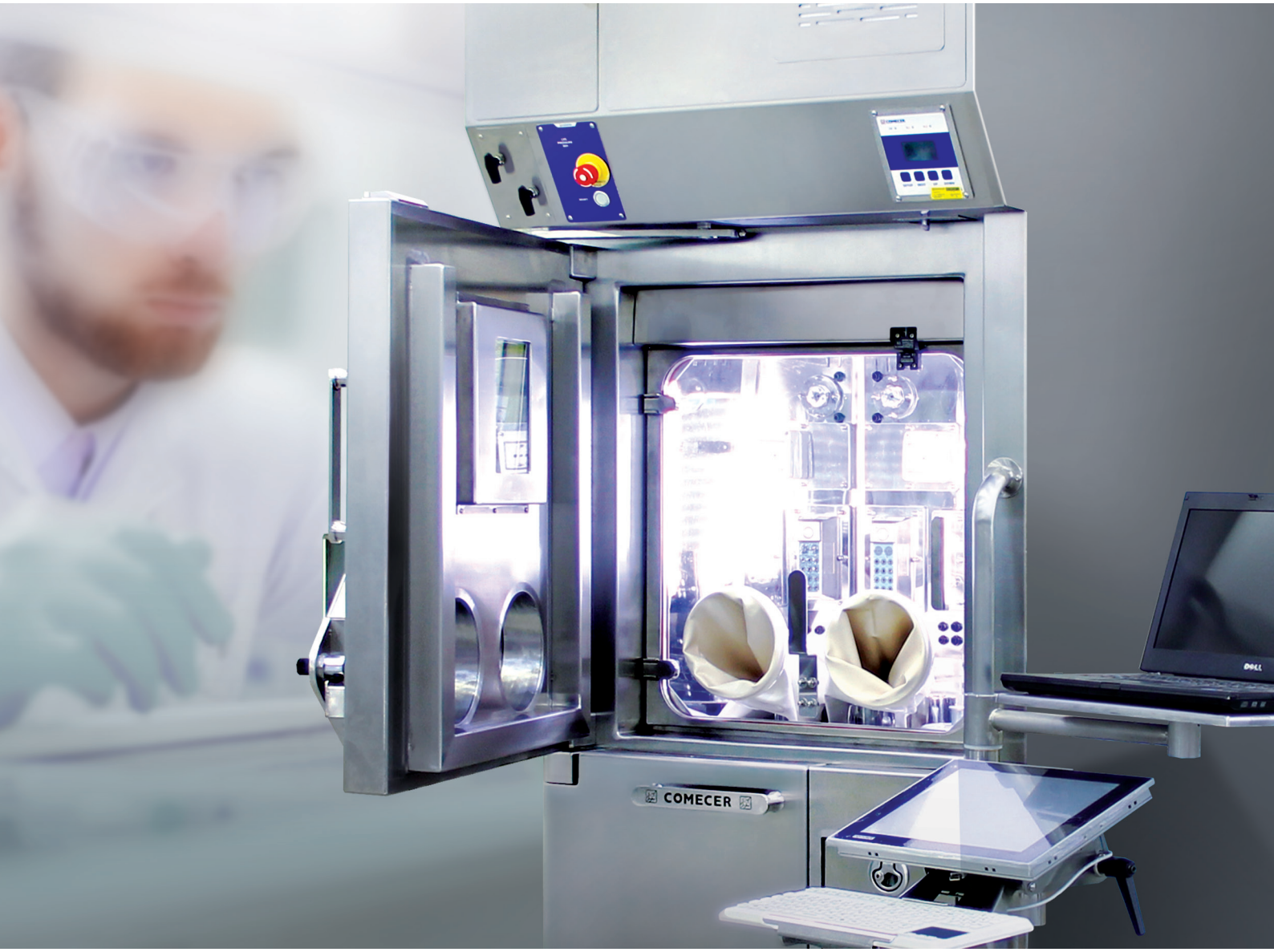
THECLA

SHIELDED ISOLATOR WITH INTEGRATED RADIOPHARMACEUTICAL DISPENSING SYSTEM



^{68}Ga ^{18}F ^{99m}Tc ^{111}In $^{123/131}$I ^{90}Y ^{177}Lu

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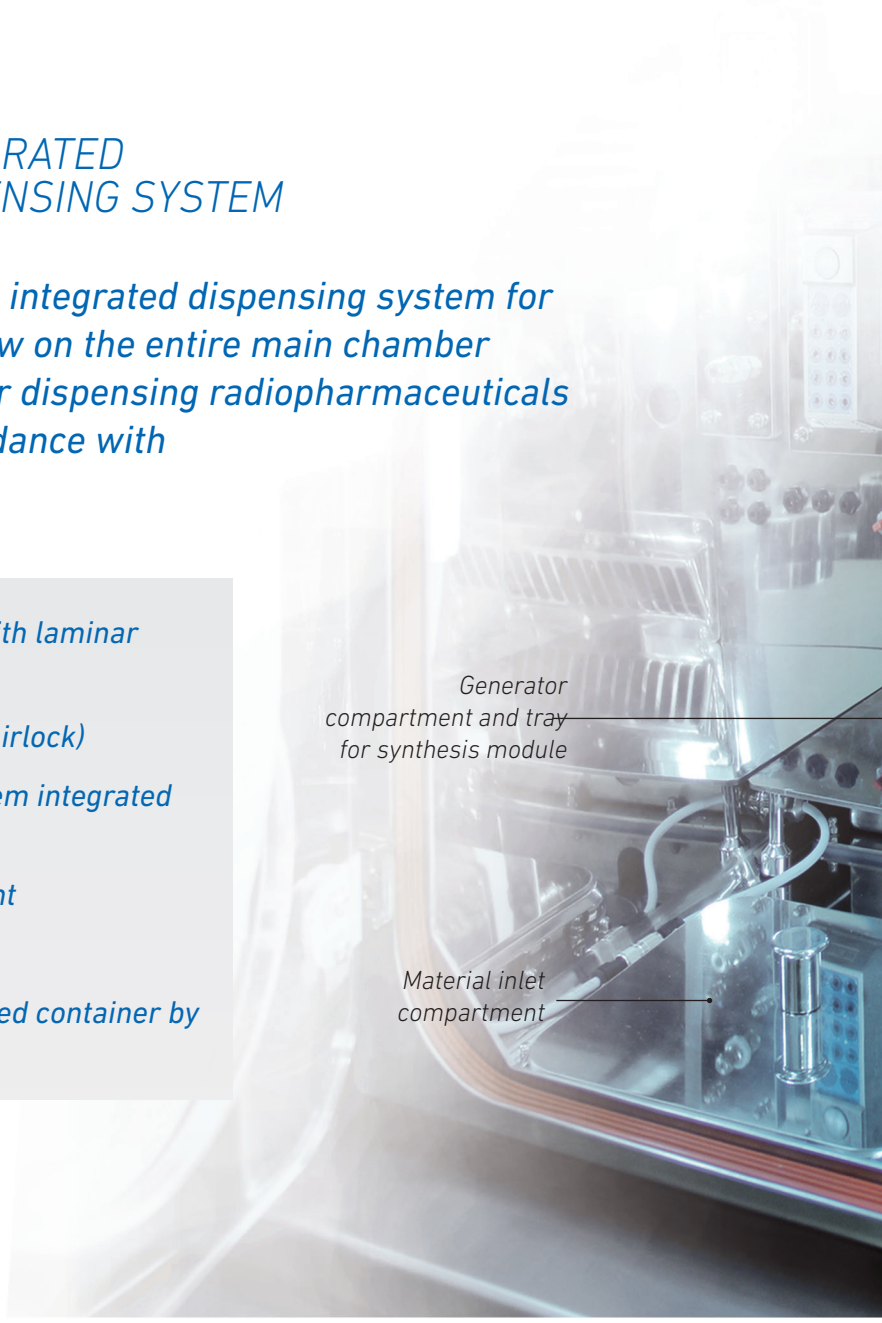
THECLA
SHIELDED ISOLATOR WITH INTEGRATED RADIOPHARMACEUTICALS DISPENSING SYSTEM

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}Ge/^{68}Ga generator housing compartment*
- *Dose calibrator up to 2 Ci*
- *Final product extraction system in shielded container by means of specific compartment*

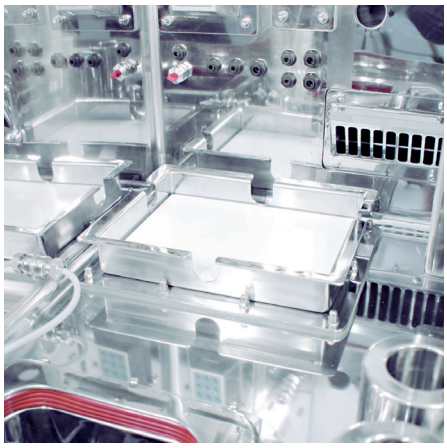


The new shielded THECLA isolator with an integrated dispensing system for radiopharmaceuticals consists of:

- a Class A main chamber featuring a shielded front door with hand access and equipped with a Comecer 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}Ge/^{68}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.

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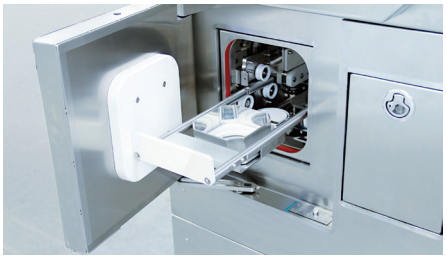
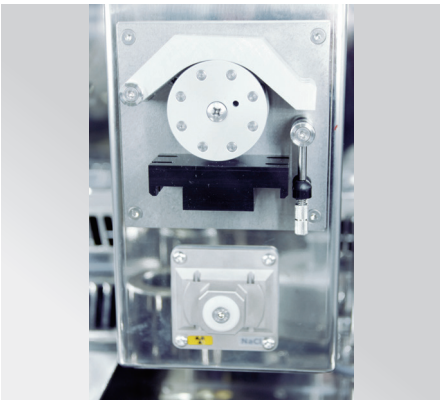


The prechamber is equipped with a sliding tray to introduce or extract materials from the work surface. It is also equipped with a pneumatic lifting device, which allows the inserted materials to reach the level of the work surface.

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

The IBC Dose Calibrator is a completely digital dose calibrator managed by IBC-LITE. 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-LITE 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 PET and SPECT isotopes and for 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 filling system is composed of a peristaltic pump with two channels: the first is dedicated to the radiopharmaceutical and the second is used for the saline solution.

Equipment lines

The machine is available with different equipment lines, to fulfil the requirements of any production centre.

Main features	***THECLA***
Shielding (mm Pb)	50
"Class B" material introduction side prechamber	S
Dose calibrator mod. IBC Dose Calibrator up to 2 Ci	S
Integrated dispensing system for syringes	S
Label printer	S
Removable tray	O
Smart Geiger (internal environmental monitoring system)	O
LED lighting	S
Light column signalling machine status	S
Internal connections for technical gases	S
Sealed cable inlet	S
Temperature and humidity sensor	S
Steel coverings reaching the laboratory ceiling	O
Shielded holder	
Shielded container mod. SSC	*O*
Shielded container mod. S5CP	*O*

S= Standard; O= Optional

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*

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*

** On the customer's request*

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