

ALTHEA-PC

AUTOMATIC DISPENSING ISOLATOR FOR SYRINGES



THE ACCURACY ABOVE ALL



COMECER

an **ATI** company

ALTHEA-PC

AUTOMATIC DISPENSING ISOLATOR FOR SYRINGES

ALTHEA-PC is a dispensing isolator that includes an **automatic system for filling and calibration of syringes** with radiopharmaceuticals (usually FDG).

The use of ALTHEA-PC considerably reduces the number of doses an operator is exposed to, while providing additional advantages for better work organisation. It is possible to fill and calibrate the syringes with the required volume and activity, since dilution of the radiopharmaceutical with physiological solution can take place whenever the volume is not sufficient for the required dose volume.

ALTHEA-PC can be directly connected to synthesis modules (internal production), or it can draw the doses from a mother vial placed inside a shielded container (external production).

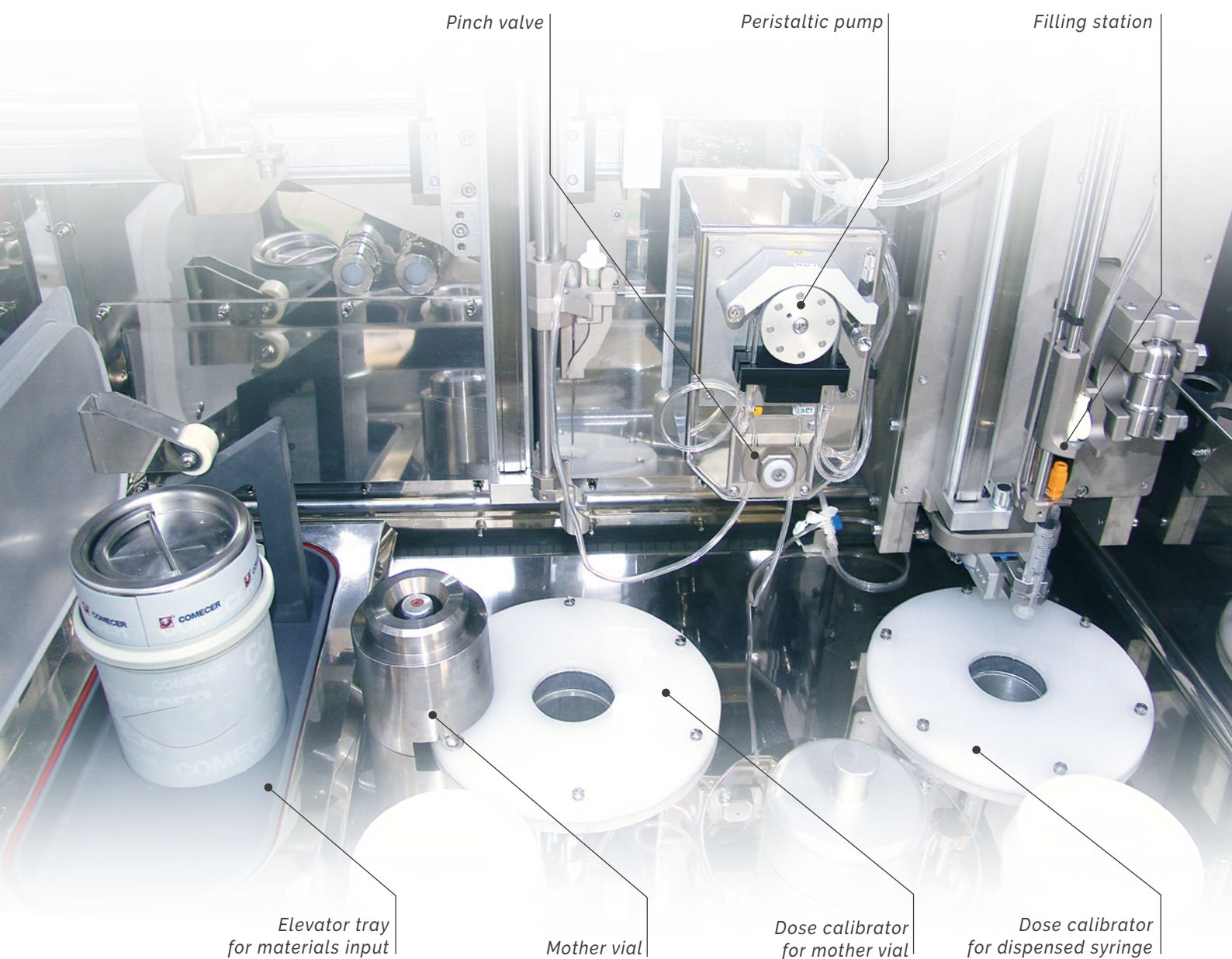
The result is a calibrated syringe, containing an adequate volume, with the selected activity, sealed with a pierceable plug, appropriately shielded and automatically placed inside a shielded transport container.



- Conceived for radiopharmaceutical dose preparation
- Filling and calibration of 5 and 10 ml syringes and Letho Cartridge
- Accurate and reliable for medium and large batches
- Flexible production system
- Guarantees full protection of the product and the operator

ALTHEA-PC offers exclusive technical solutions which guarantee unique performance in terms of:

- **Sterility:** the laminar air flow work area (Class A according to EEC-cGMP) allows handling radiopharmaceuticals in absolute safe conditions for the product. All the outward accesses are equipped with airtight interlocked pre-chambers (Class B according to EEC-cGMP).
- **Radiation protection:** shields are made to ensure the full protection of the operator.
- **Ergonomics:** all the components required for the dose preparation are placed within the range of action of the operator's hands.
- **Safety:** the main door of the isolator is equipped with a lock system, controlled by an internal double probe G.M. detector.
- **Management of critical parameters:** the isolator is equipped with a modern operator panel which allows for the control, registration and exportation of internal cell parameters, of notifications and of alarms. The integrated activity calibrator is classified as a Medical Device according to Directive 93/42/EEC and subsequent amendments and integrations.
- **Duration through time:** the high-quality of the components used ensures duration over time and performance consistency.



Comecer produces automatic systems for the dispensing of radiopharmaceuticals used in radiopharmacy laboratories and Nuclear Medicine hospital facilities.

Automatic systems permit the dispensing and the calibration of the radiopharmaceutical in syringes and

vials, with sterilisation possible through an autoclave.

These systems allow a reduction in the number of doses the operator is exposed to and, at the same time, provide additional advantages for better work organisation.

FEATURES AND BENEFITS

Features and Benefits

- Modular design and flexible configuration
- Touch screen for hot cell and dispensing system
- Airtight connections for radioactive fluids
- DOP test connections (filter leakage test)
- Dose calibrator (available in the versions 2 Ci or 20 Ci) with touch screen console
- Product extraction system (Drawing System)
- Particle counter connection
- Air-lock for material introduction

Equipment lines

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

Main equipment	ALTHEA-PC
European electrical power supply	R
American electrical power supply	R
Hand insertion doors	S
Operator panel with integrated dosing calibrator control	S
Light column signalling machine status	S
Dose calibrator for syringe - IBC Dose Calibrator up to 2 Ci	S
Dose calibrator for multi-dose vial - IBC Dose Calibrator up to 20 Ci	S
CFR21 licence PART 11	S
Particle counter	S
Vial shielded container mod. CF18	S
Tungsten shielding for syringe mod. PST 5ml	S
Steel coverings reaching the laboratory ceiling	O
Smart Geiger (environmental monitoring system)	O
Sealed cable input	O
Radiofluids inlet with shielded chimney	O
Tungsten shielding	
Syringe shielding mod. PST 10ml	O
Cartridge shielding mod. PST LETHO	O
Shielded container for syringe transport	
Shielded container mod. S5CP 5ml	O
Shielded container mod. S10CP 10ml	O
Shielded container mod. LETHO HOLDER	O
Shielded container for vial transport	
Shielded container mod. CF18-T	O

S= Standard; O= Option; R= Configurable when placing order

Technical data

Support frame material		Carbon steel treated with epoxy paints
External casing material		AISI 304 - Scotch-Brite™
Working chamber material		AISI 316L - Mirror-Bright
Lead purity	Title	Pb 98% + Sb 2%
Electrical panel protection rating	IP	54
Weight	kg	7530
Working chamber internal dimensions	mm	900 x 500 x 740 (w x d x h)
External dimensions	mm	1280 x 930 x 2400 (w x d x h)
Main power supply		230V (1Ph+N+PE) 50/60Hz 16A TN-S 208/120V (2Ph+N+PE(GND)) 60Hz 15A
Radiofluids connections	n°	3 in main chamber
Particle counter connection	n°	1 in main chamber



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