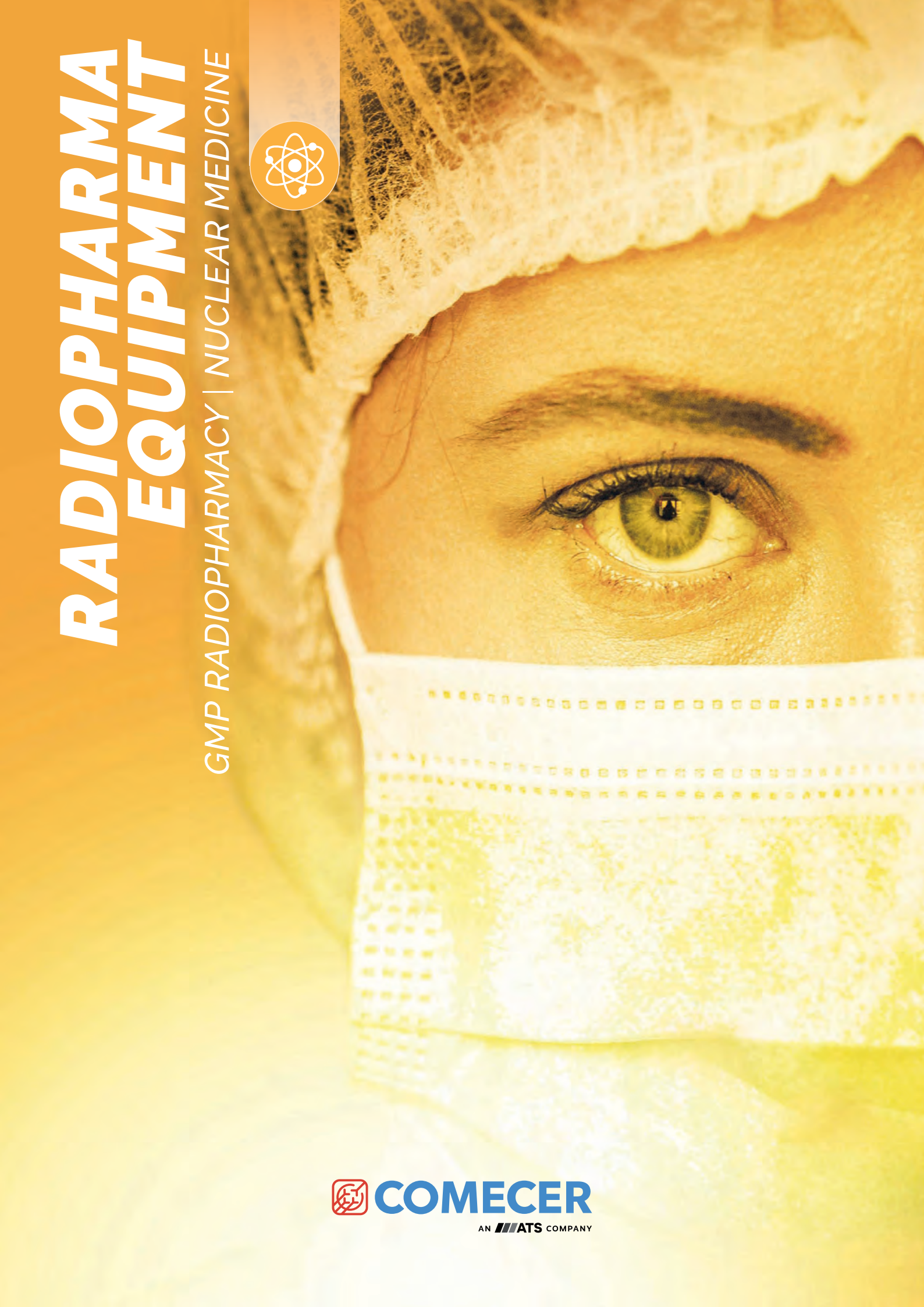
RADIOPHARMA EQUIPMENT

GMP RADIOPHARMACY | NUCLEAR MEDICINE



COMECER

AN ATS COMPANY

RADIOPHARMA

GMP RADIOPHARMACY
NUCLEAR MEDICINE

INDEX

AUTOMATIC DISPENSING SYSTEMS

Comecer produces automatic systems for the dispensing of radiopharmaceuticals GMP production laboratories and Nuclear Medicine hospital departments.

Automatic systems permit the dispensing and the calibration of the radiopharmaceutical in syringes and vials, with sterilization possible through an autoclave. These systems allow a reduction of the operator's exposure to ionizing radiation and, at the same time, provide further advantages for a better work organization.

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 machine 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 use of ALTHEA PC considerably reduces the operator's exposure to ionizing radiation and, at the same time, provide further advantages for a better work organization. It is possible to fill, dilute and calibrate the syringes with the required volume and activity.

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.

FIELD OF WORK

NUCLEAR MEDICINE | GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Modular design and flexible configuration
- Touch-screen panel for hot cell and dispensing system control
- Dose calibrator (available in the 2 Ci or 20 Ci versions)
- Product extraction system in transport shielded container
- Particle counter connection
- Air-lock for material introduction

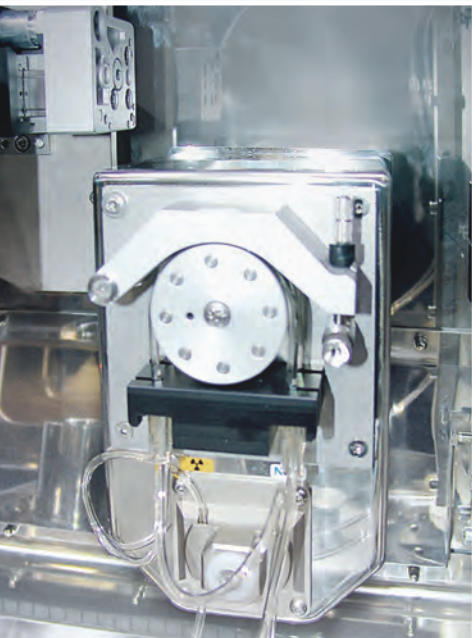
TECHNICAL DATA

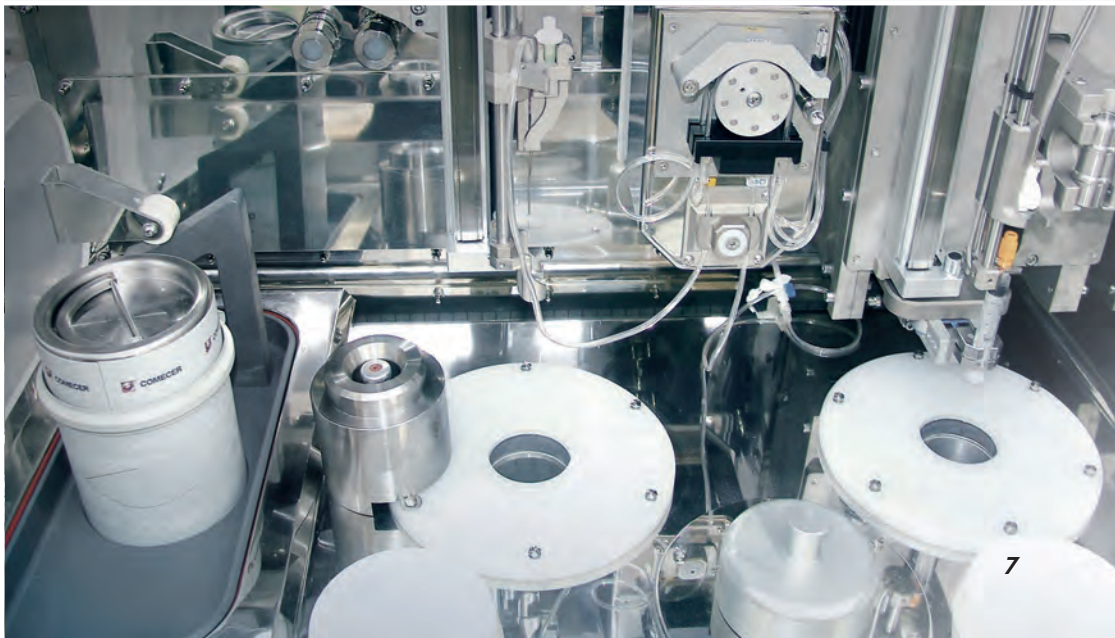
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shieldings (Pb)	50 mm
Weight	7530 kg
Working chamber internal dimensions	900 x 500 x 740 mm (w x d x h)
External dimensions	1280 x 930 x 2400 mm (w x d x h)

RELATED PRODUCTS

BH SERIES
Biohazard class A hood | **80**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**





THEODORICO 2

ROBOTIC DISPENSING ISOLATOR FOR VIALS

Theodorico 2 is an automatic shielded system for dispensing radiopharmaceuticals into open and closed vials. Its flexible system configuration allows it to handle a variety of production needs.

The dispensing chamber is equipped with a robot for vial handling throughout all dispensing phases. This considerably reduces operator exposure to radiation.

Theodorico 2 is designed to comply with GMP requirements; it features a Class B pre-chamber for the introduction of the materials, while the dispensed vials are extracted using an automatic and ventilated transfer system from the dispensing chamber (Class A) to the shielded container placed in the drawing system (Class B).

Theodorico 2 supports both aseptic dispensing and dispensing with final sterilization in an autoclave.

FIELD OF WORK

NUCLEAR MEDICINE | GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Touch-screen panel for hot cell and dispensing system control
- Bubble Point Test (BPT)
- Air sampling, particle counting, VPHP cycle
- Bio-burden sample collection and filling speed test
- Two dose calibrators: up to 2 Ci for final product and up to 20 Ci for mother vial
- Pressure, temperature and humidity monitoring
- Ethanol line flushing for residual kit activity reduction
- Product extraction system in transport shielded container

TECHNICAL DATA

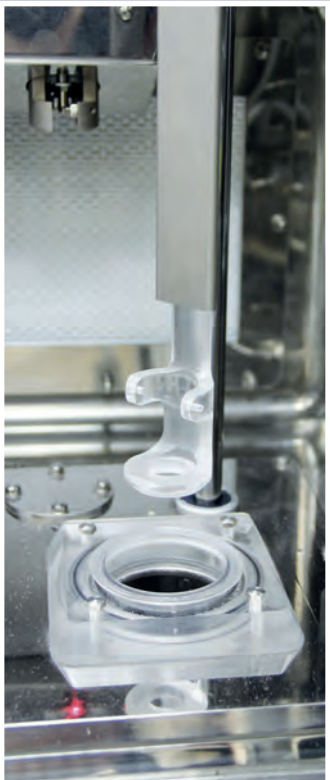
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shieldings (Pb)	75 ÷ 100 mm
Weight	10700 ÷ 14500 kg
Working chamber internal dimensions	725 x 545 x 800 mm (w x d x h)
External dimensions	2215 x 1355 x 2400 (w x d x h)

RELATED PRODUCTS

BBS SERIES
Shielded cells for synthesis modules | **14**

TALIA SERIES
Shielded isolators for dispensing | **30**

IRIS
Automated multidose injection system | **96**



HELIOS

HIGH-THROUGHPUT ASEPTIC ISOLATOR FOR VIALS AND SYRINGES FILLING

HELIOS is a fully automatic system, able to provide an aseptic GMP dispensing process on vials and syringes. It is possible to have in the same batch, different vial format, different syringe format or even a hybrid batch of vials and syringes.

HELIOS is designed for radiopharmaceutical production center, laboratories or hospitals following cGMP guidelines. The system can be equipped with an integrated particle counter and a VPHP sterilization cycle.

The dispensing system consists of fully automated components: an "invisible" conveying system with a magnetic transport system for vials and syringes and two actuators with automatic grippers. The actuators move vials and syringes from the conveying system to the filling systems and from the conveying system to the pass-through calibrator.

FIELD OF WORK

NUCLEAR MEDICINE | GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Modular design and flexible configuration
- Touch-screen operator panel for hot cell and dispensing system control
- Easy change of formats between vial size and syringes
- No visible mechanical parts in the area
- Airtight connections for radioactive fluids
- Product extraction system equipped with "Pass-through dose calibrator"
- Air-lock for material introduction

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shieldings (Pb)	75 ÷ 100 mm
Weight	11780 ÷ 13800 kg
Working chamber internal dimensions	930 x 725 x 630 (w x d x h)
External dimensions	2000 x 1290 x 2400 (w x d x h)

RELATED PRODUCTS

BBS SERIES
Shielded cells for synthesis modules | **14**

TALIA SERIES
Shielded isolators for dispensing | **30**

IRIS
Automated multidose injection system | **96**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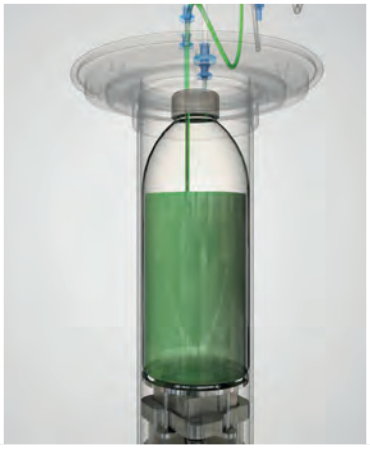


HOT CELLS FOR SYNTHESIS & RESEARCH

Comecer hot cells are made for nuclear medicine departments and cGMP radiopharma production facilities. They are used, according to cGMP guidelines, for the labeling and manipulation during radiopharmaceuticals production.

Comecer hot cells are designed to house synthesis modules or to manage the processes of radiopharmaceutical preparation with maximum operator safety, respecting cGMP requirements. Our hot cells make use of heavy leaded shielding around the containment boxes, that are made of 316L stainless steel. The shielded chambers are in constant negative pressure and the tightness is ensured by an inflatable gasket system.

BBS SERIES

SHIELDED CELLS FOR SYNTHESIS MODULES

The BBS series of hot cells for synthesis modules is specially designed to host specific automatic synthesis modules for the production of radiopharmaceuticals for experimental use or for daily production in cGMP radiopharmacies.

The BBS hot cell, single or double (lined horizontally or vertically), triple and also quadruple, can have different configurations for the overall dimensions, shielding and various accessories.

FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Working chamber air quality up to Class B
- Modular design and flexible configuration
- Shielded chambers under constant negative pressure
- Chamber tightness ensured by inflatable gasket system
- Touch-screen operator panel
- Removable tray for synthesis module
- Geiger-Muller probe to detect radioactivity inside the hot cell and door interlock management

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Working chamber internal dimensions	634 x 735 x 674 mm (w x d x h)
Shielding (Pb)	75 ÷ 100 mm
Weight	5500 ÷ 7000 kg
External dimensions	1088 x 1170 x 2400 mm (w x d x h)

*Overall dimensions and weight refer to the model BBS1

RELATED PRODUCTS

TADDEO
Synthesis module for radiopharmaceuticals | **93**

ALCEO SERIES
Solid target processing system | **86**

THEODORICO 2
Robotic dispensing isolator for vials | **8**

MIP SERIES

SHIELDED CELLS FOR SYNTHESIS AND RESEARCH

The MIP series of shielded hot cells is designed to host automatic modules for routine production or research equipment of radioisotopes and radiopharmaceuticals for experimental use. The MIP shielded isolator is available in two sizes: 1100 mm and 1390 mm (work chamber width).

The MIP series enables you to host large sized automatic synthesis modules or complex equipment (such as HPLC). It has suitable shielding for isotopes with very energetic gamma emissions. It is possible to install tele-manipulators and a side autoclave to sterilize the product, which makes this cell ideal for advanced research.

FIELD OF WORK

GMP RADIOPHARMACY

- DOSE CALIBRATION
- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Working chamber air quality up to Class B
- Modular design and flexible configuration
- Shielded chambers under constant negative pressure
- Chamber tightness ensured by inflatable gasket system
- Touch-screen operator panel
- Right side tele-pliers
- Dose calibrator compartment
- Tele-manipulators
- Autoclave
- Product extraction system in transport shielded container
- Hinged or sliding front door equipped with a large shielded glass window

TECHNICAL DATA

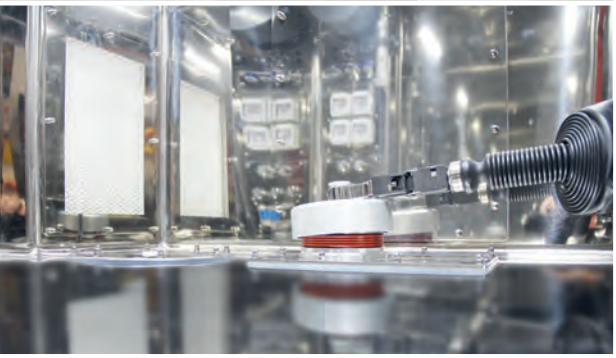
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 ÷ 100 mm
Weight	MIP-1100-1SP-75: 9500 kg MIP-1390-1SP-75: 11500 kg
Working chamber internal dimensions	MIP-1100: 1116 x 860 x 985 mm (w x d x h) MIP-1390: 1390 x 850 x 1259 mm(w x d x h)
External dimensions	MIP-1100: 1370 x 1280 x 2400 mm (w x d x h) MIP-1390: 1644 x 1280 x 2600 mm (w x d x h)

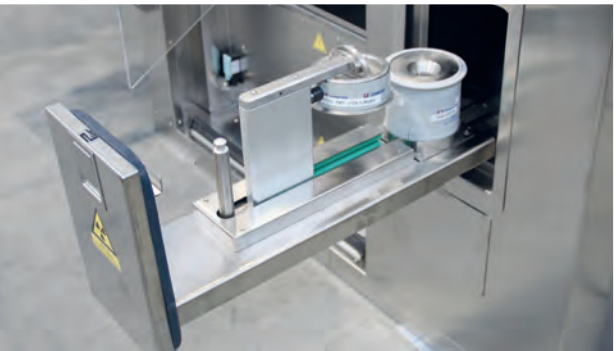
RELATED PRODUCTS

BBS SERIES
Shielded cells for synthesis modules | **14**

ACS
Air compressing station | **106**


COMECER





MINIMA

MANUAL R&D SHIELDED CELL

MiniMa hot cell is an airtight and shielded dispensing box ideal for R&D manual operation. MiniMa can be used for either manual syringe dispensing of radiopharmaceuticals or for use in combination with (semi-) automatic dispensing systems of various brands.

The box with an integrated lead glass viewing window comes with two arm openings and one large shielded door on the front side for bringing items in or out. The internal workspace is provided with an opening on the lower floor under which, in a particular shielding 50 mm lead, can accommodate an ionization chamber. There is also a second opening on the left to access the waste compartment, shielded in lead. All shielding are 30 mm of lead. The ionization chamber is shielded with 50 mm lead. Standard the box comes with a Hepa filter on the air inlet and a charcoal filter on the air-outlet as well gloves in the arm-openings.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Chamber tightness ensured by static gasket system
- Frontal large window
- Dose calibrator compartment
- Waste compartment
- Hand passage doors

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	30 mm (only ionization chamber compartment 50 mm)
Weight	~2930 kg
Working chamber internal dimensions	560 x 580 x 630 mm(w x d x h)
External dimensions	800 x 1025 x 2400 mm (w x d x h)

DISPENSING SHIELDED ISOLATORS

Comecer produces shielded isolators ideal for radiopharmaceuticals dispensing in radiopharma production facilities and nuclear medicine departments. For the mass production (radiopharma production facilities) the machines are equipped with shieldings up to 100 mm Pb, tele-pliers and manipulators, pre-chambers equipped with gloves, shielded waste compartments and high production capacity according to cGMP standards. For nuclear medicine departments isolators are available for dispensing small batches, with shielding up to 50 mm Pb, hand passage doors, material transfer chambers, waste and generators shielded compartments and even synthesis modules.

MIP FULL LAF SERIES

SHIELDED ISOLATORS FOR DISPENSING

The series of MIP-LAF hot cells is specially designed to house various dispensing system and radiochemistry modules. The MIP-LAF shielded isolator has a laminar flow area for aseptic operation in compliance with cGMP.

The hot cell can be provided with several accessories such as several models of tele-manipulators, lateral autoclave and shielded or not shielded pre-chamber.

The series is designed to guarantee radioprotection to the operator and the utmost decontamination and cleaning procedures effectiveness. The work chamber is sealed, shielded on every side and kept under negative pressure.

FIELD OF WORK

GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Shielded chambers under constant negative pressure
- Spacious work chamber for maximum ergonomics
- Right side tele-pliers to handle the vial
- Touch-screen operator panel
- Dose calibrator compartment
- Product extraction system in transport shielded container
- Two tele-manipulators
- Autoclave
- Hinged or sliding front door equipped with a large shielded glass

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 mm
Weight	13500 kg
Working chamber internal dimensions	1390 x 848 x 1250 mm (w x d x h)
External dimensions	1280 x 930 x 2400 mm (w x d x h)

RELATED PRODUCTS

ARGO SERIES
Vials dispensing systems | **50**

CLIO
Vials and syringes dispensing system | **48**

IRIS
Automated multidose injection system | **96**

BBST SERIES

SHIELDED ISOLATORS FOR DISPENSING

The BBST series is a family of Class A shielded isolators equipped with laminar flow on the entire main chamber. They can house automatic modules or dispensing systems in sterile conditions and in observance of cGMP regulations.

The BBST series is specifically designed for filling, calibrating and dispensing operations on vials/syringes. The equipment is ideal for small/medium productions of vials and, upon express request, for small productions of syringes.

The hot cell guarantees maximum protection for the operator against ionizing radiation. These characteristics, along with the integrated tools such as the COMECER automatic dispensers, make it particularly suitable for radiopharmaceutical dose preparation, in accordance with cGMP regulations.

FIELD OF WORK

GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- VIAL FILLING

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Shielded chambers under constant negative pressure
- Modular design and flexible configuration
- Product extraction system in transport shielded container
- Touch-screen operator panel
- Dose calibrator (available in the versions 2 Ci or 20 Ci)
- Waste compartment
- Product extraction system equipped with “Pass-through dose calibrator”

TECHNICAL DATA

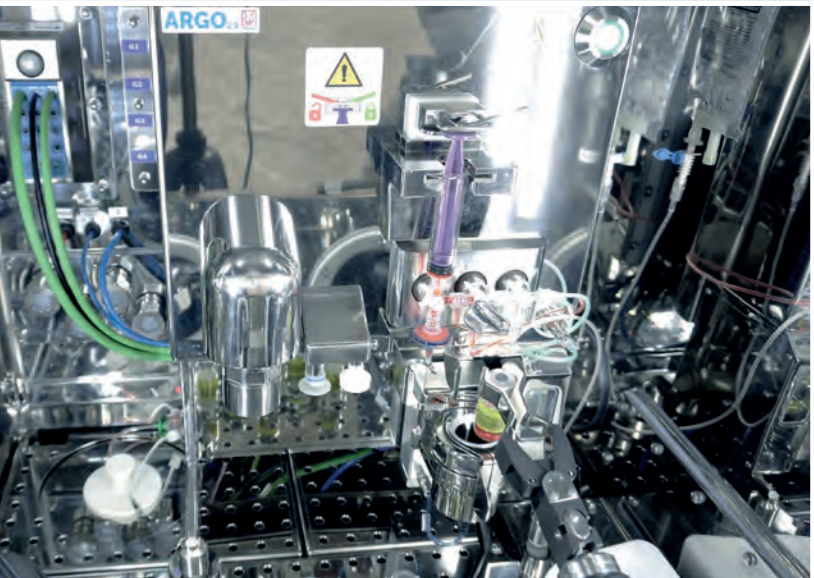
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 mm
Weight	5700 ÷ 8100 kg
Working chamber internal dimensions	594 x 587 x 662 mm (w x d x h)
External dimensions	1060 x 1090 x 2400 mm (w x d x h)

RELATED PRODUCTS

ARGO SERIES
Vials dispensing systems | **50**

VPHP GENERATOR
Vapor Phase Hydrogen Peroxide generator | **110**

PHAEDRA SERIES
Shielded isolators for dispensing | **26**


ARGO

BBST COMBO SERIES

SHIELDED ISOLATORS FOR SYNTHESIS AND DISPENSING

The BBST COMBO shielded isolator is designed to combine a shielded housing for synthesis modules and a dispensing area in sterile conditions (Class A - Laminar Flow) in one system, in compliance with cGMP standards.

Its features guarantee radio-protection to the operator and the utmost effectiveness in decontamination and cleaning. An airtight compartment, which is shielded on every side, is kept under negative pressure in order to produce the radiopharmaceutical (automatic synthesis).

FIELD OF WORK

GMP RADIOPHARMACY

- SYNTHESIS
- DISPENSING
- DOSE CALIBRATION
- VIAL FILLING
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Synthesis chamber air quality up to Class B
- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Waste compartment air quality Class B
- Modular design and flexible configuration
- Synthesis and dispensing in a single hot cell
- Product extraction system in transport shielded container
- Dose calibrator (available in the versions 2 Ci or 20 Ci)
- Touch-screen operator panel
- Product extraction system equipped with "Pass-through dose calibrator"

TECHNICAL DATA

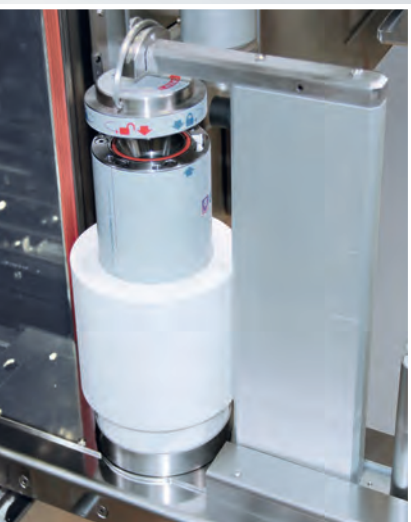
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 mm
Weight	10000 kg
Synthesis chamber internal dimensions	634 x 682 x 674 mm (w x d x h)
Dispensing chamber internal dimensions	594 x 587 x 662 mm (w x d x h)
External dimensions	2040 x 1090 x 2549 mm (w x d x h)

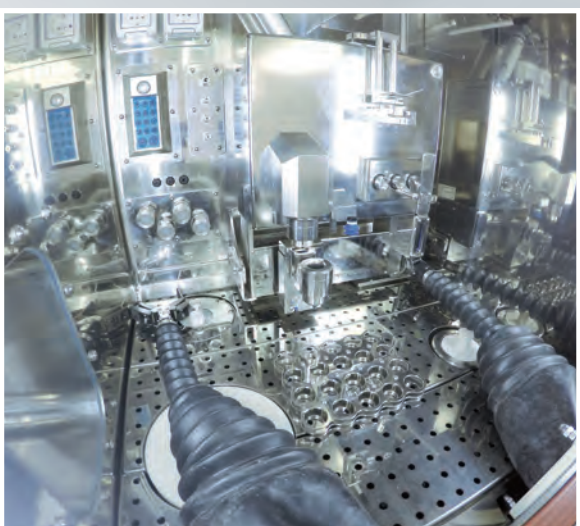
RELATED PRODUCTS

TADDEO
Synthesis module for radiopharmaceuticals | **93**

ARGO SERIES
Vials dispensing systems | **50**

VPHP GENERATOR
Vapor Phase Hydrogen Peroxide generator | **110**





PHAEDRA SERIES

SHIELDED ISOLATORS FOR DISPENSING

The Phaedra series is a family of Class A shielded isolators equipped with a laminar flow throughout the entire main chamber and designed to house automatic modules or dispensing systems in sterile conditions in compliance with the cGMP guidelines. For this reason, they are equipped with a Class B pre-chamber for material input.

The main chamber is equipped with tele-plier, which enable high activity manipulation operations in total safety, as well as hand passage doors that enable manual operations in compliance with radioprotection standards. The tele-plier is equipped with a "QuickPlug" system that enables rapid passage from tele-plier to manual operations. The operational change is done without seal and class loss.

FIELD OF WORK

GMP RADIOPHARMACY

- DISPENSING
- VIAL AND SYRINGE FILLING
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Ideal for aseptic dispensing of vials or syringes in cGMP field
- Ergonomic and responsive thanks to the combination of gloves for manipulation and tele-plier
- Extraction system for vials and syringes in transport shielded container equipped with pass-through dose calibrator
- Compact solution, also suitable for small laboratories
- Touch-screen operator panel
- Tele-plier with "QuickPlug" system for quick tight release
- Dose calibrator (available in the versions 2 Ci or 20 Ci)
- Waste compartment

TECHNICAL DATA

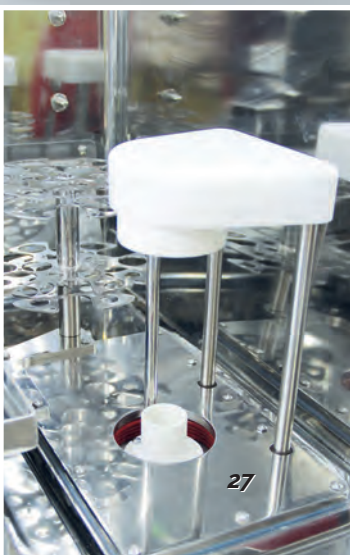
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 mm
Weight	8700 kg
Dispensing chamber internal dimensions	700 x 750 x 725 mm (w x d x h)
External dimensions	1800 x 1350 x 2400 mm (w x d x h)

RELATED PRODUCTS

CLIO
Vials and syringes dispensing system | **48**

ARGO SERIES
Vials dispensing systems | **50**


COMECER



PHAEDRA COMBO SERIES

SHIELDED ISOLATORS FOR SYNTHESIS AND DISPENSING

The Phaedra Combo series is a family of shielded isolators specifically designed to combine, in a single system, a shielded housing for synthesis modules and a fractioning area in sterile conditions (Class A LAF).

The housing for the synthesis modules is hermetically sealed and shielded on each side, maintained in negative pressure for the production of the radiopharmaceutical.

The main chamber is equipped with a tele-pliers, which allows high-security handling operations in total safety, and hand passage doors, which facilitate manual operations. The tele-pliers is equipped with a "QuickPlug" system that allows the rapid passage from mechanical to manual operations.

FIELD OF WORK

GMP RADIOPHARMACY

- SYNTHESIS
- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Synthesis chamber air quality up to Class B
- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Waste compartment air quality Class B
- Synthesis and dispensing in a single hot cell
- Ideal for aseptic dispensing of vials or syringes in cGMP field
- Extraction system for vials and syringes in transport shielded container equipped with pass-through dose calibrator
- Dose calibrator (available in the 2 Ci or 20 Ci versions)
- Touch-screen operator panel
- *Tele-pliers with "QuickPlug" system for quick tight release*

TECHNICAL DATA

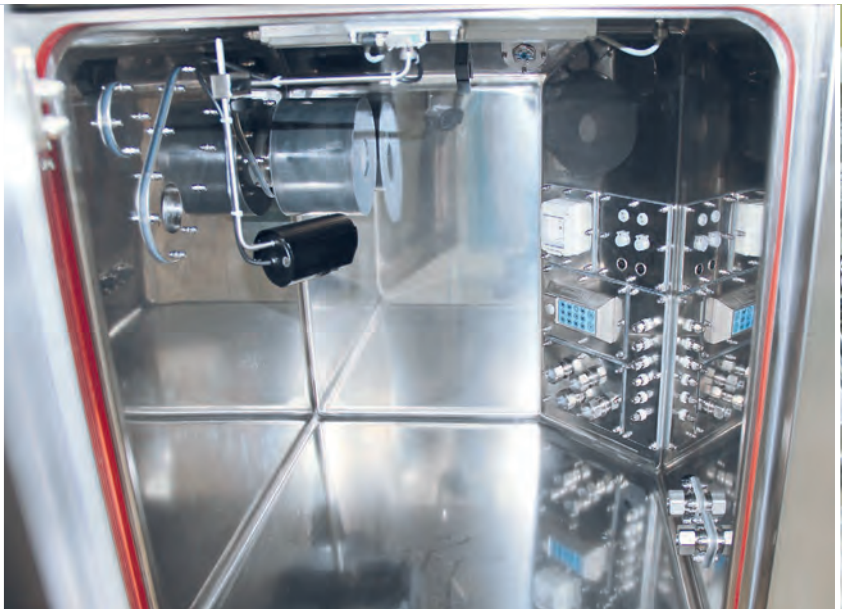
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 mm
Weight	14000 kg
Synthesis chamber internal dimensions	630 x 670 x 670 mm (w x d x h)
Dispensing chamber internal dimensions	700 x 750 x 725 mm (w x d x h)

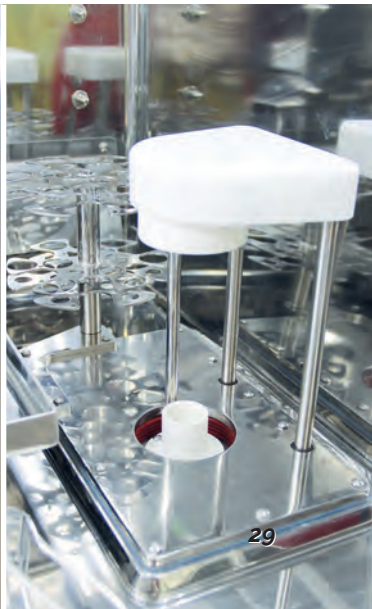
RELATED PRODUCTS

TADDEO
Synthesis module for radiopharmaceuticals | **93**

CLIO
Vials and syringes dispensing system | **48**

ARGO SERIES
Vials dispensing systems | **50**





TALIA SERIES

SHIELDED ISOLATORS FOR DISPENSING

The series of TALIA shielded cells is a family of Class A isolators equipped with laminar flow on the entire main chamber. They can house automatic modules or dispensing systems in sterile conditions and in observance of cGMP standards.

The TALIA series is specifically designed for filling, calibrating and dispensing operations on vials or syringes. The machine is ideal for medium/large vial (30 vials per batch) or 5 ml syringe (10 syringes per batch) productions.

The machine has unique features such as up to 100 mm lead shielding, double dose calibrator, pass through calibrator integrated into extraction system, in-line bubble point test and control with 17" touch screen.

FIELD OF WORK

GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Ideal for medium and large productions
- Spacious work chamber for maximum ergonomics
- Up to two dose calibrators (available in the versions 2 Ci or 20 Ci)
- Product extraction system in transport shielded container
- Touch-screen operator panel
- Second pre-chamber for introducing materials with laminar flow
- Waste compartment air quality Class B
- Product extraction system equipped with "Pass-through dose calibrator"
- Sanitation system with VPHP (vapor phase hydrogen peroxide)

TECHNICAL DATA

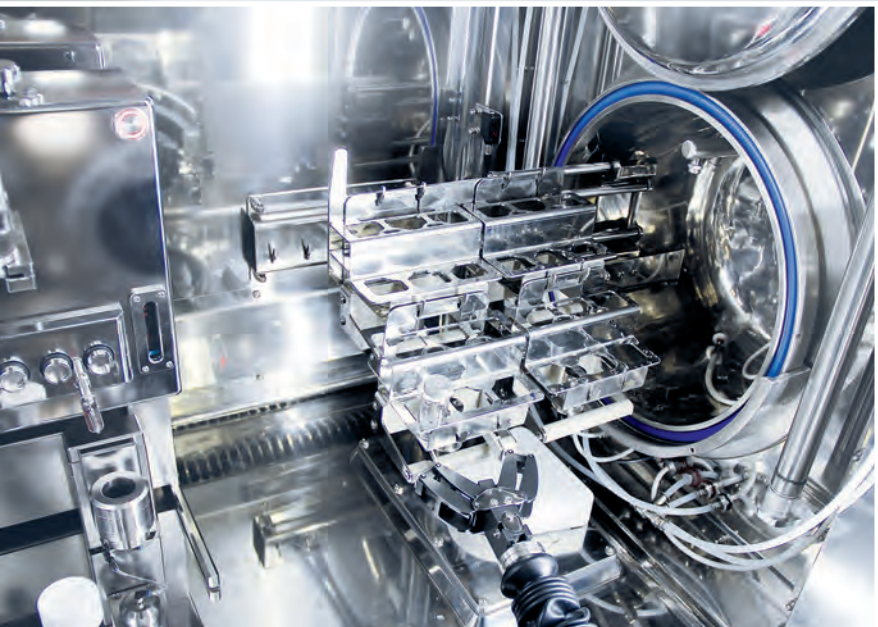
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	75 ÷ 100 mm
Weight	11500 ÷ 14400 kg
Working chamber internal dimensions	969 x 690 x 830 mm (w x d x h)
External dimensions	TALIA-PC1: 1961 x 1414 x 2600 mm (w x d x h) TALIA-PC2: 2550 x 1414 x 2600 mm (w x d x h)

RELATED PRODUCTS

CLIO
Vials and syringes dispensing system | **48**

ARGO SERIES
Vials dispensing systems | **50**

THEODORICO 2
Robotic dispensing isolator for vials | **8**



MANUELA

SHIELDED ISOLATOR FOR DISPENSING

MANUELA is a shielded isolator (Class A) with laminar flow over the entire work area and designed to handle radiopharmaceuticals.

This system is particularly suitable for preparation and dispensing of PET radiopharmaceuticals. The MANUELA hot cell can be equipped with a material introduction chamber in full compliance with cGMP guidelines.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Shielded chambers under constant negative pressure
- Dose calibrator (available in the versions 2 Ci or 20 Ci)
- Shielded front hinged door with glass and hand passage doors for hot manipulation
- Chamber tightness ensured by inflatable gasket system
- Touch-screen operator panel
- Connection for particle counter probe

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	50 mm
Weight	5000 kg
Working chamber internal dimensions	870 x 524 x 716 mm (w x d x h)
External dimensions	1125 x 1100 x 2400 mm (w x d x h)

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | **52**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**

THECLA

SHIELDED ISOLATOR WITH INTEGRATED

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

The THECLA isolator has a compact and essential design, as well as being supplied with standard equipment: this makes THECLA extremely easy to use, making it one of the most competitive shielded isolators on the market. Thanks to its small size, it can be positioned in confined spaces. The main chamber is fitted with a semiautomatic dispensing system for radiopharmaceuticals in single dose syringes of PET and SPECT radiopharmaceuticals and for RADIO METABOLIC THERAPY.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Airlock for material introduction air quality Class B
- Ideal for dispensing of syringes in cGMP aseptic environment
- Integrated dispensing system for syringes
- Compact solution also suitable for small laboratories
- Easy to use
- Complete solution thanks to the preset equipment
- Dose calibrator up to 2 Ci
- ^{68}Ga generator housing compartment
- Product extraction system in transport shielded container
- Touch-screen operator panel
- Temperature and humidity sensor

TECHNICAL DATA

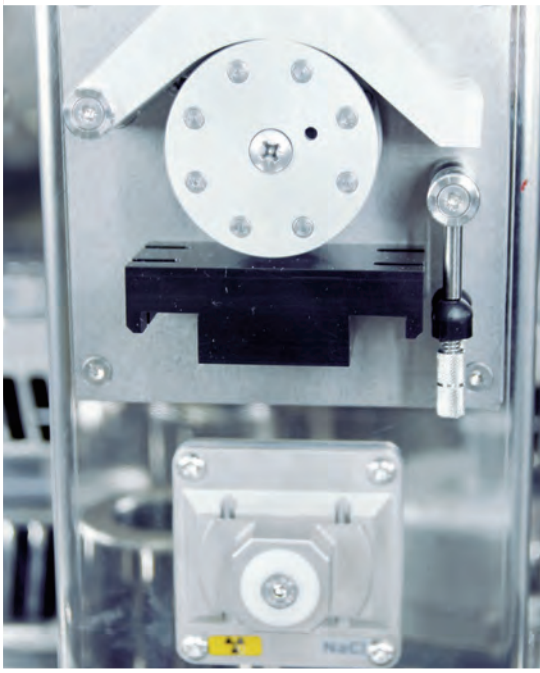
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	50 mm
Weight	4400 kg
Dispensing chamber internal dimensions	566 x 597 x 684 mm (w x d x h)
External dimensions	800 x 1070 x 2400 mm (w x d x h)

RELATED PRODUCTS

BH SERIES
Biohazard class A hood | **80**

ELIZA SERIES
Shielded dispensing isolators for ^{99m}Tc | **38**


COMECER



MUSA SERIES

SHIELDED ISOLATORS FOR ^{68}GA AND ^{18}F DISPENSING

MUSA ^{68}Ga is a shielded laminar flow isolator suitable for handling beta- and gamma-emitting radiopharmaceuticals in an aseptic environment, in accordance with the Good Radiopharmacy Practice Standards in the Preparation of Radiopharmaceuticals in Nuclear Medicine (simple preparations and extemporaneous preparations).

The hot cell is designed to optimize the ^{68}Ga processes (elution of ^{68}Ge/^{68}Ga generators, synthesis and dispensing) and ^{18}F-based products dispensing. In addition, by means of compact synthesis modules and thanks to the specific configuration for beta emitters, it is suitable for labeling and dispensing of different beta emitting radiopharmaceuticals like ^{177}Lu and ^{90}Y.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Airlock for material passage air quality Class B
- Gloves pre-chamber air quality Class B
- Gallium generator compartment air quality Class B
- Suitable for handling beta and gamma-emitting radiopharmaceuticals
- Designed to optimize the processes of ^{18}F or ^{68}Ga-based radiopharmaceuticals
- Touch-screen operator panel
- Modular design and flexible configuration

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	50 mm
Weight	6500 ÷ 8500 kg
Working chamber internal dimensions	970 x 590 x 658 mm (w x d x h)
External dimensions	1276 x 1412 x 2400 mm (w x d x h) with pre-chamber: 1864 x 1412 x 2400 mm (w x d x h)

RELATED PRODUCTS

THECLA
Shielded isolator with integrated | **34**

ELENA SERIES
Shielded isolators for dispensing | **40**


SIMATIC HMI
TOUCH

ELIZA SERIES

SHIELDED DISPENSING ISOLATORS FOR ^{99m}Tc

ELIZA is a shielded isolator with laminar flow for the manipulation and calibration of SPECT-emitting radiopharmaceuticals pursuant to cGMP guidelines. The large aseptic chamber and the presence of a generator compartment make it suitable for handling ^{99m}Tc compounds for micro-biologically critical processes, such as cellular labeling.

ELIZA meets all calibration, manipulation and dispensing requirements of Nuclear Medicine departments.

It is equipped with a laminar flow work chamber and ventilated pre-chambers for the transit of materials, to house generators and to confine waste. The main chamber can be equipped with plastic supports to handle beta-emitting radiopharmaceuticals.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Generator compartment air quality Class B
- Air-lock for material introduction air quality class B
- Waste compartment air quality Class B
- Touch-screen operator panel
- Technical gases supply lines with ball shut-off valves
- DOP test connections (filter leakage test)
- Dose calibrator (available in the versions 2 Ci or 20 Ci)
- cGMP compliant

TECHNICAL DATA

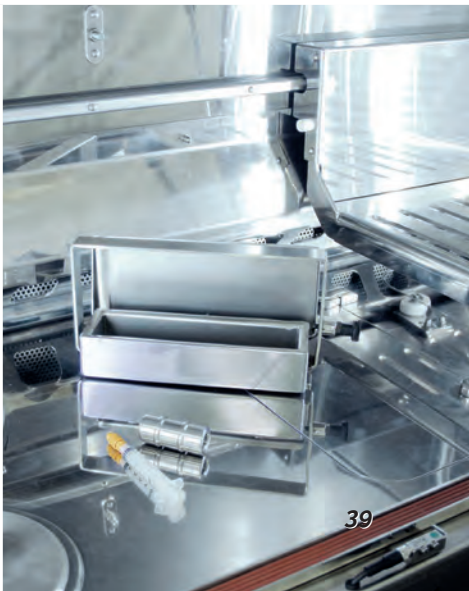
External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	20 mm
Weight	3700 kg
Working chamber internal dimensions	1350 x 474 x 612 mm (w x d x h)
External dimensions	1700 x 947 x 2400 mm (w x d x h)

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | **52**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**

ELENA SERIES
Shielded isolators for dispensing | **40**



ELENA SERIES

SHIELDED ISOLATORS FOR DISPENSING

ELENA is the top level of shielded isolator for dispensing in Nuclear Medicine.

ELENA is a dispensing isolator with laminar flow for the manipulation and calibration of Beta or Gamma-emitting radiopharmaceuticals pursuant to cGMP guidelines.The unique plastic manipulation chamber and the different shielding thicknesses available make it suitable for manipulating any type of radiopharmaceutical, including those specific for metabolic or high energy Beta-emitting radiotherapy.

ELENA meets all calibration, manipulation and dispensing requirements of Nuclear Medicine departments. It is equipped with a laminar flow work chamber and ventilated pre-chambers for the transit of materials, to house generators and to confine waste.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Dispensing chamber air quality Class A with laminar flow
- Gloves pre-chamber air quality Class B
- Generator compartment air quality Class B
- Air-lock for material introduction air quality Class B
- Waste compartment air quality Class B
- Suitable for Beta or Gamma-emitting radiopharmaceuticals
- Modular design and flexible configuration
- Dose calibrator (available in the versions 2 Ci or 20 Ci)
- Touch-screen operator panel
- Spacious work chamber for maximum ergonomics
- Connection for particle counter probe

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Work chamber material	Polypropylene RAL 7032
Shielding (Pb)	30 ÷ 50 mm
Weight	5950 ÷ 8250 kg
Working chamber internal dimensions	1400 x 570 x 628 mm (w x d x h)
External dimensions	2321 x 1093 x 2600 mm (w x d x h)

RELATED PRODUCTS

TADDEO
Synthesis module for radiopharmaceuticals | **93**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**

PHL SERIES

STERILE ISOLATORS FOR CELLULAR LABELING

Cellular Labeling in nuclear medicine is classified by Good Radiopharmacy Practice Standards in the Preparation of Radiopharmaceuticals in Nuclear Medicine as "extemporaneous preparations" and must be carried out within an isolator, which can maintain sterility, located in a Class D environment.

The labeling operations are carried out inside the chamber, thanks to a pair of gloves found on the main wall. The material passes through the pre-chamber (in Class B) so the main chamber is never in direct communication with the external environment.

The handling environment, just like the pre-chamber, is in negative pressure with respect to the external environment, thereby ensuring compliance with radiation protection standards.

FIELD OF WORK

NUCLEAR MEDICINE

- QUALITY CONTROL
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Working chamber air quality Class A
- Modular design and flexible configuration
- Avoids having to set up a clean room within the Nuclear Medicine Department
- Suitable for cellular labeling operations
- Frontal large windows
- Pharmaceutical pre-chamber for the introduction and manipulation of materials (air quality Class B)
- Guarantees full protection of the product and the operator
- Touch screen for hot cell and dispensing system control
- Touch-screen operator panel
- UVC germicidal lamp

TECHNICAL DATA

External casing material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)*	3 mm
Weight	650 kg
Working chamber internal dimensions	1200 x 520 x 730 mm (w x d x h
External dimensions with pre-chamber	1895 x 930 x 2140 mm (w x d x h)

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | **52**

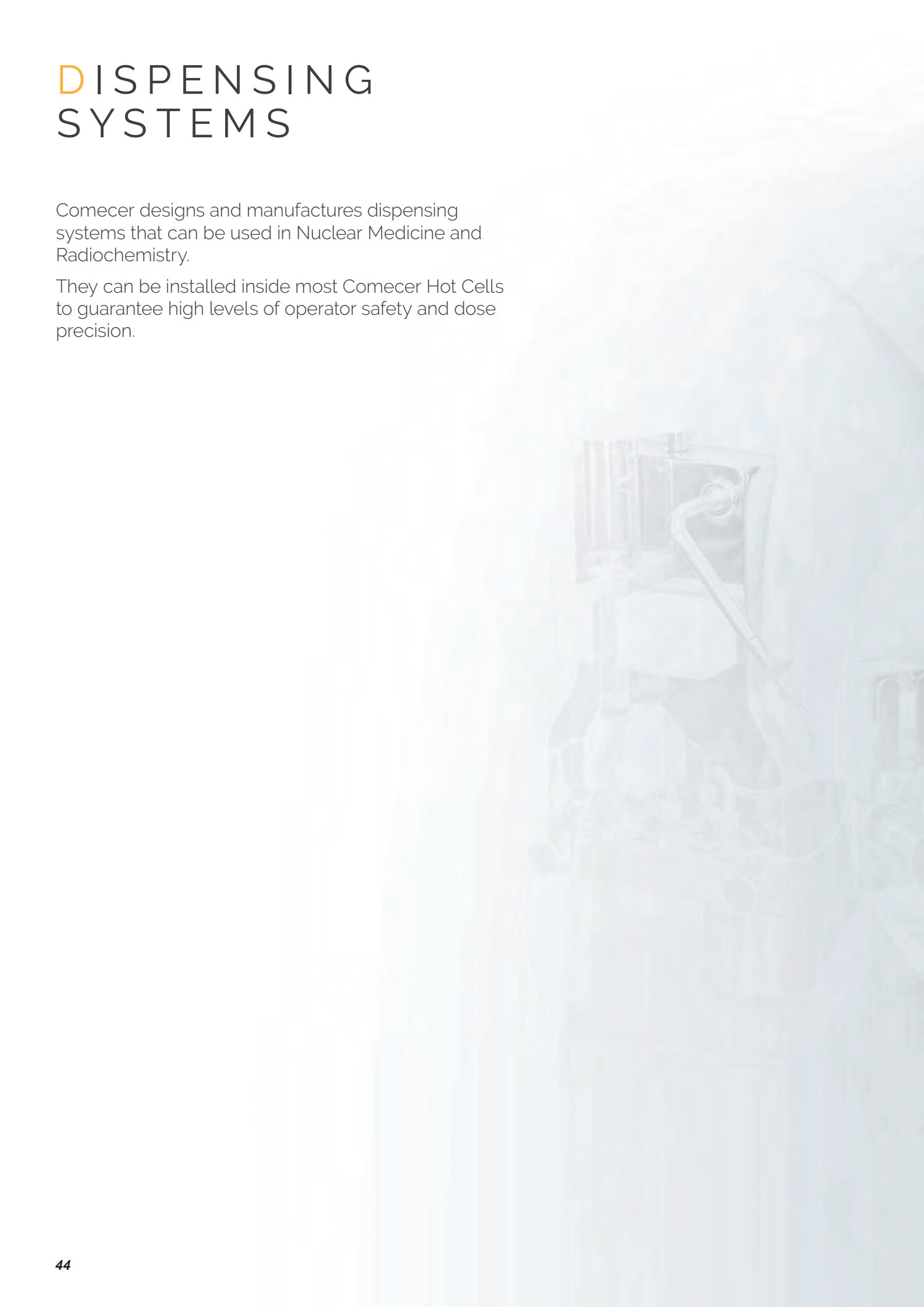
BH SERIES
Biohazard class A hood | **80**

ELIZA SERIES
Shielded dispensing isolators for ^{99m}Tc | **38**

DISPENSING SYSTEMS

Comecer designs and manufactures dispensing systems that can be used in Nuclear Medicine and Radiochemistry.

They can be installed inside most Comecer Hot Cells to guarantee high levels of operator safety and dose precision.



MIKROS

MICRO-DISPENSER FOR LU-177 AND AC-225

MIKROS is a dispensing system for carrier-free radioisotopes like 225Ac or 177Lu (or more therapeutic /theragnostic isotopes) inside 2 ml conical DIN ISO 20 and 10 ml flat bottom DIN ISO 20 vials.

Using pipette tips for Tecan, MIKROS withdraws the radiofluid from a conical 10 ml vial and the HCl from a 20 ml vial. MIKROS is designed to be used in a pharmaceutical or similar environment with suitable management of cleaning activities and environmental parameters.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION

PRODUCT HIGHLIGHTS

- Barcode reader used to identify the empty vial before it is moved to the vial transfer system by the telemanipulator.
- Dispensing unit consists of two TECAN modules that move horizontally and vertically by means of a motorised sledge. The unit fills vials by dispensing the radio fluid or the diluent with pipettes and can fill from 10 µl up to 5000 µl.
- Crimping unit consists of two stopper removal/positioning stations that move vertically by means of a motorised sledge The stopper removal/positioning stations remove and position the stoppers.
- Vial transfer system consists of a mechanical arm fitted with a gripper that automatically moves the vials under the various stations. The unit is equipped with a drip tray to protect the module from any fluid leaks.
- Scales for vial weighing

TECHNICAL DATA

External casing material	AISI 304 - Mirror-Bright
Weight	15 kg

RELATED PRODUCTS

THECLA
Shielded isolator with integrated | **34**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**

ELIZA SERIES
Shielded dispensing isolators for ^{99m}Tc | **38**

89 225
Ac
ACTINIUM

71 177
Lu
LUTETIUM

CLIO

VIALS AND SYRINGES DISPENSING SYSTEM

The CLIO dispenser is designed for the formulation and automatic dispensing of radiopharmaceuticals (PET, SPECT and radio-treatments) in vials and syringes. CLIO is a dispensing system compliant with cGMP guidelines for filling open and closed vials or single-dose syringes.

Functional and validated to dispense FDG, upon technical approval, it can be used for different radiopharmaceuticals and molecules. CLIO can dispense radiopharmaceuticals from a multi-dose vial or from a synthesis module, while its particular aerodynamic shape allows you to optimize the interaction with the laminar flow.

FIELD OF WORK

GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- OPEN VIAL FILLING
- CLOSE VIAL FILLING
- SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Dispensing in open vials
- Transeptal dispensing in closed vials
- Dispensing in syringes
- Accurate dispensed monodose
- Automatic vials open/close system
- Pre-assembled, compact, easy-to-install consumable kit
- Bubble point test connection
- Easy handling
- cGMP compliant
- In combination with the dispensing process software (DPS) provides strictest compliance with cGMP

TECHNICAL DATA

Support frame material	AISI 316L - Mirror-Bright
External casing material	Polyurethane - AISI 316L
Classification	IIA
Weight	30 kg
External dimensions	417 x 600 mm (Ø x h)

RELATED PRODUCTS

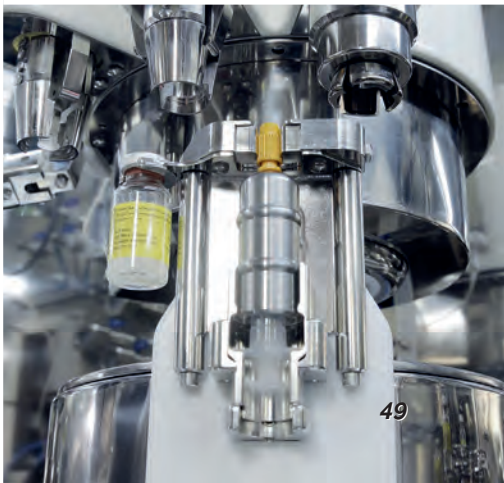
PHAEDRA SERIES
Shielded isolators for dispensing | **26**

TALIA SERIES
Shielded isolators for dispensing | **30**

IRIS
Automated multidose injection system | **96**


COMECER


COMECER



ARGO SERIES

VIALS DISPENSING SYSTEMS

ARGO series is a family of automatic dispensing systems for vials. The equipment is designed and produced to dispense radiotracers used in PET and SPECT diagnosis and therapeutic radiopharmaceuticals. ARGO is a system that complies with the cGMP guidelines for filling open vials. Functional and validated to dispense FDG, upon technical approval, it can be used for different radiopharmaceuticals and molecules.

ARGO-T (TRANSSEPTAL) is an automatic dispensing system for closed vials able to fill a vial through rubber stopper.

ARGO Series offers a reliable and complete work flow. It is usually integrated in Class A shielded isolators equipped with manipulators, thus ensuring the utmost in ergonomics and convenience in total compliance with the cGMP guidelines.

FIELD OF WORK

GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- VIAL FILLING

PRODUCT HIGHLIGHTS

- Dispensing in open and closed vials
- Complete filling cycle in 30 seconds
- Accurate volume dispensing
- cGMP compliance
- A system based on sterile disposable use
- Opening time of the vial, which is the most critical phase of the cycle from an aseptic viewpoint, is less than 10 seconds
- In combination with the dispensing process software (DPS) provides strictest compliance with cGMP

TECHNICAL DATA

External casing material	AISI 316L*
Volumetric dispensing accuracy	0.5 ÷ 1 ± 0.05 ml 1 ÷ 10 ± 5% ml
Weight	ARGO: 30 kg ARGO T: 15 kg
External dimensions	ARGO: 320 x 186 x 501 mm (w x d x h) ARGO T: 225 x 206.5 x 505 mm (w x d x h)

*Material compatible with Vapor Phase Hydrogen Peroxide (VPHP)

RELATED PRODUCTS

PHAEDRA SERIES
Shielded isolators for dispensing | **26**

TALIA SERIES
Shielded isolators for dispensing | **30**

IRIS
Automated multidose injection system | **96**

TIMO 2

SYRINGES DISPENSING SYSTEM

TIMO 2 is a semi-automatic dispensing system that makes use of components and software developed and adopted by COMECER on automatic dispensing system.

TIMO 2 dispensing system allows the dispensing of radiopharmaceuticals in single-dose syringes of PET and SPECT radiopharmaceuticals and for radiotherapy.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- SYRINGE FILLING

PRODUCT HIGHLIGHTS

- Compact size that allows installation in hot cells with small working areas
- Ergonomic design to facilitate loading/unloading of syringes and disposables
- Suitable for the dispensing of radiopharmaceuticals in single-dose syringes of PET, SPECT radiopharmaceuticals and for radiotherapy
- Workflow control by means of an operator interface developed in accordance with cGAMP regulation

TECHNICAL DATA

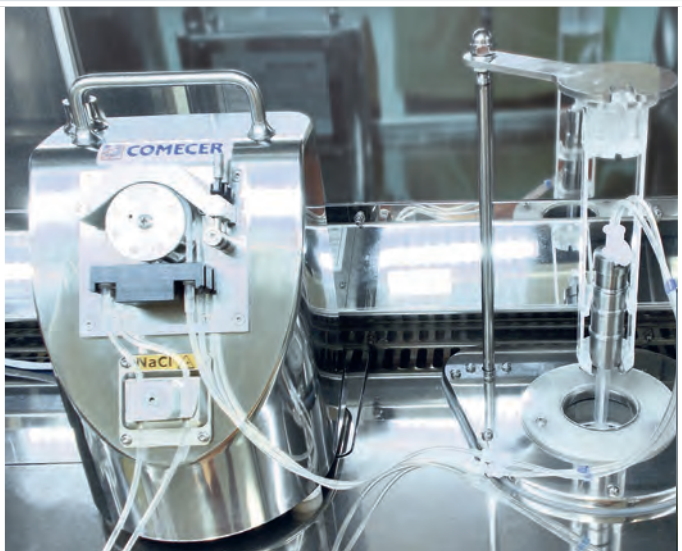
External casing material	AISI 304 - Mirror-Bright
Weight	15 kg

RELATED PRODUCTS

THECLA
Shielded isolator with integrated | **34**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**

ELIZA SERIES
Shielded dispensing isolators for ^{99m}Tc | **38**


COMECER

MANAGEMENT SOFTWARE

Comecer produces Management System and Quality Control Software able to provide a state-of-the-art software environment based on client-server connection.

It will help you to manage, administer and control all daily routines in your radiopharmacy, hospital PET department, radiopharma production facility and nuclear medicine hospital department.

ILLUMINATE

INDUSTRY 4.0 RADIOPHARMA PRODUCTION SOLUTION

Illuminate™ Manufacturing Intelligence is a production management system for both single isolators and complex production lines. Illuminate provides critical information on the essential processes of the production activity in pharmaceutical and radiopharma laboratories, nuclear medicine plants and ATMP research centers.

4 Core Values Drivers

Decrease Cost
Reduce downtime, diagnosis and repair time to improve profitability

Maximize Throughput
Improve throughput which increases revenue

Improve Quality
Lower reject rates and decrease production waste resulting in more efficient production and more profitable operations

Increase Uptime
Improve asset utilization leading to increased profitability
Make more with less

Improve Your Production Operations

Single pa nel of glass
Monitor operations anytime, anywhere from our turnkey, integrated, and secure single-point platform. Your total production monitoring system.

Real-time OEE
Capture real-time OEE intelligence across lines, machines, and locations for top-down, bottom-up continuous improvement. Real-time view of the processing area.

Visual KPIs
At-a-glance insight with dynamic charts & graphs of key data and metrics.

Predictive maintenance
Improve equipment efficiency, yield, and lifespan through predictive maintenance. Get advance warning of any issues in order to respond more rapidly. Reduce unnecessary maintenance tasks.

Faster response times
Real-time SMS or e-mail notifications and alerts for quicker corrective action.

Unified communications
Keep operational teams informed and engaged across shifts and locations.

Parts traceability
Reduce future downtime using historical information. Track dosages and batches for future reporting and accountability measures for quality and compliance.

Illuminate™ Manufacturing Intelligence is a device-agnostic Industry 4.0 Smart Manufacturing Production solution that uses real-time machine performance data to pinpoint where to focus efforts to reduce downtime, maximize line throughput, improve product quality, and make sustainable production improvements.

Illuminate is developed by machine builders for machine operators, with continual improvements driven by feedback from production data and subject matter experts and technicians. Embedded in ATS' global services network spanning 20 manufacturing facilities and 50 offices, and drawing from 40+ years experience building machines, Illuminate currently runs on world-class life science, transportation, energy, and consumer product systems.

IBC SERIES

MANAGEMENT SOFTWARE

IBC software is a complete client/server system for a cyclotron facility, central radio-pharmacy, academic hospital and nuclear medicine departments.

IBC is the most complete workflow management software from isotope production to patient injection for your nuclear medicine and radio pharma departments and facilities. To get the right dose of the right radiopharmaceutical at the right time to the right patient

IBC CLINIC

The IBC CLINIC nuclear medicine management software is a state of the art client-server software system for nuclear medicine departments and imaging centers.

IBC NM

The IBC NuclearMedicine software is a complete client-server software system for nuclear medicine departments.

IBC RP

IBC RadioPharma is the complete radio pharmacy management software that allows its users to produce batches of radiopharmaceuticals and inject them or export them serving as a supplier for external customers

FIELD OF WORK

NUCLEAR MEDICINE | GMP RADIOPHARMACY

- LAB MANAGEMENT
- QUALITY CONTROL
- VALIDATION

PRODUCT HIGHLIGHTS

- User experience: Easy management of workflow and measurements
- Traceability of data: full traceability over all processes within your facility
- Compliance: Fully compliant to regulatory

RELATED PRODUCTS

IRIS
Automated multidose injection system | **96**

THECLA
Shielded isolator with integrated | **34**

BH SERIES
Biohazard class A hood | **80**

IBC MANAGEMENT SOFTWARE

THERABED

METABOLIC RADIOTHERAPY MANAGEMENT SYSTEM

Therabed software allows you to manage protected hospitalizations of patients undergoing metabolic radiotherapy; you can plan hospitalizations, manage the administration of sources, create totally customizable reading algorithms and monitor the dose emitted by patients by reading with appropriate probes. It also allows you to predict the patient discharge time.

FIELD OF WORK

NUCLEAR MEDICINE

- HEALTH PHYSICS
- VALIDATION

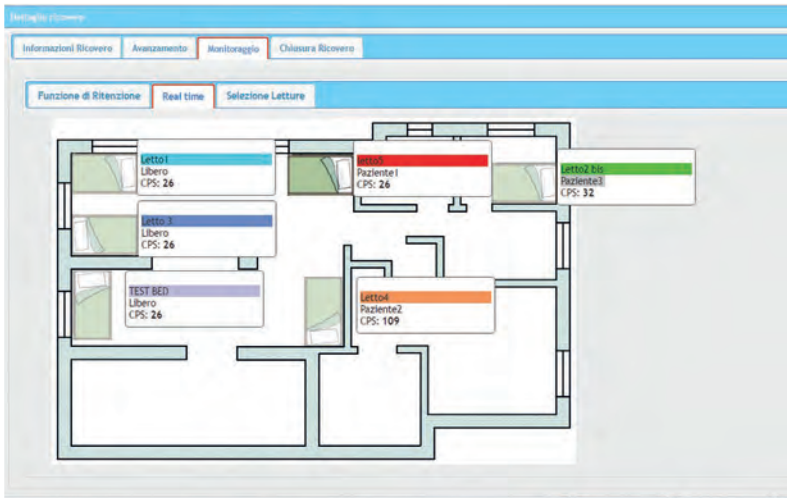
PRODUCT HIGHLIGHTS

- Retrieval of patient records
- Planning of hospitalizations
- Injection management
- Acquisition of dosimetric readings at set intervals
- Readings stored in a local repository
- Patient discharge forecast
- Traceability and result history

Main features

- *Retrieval of patient records (from RIS/PACS systems or Nuclear Medicine management software) with the possibility to enter the information manually*
- *Planning and management of hospitalizations and room preparation via a dedicated digital agenda*
- *Probe management with bed assignment and calibration management; the system will provide an alert in the case of expired calibration*
- *Injection management with activity and isotope information*
- *Acquisition of dosimetric readings at set intervals with the possibility of additional readings compared to the number provided by the chosen algorithm, changes or deletion of inadequate readings*
- *Real-time monitoring of dosimetric readings for each patient with the possibility of manually changing the acceptance range*
- *Readings stored in a local repository*
- *Patient discharge forecast: automatic processing of a statistical prediction of discharge and calculation of the residual activity using two methods: Weibull Regression and Exponential Weighted Regression*
- *Development of a summary report containing the clinical diary and the hospitalization endnotes*
- *Dedicated collimated probe to be mounted over the bed to read the patient radioactivity emissions after the treatment.*
- *Digital signature of the report*

COLLIMATED PROBE



TLC-204

THIN LAYER RADIOCHROMATOGRAPH (TLC-SCANNER)

The TLC-204 is a versatile state-of-the-art radio TLC system. The new motor technology reduces considerably the running noise. A complete range of detector probes allow the measurement of nearly every isotope. It is designed for optimal use in nuclear medicine, SPECT or PET laboratories.

Simply exchange the detector and the collimators to get the best performance for every application.

Our detectors work gas free, ensuring long life time and low maintenance costs. The high sensitivity combined to the moving sample table allows a very fast analysis, with an average scanning time of less than 1 minute.

GxP features, spectrum scan capabilities and a basic half life time mode make the TLC-204 a versatile system for your quality control lab. Outstanding detection capabilities, excellent signal-to-noise ratio and optimal signal resolution make the TLC-204 the perfect workhorse for your lab.

Testing the radiochemical purity with thin layer chromatography and the execution of basic gamma spectrometry are a routine for many nuclear medicine laboratories and Spect or PET facilities.

Having a reliable, easy-to-use system, meeting today's standards in GMP and documentation rules is mandatory for optimal working conditions.

By nature of the measurement scanning resolution, sensitivity, limit of detection, dynamic range and spectrum analysis need antipodal technical solutions.

The complete TLC-204 range was designed to be as flexible and adjustable as possible, to ensure the highest performance and the best compromise depending on your actual application.

The new software allows 3 different measuring modes for chromatography, spectrum analysis and halflife time determination.

The half-life time and the spectrum mode enable fast and simple analysis. They are very helpful in daily routine but depending on he application, a dedicated ionization chamber or multi-channel analyzer might be necessary.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

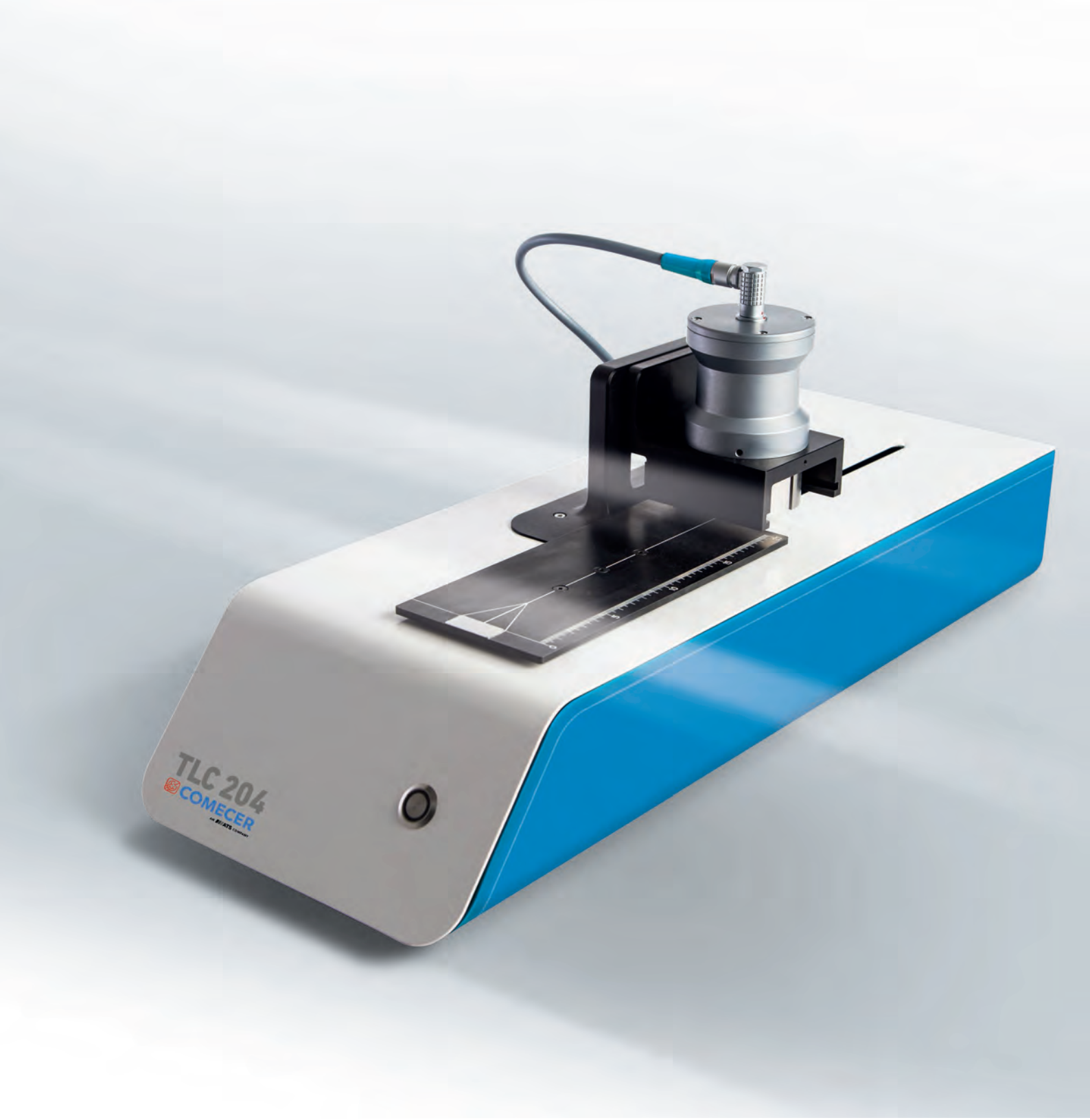
- QUALITY CONTROL

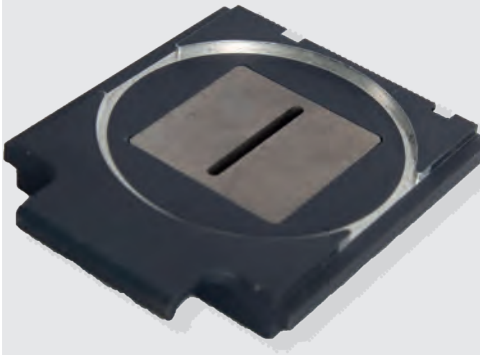
PRODUCT HIGHLIGHTS

- Collimators for different energy ranges
- Extremely high counting rate
- Manual or automatic peak integration and TLC evaluation
- Limit of detection calculation

TECHNICAL DATA

Probe holder	with automatic probe recognition
Collimators	5, 10, 15, 20 mm tungsten collimators with automatic recognition
Scan area	25 x 200 mm
Scan time	selectable
Probe/detector	miniGita OFA
Energy range	30 – 2000 KeV
Count rate	0 – 500.000 cps
Communication	USB 2.0 e 10/100 Ethernet
Dimensions	640 x 220 x 280 (w x d x h)


TLC 204
COMECER



RADIONUCLIDE DOSE CALIBRATORS

Comecer is one of the leading manufacturers of dose calibrators for nuclear medicine and radiopharmacology departments. We are specialised in checking, measuring and safely managing radiation. In addition to this specific know-how, Comecer also takes care of design, software, mechanics and electronics, obtaining a wide range of unique products for nuclear medicine, radiochemistry, radiopharmacy and calibration laboratories.

IBC

DOSE CALIBRATOR

The IBC Dose Calibrator is a completely digital dose calibrator managed by IBC-LITE. The ionization chamber is connected directly to a Microsoft® Windows PC.

Like all Comecer dose calibrators, each model is used in combination with a completely digital VIK-202 or VIK-203 model ionization chamber. The IBC-LITE software offers a simple and user-friendly interface that supports all functions required for dose calibration when preparing radiopharmaceuticals.

IBC Dose Calibrator can work simultaneously with two ionization chambers connected in parallel. Both measures are displayed next to each other.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DOSE CALIBRATION

PRODUCT HIGHLIGHTS

- Quality control tests for the ionization chamber
- Simultaneous control of two ionization chambers
- Interface with IBC management software
- Radionuclide purity test of the radiopharmaceutical.
- FDA and Medical Device approved

IBC LITE software

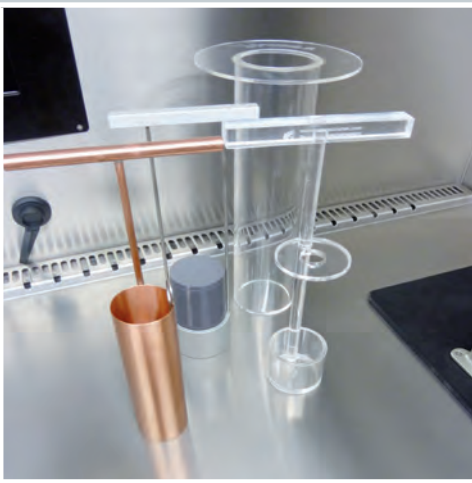
- Developed according to the GAMP-5 methodology
- Built-in isotope list
- Isotope preset list
- Suitable for measuring vials and syringes
- User-definable containers
- Future dose calculation
- Vial/syringe preparation with patient information
- Quality control tests for the ionization chamber
- Molybdenum breakthrough measurement
- User-definable labels
- Suitable for any Microsoft® Windows platform

TECHNICAL DATA	*READ OUT UNIT*
Reading	Curie/Becquerel (touch screen selectable)
Resolution	0.001 MBq 0.01 µCi
Operating system	Microsoft® Windows
Peripheral interface	1 x RS-232 interface for each ionization chamber 1 x USB interface for the label printer*
Defined Isotopes	> 55 touch screen selectable isotopes
User-definable isotopes	Limitless
Pre-set isotopes	15

VDC 606 Touch-screen

Label printer

Dipper lift



Dose calibrator inserts

VIK-202 & VIK-203

IONIZATION CHAMBERS

The heart of every Comecer dose calibrator is the ionization chamber: a completely digital detector that gives a fast, reliable reading. The 100% digital output allows the detector to be flexibly integrated into other instruments or structures with no need for a converter or a separate reading unit.

The VIK-202 ionization chamber is pressurised at 14 bar (absolute) of Argon and its measurement range is up to 2 Ci (74 GBq) of F-18; the VIK-203 ionization chamber is also available, pressurised at 1.4 bar (absolute) of Argon, for a measurement range of up to 20 Ci (740 GBq) of F-18.

TECHNICAL DATA	***VIK-202***	***VIK-203***
Ionisation chamber	Pressurised (14 bar abs. Argon)	Pressurised (1.4 bar abs. Argon)
Well size	69 mm Ø x 280 mm	
Well liner (inside)	57 mm Ø x 270 mm	
Saturation	>200 GBq (Tc-99m), >70 GBq (F-18) >6 Ci (Tc-99m), >2 Ci (F-18)	>2000 GBq (Tc-99m), >700 GBq (F-18) >60 Ci (Tc-99m), >20 Ci (F-18)
Energy range	25 keV - 3 MeV	
Lead shielding	3 mm Pb	
Linearity	± 1 % between 1 MBq and 200 GBq (Tc-99m)	± 1 % between 50 MBq and 2000 GBq (Tc-99m)
Electrometer accuracy	± 1 %	
Reproducibility	± 1% over 24 hours, stable conditions	
Overall accuracy	± 3 % dependant of specific calibration source and geometric variations	
Response time	Maximum 2 seconds for 95% of the end value	
Power supply	5 VDC, 250 mA	
Cable	2,5 meters	
Dimensions	150 mm Ø (bottom 160 mm) x 451 mm height	
Weight	15.5 kg	

FUME HOODS

Comecer shielded and unshielded fume hoods are ventilated compartments in which chemical procedures may be undertaken without the escape of noxious fumes into the local environment.

All hazardous fumes are filtered and exhausted before operators can potentially breathe them.

FHR1-FHR3

LABORATORY FUME HOODS

The FHR-1 and FHR-3 radiochemistry fume hoods are workstations for the removal of air-hanging radioisotopes generated during the manipulation of liquid substances, whether volatile or gaseous.

In order to have the maximum degree of decontaminability, the structure is completely made of AISI 304 stainless steel. This structure is subdivided into two work areas: an upper manipulation and aspiration hood, and a lower storage and support bench.

FIELD OF WORK

NUCLEAR MEDICINE

- QUALITY CONTROL

PRODUCT HIGHLIGHTS

- Complete air extraction
- Filtration system with absolute and activated carbon filters
- Double-walled aspiration system, frontal air speed of 50 cm/sec
- Frontal closing with Plexiglas vertical sliding door
- Trolley for container transport
- Controlled discharge
- Remote control for the warm/cold water regulation
- Polyethylene containers
- Filter clogging control pressure gauges

TECHNICAL DATA

Frame material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Weight	420 ÷ 460 kg
Working area dimensions	1000 ÷ 1300 x 655 x 790 mm (w x d x h)
External dimensions	1200 ÷ 1500 x 770 x 2660 mm (w x d x h)

FHR1-50

HOOD FOR MANIPULATIONS AT MEDIUM ACTIVITY

Workstation for the breakdown of the airborne radioisotopes coming from the manipulation of the volatile liquid or gas substances. Completely made from 1.5 mm thick AISI 304 stainless steel with Scotch-Brite™ finish.

Designed in accordance with the current radioprotection standards. A connection hole to the lower technical compartment can be used as a passage for the capillary tubes and to discharge waste materials or it can be used as a passage for the radioactive fluids with a connection from the floor by means of a lead duct, with 30 mm thickness.

Two precision pressure gauges for the continuous measurement of the filter obstruction (absolute filter and active charcoal filters) and the switch to turn on the internal lights and the controls for the manual valves that open/close the technical gases are located on the front upper part of the hood.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

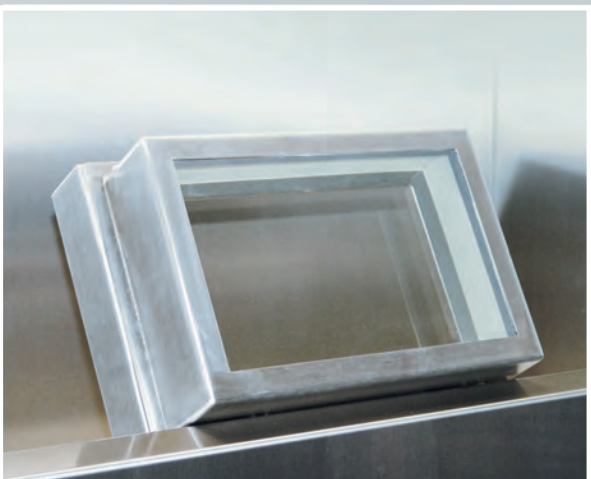
- QUALITY CONTROL
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Complete air extraction
- Completely shielded working area
- Shielded sliding front protection
- Lower technical compartment connected to the working area
- Ideal for manipulations at medium activity
- Absolute filter and active charcoal filter fitted with barrier bag housing for safe replacement operations
- Connection lines for technical gases
- Lighting with LED lamps

TECHNICAL DATA

Frame material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	50 mm
Weight	2800 kg
Working area dimensions	1300 x 600 x 800 mm (w x d x h)
External dimensions	1500 x 850 x 2560 mm (w x d x h)



FHR1-50-LAF

LAMINAR FLOW HOOD FOR MEDIUM ACTIVITY

Radiochemistry shielded hood for manipulations at medium activity, with frontal sliding shield and laminar flow.

Workstation suitable for the breakdown of the air-hanging radioisotopes coming from the manipulation of liquid or volatile gaseous substances. Completely made from 1.5 mm thick AISI 304 stainless steel with Scotch-Brite™ finish and designed in accordance with the current radioprotection standards.

Connections for the technical gases and electrical sockets are available in the work area. Two precision pressure gauges for the continuous measurement of the filters obstruction and the switch to turn on the internal lights are located on the front upper part of the hood.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DISPENSING
- VIAL AND SYRINGE FILLING
- QUALITY CONTROL

PRODUCT HIGHLIGHTS

- Working chamber air quality Class A with laminar flow
- cGMP compliance
- Completely shielded working area
- Shielded sliding front protection
- Ideal for manipulations at medium activity
- Filter clogging control pressure gauges
- Anemometer for Class A laminar flow chambers
- Lighting with one or more LED lamps

TECHNICAL DATA

Frame material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	50 mm
Weight	2300 kg
Work area dimensions	1294 x 647 x 616 mm (w x d x h)
External dimensions	1500 x 906 x 2925 mm (w x d x h)

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | **52**

ARGO SERIES
Vials dispensing systems | **50**

FHR SSC

HOOD WITH LAMINAR FLOW

Laminar flow hood for preparations under aseptic "non-radioactive" conditions. It guarantees the protection for the materials and the product whilst maintaining sterility.

It's characterized by a laminar vertical flow on the work bench. The entering air is filtered via a HEPA filter. The hood can be used for the introduction of the materials in the pharmaceutical production lines and for the management of the reagents of the synthesis modules in radiochemistry.

The quantity of the particles in the air corresponds to the characteristics required for Class ISO 5 (EN 14644-1), Class A (cGMP - Annex1) and for the critical zones: ≤ 3500 particles/m^3 with ø ≥ 0.5 µm.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- QUALITY CONTROL
- DISPOSABLE PREPARATION

PRODUCT HIGHLIGHTS

- Working chamber air quality Class A with laminar flow
- cGMP compliance
- Suitable for non-radioactive aseptic preparations
- Filtration system with HEPA filter
- Frontal closing with Plexiglas
- Lighting with LED lamps
- Pressure gauges for filters obstruction control
- Technical compartment with door and key lock
- Air extraction fan

TECHNICAL DATA

Frame material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Weight	280 kg
Working area dimensions	650 x 640 x 740 mm (w x d x h)
External dimensions	770 x 954 x 2400 mm (w x d x h)

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | **52**

ARGO SERIES
Vials dispensing systems | **50**


COMECER

BH SERIES

BIOHAZARD CLASS A HOOD

The BH SERIES microbiological safety hood, also known as laminar flow workbench, is designed to work specifically with radiopharmaceuticals. It provides the user, product and environment with the utmost safety. It enables the preparation of radiopharmaceuticals under sterile and safe conditions in one single laminar flow workbench.

The hood is manufactured in compliance with standards EN12469 (Class II). The work area complies with directives relative to Class A cGMP and it is ideal for handling ^{99m}Tc compounds or other SPECT emitters. The hood is partially shielded with lead and it can be equipped with systems for the Mo99/Tc99m generators elution, use of dose calibrator and temporary waste storage.

FIELD OF WORK

NUCLEAR MEDICINE

- DISPENSING
- DOSE CALIBRATION
- VIAL AND SYRINGE FILLING
- QUALITY CONTROL
- R&D RADIOCHEMISTRY AND RADIOPHARMA

PRODUCT HIGHLIGHTS

- Class II Biological Safety Cabinets
- Working chamber air quality Class A with laminar flow
- Designed to work specifically with radiopharmaceuticals
- Maximum safety for the user, for the product and for the environment
- Dose calibrator compartment
- Shielded generator compartment to automatically lift 2 Mo99/Tc99m generators up to the work surface*
- Spacious work chamber for maximum ergonomics

TECHNICAL DATA

Structure material	AISI 304 - Scotch-Brite™
Working chamber material	AISI 316L - Mirror-Bright
Shielding (Pb)	0 - 5 -10 mm
Weight	310 ÷ 415 kg
Internal dimensions	1190 ÷ 1800 x 580 x 740 mm (w x d x h)
External dimensions	1350 ÷ 1960 x 860 x 2535 mm (w x d x h)

Note: Data could vary depending on the model chosen

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | 52

ARGO SERIES
Vials dispensing systems | 50


MBq


0,035

FHB-10

LAMINAR FLOW HOOD WITH SHIELDED GLASS

Conserve energy with FHB-10 Comecer Class II Biological Safety Cabinets, which combine smart design and extraordinary value with best-in-class energy efficiency, reliability and usability resulting in an overall improvement to operation and maintenance. Units feature 60% less energy consumption and heat output. Cabinets are certified to EN 12469 safety standard.

Dedicated to laboratory and industry use, specifically for the protection of the product being manipulated. Moreover, it ensures excellent laminar flow at the worktop level thanks to the balanced perforation, and thanks to the considerable level of suction in the front part, which is calculated to also obtain better vertical supply in front part of the work zone.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DISPENSING
- VIAL AND SYRINGE FILLING
- QUALITY CONTROL

PRODUCT HIGHLIGHTS

- Class II Biological Safety Cabinets
- Working chamber air quality Class A with laminar flow
- High energy efficiency
- Large front-panel display
- Airflow alarms signal
- Removable worktop
- Filtration system with HEPA filter
- Protected electrical power supply sockets with external and individual control
- Fluid socket (empty/nitrogen) with manual faucet
- Shielded glass window
- Hand passage doors

TECHNICAL DATA

Weight (fume hood)	200 kg
External dimensions (fume hood)	1300 x 800 x 2490 mm (w x d x h)
Working area dimensions (fume hood)	1200 x 465 x 780 mm (w x d x h)
Front shielding (mobile shield) (Pb)	10 mm
Weight (mobile shield)	240 kg
External dimensions (mobile shield)	1190 x 800 x 1455 mm (w x d x h)

RELATED PRODUCTS

TIMO 2
Syringes dispensing system | **52**

ARGO SERIES
Vials dispensing systems | **50**

SOLID TARGET PROCESSING SYSTEM

ALCEO series is an integrated system designed for the production of radioisotopes through the irradiation of a solid target.

ALCEO SERIES

SOLID TARGET PROCESSING SYSTEM

ALCEO SERIES is an integrated system designed for the production of radioisotopes through the irradiation of a solid target. The system is based on disposable technology, which allows a disposable kit to be used, dedicated to the production of each isotope.

The following radioisotopes can be produced: ^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{124}I, ^{123}I, ^{86}Y, ^{44}Sc, ^{45}Ti. The series is set up as a family of machines that can be configured according to various parameters that will eventually define the machine accessories:

- Possibility to transfer the target to a cell after the irradiation (Standard configuration or retrofit);
- The type of isotope to produce (Metal or Halogen);
- The isotope of specific interest (^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{124}I, ^{123}I, ^{86}Y, ^{44}Sc, ^{45}Ti);
- The type of process chosen for the production of multiple isotopes (Mixed: multiple production processes are carried out by the same configuration; Separated: each production process has its own dedicated configuration).
- Possibility to introduce r&d shuttles for the development of more and new radioisotopes (not listed above)

The Retrofit mode allows the ALCEO to be installed even in a pre-existing structure where there is no possibility of creating a trench dedicated to the transfer of the target from the cyclotron to the cells installed in the radiopharmacy.

The complete configurations of the ALCEO, in which multiple isotopes are produced, include a single PTS unit and a Cooling System: the transport of the target to the corresponding module is carried out through a target switch. The integrated system allows the execution of all operations without the manual intervention of the operators.

The system is designed for application in commercial cyclotron with energy between 10 and 30 MeV.

The BBS family of hot cells is particularly suited to host ALCEO integrated systems and it is advisable to always consider the configurations with 100 mm Pb shielding.

ALCEO ACTINIUM is an upgraded version of the ALCEO: the PTS is angled at 30°, allowing better yields. The starting material is an elliptical Radium-226 plating a special line of hot cells has to be designed in order to handle and shielding the Ra-226/Ac-225.

FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Modular design
- Halogen system (for ^{123}I and ^{124}I)
- Metal system (for ^{64}Cu, ^{89}Zr and ^{68}Ga)
- Bi-directional pneumatic target transfer between cyclotron and hot cells
- One cyclotron port is required for all systems
- Irradiation unit with foil supported by water-cooled grid
- Independent water and helium cooling
- No operator contamination

Diagnostic field

ALCEO METAL

for ^{89}Zr ^{61}Cu ^{64}Cu ^{68}Ga ^{44}Sc ^{86}Y ^{45}Ti production

20 44 Ca CALCIUM	21 44 Sc SCANDIUM	28 61-64 Ni NICKEL	29 61-64 Cu COPPER
21 45 Sc SCANDIUM	22 45 Ti TITANIUM	38 86 Sr STRONTIUM	39 86 Y YTTRIUM
30 68 Zn ZINC	31 68 Ga GALLIUM	39 89 Y YTTRIUM	40 89 Zr ZIRCONIUM

ALCEO HALOGEN

for ^{123}I ^{124}I production

52 123 Te TELLURIUM	53 123 I IODINE
52 124 Te TELLURIUM	53 124 I IODINE

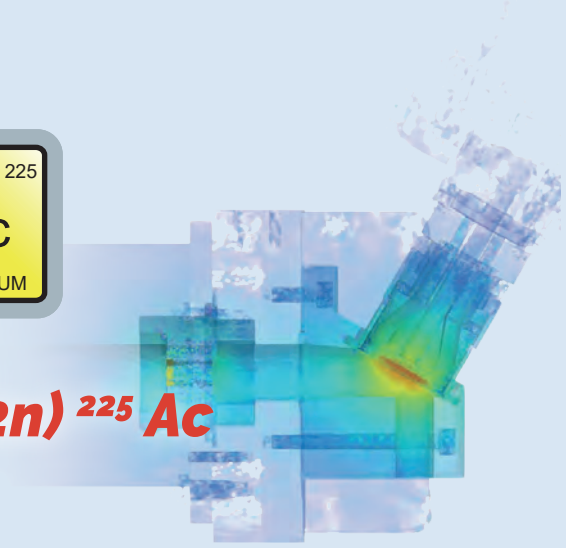
CYCLOTRON

Therapeutic field

ALCEO ACTINIUM

for ^{225}Ac production

88 226 Ra RADIUM	89 225 Ac ACTINIUM



$^{226}Ra(p,2n)\,^{225}Ac$

ALCEO HALOGEN

^{123}I / ^{124}I PRODUCTION

It allows the irradiation of a Tellurium oxide deposit ^{124}Te and ^{123}Te to obtain the equivalent radionuclide ^{124}I and ^{123}I.

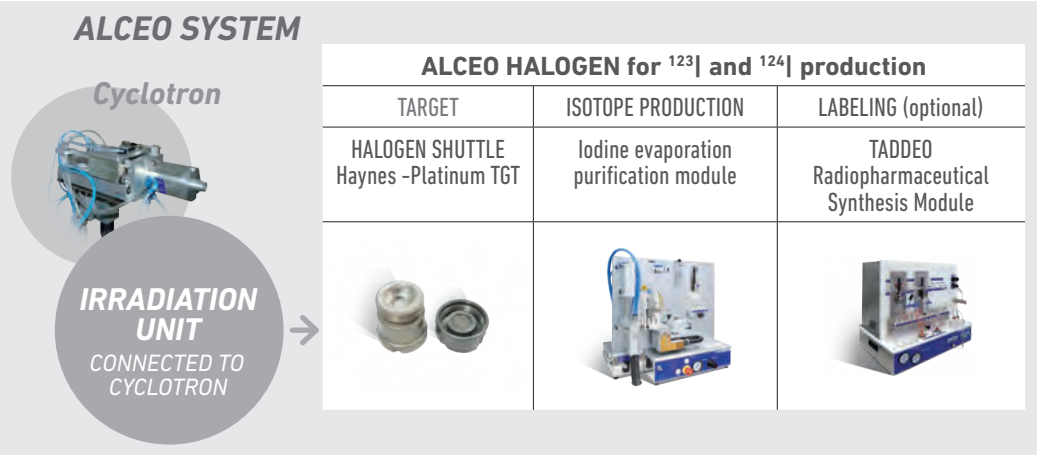
FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Modular design
- Halogen system (for ^{123}I and ^{124}I)
- Bi-directional pneumatic target transfer between cyclotron and hot cells
- Irradiation unit with foil supported by water-cooled grid
- Independent water and helium cooling
- No operator contamination



TGT ^{124}I - Target shuttle

The target is the component which is directly irradiated by the cyclotron beam.

Irradiation unit

The irradiation unit is directly connected to the cyclotron and guarantees the correct positioning of the target in front of the beam port. Target positioning is fully automated.

Iodine Evaporation/Purification unit

The unit can be placed inside a hot cell and must be connected to the PTS unit with the target transfer tube.

The EVP module contains the necessary components for the following operations:

- *automatic transfer of the target shuttles between the hot cell and the cyclotron*
- *plating of the target (tellurium dioxide) on the target shuttle*
- *evaporation of the iodine radioisotope from the irradiated target.*

The purification task makes use of a "disposable cassette", in order to avoid the module contamination.

ALCEO METAL

^{64}Cu, ^{89}Zr, ^{61}Cu, ^{44}Sc, ^{86}Y, ^{45}Ti AND ^{68}Ga PRODUCTION

It allows the simple upgrade for the production of the metal radioisotopes (^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{86}Y, ^{44}Sc, ^{45}Ti). In the fully equipped configuration, it allows the irradiation of:

- a Nickel layer (plating) ^{64}Ni/ ^{61}Ni aimed at obtaining radionuclide ^{64}Cu/ ^{61}Cu
- a Yttrium natural foil ^{89}Y aimed at obtaining radionuclide ^{89}Zr or a Scandium natural foil ^{45}Sc aimed at obtaining radionuclide ^{45}Ti
- a Zinc layer (plating) ^{68}Zn aimed at obtaining radionuclide ^{68}Ga
- a Calcium carbonate/Strontium carbonate ($^{44}CaCo_3$/$^{86}StCo_3$) pellet aimed to obtaining radiuclide ^{44}Sc/^{86}Y.

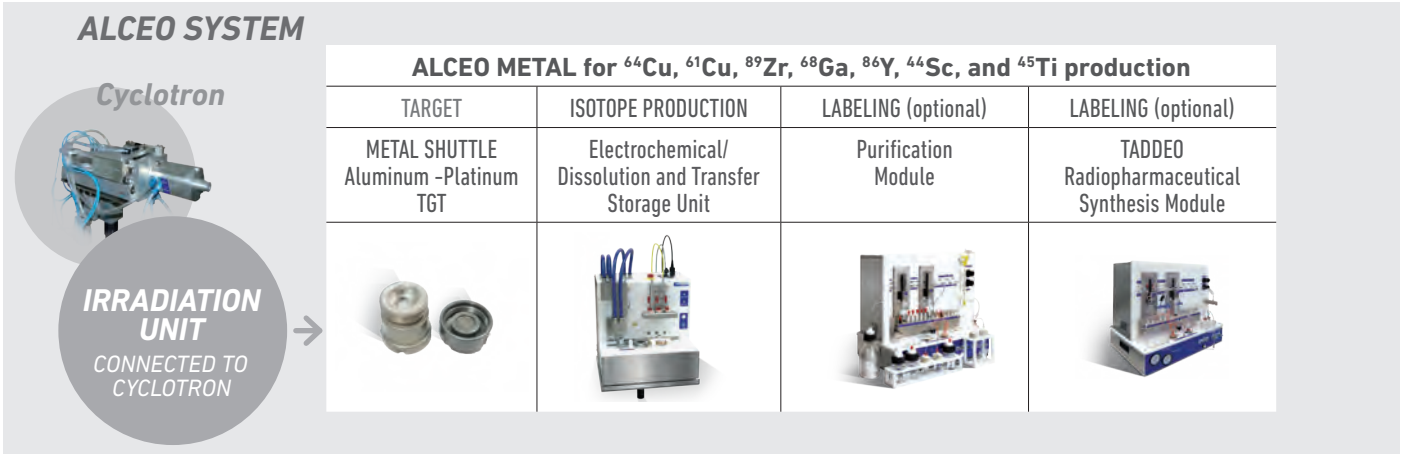
FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Modular design
- Metal system (for ^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{86}Y, ^{44}Sc, ^{45}Ti)
- Bi-directional pneumatic target transfer between cyclotron and hot cells
- Irradiation unit with foil supported by water-cooled grid
- Independent water and helium cooling
- No operator contamination



METAL Target shuttle

The target is the component which is directly irradiated by the cyclotron beam. The new shuttle has a cap which is functioning as an integrated degrader foil with different thickness (from 100 to 300 µm) according to the different cross section to reach. Moreover the cap has also the feature to seal the shuttle.

Irradiation unit

The irradiation unit is directly connected to the cyclotron and guarantees the correct positioning of the target in front of the beam port. Target positioning is fully automated.

Electrochemical/Dissolution/Transfer/Storage unit

It can be placed inside a hot cell which is connected to the cyclotron by a flexible tube for the target transfer. It is a pneumatic system that automatically carries out the following operations:

- *automatic transfer of the targets between the hot cell and the cyclotron*
- *electrochemical deposition of the enriched metal isotope on the shuttle platinum well*
- *dissolution of the irradiated isotope*
- *storage of target shuttles.*

Purification module

The Purification module contains the necessary components for the purification by ion chromatography of the produced radioisotope (^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{86}Y, ^{44}Sc, ^{45}Ti). The module is based on disposable cassettes.

ALCEO METAL RETROFIT

^{64}Cu, ^{89}Zr, ^{61}Cu, ^{44}Sc, ^{86}Y, ^{45}Ti AND ^{68}Ga

PRODUCTION FOR LABORATORIES WITHOUT SOLID TARGET PRESETTING

ALCEO METAL RETROFIT is the best solution for a pre-existing laboratory, where hot cells and trenches for capillary passage do not possess the requirements for proper installation of the ALCEO METAL.

ALCEO METAL RETROFIT is based on 'accessories' as the standard Alceo Metal, but the dissolution and purification phases are separated in distinct areas. In this configuration, connection between the two areas consists of a single fluid transfer capillary and not of a complex pneumatic transfer system of the target using corrugated pipe. In the fully accessorized configuration, it allows the production of ^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{86}Y, ^{44}Sc, ^{45}Ti.

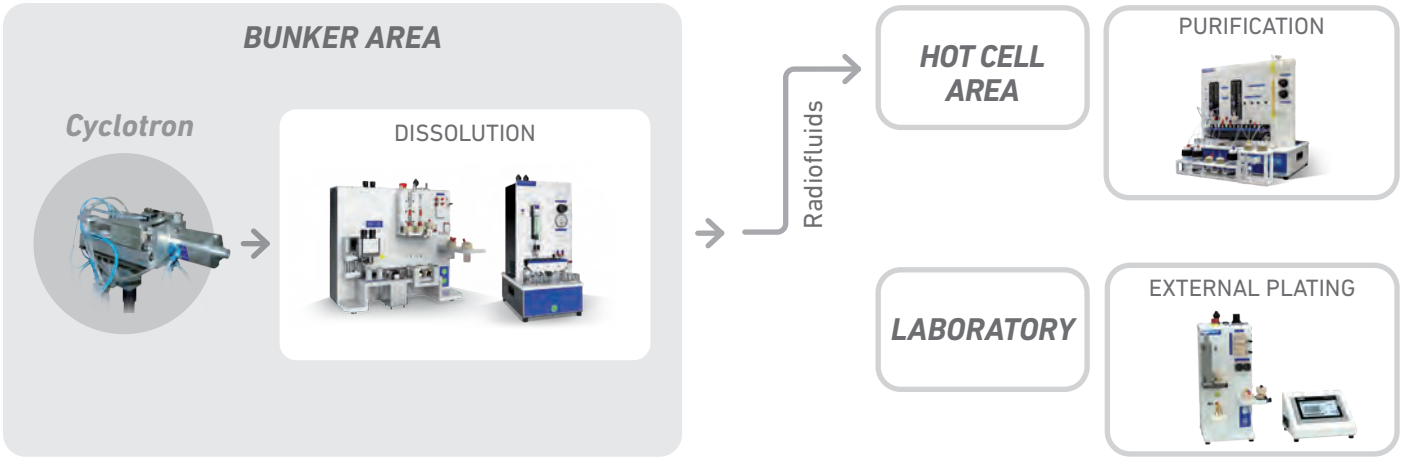
FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Modular design
- Metal system (for ^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{86}Y, ^{44}Sc, ^{45}Ti)
- Irradiation unit with foil supported by water-cooled grid
- Delivery of dissolution solution to Purification unit
- Independent water and helium cooling
- External plating unit



METAL Target shuttle

The Alceo Metal target shuttle allows the automatic positioning of the metal isotope in front of the cyclotron beam.

Irradiation unit

The irradiation unit is directly connected to the cyclotron and guarantees the correct positioning of the target in front of the beam port. Target positioning is fully automated.

Dissolution system

It can be placed inside a hot cell in the bunker area. The system is connected to the PTS for the target transfer. It is a pneumatic system that automatically carries out the following operations:

- *automatic transfer of the targets to the PTS*
- *dissolution of the irradiated isotope*
- *delivery of the dissolved isotope to the Purification unit*
- *storage of target shuttles.*

Purification module

The Purification module contains the necessary components for the purification by Ion Chromatography of the produced radioisotope (^{64}Cu, ^{61}Cu, ^{89}Zr, ^{68}Ga, ^{86}Y, ^{44}Sc, ^{45}Ti). The module is based on disposable cassettes.

External plating module

It can be placed stand-alone inside a fume hood. It is a pneumatic system that carries out the electrochemical deposition of the enriched metal isotope on the shuttle platinum well. It is managed by a proper control panel. The shuttle positioning from/to the Dissolution system has to be done manually.

ALCEO LIGHT

SERIES

The ALCEO series is available also in the LIGHT version. In this specific case, the target, which is the component irradiated directly by the cyclotron beam, is a coin (Siemens, ACSI, IBA). The coin's function is to support the initial isotope (non radioactive), which is activated after bombardment. The dimensions of the coin are agreed with the customer. The operator is in charge of transferring the coin towards/from the cyclotron. The system does not carry out this operation automatically.

FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

ALCEO LIGHT SYSTEM

ALCEO HALOGEN for ^{123}I and ^{124}I production and labeling		
TARGET	ISOTOPE PRODUCTION	LABELING
HALOGEN COIN	EVP Iodine evaporation purification module	TADDEO - Radiopharmaceutical Synthesis Module
		

ALCEO METAL for ^{61}Cu and ^{64}Cu production and labeling			
TARGET	ISOTOPE PRODUCTION		LABELING
METAL COIN ^{64}Cu	EDL Dissolution/Electroplating unit	TADDEO-PRF Purification Module	TADDEO Radiopharmaceutical synthesis module
			

ALCEO METAL for ^{68}Ga production and labeling			
TARGET	ISOTOPE PRODUCTION		LABELING
METAL COIN ^{68}Ga	FDL Dissolution Unit	TADDEO-PRF Purification Module	TADDEO Radiopharmaceutical synthesis module
CUSTOM			

The series is presented as a family of configurable machines according to various parameters, such as:

- *the type of isotope*
- *the specific radioisotopes to be produced*
- *the type of process chosen for the production of several radioisotopes:*
- *Mixed: several production processes are carried out from the same configuration*

Separated: each production process has its specific configuration.

SYNTHESIS MODULES

Comecer produces compact synthesis modules to perform, in a fully automatic way, the radiopharmaceutical synthesis and the molecular labeling procedures.

The substances obtained from these systems could be used for research purposes in the field of Nuclear Medicine (p.e. PET, SPECT imaging).

TADDEO 93
SYNTHESIS MODULE FOR RADIOPHARMACEUTICALS

TADDEO

SYNTHESIS MODULE FOR RADIOPHARMACEUTICALS

The growing clinical demand of radiopharmaceuticals combined with the severe operator exposure for high activity routine handmade preparations, has prompted us to investigate the feasibility of an automated process combining the radioprotection issues and the cGMP pharmaceutical requirements.

The result of our investigation is Taddeo, a fully automated module for the preparation of therapeutic radiopharmaceuticals R&D investigations were performed in cooperation with a well-known radiopharmaceutical institution

FIELD OF WORK

GMP RADIOPHARMACY

- R&D RADIOCHEMISTRY AND RADIOPHARMA
- SYNTHESIS

PRODUCT HIGHLIGHTS

- Multipurpose synthesis module
- Disposable sterile cassette
- Disposable sterile reactor high temperature resistant
- Multiple scintillation crystal radioactivity detectors
- Human-Machine Interface on laptop

TECHNICAL DATA

Structure material	POM
Weight	33 kg
External dimensions	530 x 375 x 550 mm (w x d x h)

RELATED PRODUCTS

ALCEO SERIES
Solid target processing system | **86**

BBS SERIES
Shielded cells for synthesis modules | **14**

ELENA SERIES
Shielded isolators for dispensing | **40**

INJECTION SYSTEMS

Comecer produces injection systems for the automatic intravenous infusion of radiopharmaceuticals or radiotracers used in central radiopharmacy laboratories and hospital facilities.

IRIS *96*

AUTOMATED MULTIDOSE INJECTION SYSTEM

IRIS

AUTOMATED MULTIDOSE INJECTION SYSTEM

IRIS automatically performs calibrated injections to patients, starting from a multi-dose solution of FDG or other diagnostic radiopharmaceutical, or a monodose vial of therapeutic/therasgnostic radiopharmaceutical. The IRIS device is compact and easy to handle thanks to its innovative design and autonomous battery power.

Flexibility - The radioactive product is administered by a disposable kit: after each injection to the patient, only the end part of the kit must be replaced. The activity of the entire radiopharmaceutical is measured by an ionization chamber integrated into the dispensing system. The multi-dose mother vial is directly loaded into the machine.

Integration - IRIS can be connected via LAN or Wi-Fi to the hospital network to acquire patient data. After each injection, a report on the individual infusions can be printed. IRIS is a class II B, CE marked, medical device.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DISPENSING
- DOSE CALIBRATION
- INJECTION

PRODUCT HIGHLIGHTS

- Integrated dose calibrator
- Medical device
- Safety of health staff
- Flexibility: system compatible with multiple radiopharmaceuticals
- Ergonomics: extremely user-friendly operation and compact design
- Measurement and dilution of mother vial concentration
- Dose calibrator compatible with multiple isotopes
- Patient safety ensured by a special filter on the disposable and bubble tester
- Dicom protocol for RIS/PACS direct connection and work list exchange
- Wireless connection to the hospital intranet network

TECHNICAL DATA

Maximum bulk activity (F18)	30 GBq
Maximum dose volume	5 ml
Dispensing accuracy	± 5 %
Weight	330 kg
External dimensions	635 x 810 x 900 mm (w x d x h)

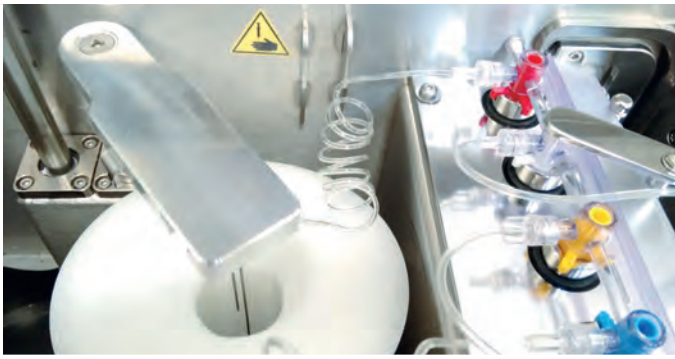
RELATED PRODUCTS

IBC SERIES
Management Software | **58**

MUSA SERIES
Shielded isolators for ^{68}Ga and ^{18}F dispensing | **36**

PHAEDRA SERIES
Shielded isolators for dispensing | **26**

^{18}F ^{64}Cu ^{123}I ^{99}Tc ^{68}Ga ^{177}Lu ^{90}Y ^{131}I ^{89}Zr



SHIELDED DOORS

Comecer is the world's leading manufacturer of shielded doors.
The shielding materials are lead, paraffin and/or polyethylene and cadmium, in various thicknesses. Comecer also supplies bunker doors filled with concrete. Top priority is given to safety devices in order to ensure the maximum safety for the operators.

Our technical experts are able to design the most suitable and cost-effective solution, according to the customer's needs in terms of shielding and dimensions.

PMC

BUNKER DOOR (NON SELF SHIELDED CYCLOTRON)

FIELD OF WORK

GMP RADIOPHARMACY

- SHIELDINGS AND DOORS

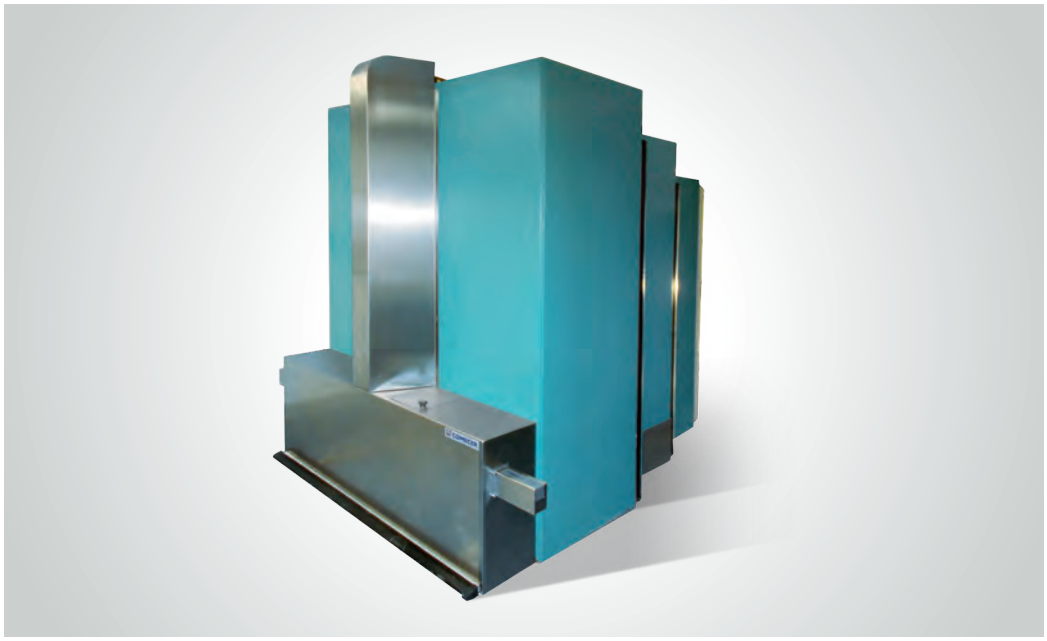
Sliding door for cyclotron bunker, mounted on rails. The door is mainly composed of two parts: a formwork fixed to the walls of the bunker and a sliding door with a concrete or barytic concrete casting.

Steel rails, placed on the ground and flush with the floor, allow the door to slide. Gear units and a chain activated by electric motor allow the sliding door to translate. The handling system includes an inverter which allows the following functions:

- Regulation of both opening and closing speed
- Regulation of the acceleration and deceleration ramps in proximity to the stop position.

FEATURES

- The door overlaps with a compartment providing protection from radiation in the area in front of the access to the bunker.
- The command for opening and closing the PMC door is semi-automatic. Specifically, after it is operated (by pressing a button), the door moves until it reaches the stop position.
- During door movement, the button does not need to be held down.
- An inflatable gasket is placed on the door's inner perimeter. When the closing position is reached, this gasket activates and creates the seal by keeping the dynamic negative pressure within the bunker.
- The electrical panel complies with CE regulations and contains the main safety switch and a door lock circuit breaker.



SPM

SLIDING SHIELDED DOOR WITH MOVABLE THRESHOLD

FIELD OF WORK

NUCLEAR MEDICINE

- SHIELDINGS AND DOORS

Door suitable for use in protected hospitalization, radiotherapy, brachytherapy and cyclotron self-shielding rooms. The SPM doors have sliding doors with pneumatic movement. To guarantee continuity of shielding of the bunker in the access cabinet, the size of the door is such that its shielding covers the four sides of the cabinet, as recommended in the safety guidelines. A special control circuit carries out two important functions:

- Regulation of both opening and closing velocity
- Providing acceleration and deceleration ramps when in proximity of the stop position.

The SPM doors are equipped with laminated panels with a colour chosen among the Print and Pine colour charts, with an aluminium frame that covers the wing when the door is open

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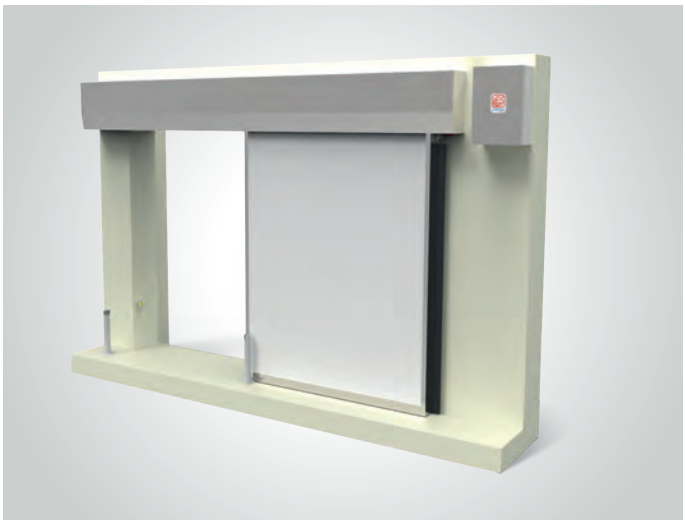
SPF

SLIDING SHIELDED DOOR WITH FIXED THRESHOLD

FIELD OF WORK

NUCLEAR MEDICINE

- SHIELDINGS AND DOORS



SPF series doors have a sliding wing and are supplied with pneumatic movement. To guarantee continuity of shielding of the bunker in the access cabinet, the size of the door is such that its shielding covers the 3 sides of the cabinet (right, left and top), as recommended in the safety guidelines. It has a shielding made of lead, paraffin, cadmium and polyethylene and it is of the fixed threshold type: the panel slides flush to the floor, at a distance of about 5 mm and the sealing against radiations in the lower part is guaranteed by a special construction solution of the shielding envisioned at the base of the panel, that has the function of realizing a sort of labyrinth between the panel itself and the floor. The doors are operated by a double-acting pneumatic cylinder which ensures smooth, linear and extremely silent movements.

SMF

SLIDING SHIELDED DOOR WITH FIXED THRESHOLD

FIELD OF WORK

NUCLEAR MEDICINE

- SHIELDINGS AND DOORS

Door suitable for use in protected hospitalization, radiotherapy, brachytherapy and cyclotron self-shielding rooms.

It has a shielding made of lead, paraffin, cadmium and polyethylene (variable thickness according to needs) and it is of the fixed threshold type: the panel slides flush to the floor, at a distance of about 5 mm, and the sealing against radiations in the lower part is guaranteed by a special construction solution of the shielding envisioned at the base of the panel, that has the function of realizing a sort of labyrinth between the panel itself and the floor.

SPI

PNEUMATIC HINGED DOOR

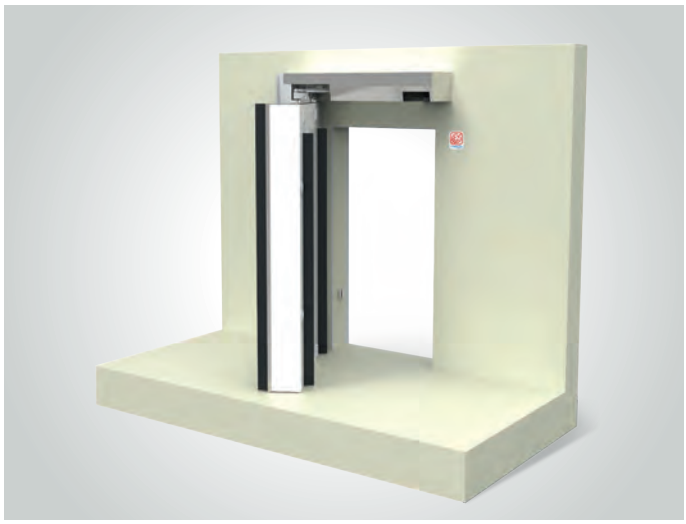
FIELD OF WORK

NUCLEAR MEDICINE

- SHIELDINGS AND DOORS

SPI shielded doors are supplied with a Comecer pneumatic control including a pneumatic cylinder.

It has a shielding made of lead, paraffin, cadmium and polyethylene (variable thickness according to needs). It is of the fixed threshold type: the panel slides flush to the floor, at a distance of about 5 mm and the sealing against radiations in the lower part is guaranteed by a special construction solution of the shielding envisioned at the base of the panel, that has the function of realizing a sort of labyrinth between the panel itself and the floor.



MEASUREMENT AND MONITORING

Comecer Radioactivity Measurement Systems aim to guarantee full personnel safety and protection from radioactive emissions.

They serve to measure radioactivity of the hands, feet and clothes of operators, and the entire environment of a radiopharmacy, hospital PET department, radiopharma production facility and nuclear medicine hospital department.

SMARTGUARD

ENVIRONMENTAL MONITORING SYSTEM

Comecer SmartGuard allows a PET-Cyclotron facility and pharmacy to implement a controlled monitoring environment, including comprehensive means to handle and document (exceeded) alarm levels and logging of measuring data.

The modular and flexible system permits operators to have a real time and continuous control of the whole facility by means of a clear and immediate visualization of all potentially dangerous events.

The system is flexible in the sense that it can be configured to meet the specific needs of a site, where these needs can be of a regulatory, production monitoring and/or safety related nature.

The system is modular in the sense that there is a choice of modules available, which modules can be used to build small scale decentralized systems up to centralized, department wide, monitoring systems..

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- LAB MANAGEMENT
- MONITORING

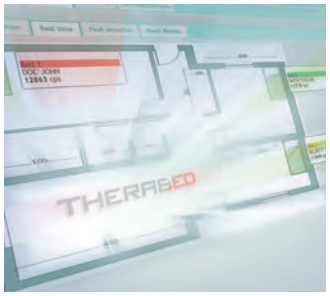
PRODUCT HIGHLIGHTS

- Modular and flexible system
- Real-time control
- Export event history
- Virtual maps
- Event notification via mail
- Up to 128 Detection Units
- cGMP compliant

Detection Units for the following tasks are available:

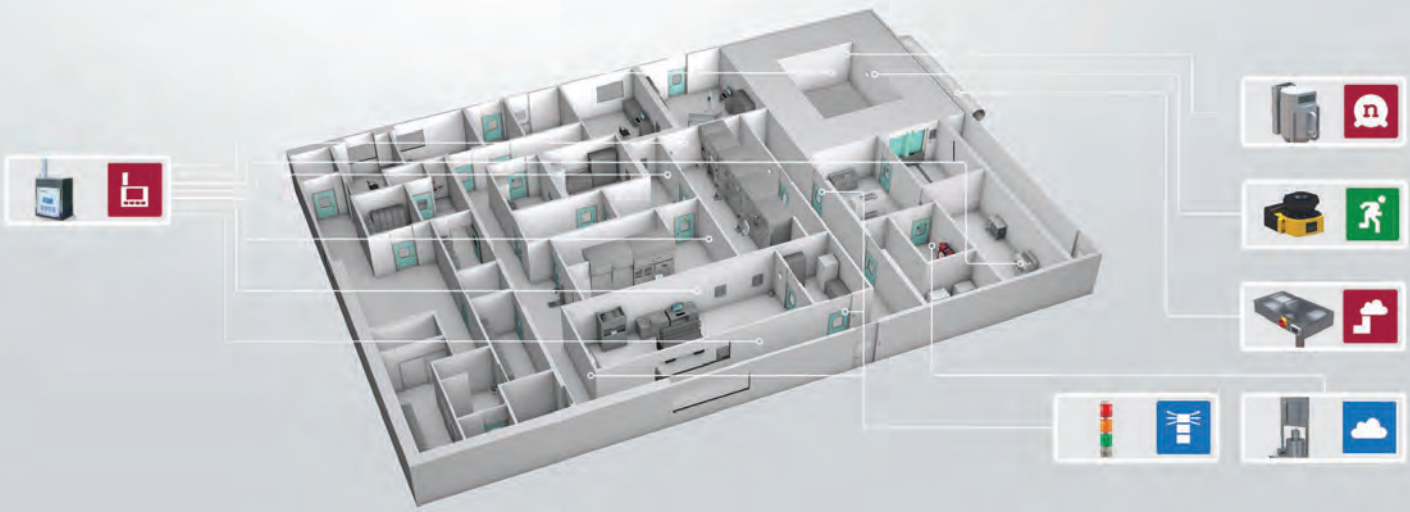
- Production monitoring (hot cell)
- Area monitoring (lab)
- Air monitoring (stack/room/hot cell)
- Neutron monitoring (vault)
- Clean room monitoring (isolator)

RELATED PRODUCTS



THERABED
Metabolic radiotherapy management system | **60**

ACS
Air compressing station | **106**



ACS

AIR COMPRESSING STATION

The system collects potentially radioactive air from inside hot cells during radiopharmaceutical production or after a malfunction of the synthesis modules.

The air is extracted from the hot cells and stored inside pressurised tanks.

Once the stored radioactivity has decayed, the air, no longer contaminated, is discharged in the extraction conduit of the laboratory general ventilation

FIELD OF WORK

GMP RADIOPHARMACY

- LAB MANAGEMENT
- MONITORING

PRODUCT HIGHLIGHTS

- Modular and flexible system
- Monitoring by Geiger probe
- Marinelli beaker
- Remote control system
- Connection to the cyclotron
- Up to 16 hot cells connected to the same system and up to 5 chambers in production simultaneously
- Pressure gauges to measure the pressure in the extraction circuit
- Available with 2 or 4 storage tanks
- 50-litre vacuum tank
- Vacuum pump to aspire the air from the hot cells and compress the air to the tanks

TECHNICAL DATA

Air storage tank capacity	200 l each
External dimensions	1200 x 800 x 1820 mm (w x d x h)
External dimensions - mobile tank	513 x 513 x 1576 mm (w x d x h)

RELATED PRODUCTS

BBS SERIES
Shielded cells for synthesis modules | **14**

THEODORICO 2
Robotic dispensing isolator for vials | **8**

PHAEDRA SERIES
Shielded isolators for dispensing | **26**

VLB SERIES

HAND-FOOT-CLOTHING MONITOR

VLB-303-2 and VLB-303-2-ST are the new hand-foot-clothing monitors where a small footprint, a robust stainless steel surface and a detection technology based on failure-safe plastic scintillation detectors are the key features. The plastic scintillation detectors are developed specifically to measure the beta and gamma emitting isotopes that are used in the Nuclear Medicine departments.

VLB-303-2 model is one of the most economical hand-foot-clothing monitors on the market. It uses two plastic scintillation detectors: one patented double-sided hands detector and one foot detector. The detachable hand detector can also be used to measure the clothes or to determine which foot is contaminated.

The VLB-303-2-ST model adds a detector for the measurement of the activity in the stomach based on an end-filter GM tube and a detector capable of measuring the activity in the thyroid. The thyroid detector is based upon a NaI detector.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- DOSE CALIBRATION
- MONITORING

PRODUCT HIGHLIGHTS

- Simple and intuitive use
- LCD touch screen
- Modern and essential design
- Reliable and accurate
- Unlimited isotopes
- Software-based settings

TECHNICAL DATA	***VLB-303-2***	***VLB-303-2-ST***
Number of channels	2, up to 10000 cps.	4, up to 10000 cps.
Hand detector	Plastic scintillator, 240 cm^2, sensitive on both sides	
Foot detector	Plastic scintillator, 1050 cm^2	Plastic scintillator, 1050 cm^2
Thyroid detector	-	2" NaI
Stomach detector	-	6.1cm^2 end window GM Tube
Weight	32 kg	43 kg
External dimensions	356 x 760 x 1234 mm (w x d x h)	808 x 760 x 1476 mm (w x d x h)

ISP

DISPOSAL SYSTEM FOR RADIOACTIVE ORGANIC WASTE WITH SEPARATE DECAY UNITS

It is a system for the storage and the decay of organic waste deriving from the use of radioactive substances for diagnostic and therapeutic purposes.

The radioactive waste produced is held for a certain amount of time inside a collecting tank and not directly introduced into the public drainage system: the system only discharges these waste products when their radioactivity level is below the values allowed by the current standards. This is achieved by the use of a system of storage tanks where the radioactivity decays until it reaches the set values.

FIELD OF WORK

NUCLEAR MEDICINE

- STORAGE AND TRANSPORT
- MONITORING

PRODUCT HIGHLIGHTS

- Liquid sorting unit
- Imhoff purification unit
- Clarified water sorting unit
- Storage unit
- Decay unit
- Containment and overflow unit
- Sample collecting unit and washing circuit
- Discharge and lifting unit
- Power and control unit
- Pneumatic supply unit

The system includes biodegradation Imhoff containers and a computer for remote management of the entire disposal cycle. Using the personal computer, plant operators can check all the disposal phases.

All operations, from the sample analysis up to the discharge into the public drainage system, take place without any contact with the tanks. Technological integration, safety and reliability of systems, simplicity of management.

HOT CELL ACCESSORIES

VPHP GENERATOR

VAPOR PHASE HYDROGEN PEROXIDE GENERATOR

In nuclear medicine, decontamination and sterilization of isolators is an important aspect in the daily practice of those who work in this field, and a requirement which today is particularly challenging and difficult.

The use of VPHP allows effective and safe decontamination.

- Automatic and repeatable decontamination process in aseptic environment
- Guaranteed reduction with 6 log reduction
- Compact size and low impact on the laboratory
- Reduced overall system cost.

Comecer is well aware of the potential of VPHP and the importance of making it also available in the field of nuclear medicine. We have worked to design integrated solutions that would allow anyone who wanted to use this method to have a product fit for their purpose.

FEATURES

- Performs decontamination tasks safely and effectively according to the highest pharmaceutical standards,
- Reduces the time spent by an operator in routine procedures,
- Automates and makes the decontamination process in an aseptic environment repeatable,
- Integrates an automatic decontamination phase into the production process
- Reduces mounting dimensions and the impact on the laboratory
- Can be located within the technical compartment of the laboratory ensuring a better approach to cGMP
- Allows a unique reference point for the installation, validation and service of the integrated isolator + generator solution

After much effort, we have finally reached this goal: a hydrogen peroxide generator that can be integrated in all our shielded isolators for aseptic processes. This integrated system can reach the target for the decontamination process: log 6 reduction.

TECHNICAL DATA

Flow rate	30 - 70 m^3/h
H_2O_2 tank capacity	2 l
Type of disinfectant	H_2O_2 hydrogen peroxide solution (30%-35%)
Weight	180 kg
External dimensions	480 x 858 x 1322 (w x d x h)

RELATED PRODUCTS

BBST SERIES
Shielded isolators for dispensing | **22**

PHAEDRA SERIES
Shielded isolators for dispensing | **26**

TALIA SERIES
Shielded isolators for dispensing | **30**

THEODORICO 2
Robotic dispensing isolator for vials | **8**

SPEEDY GLOVE

AUTOMATIC PORTABLE GLOVE INTEGRITY TESTER

Speedy Glove is a battery-powered glove tester that performs leak testing on gloves installed on isolators or RABS where a strict separation between the isolated area and the external environment is required.

The system performs pressure decay integrity tests that comply with the requirements of ISO 14644-7 Annex E.5.

Speedy Glove is compatible with all currently available glove flanges, is fitted with a touch-screen that can be used with gloves, and is extremely fast in carrying out the test (up to 30% faster than the market standard).

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- TESTING

PRODUCT HIGHLIGHTS

- Compact size
- Extremely fast operation
- Highest accuracy
- Complete touch-screen
- RFID technology
- Wi-Fi ready
- VPHP compatibility for Reverse Test
- cGMP compliance

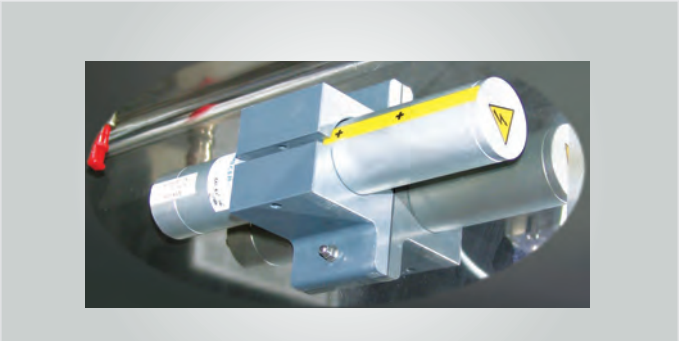
The system boasts a number of peculiar and patented characteristics which make the Speedy Glove unique on the market in terms of performance and flexibility.

There is, in fact, a unique system of rapid inflation of the glove that fills it with air in a few seconds during the leak test, saving between 3 and 5 minutes each test compared to the times usually required by similar devices on the market.

It does not need to be connected to pneumatic circuits or compressed air tanks but can independently manage all the phases of the glove integrity testing process.

SMART GEIGER

HOT CELL RADIATION MONITOR



SMART GEIGER is a device for detecting radioactivity inside hot cells. Its main function is to lock the door when the dose rate rises above a pre-set alarm threshold.

Alternatively, the instrument can be used to monitor the outlet air duct. In the event an alarm is triggered, the hot cell air inlet and outlet valves are closed (optional supply). The alarm threshold can be set from the membrane keyboard.

The device consists of a detector probe and counting electronics that allows reading the measurements and managing the alarms. The radiation-sensitive element (detection probe) is installed inside the hot cell, whereas the counting unit is mounted on the panel. The device has a beam-on signal inlet, which is used to turn off the probe high voltage. This ensures a longer life of the Geiger.

The detection unit includes two energy compensated GM tubes (model ZP1201 and ZP1313 or equivalent); this unique solution allows it to:

reach an high dose rate range

increase GM tubes lifetime due to minimisation of GM saturation

use a single probe both for air exhaust monitoring and for radiation detection inside the hot cells.

The device is password-protected (two password levels, which can be changed by the user).

AVC & AVCL

AUTOMATIC VENTILATION CLOSING SYSTEM FOR CHAMBERS AND/OR PRE-CHAMBERS

AVC is an automatic ventilation closing system which allows, in the event of radioactive substance release via hot cell ventilation conduits, to block ventilation, close the inlet conduit and the air outlet of the hot cell and simultaneously open the valve connecting the hot cell to the contaminated air storage system (see Comecer ACS).

The system starts automatically Geiger notices an excessive value of radioactivity in the air exit, or if the operator manually selects the starting controls of a hot cell.

AVCL is an automatic ventilation closing system that includes also a includes set-up for sanitisation system with VPHP (Vapor Phase Hydrogen Peroxide) connected directly to the hot cell ventilation system and managed separately from the chambers in decontamination.

The system also automatically runs a leak test inside the main chamber and pre-chamber.

AVCL provides:

- chamber isolation with the aim of periodically checking the seal (leak test)
- support for the VPHP generator for bio-decontamination.

RTS - RADIONUCLIDE TRANSFER SYSTEM

LIQUID AND GAS RADIOFLUIDS DISTRIBUTION SYSTEM

The radiofluids (liquid or gas) distribution system has the following features:

- modular architecture and availability of various configurations for the desired number of destination cells.
- direct transfer of the radioactive material from the cyclotron to the destination cells,
- possibility to avoid manual operations, also minimizing any dead times between bombardments,
- possibility for the operator to select the destination cells for release of the radioactive material,
- control over the destination cells, with radionuclide release authorization only if all safety conditions are complied with,
- real time management, monitoring and control.
- waste management: always present one valve to wash the line after the delivery
- possibility to have the RTS with or without shielding, according to the customer's layout. The shielding can be 80mm of lead or absent.

These features are assured by a system of automatic valves controlled via Ethernet, through designated software, which also makes it possible to release the radionuclide through the operator panel.

The high flexibility and modularity represent this product's added value.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

PRODUCT HIGHLIGHTS

- Modular architecture and customizable solution
- Real time management, monitoring and control
- Easy waste management
- Low dead volume
- Easy maintenance

PASS-THROUGH BOXES

Comecer produces Pass-through Boxes with double interlocked doors for the passage of prepared items and substances between two rooms that must be kept isolated from each other.

Specifically designed for nuclear medicine departments, hospitals and laboratories, they can also be used in research facilities.

ILK-102 & ILK-202

SINGLE AND DOUBLE SHIELDED PASS-THROUGH BOXES

ILK-102 and ILK-202 are lead stainless steel pass-through boxes for the delivery of radiopharmaceuticals and radioisotopes by the suppliers. The pass-through box needs to be built into an outside wall of the laboratory or hospital; it is accessible on both sides by a door.

The doors are shielded with lead and can be locked. For easy transportation of the packages a special rolling mechanism is integrated in the bottom of compartment. The doors open to the right. A special model is available with the doors mounted at an angle of 90°.

ILK-202 pass-through box consists of two compartments. The upper compartment is big enough to store two generators boxes. The lower compartment can be used, for example, for the storage of a mobile Krypton generator.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- ACCESSORIES
- SHIELDINGS AND DOORS
- STORAGE AND TRANSPORT

PRODUCT HIGHLIGHTS

- Ideal for delivery of radiopharmaceuticals and radioisotopes by suppliers
- Positionable on the external walls
- Accessible on both sides
- Internal special rolling mechanism
- Shielded doors on both sides

TECHNICAL DATA

Shielding (Pb)	10 mm
Front door shielding (Pb) (side of the laboratory)	30 mm
Weight	500 kg
Passage dimensions	655 x 955 mm (w x h)
Internal dimensions	600 x 700 x 900 mm (w x d x h)

BU-ID

PASS-THROUGH BOX WITH INTERLOCKED DOORS

This pass-through box is used for passing mixtures and substances from one laboratory room to another.

It is equipped with two hinged doors, one on the frontal part and one on the posterior part, with a pneumatic interlocking system: it is therefore only possible to open one of the doors if the other is closed, thereby guaranteeing the safety of the operators by maintaining the quality of the relative rooms.

FIELD OF WORK

NUCLEAR MEDICINE	GMP RADIOPHARMACY

- ACCESSORIES
- SHIELDINGS AND DOORS
- STORAGE AND TRANSPORT

PRODUCT HIGHLIGHTS

- Internal chamber made of AISI 316L stainless steel
- Mirror-Bright internal surface finish
- Maximum ease and effectiveness of decontamination procedures
- Interlocked doors

TECHNICAL DATA

Shielding (Pb)	5 mm
Weight	60 kg
Maximum load	20 kg
Wall thickness	100 ÷ 300 mm
Passage dimensions	295 x 295 mm (w x h)

BU-IV & BU-IV-EXP

VENTILATED PASS-THROUGH BOXES WITH INTERLOCKED DOORS

This pass-through box is studied to solve the problem of materials transiting through different environments, for example the hot chamber and the quality control area, avoiding potential downgrading of classified environments. The air is aspirated by the external area and sent to the hot chamber, after having been filtered by a HEPA filter inside the pass-through box, keeping it at positive pressure compared to both the hot chamber and the exterior.

The pass-through box, classified in Class D, enables the opening of the interior hatch only if the exterior one is closed and vice versa, enabling the air present inside it to be switched between closure of one hatch and opening of the other. Also, the shielding made with Pb 10 mm allows protection of the operators outside the hot chamber from risk of exposure.r.

FIELD OF WORK

NUCLEAR MEDICINE | GMP RADIOPHARMACY

- ACCESSORIES
- SHIELDINGS AND DOORS
- STORAGE AND TRANSPORT

PRODUCT HIGHLIGHTS

- Ventilation system by HEPA filter
- Internal chamber made of AISI 316L stainless steel
- Mirror-Bright internal surface finish
- Maximum ease and effectiveness of decontamination procedures
- Interlocked doors
- Shielded door

TECHNICAL DATA	***BU-IV***	***BU-IV-EXP***
Shielding (Pb)	10 mm *(only hot chamber side)*	10 mm *(only hot chamber side)*
Weight	137 kg	185 kg
Maximum load	20 kg	20 kg
Internal dimensions	354 x 550 x 354 mm (w x d x h)	454 x 660 x 454 mm (w x d x h)
Functional frontal aperture	295 x 295 mm	395 x 395 mm
External dimensions	522 x 708 x 1631 mm (w x d x h)	624 x 817 x 1621 mm (w x d x h)

OPERATOR SHIELDINGS

VLS SERIES
MOBILE BED SHIELD

These bed shields are used to protect personnel from radiation during the visit of a patient. The lead shielding has a variable thickness depending on the model. The shields are mounted inside a stainless steel frame on 4 swivel wheels. The window is made of acrylic lead glass and provides a shielding equivalent to a lead thickness of 0.8 mm (for 110 KeV)

TECHNICAL DATA

Window material	Acrylic lead glass
Structure material	INOX AISI 304 - Scotch-Brite™
Shielding (Pb)	2 ÷ 3 mm
Weight	50 ÷ 100 kg
External dimensions	660 ÷ 1260 x 1130 ÷ 2000 mm (w x h)

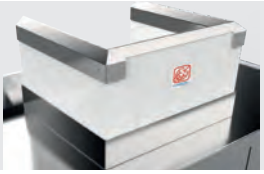
VLS-PET
MOBILE PET LEADSHIELD

This movable bed shield is used to protect personnel from radiation during injection of PET radiopharmaceuticals and examination of the patient. Due to the small size of this shield, contact with the patients is not inhibited. The shield can be used in the application and gamma camera room as well. Two handles are integrated on the sides for easy manipulation of the shield. The angled lead glass window is mounted on top of the shield. At the patient side a small height adjustable shelf is mounted which can carry a weight of approx. 10 kg.

TECHNICAL DATA

Shielding window (eq. Pb)	10 mm
Weight	approx. 120 kg
Dimensions lead glass window	400 x 280 mm (w x h)
External dimensions	400 x 1500 mm (w x h)

OLK-101
LEAD BRICK ENCLOSURE



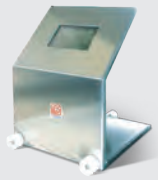
This enclosure wall is made of interlocking euro norm lead bricks, which eliminated radiation leakage. The bricks are all coated with epoxy paint. The structure has two stainless steel trays: an external one for the containment of bricks and an internal one for a simple decontamination. An upper casing, always in stainless steel, makes the structure extremely stable.

TECHNICAL DATA

Frame material	INOX AISI 316L - Scotch-Brite™
Shielding (Pb)	50 mm
Weight	~260 kg
External dimensions	518 x 458 x 346 mm (w x d x h)

BMI
SLIDING PROTECTION FOR BENCHES

Stainless steel sliding protection with lead shielding and shielded glass window.



TECHNICAL DATA

Structure material	INOX AISI 304 - Scotch-Brite™
Shielding (Pb)	10 ÷ 50 mm
Weight	45 ÷ 175 kg
Glass dimensions	180 x 120 mm (w x h)
External dimensions	350 x 350 x 490 mm (w x d x h)

LKV SERIES
LEAD GLASS BARRIER

Protective lead glass shield, ideal to go with the bench brick protection.

TECHNICAL DATA

Material	Lead glass
Coating	INOX AISI 304 - Scotch-Brite™
Shielding (Pb)	***LKV-10*** 10 mm - ***LKV-13*** 30 mm ***LKV-50*** 50 mm
Shielded glass window dimension	250 x 200 (d x h)
External dimensions	500 x 500 x 340 mm (w x d x h)

SHIELDED CONTAINERS

PSN

SHIELDED CONTAINER FOR SYRINGE TRANSPORT

Shielded container for safe transport of syringes already equipped with their own shield

TECHNICAL DATA

Structure material	INOX AISI 304 - Scotch-Brite™
Shielding	5 ÷ 6 mm
Weight	5 kg
Internal dimensions	200 x 50 x 40 mm (w x d x h)
External dimensions	288 x 108 x 133 mm (w x d x h)

PF SERIES

TRANSPORT AND COLLECTION CONTAINER

Suitable for transport and drawing of radioactive substances contained in glass vials. Cylindrical body with screw-on plug for vial placement and pierced plug for drawing the radioactive liquid. Surface treated with epoxy paints.

TECHNICAL DATA

Shielding (Pb)	20 mm
Weight	4.5 ÷ 5.5 kg
Pit dimensions	29 ÷ 38 x 79 ÷ 98 mm (Ø x h)
External dimensions	62 ÷ 79 x 123 ÷ 142 mm (d x h)

CP SERIES

CONTAINER FOR TRANSPORT AND STORAGE

Container for safe transport and storage inside the laboratory of sources and bottles /vials containing radioactive substances. Cylindrical body treated with epoxy decontaminable paints.

TECHNICAL DATA

Shielding (Pb)	30 ÷ 50 mm
Weight	15 ÷ 70 kg
Pit dimensions	40 ÷ 80 x 80 ÷ 140 mm (Ø x h)
External dimensions	110 ÷ 180 x 320 ÷ 430 mm (w x h)
External dimensions	288 x 108 x 133 mm (w x d x h)

CP-CTC

TROLLEY FOR TRANSPORT OF SHIELDED CONTAINERS

Made of steel with rubber wheels, equipped with refolding pole for pulling and screwing device for locking in the container. Epoxy decontaminable painting. Suitable for transporting all containers.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Maximum load	150 kg
Weight	15 kg
External dimensions	420 x 370 mm (w x h)

VC SERIES

STAINLESS STEEL VIAL CONTAINER

Vial container for personal protection. The vial containers are made of stainless steel with 4 mm lead shielding. The VC comes standard with one adapter for your vial.

TECHNICAL DATA

Construction material	INOX AISI 304 - Scotch-Brite™
Lead shielding	4 mm
Height	59 mm
Inside diameter	34 mm
Lead glass windows	**VC-0** None - **VC-1** 1 - **VC-2** 2

CF18-T

TUNGSTEN SHIELDED CONTAINER FOR VIAL TRANSPORT

The CF18-T shielded container is in tungsten and is used to transport radioisotope vials. The top is locked by means of a fixed joint (Bayonet catch). The lock is equipped with an O-ring seal that ensures a perfect tightness. The CF18-T shielded container is also equipped with a built-in handle to enable easy transport.

TECHNICAL DATA

Shielding (W)	29.5 mm
Weight	14 kg
Pit dimensions	33 x 57 mm (Ø x h)
External dimensions	93 x 130 mm (Ø x h)

CF18-PB

LEAD SHIELDED CONTAINER FOR VIAL TRANSPORT

The CF18-PB shielded container is made of 40 mm lead and fully coated with AISI 304 stainless steel. It is used for the transportation of radioisotope vials. The perfect cover latch is obtained by a locking ring, also in stainless steel, and air sealing is guaranteed by a silicon gasket on the upper part of the container itself. The CF18-PB cover is equipped with a stainless steel retractable handle, for easy transport. The design of the CF18-PB allows many containers to be easily stacked, optimizing your storage operations.

TECHNICAL DATA

Shielding (Pb)	40 mm
Weight	18 kg
Pit dimensions	33 x 58 mm (Ø x h)
External dimensions	134 x 167 mm (Ø x h)

PVC-O

PERSPEX VIAL CONTAINER

Perspex vial container for the shielding of beta radiation. The vial shield is polished on the inside to guarantee a clear view.

TECHNICAL DATA

Construction material	Perspex
Thickness	10 mm minimum
Vial shield	Standard for 5 mm vials

CF18-TA

"TYPE A" EXTERNAL CASE FOR FDG TRANSPORT CONTAINERS

For the transport of radioactive material we provide a special case where materials are placed inside the shielded containers. The case is made of polyethylene (plastic material ensuring resistance and lightness at the same time). It is equipped with an airtight closure with perimeter gaskets, reinforced corners, safety lockups, handle for an easy transporting and an internal pressure compensation valve for airfreight. The interior of the case is coated with a shock-absorbing material.

TECHNICAL DATA

Brand	PELI
External material	Polyethylene
Case weight	3.9 kg
Total Weight (Case + CF18-T)	17.9 kg
Max. activity which can be transported	3500 mCi
Dose ratio on the "Type-A" case surface	<2 mSv/h
Total Weight (Case + CF18-PB)	21.9 kg
Max. activity which can be transported	3500 mCi
Dose ratio on the "Type-A" case surface	<2 mSv/h
Total weight (Case + SSC (3 units))	17.4 kg
Max. activity which can be transported	25 mCi
Dose ratio on the "Type-A" case surface	<2 mSv/h
External dimensions	300 x 300 400 mm (w x d x h)

SXC SERIES

LEAD SHIELDED CONTAINER FOR SYRINGE TRANSPORT

Containers to transport Comecer 10 ml and 5 ml BD type syringes with pierceable cap (equipped with PST or "nude" shielding). Series SXC containers are made of lead and covered in fibre-reinforced plastic composite materials.

The total equivalent shielding (including the PST, if applicable) is 15 mm of lead. The containers are closed by a threaded device and are equipped with a stainless steel built-in handle for transport. The type is distinguished by color coding:

- S5C container for a 5 ml syringe with Comecer pierceable cap or needle* - blue
- S5CP container for a 5 ml syringe with Comecer pierceable cap and PST shielding - light blue
- S10C container for a 10 ml syringe with Comecer pierceable cap - dark green
- S10CP container for a 10 ml syringe with Comecer pierceable cap and PST shielding - light green.

TECHNICAL DATA	**S5C**	**S5CP**
Shielding (Pb)	15 mm	15 mm(with PST)
Weight	5.2 kg	5.2 kg (with PST)
Color code	Blue	Light blue
External dimensions	65 x 250 mm (Ø x h)	55 x 250 mm (Ø x h)

TECHNICAL DATA	**S10C**	**S10CP**
Shielding (Pb)	15 mm	15 mm (with PST)
Weight	5.4 kg	5.4 kg (with PST)
Color code	Green	Light green
External dimensions	65 x 250 mm (Ø x h)	55 x 250 mm (Ø x h)

** The S5C container can contain 5 ml syringes with maximum total needle length of 45 mm (including the Luer Lock fitting)*

SHIELDED SAFES

CTF-50

SHIELDED SAFE FOR ACTIVATED FOILS AND TARGETS

Shielded safe suitable for the storage of activated foils and targets under complete safety conditions. Continuous lead shielding and hinged front door with key lock.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Shielding (Pb)	50 mm
Weight	213 kg
Internal dimensions	211 x 158 x 237 mm (w x d x h)
External dimensions	315 x 306 x 366 mm (w x d x h)

CCR SERIES

SHIELDED SAFE FOR RADIOISOTOPES

Shielded safe suitable for the storage of radioisotope vials under complete safety conditions. Continuous lead shielding with changeable thickness. Hinged front door with key lock

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Number of internal compartment	1 ÷ 6
Shielding (Pb)	25 ÷ 50 mm
Weight	120 ÷ 280 kg
External dimensions	315 x 306 x 366 mm (w x d x h)

SHIELDED WASTE CONTAINERS

CR SERIES
CANISTER FOR RADIOACTIVE WASTE

Container suitable to collect, in conditions of absolute safety, radioactive solid waste.

Equipped with a special opening that enables the lid to be lifted and translated. The system operates via an helical screw controlled by a foot pedal.

TECHNICAL DATA

Structure material	INOX AISI 304 - Scotch-Brite™
Shielding (Pb)	3 ÷ 5 mm
Weight	25 ÷ 30 kg
Capacity	20 ÷ 40 l
External dimensions	280 ÷ 380 x 500 ÷ 515 mm (Ø x h)

WC-101
WASTE CONTAINER

This is a single cylindrical waste container with lid.

TECHNICAL DATA

Shielding (Pb)	10 mm
Weight	20 kg
Internal Ø	150 mm
Internal height	230 mm

SNC-103
SHARP NEEDLE CONTAINER

This shielded container is used for storage of contaminated needles. The exterior of the container is finished with an impact proof powder coating. The container is covered with a stainless steel top lid. The lid, which covers the hole, is made of aluminium.

TECHNICAL DATA

Shielding (Pb)	3 mm
Internal dimensions	290 x 177 x 250 mm (w x d x h)

WC-300/WC-303
WASTE CONTAINER

These movable containers are used for radioactive waste. They have been designed specifically to fit the standard blue plastic hospital containers. The containers are made of stainless steel. The plastic hospital container is placed inside the waste container underneath the opening. A shielded lid covers the opening. The door is lockable. The WC-303 waste container has a foot-pedal operated lid.

TECHNICAL DATA

Shielding (Pb)	3 mm
Weight	100 kg
Internal dimensions	340 x 420 x 650 mm (w x d x h)
External dimensions	410 x 450 x 810 mm (w x d x h)

SYRINGE SHIELDINGS

PST SERIES

TUNGSTEN SYRINGE SHIELD

Tungsten shield for syringes, equipped with an ergonomic notch in the central part to make the syringe handling easier. Suitable for 5 ml and 10 ml syringes.

TECHNICAL DATA

Construction material	Tungsten
Shielding (W)	4 ÷ 7

Suitable for Comecer dispensing systems

BHT SERIES

TUNGSTEN SYRINGE SHIELD

This is a compact syringe shield with a lead glass window and clamp lock. The lead glass is completely encapsulated in tungsten material. For this reason radiation leakage is not possible. The interior of the shield is colored white for clear visibility. The shields offer a shielding of 2 mm tungsten. Suitable for 1 ml, 2 ml, 3 ml, 5 ml and 10 ml syringes.

TECHNICAL DATA

Construction material	Tungsten
Shielding (W)	2 mm

BHP SERIES

UNI-LOCK TUNGSTEN PET SYRINGE SHIELD

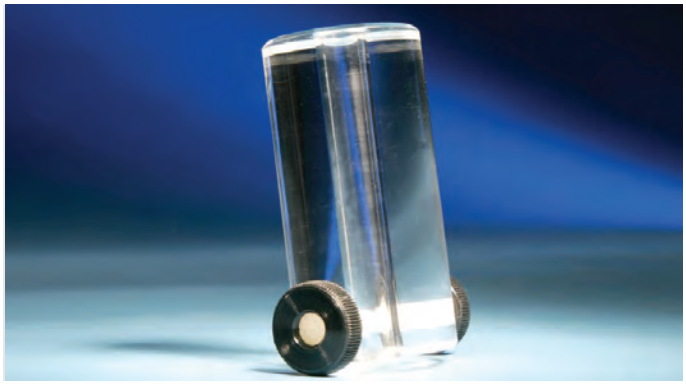
New 511 Kev tungsten syringe shield for use with PET radiopharmaceuticals with ABS cover. The shield is fitted with screw locking mechanism and with lead glass window. The lead glass window is 11-13 mm thick offering 3-4 mm Pb equivalent shielding. The new hexagon body shape helps to prevent the syringe shield from rolling when left on a table. Suitable for 1 ml, 2 ml, 3 ml, 5 ml and 10 ml syringes.

TECHNICAL DATA

Construction material	Tungsten
Shielding (W)	7.5 mm

PH SERIES

PERSPEX SYRINGE SHIELD



Perspex syringe shields for the shielding of beta radiation.

The shield is polished on the inside to guarantee a clear view on the syringe. The syringe is fixed with 2 Teflon screws. The syringe shields will be made to fit the syringe models. Suitable for 1 ml, 2 ml, 5 ml and 10 ml syringes.

TECHNICAL DATA

Construction material	Perspex
Thickness	PH-1: ~8 mm PH-2: ~12 mm PH-5: ~10 mm PH-10: ~11 mm

LABORATORY FURNITURE

DKR
SHIELDED CUPBOARD

Stainless steel cabinet to store low activity radioactive kits.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Shielding (Pb)	3 mm
Weight	331 kg
External dimensions	700 x 700 x 1800 mm (w x d x h)
Number of shelves	2

ISOLA
WORK BENCH WITH REAGENT SHELVES

Stainless steel double work bench with reagent holder. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	275 kg
External dimensions	2000 x 1200 x 1830 mm (w x d x h)
Number of drawers	12 (6 each side)
Drawer internal dimensions	500 x 600 x 250 mm (w x d x h)
Number of shelves	3

FSI-C
SHIELDED REFRIGERATOR

Stainless steel cooling cabinet with freezer for low activity heat-sensitive radioactive kit.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Shielding (Pb)	3
Weight	359 kg
External dimensions	700 x 700 x 1800 mm(w x d x h)
Capacity refrigerator	180 l
Capacity freezer	40 l

SR4
SHIELDED STORAGE BENCH FOR RADIOACTIVE WASTE

Stainless steel work bench for radioactive waste deposit. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals. The extractable trolley to transport radioactive waste containers, with key lock and a handle, is shielded on the front and on the back. The trolley ensures the operator's protection during the loading and unloading. The lower part is sealed to avoid accidentally poured liquid spilling. The rubber lined treated steel wheels ensure a good sliding movement.

TECHNICAL DATA

Frame Material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Shielding (Pb)	3 mm
Weight	175 kg
External dimensions	700 x 700 x 1020 (w x d x h)
Number of containers	4
Container capacity	20 l

LRI/LRI-SC
WASH BASIN

Stainless steel sink with hinged door. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals. Sealed lower containment compartment to prevent the leakage of liquids. Hinged front door with a key lock. Swan neck faucet for the regulation of water flow. Water flow command via photoelectric cell. Liquid collecting polyethylene container for decay, placed in the right compartment underneath the sink, and sensor that automatically stops the water flow once the maximum level is reached (only for SC model).

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	80 kg
External dimensions	700 x 700 x 1020 mm (w x d x h)

WT1
WORK BENCH

Stainless steel work bench with double door and 3-drawer unit. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals. Compartment with hinged doors

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	145 kg
External dimensions	1500 x 700 x 1020 mm (w x d x h)
Number of drawers	3
Drawer internal dimensions	500 x 600 x 250 mm (w x d x h)

WT3
WORK BENCH

Stainless steel work bench with open structure and 3-drawer unit. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	106 kg
External dimensions	1500 x 700 x 1020 mm (w x d x h)
Number of drawers	3
Drawer internal dimensions	500 x 600 x 250 mm (w x d x h)

WTL/WTL-SC
WORK BENCH WITH WASH BASIN

Stainless steel work bench with sink and hinged doors. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals. Lower containment compartment sealed to prevent the leakage of liquids. Hinged front door with a key lock. Swan neck faucet for the regulation of water flow. Water flow command via photoelectric cell. Liquid collecting polyethylene container for decay, placed in the right compartment underneath the sink, and sensor that automatically stops the water flow once the maximum level is reached (only for SC model).

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	130 kg
External dimensions	1500 x 700 x 1020 mm (w x d x h)

MWC-102
WASTE MODULE

This is a stainless steel work bench with shielded waste compartment used for storage of radioactive waste. The stainless steel waste module is shielded with 3 mm lead in all directions. A plastic container can be placed inside the module to collect the radioactive waste. An opening on the top of the work top allows access to the plastic container. The opening is covered with a shielded lid. The plastic container can be reached through the door in the front of the module. The door is lockable. The door opens to the right.

TECHNICAL DATA

Frame Material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	140 kg
Internal dimensions	735 x 630 x 725 mm (w x d x h)
External dimensions	790 x 700 x 1020 mm (w x d x h)
Capacity waste containers	40 l
Waste passage on work plan	**MWC-102** n°1 - **MWC-202** n°2

MGL-102/MGL-103/MGL-104
DRAWER SAFE

This drawer safe is used for the combined storage of radiopharmaceuticals and Tc-99m generators. The safe is also perfectly suited for the storage of PET waste. The drawers are shielded with lead and are lined on the inside with stainless steel. All drawers share a common lock. The outside of the safe is made stainless steel with Scotch-Brite™ surface finish.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Front shielding (Lead)	18 ÷ 30 mm
Lateral shielding (Lead)	12 ÷ 30 mm
Weight	475 kg
External dimensions	498 x 700 x 1020 mm (w x d x h)
Number of drawers	2 ÷ 4

KK-102
SHIELDED REFRIGERATOR

The model KK-102 consists of a stainless steel work top with an integrated shielded laboratory refrigerator (Kirsch model Labo-125) with a capacity of 120 litre and a temperature range from 2° to 20° C (digital read-out) with an acoustic alarm in case of deviation. The refrigerator has 2 interior racks allowing different heights for storage. The interior of the storage safe is lined with stainless steel. The exterior of the storage is made of stainless steel with Scotch-Brite™ surface finish. Optionally the refrigerator can be provided with a PT-100 temperature sensor.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	180 kg
External dimensions	657 x 700 x 1020 mm (w x d x h)
Refrigerator external dim.	540 x 540 x 810 mm (w x d x h)
Refrigerator capacity	120 l
Shielding (Pb)	3 mm

WBT-30
WORK BENCH FOR TARGETS MAINTENANCE

Stainless steel work bench with double door and 3-drawer unit. Front and side shielding with mobile protection, equipped with shielded glass on the front side. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals. Compartment with hinged doors.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Shielding worktop (Pb)	20 mm
Front and side shielding (Pb)	30 mm
Working surface height from the ground	920 mm
Glass dimensions	180 x 120 mm (w x h)
Weight	359 kg
External dimensions	1500 x 700 x 1020 mm (w x d x h)
Number of drawers	3
Drawer internal dimensions	500 x 600 x 250 mm (w x d x h)

DMI/DMI-SC

DECONTAMINATION SHOWER

Decontamination Shower with discharge into the drainage system. Basement stainless steel shower tray with raised edge to contain liquids. Column equipped with mixer for the manual regulation of the water flow and upper spray nozzle.

- Upper spray nozzle
- PVC tent

Liquid collecting polyethylene container for decay, placed in the right compartment underneath the shower, and sensor that stops automatically the water flow once the maximum level is reached (only for SC model).

TECHNICAL DATA

Structure material	AISI 304 - Scotch-Brite™
Diameter draining pipe	20 mm
Tank capacity	60 l
External dimensions	700 x 700 x 2100 mm (w x d x h)

WDL SERIES

SHIELDED WC FOR DISPOSAL OF ORGANIC RADIOACTIVE WASTE

The system allows the collection and the decay of radioactive liquid and organic waste produced in nuclear medicine by the use of Technetium for diagnostic purposes.It consists of a WC equipped with a shredder, which sends the sewage to a collection tank in plastic reinforced by fiberglass. When this tank is full the sewage is deviated to the second tank. A timer is present which evaluates the decaying time of the sewage.

Measurement begins when the basin reaches the maximum level. It can be emptied using a key selector. The system also allows the sewage to be sampled via ball valves located on the front of the structure.

TECHNICAL DATA

Structure material	AISI 304 - Scotch-Brite™
Diameter draining pipe	20 mm
Tank capacity	60 l
External dimensions	700 x 700 x 2100 mm (w x d x h)

MOK-101

SHIELDED WORK BENCH WITH WHEELS

Stainless steel work bench with shielded compartment with hinged door. Work top with raised border for holding the liquid and no sharp edges to allow the perfect removal of any radioactive residuals. The workbanch is equipped with swivel wheels.

TECHNICAL DATA

Frame material	INOX AISI 304 - Scotch-Brite™
Steel thickness	1.5 mm
Working surface height from the ground	920 mm
Weight	180 kg
External dimensions	817 x 700 x 1020 mm (w x d x h)
Shielding (Pb)	3 mm

According to the GMP requirements (Good Manufacturing Requirements), each manufacturer has the task of identifying the validation steps which are necessary in order to prove that the critical aspects of his particular operation are under control.

Main steps of Validation:
1. URS - User Requirement Specification (by User)
2. DQ-Design Qualification (standard supply, can be covered in normal design reviews)
3. FAT-Factory Acceptance Test (standard supply)
4. SAT-Site Acceptance Test (sta ndard supply)
5. IQ-Installation Qualification (optional supply)
6. OQ-Operation Qualification (optional supply)
7. PQ-Performance Qualification (by User).

Comecer supply FAT (Factory Acceptance Test) validation protocols for every Hot Cell/Dispensing system/Isolator. Comecer perform SAT (Site Acceptance Test) and supply if requested IQ & OQ protocols (Installation Qualification & Operational Qualification). The validation protocols comply with the following standards:

- ISO 14644 (Clean-rooms and associated controlled Environments)
- ISO 10648 (Containment enclosures)
- EEC-GMP (Good Manufacturing Practice - Annex 1 Manufacture of sterile Medicinal Products)
- PDA -TR Nr 34 (Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products).

FAT (Factory Acceptance Test)
- The complete validation test for the equipment will be performed at Comecer's site. The FAT protocol will include the following tests:
- Test Instrument Data (Calibration Certificates of the reference instruments)
- System Documentation Verification (documents list for the equipment qualification)
- Construction Design Verification ("As Built drawings and diagrams")
- Main Equipment Specification Verification (correspondence with the design)
- Functionality/Interlocks Verification (Mechanical & Software)
- Glove Breach Test (only where gloves are provided)
- Unidirectional Air Flow Verification (Smoke pattern test-only with Laminar flow)
- Air Change Rate
- Air Velocity Verification (only with Laminar flow)
- Filter Leakage (Integrity test)
- Leak Tightness Test (only if applicable)
- Non Viable Particle Counts (Air classification).

SAT (Site Acceptance Test)
- The SAT will include the following tests:
- Finishing Visual check
- Main components visual check
- Internal box pressure and ventilation setting
- Utilities functionality and setting check
- Functionality/Interlocks Verification (Mechanical & Software)
- Hot test for dispensing systems (activity source supplied by Customer)
- Dose calibrator verification (activity source supplied by Customer)
- Safety devices and interlocks check
- Operator's training
- Delivery of the performed FAT protocol and documentation package including:
- Performed FAT Protocol
- Maintenance and User's manual
- Recommended spare parts list
- Certificate of compliance
- As built technical drawings (electrical, mechanical, pneumatic & process diagrams)
- Materials certificates/data sheets
- Main equipments data sheets
- Instruments calibration certificates
- Welding Processes qualification.

Optional: IQ & OQ (Installation Qualification & Operational Qualification)

If requested, as an optional service, Comecer can perform IQ-OQ validation at customer's site.

The IQ-OQ validation will be performed by qualified technicians (Comecer Validation Dept.) using calibrated instruments and the protocol will include the complete tests list as performed during the FAT, repeated again at customer's site.

Welding qualification

Stainless steel welding is the more relevant production process for Comecer. This process and the use of high quality materials such as stainless steel AISI 316L with Mirror-Bright finish grade, allow Comecer to qualify its products in the top standard in the field of isolation technology. All the boxes used for containment are welded with TIG method (Tungsten Inert Gas). The welding are made from operators that follow processes certified from the notify institution RINA, in compliance with the following norms:

EN ISO 15614-1

(PQR) Procedure Qualification Record

EN 15609-1
(WPS) Welding Procedure Specification

EN 287-1
(WPQ) Welder Performance Qualification

EN 1418
Welding operator approval certificate
All the welding qualifications are also in agreement with **the section IX of ASME Code.**

The weldings are tested by Comecer qualified operators for Penetrating Liquid Examination in according with SNT-TC-1A level II and following the specifications of the ASME rules.

Software / Hardware
Optional Requirement for Software/Hardware Control System

GAMP5 (Guide for Validation of Automated Systems)
The automation compliance with GAMP5 is self-certified by Comecer following a development sequence of the project called "Life cycle".

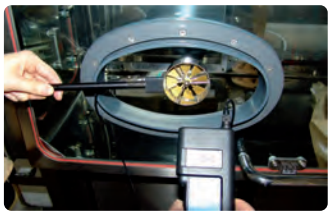
This self-certification is done by preparing the following documents, that describe the functional charateristic of Hardware/Software and their test validation:
FDS (Functional Design Specification)
HDS (Hardware Design Specification)
STS (Software Test Specifications)
HTS (Hardware Test Specifications)
Change Control.

CFR21 part11 (Electronic records; electronic signatures)
The compliance of software with the regulation CFR21 part11 is self-certified by Comecer following a documented analysis of the regulation requirements; Comecer describes how these requirements are applied in software development.

Also the requirements of CFR21 part11 are validated with a test protocol (STS Software Test Specifications).


Laminar Flow Air Velocity

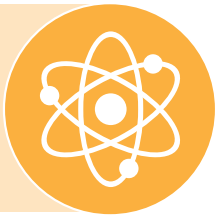

Leak tightness test


Glove Breach test


Particle Counting Test (Air classification)


Filter Leakage


Unidirectional Air Flow Verification (Smoke pattern test)



RADIOPHARMA

GMP RADIOPHARMACY
NUCLEAR MEDICINE

Официальный дистрибьютор на территории
Республики Казахстан

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COMECER

AN ATS COMPANY

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