



OUR VISION FOR DESIGN



The Easypharma Compact® shielded hot cell has been designed to provide an **ergonomic workspace** for operators. They can choose their **working position** (standing or sitting) and the “Vision +” option provides a **complete overview** of the work surface (total surface of the front door in laminated lead glass). This unprecedented comfort is complemented by **optimised radiation protection** allowing operators to work without the need for a lead apron, further improving the quality and comfort at work.



EASYPHARMA COMPACT®

CLASS A

ULTRA-COMPACT UNIT FOR THE PREPARATION OF RADIOPHARMACEUTICALS

LOW & MEDIUM ENERGY



ASSOCIATED PRODUCTS

- Scintidose dose calibrator
- Medi 405 dose calibrator
- Cont'Elu elution pots
- PFE/PME vial shields
- PDA support
- Positong handling tongs
- Easyview syringe shields





The Lemer Pax Easypharma Compact® shielded hot cell with 2 glove ports is a manual preparation hotcell for low and medium energy radioisotopes. It has been designed to assure the safety of the radioisotopes during the various operations: elution, fractionating, radiolabelling, reconstitution of radiopharmaceuticals and measurement kits, while protecting the operator from contamination and exposure (full-body) to ionising radiation from the radioactive element handled. With the Class A laminar flow (ISO 5), the integrity of the preparations and medication is ensured during each operation.

Radiobiological protection is provided by lead screens (15 mm) and lead panels (58 mm) to achieve a very low uniform dose equivalent rate outside the hot cell during all the handling phases.

The hot cell shielding allows the handling of radioisotopes common to all scintigraphic examinations in nuclear medicine (^{99m}Tc, ²⁰¹Tl, ¹¹¹In, ¹²³I, etc.).

FOCUS

The lockable generator compartment, for improved security, is equipped with two independent lifts compatible with all ⁹⁹Mo/^{99m}Tc generators and allows for the simultaneous use of two generators for daily elutions.

The 20 mm lead shielded lateral air-locks chambers are each fitted with robust stainless steel sliding trays allowing for the entrance and removal of equipment and disposable accessories used every day for work in a confined shielded area.

Opening and closing of the air-lock chambers are facilitated by a **foot pedal opening system** (to avoid unnecessary movement of the operator in the work space).

A dose calibrator compartment allows the installation of the measuring device as required, for improved versatility. Radiation to the user's hands and fingers is considerably reduced with

the "Posilift" automatic dose calibrator dipper raising system available with the Lemer Pax & Medisystem group dose calibrator references.

Two accesses are available for the two waste compartments, each with full access opening and partial magnetic opening to reduce the radiation cone. The bins are removed from inside the enclosure to secure the users and offer optimum full-body radiation protection (front removal available as an option).

Numerous sockets (electrical, USB, RJ45) are also available to the operator (4 strips) to facilitate the installation and programming of the accessories required for the various radiolabelling operations: stirrer, water bath, etc.

To guarantee effective disinfection, the shielded cell is equipped with **germicidal UV tubes with adjustable timer**.

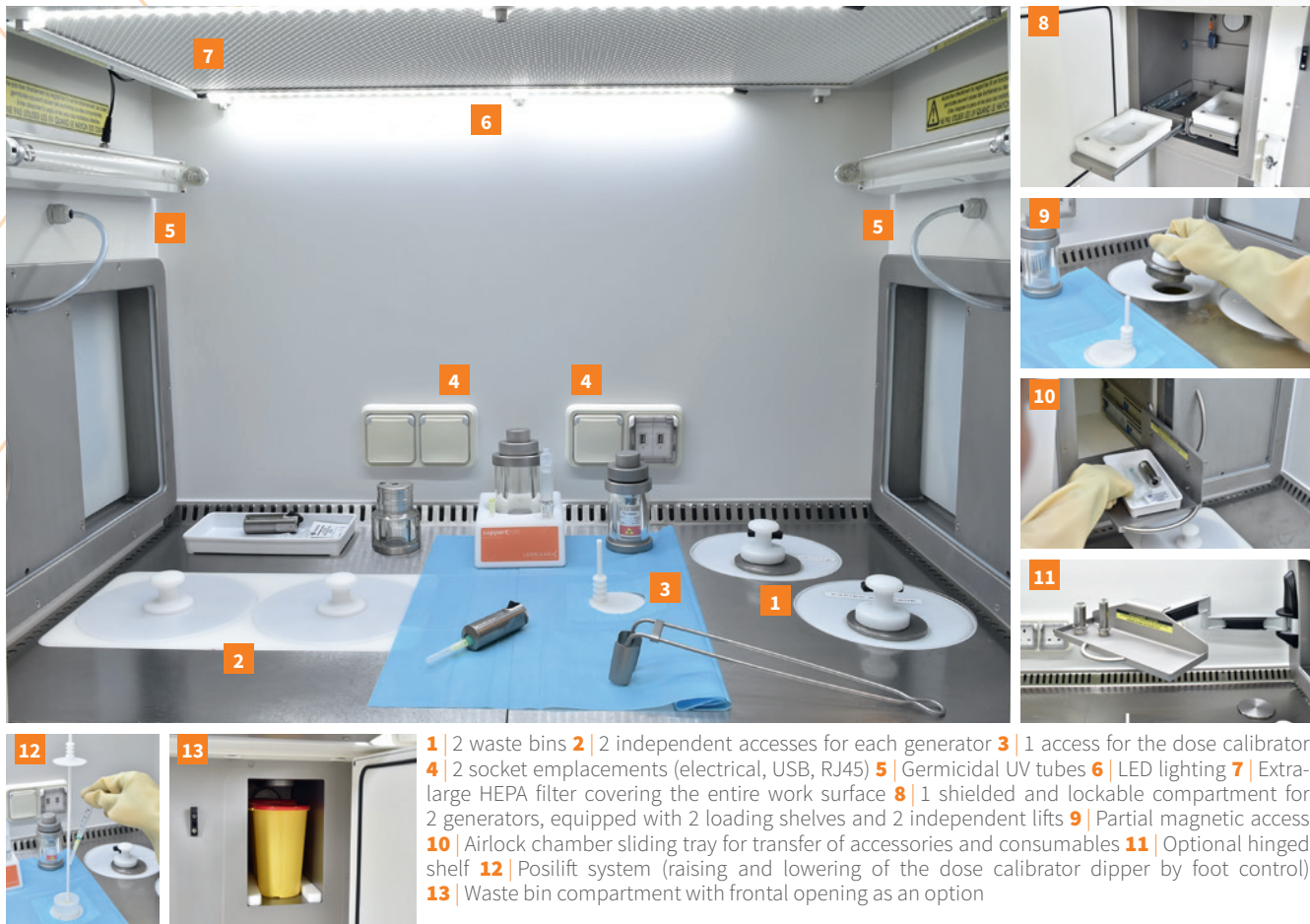
REGULATORY FRAMEWORK

The Easypharma Compact® shielded hot cell meets the requirements of the **European machinery 2006/42/EC** and electromagnetic compatibility **2004/108/EC** directives. It fulfils the requirements of the **good preparation practices** (GPP & GMP) for radiopharmaceutical drugs, provided that the customer also implements suitable procedures.

In terms of radiation protection, the Easypharma Compact® meets the requirements of the **European Directive 96/29 EURATOM of 29 June 1996**. It guarantees a **dose rate at 5 cm from the walls of less than 25 µSv/h** for the operator. Also meet the requirements of the **order of 16 January 2015 approving Decision No. 2014-DC-0463 of the French Nuclear Safety Authority (ASN)** mainly concerning the ventilation and negative pressure of the shielded hot cell, the Easypharma Compact® can be immediately connected to the ventila-

tion network, independently of the rest of the building, with a 100 mm diameter suction outlet located on the ceiling of the room. It is fitted with an exhaust fan (measurement at the cell outlet 120 m³/h, 1.7 m/s) located after the filtration system and allows to obtain a 250 Pa negative pressure inside the cell.

The different air classes in the cell are measured per standard ISO 14644. The hot cell is fitted with a self-contained ventilation and filtration system composed of a HEPA inlet filtration and aerosol and active carbon outlet filters. An **ISO 5 Class A** controlled atmosphere zone (GMP criteria) under laminar flow is provided along the entire length of the work surface by 2 fans. The generator compartment and the airlock chambers have independent air ventilation/filtration systems that ensure an ISO 7 air quality in class C (GMP criteria).



1 | 2 waste bins **2** | 2 independent accesses for each generator **3** | 1 access for the dose calibrator
4 | 2 socket emplacements (electrical, USB, RJ45) **5** | Germicidal UV tubes **6** | LED lighting **7** | Extra-large HEPA filter covering the entire work surface **8** | 1 shielded and lockable compartment for 2 generators, equipped with 2 loading shelves and 2 independent lifts **9** | Partial magnetic access
10 | Airlock chamber sliding tray for transfer of accessories and consumables **11** | Optional hinged shelf **12** | Posilift system (raising and lowering of the dose calibrator dipper by foot control)
13 | Waste bin compartment with frontal opening as an option

OPTIONS

VISION +	radiation protected front door made entirely of laminated lead glass for full visibility of the work surface.
SCREEN DISPLAYING DOSE CALIBRATOR MEASUREMENT	within the hot cell, allows for unprecedented working ergonomics for the operator.
VOCAL CONTROLS	for voice-activated use of the dose calibrator.
TWO-WAY INTERLOCKING AIRLOCK CHAMBER	allows for perfectly safe working conditions in terms of hygiene, air flow and allows to insert and remove the equipment within the work surface.
20 MM LEAD SHIELDED LARGE LATERAL AIRLOCK CHAMBER	to accommodate the dose carrier cases.
LIFT	allows the height of the hot cell to be adjusted for greater working comfort regardless of the operator's height.
RADIOACTIVITY MONITORING	informs users of the types of radiation and dose rates measured in the hot cell. Possibility of setting alert thresholds.
AIR QUALITY MONITORING (CLASS A)	allows particle counting on the work surface in real time.
30 MM ADDITIONAL LEAD SHIELDING	allows the handling of high-energy radiopharmaceuticals (^{18}F , ^{68}Ga , ^{131}I) for certain activities. A perfect backup solution for the PET preparations in case of the unavailability of the routine automatic service system.
ELECTRICAL CONTROL OF INTERIOR POWER SOCKETS	allows the use of the sockets to be managed from the external control panel, thus facilitating the programming of the use of electrical accessories present on the work surface (water bath, heating unit, etc.).
ARTICULATED SHELF	allows the placement of accessories and consumables without obstructing the work surface.
EXTERNAL ERGOTRON ARM	allows the installation of a screen and a keyboard to control the dose calibrator.
FRONT WASTE REMOVAL	to limit contamination of the work area by waste.
LOAD-DISTRIBUTION PLATES	recommended for load distribution in facilities where the permitted floor load does not correspond to the weight of the hot cell.

General

External dimensions* (1/2 airlock chamber):
L 1,553/1,894 x D 959 x H 2,165 mm

Hot cell tare weight (1/2 airlock chamber):
2 500/2 600 kg

Exterior finish: ABS white grain

Interior finish: White anti-UV PVC

Standard equipment:

- 1 airlock chamber
- 1 shielded compartment - 2 generators
- 1 shielded compartment - dose calibrator
- 2 shielded housings (1 bin each)

Type of lighting: LED

Brightness: > 1 000 Lux

Germicidal UV: 2 x 8W UVC tubes with timer

Noise level: < 63 dB(A)

Shielding thickness: 15 mm of lead

Radiation protection:

Maximum radioactivity that can be handled to obtain a dose rate less than 25 µSv/h at 5 cm from the walls**

Radionuclides	Maximum radioactivity that can be handled
^{99m} Tc	7,07.10 ⁹ TBq
¹¹¹ In	0,129 TBq
²⁰¹ Tl	1,04.10 ⁹ TBq
¹⁷⁷ Lu	0,185 TBq
¹²³ I	307 MBq

Calculation conditions: exposed sources in contact with the inner wall of the hot cell

Work surface

Dim. : L 954 x D 585 x H 565 mm

Effective dimensions:
L 954 x D 520 x H 565 mm

Work surface height: 995 mm

Work surface finish: 316L stainless steel

Shielding thickness: 15 mm of lead

Number of glove ports: 2

Diameter of the glove ports: 156 mm

Glove port axis height: 1 080 mm

Effective dimensions of the standard lead glass viewing window:
L 535 x H 368 x Th. 58 mm

Generator compartment:

Internal dimensions of the generator compartment: L 369 x D 390 x H 410 mm

Effective dimensions for each generator:
L 180 x D 350 x H 364 mm

Security and closing of the compartment:
lockable door

Shielding thickness: 50 mm of lead

Number of generators: 2

Generator models: Tecnis®, Ultra Technekow™ (other upon request)

Dose calibrator compartment

Effective dimensions of the dose calibrator compartment: Ø 220 x H 510 mm

Shielding thickness: 15 mm of lead

Dose calibrator brand: Lemer Pax, Medisystem, Capintec, Veenstra

Bin housings

Number of housings: Ø 145 x H 210 mm

Effective dimensions of a 1-bin housing: 2

Compatible waste container models:

Dispo 2L - Septoeco PBS New 2L (AP Medical)

2 opening systems available: full manual, partial magnetic

Shielding thickness: 15 mm of lead

Removal of the waste bins: from inside the hot cell as standard

Airlock chamber

Inner dimensions: L 319 x D 182 x H 232 mm

Dim. Effective dimensions:
L 246 x D 150 x H 211 mm

Sliding tray: on slide rail - max. load 10 kg

Effective dimensions of the sliding tray:
L 246 x D 150 x H 211 mm

Shielding thickness: 20 mm of lead

Effective dimensions of airlock chamber door shielded window:
L 155 x H 195 x Th. 24 mm

Options

Vision+

Effective dimensions of the window:
L 765 x H 613 x Th. 58 mm

Articulated shelf

Effective dimensions: L 300 x D 100 mm
Maximum load: 10 kg

Measurement display screen (inside the hot cell): 15 inches

Large airlock chamber

Inner dimensions: L 419 x D 182 x H 232 mm
Effective dimensions: L 346 x D 150 x H 211 mm
Effective dimensions of airlock chamber door shielded window: L 255 x H 195 x Th. 33 mm
Shielding thickness: 20 mm of lead

Removal of the waste bins from the front
Effective dimensions of the bin compartment: L 166 x D 390 x H 270 mm
Number of bins: 2
Shielding thickness: 15 mm of lead

Programmer: controls 1 socket

Adapter kit for sterile gloves

Dry contact: information on the machines status

Aeraulic

Exhaust air flow rate: 120 m³/h

Extraction filtration: HEPA filter and active carbon filter

Work surface air quality: Class A

Laminar flow filtration: HEPA filter

Negative pressure inside the hot cell:
-180 Pa (+/- 20 %)

Airlock chamber and generator air quality:
Class C

Controls: extraction shutdown

Electrical

Electrical: 230 V

Maximum absorbed current / Electrical data / Current consumption:
16 A / 2 Poles+G 50 Hz / 3 A

Interior power sockets: 4 sockets (electrical, RJ45 or USB as required)

Installation requirements

Floor load: 2 900 kg/m²

Door passage width: ≥ 90 cm

Diameter required for air extraction from the hot cell: Ø100 mm

Compressed air (service or compressor):
6 bar, 20 L/min.

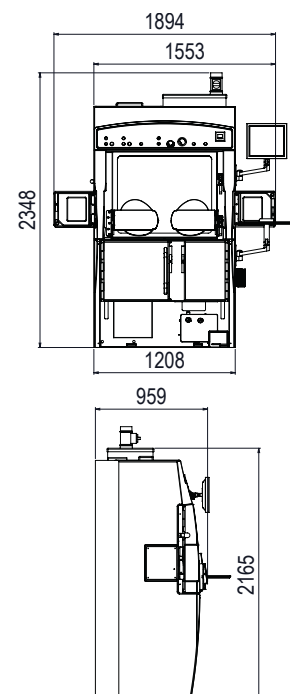
Package

Package dimensions:
L 2 200 x D 1 500 x H 2 500 mm

Package weight (product without options): 3 000 kg

Ref.: 00017860

EFFECTIVE DIMENSIONS (mm)



* The dimensions must be confirmed by a layout drawing

**Regulations in ASN Guide No.32 "In vivo nuclear medicine facilities: minimum technical rules for design, operation and maintenance"