MEDI **9000 PET 2R** CLASS A

SHIELDED HOT CELL FOR PREPARATION AND FRACTIONATING OF RADIOPHARMACEUTICALS

HIGH **ENERGY**

PET

DIAMOND GLASS

The **Medi 9000 PET shielded hot cell with 2 glove ports** is for manual preparation and designed for **measurement and fractionating of high-energy radiopharmaceuticals** for nuclear medicine **PET** activities. With its controlled **Class A (ISO 5) laminar air flow** environment over the entire work surface, it also allows **radiolabelling** to be carried out in **safe** conditions and in **compliance with good preparation practices and manufacturing practices.**

The Medi 9000 PET 2R shielded hot cell is the **most ergonomic high-energy hot cell on the market** with its **large shielded viewing window**, thus offering enhanced **working comfort**, while guaranteeing **maximum radiation protection** when handling the most irradiating radioisotopes such as ^{18}F, ^{131}I, etc.

This **multi-purpose and scalable** hot cell allows for **automatic patient dose collection** with the **"Mediflash" option** (patented product), thus contributing to additional exposure reduction for the user.

REGULATORY FRAMEWORK

The Medi 9000 PET 2R hot cell meets the requirements of the **European machinery 2006/42/EC and electro-magnetic compatibility 2014/30/EU directives.** It makes it possible to meet the requirements of ANSM's (French National Agency for the Safety of Medicines and Health Products) 2023 good preparation practices (GPP & GMP) for radiopharmaceutical drugs, subject to the implementation of suitable procedures, jointly with the customer.

In terms of radiation protection, the Medi 9000 PET 2R meets the requirements of the **European Directive 2013/59/EURATOM**. It guarantees a **dose rate at 5 cm from the walls of less than 25 µSv/h** for the operator. In order to also meet the requirements of **the order of 16 January 2015 approving Decision No. 2014-DC-0463 of the French Nuclear Safety Authority and Radiation protection Authority (ASNR)** mainly concerning the ventilation and negative pressure of the shielded hot cell, the Medi 9000 PET 2R can be immediately connected to the ventilation network, independently of the rest of the building, with a 125 mm diameter suction outlet located on the ceiling of the room. It is fitted with an exhaust fan located after the filtration system and allows to obtain a 250 Pa negative pressure inside the hot cell.

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.

Class A controlled atmosphere zone (GMP criteria) under laminar flow is provided along the entire surface of the work surface by two fans. The pot compartment and the air chambers have an independent air ventilation/filtration system which ensures **class C** air quality (GMP criteria) or **class B as an option**. The different air classes in the hot cell are measured in accordance **with the ISO 14644 standard.**

FOCUS

The work surface combines **comfort and radiation protection** with its **very large shielded viewing window made of Diamond Glass scratch and chemical resistant laminated lead glass** (thickness 130 mm). The organisation of each element and its accesses (pot, dose calibrator, waste bin) have been designed and laid out in order to allow users to carry out any manipulation operation (measurement, fractionating, etc.) in an **ergonomic** and **secure** environment. The **robust construction** of the 316L stainless steel plate construction allows **easy daily maintenance** for radioactive and bacteriological decontamination.

The lockable pot compartment with a 50 mm lead shield, for **enhanced security**, is equipped with an **electric lift**, so that the user does not have **to handle heavy loads. It is compatible with all models** of shielded multi-dose radiopharmaceutical vial models with a customised shim system, it can accommodate a pot and transfers the vial directly to the work space using the lift.

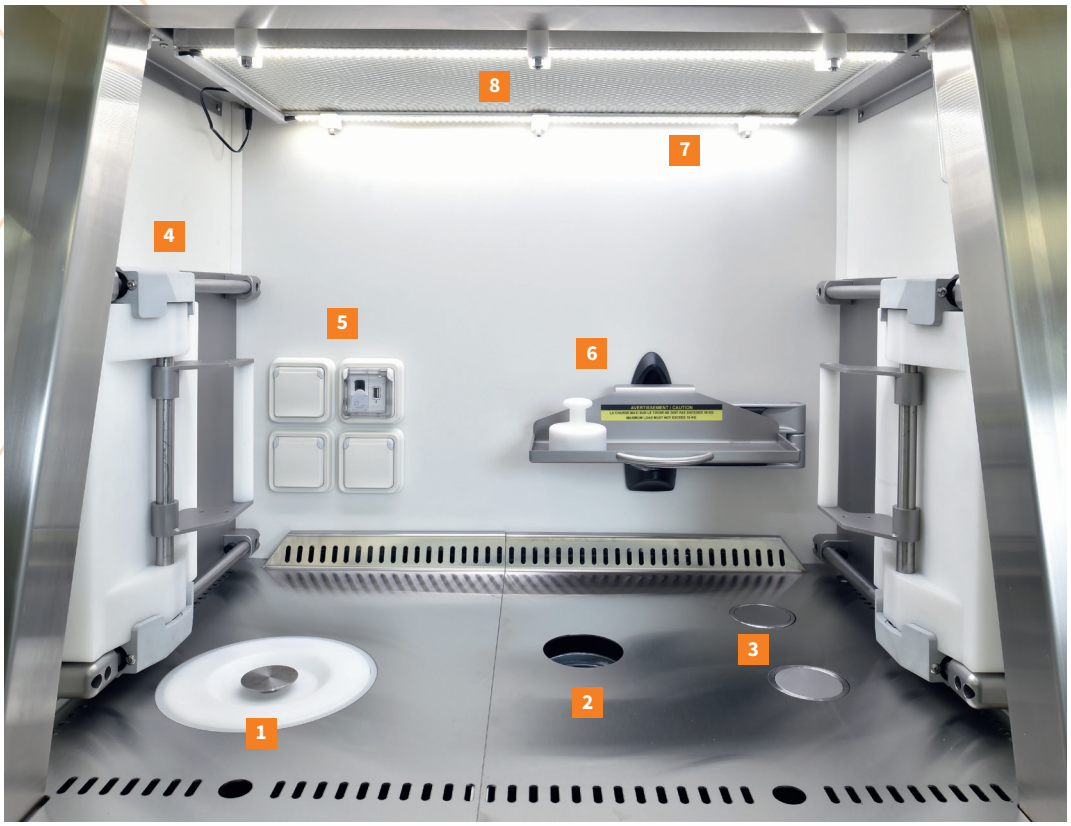
The 40 mm lead shielded dose calibrator compartment allows the installation of the measuring device of choice for improved versatility. Exposure to the user's hands and fingers is considerably reduced with the **innovating pneumatic dose calibrator dipper raising and lowering system**, available with the Lemer Pax group dose calibrator references, and the Capintec models.

The waste bin compartment features a 40 mm lead shield. It **facilitates the sorting of contaminated waste** as it can accommodate 2 independent collectors accessible under the work surface. It is lockable and secures the decay of waste. The work surface features magnetic openings, no need for an inconvenient cover with a handle. **An additional storage** space is available under the shelf supporting the waste collectors, thus allowing: the storage of constancy sources, the decay of any residual content of vials or it even allows the installation of large capacity PIMW collectors.

The shielded lateral airlock chamber with 20 mm lead is equipped with a stainless steel **sliding tray** mounted on a slide rail, **withstanding** loads of up to 10 kg, allowing to insert and remove equipment and patient doses. The airlock chamber inner doors are opened and closed with a manually-operated mechanical system. **Interlocking with the outer doors is available as an option.**

ASSOCIATED PRODUCTS

- Mediflash airlock chamber
- Exposure reduction cover
- Manujet injection unit



1 | Pot access **2** | Dose calibrator access **3** | 2 bin accesses with magnetic plugs **4** | Airlock chamber inner door with handle for manual opening **5** | Socket emplacements (electrical, USB, RJ45) **6** | Hinged shelf (optional) **7** | LED lighting **8** | HEPA filter **9** | Pot shielded compartment **10** | Pneumatic dose calibrator dipper raising and lowering system (optional) **11** | Shielded 2-bin compartment with mini storage cabinet for decay underneath **12** | 2 independent accesses with magnetic opening for waste separation **13** | Mediflash airlock chamber as a second airlock chamber to automate dose collection (optional) **14** | 4:3 or 16:9 built-in screen (optional)

OPTIONS

INTERLOCKING OF AIRLOCK CHAMBER	ensures that the air class in the work space is maintained when equipment is inserted and removed.
MEDIFLASH AIRLOCK CHAMBER	allows for automatic patient dose collection.
POSILIFT	pneumatic system for raising and lowering the sample dipper pf the Accurion$^{-226®}$ dose calibrator using the foot control.
HINGED SHELF	facilitates the storage of the various accessories and consumables used on a daily basis without cluttering the work surface.
BUILT-IN SCREEN	positioned in the hot cell, allows for unprecedented working ergonomics for the operator. Available in 4:3 and 16:9 formats.
OUTLET PROGRAMMER	manages the use of the electrical accessories present on the work surface.

CHARACTERISTICS

General

External dimensions* (1/2 airlock chambers): L 1,511/1,879 x D 1,037 x H 2,018 mm

Hot cell tare weight (1/2 airlock chambers): 4,000/4,200 kg

Exterior finish: painted steel RAL 9010 + ABS

Interior finish: Corian® + 316 L stainless steel

Standard equipment:
- 1 airlock chamber
- 1 shielded compartment - pot
- 1 shielded compartment - dose calibrator
- 1 shielded compartment - 2 waste bins

Type of lighting: LED strip

Brightness: > 1,000 Lux (ajustable via remote control)

Germicidal UV: 2 x 9W UV bulbs

Noise level: < 60 dB(A)

Shielding thickness: 40 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
^{18}F	97.9 GBq
^{131}I	71 GBq
^{68}Ga	3.22 GBq
^{177}Lu	185 GBq

Calculation conditions: sources positioned in a 30 mm lead pot

Work surface

Dim.: L 794 x D 588 x H 581 mm

Effective dimensions: L 792 x D 554 x H 560 mm

Work surface height: 1,068 mm

Work surface finish: 316L stainless steel

Shielding thickness: 40 mm of lead

Number of glove ports: 2

Diameter of the glove ports: Ø 156 mm

Glove port axis height: 1,160 mm

Effective dimensions of the Diamond Glass lead glass viewing window: L 563 x H 405 x Th. 130 mm

Pot compartment

Total dimensions: L 236 x D 437 x H 560 mm

Number of pots: 1

Max. pot size: L 160 x D 300 x H 460 mm

Security and closing of the compartment: lockable

Shielding thickness: 50 mm of lead

Lift: electrical, stroke 300 mm

Compatible pot models: Curium, AAA, PETNET, Posisafe®, Comecer (other on request)

Dose calibrator compartment

Effective dimensions of the compartment: L 208 x D 437 x H 570 mm

Shielding thickness: 40 mm of lead

Compatible dose calibrator brands: Accurion-226® from Lemer Pax and other models of the market upon request

Bin compartment

Total dimensions: L 160 x D 437 x H 470 mm

Effective dimensions: L 160 x D 424 x H 240 mm

Number of containers: 2

Compatible container models: Dispo 2L - Septoeco PBS New 2L AP Medical

Shielding thickness: 40 mm of lead

Removal of the waste bins: from the front

Airlock chamber

Inner dimensions: L 401 x D 170 x H 230 mm

Sliding tray on slide rail
Max. load: 10 kg

Effective dimensions of the sliding tray: L 406 x D 134 x H 219 mm

Shielding thickness: 20 mm of lead

Options

Interlocking of airlock chamber doors

Mediflash airlock chamber

Articulated shelf

Built-in screen (inside the hot cell):
15 inches
4:3 format (Ref: 00055560)
16:9 format (Ref: 00055564)

Socket programmer

Pneumatic dipper raising system

Isokinetic probe: real-time measurement of air quality

Aeraulic

Exhaust air flow rate: depending on configuration - contact us

Extraction filtration: Active carbon filter

Work surface air quality: class A

Laminar flow filtration: HEPA filter

Negative pressure inside the hot cell: depending on configuration - contact us

Airlock chamber and generator air quality: class C (class B as an option)

Extraction fan shutdown

Electrical

Supply voltage: 230 V

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

Interior power sockets: 2 power sockets + 1 RJ 45 / USB socket

Dry contact: for on/off status relay

Installation requirements

Floor load: 8.2 t/m^2

Door passage width: 90 cm

Diameter required for air extraction from the hot cell: Ø 125 mm

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

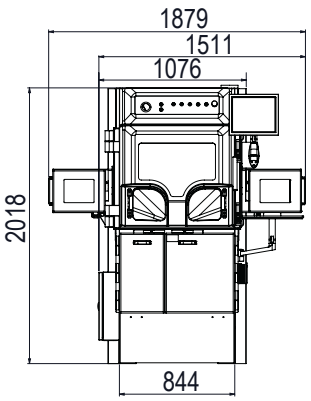
Package

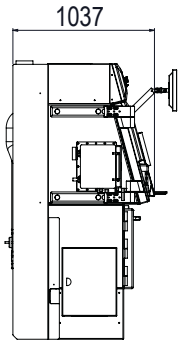
Package dimensions: contact us

Package weight (product without options): contact us

Ref.: 00034074

EFFECTIVE DIMENSIONS (mm)





* The dimensions must be confirmed by a layout drawing

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

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