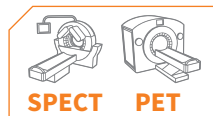


MEDI 9000 PET 4R CLASS A



SHIELDED HOT CELL FOR PREPARATION AND FRACTIONATION
OF RADIOPHARMACEUTICALS

HIGH ENERGY



The Medi 9000 PET shielded hot cell with 4 glove ports is for **manual** preparation and designed for **measurement** and **fractionation** of **high-energy radiopharmaceuticals** for nuclear medicine **PET** and **SPECT** activities. With its controlled **Class A (ISO 5)** laminar airflow across the entire work surface, it provides a **safe environment for radiolabelling** while ensuring **compliance with good preparation practices and manufacturing practices**.

The Medi 9000 PET 4R shielded hot cell features a very spacious work surface with **two workstations** for one or two users. Thanks to its **large lead glass viewing window made from**

scratch-resistant and chemical-resistant laminated Diamond Glass, the Medi 9000 PET 4R hot cell offers **unique working comfort**, while guaranteeing **maximum radiation protection** when handling the most highly irradiating radioisotopes such as ^{18}F and ^{131}I .

The hot cell is **versatile and scalable**, offering **automated collection of patient doses** with the **optional Mediflash airlock chamber** (patented product), further reducing user exposure.

FOCUS

The **work surface** (L 1700 x D 550 mm) offers both **convenience and radiation protection**, featuring two **large lead glass viewing windows (130 mm thick) made from scratch-resistant and chemical-resistant laminated Diamond Glass**. The layout and access points for the generator, dose calibrator and waste bin have been carefully designed to allow users to perform tasks such as measurement and fractionation in an **ergonomic and safe manner**. The **robust 316L stainless steel construction** makes **daily radioactive and bacteriological decontamination easy**.

The 50 mm lead-shielded, key-lockable **generator compartment** is equipped with two independent lifts, compatible with all commercially available generators, enabling the simultaneous use of two generators for daily elution procedures.

The 40 mm lead-shielded, **key-lockable pot compartment** features an **electric lift to avoid manual handling of heavy loads**. It is **compatible with all shielded multi-dose radiopharmaceutical transport containers** thanks to custom spacers, and facilitates direct transfer of the vial into the work area via the lift.

The 40 mm lead-shielded **dose calibrator compartment** can accommodate any **preferred measuring device**, providing **greater flexibility**. The optional pneumatic dipper lift **reduces operator exposure** and provides **unparalleled freedom of movement**.

The **waste bin compartment** is shielded with 40 mm of lead and includes two containers, accessible beneath the work surface, to **facilitate contaminated waste sorting**. It can be locked with a key to securely store waste for decay. The openings on the work surface are secured magnetically, preventing clutter caused by caps with handles. **Additional storage** is available below the waste container shelf, providing space for source storage, decay of any residual activity in vials, or large-capacity waste containers for potentially infectious medical waste.

The **lateral airlock chamber** features a 20 mm lead shield and is equipped with a 316L stainless steel **sliding tray** mounted on a slide rail, withstanding loads of up to 10 kg, for moving equipment and patient doses in and out. The inner doors of the airlock chamber are operated manually via a mechanical system. **An optional interlock system with the outer doors is available.**

ASSOCIATED PRODUCTS

- Mediflash airlock chamber
- Exposure reducing cover
- Manujet

REGULATORY FRAMEWORK

The Medi 9000 PET 4R shielded hot cell complies with the European Machinery **Directive 2006/42/EC** and Electromagnetic Compatibility Directive **2004/108/EC**.

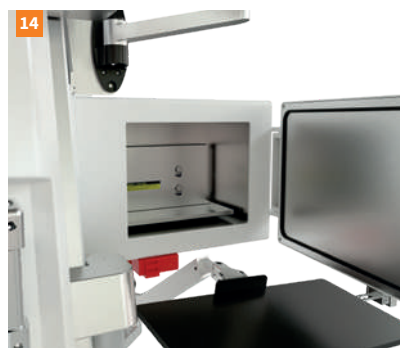
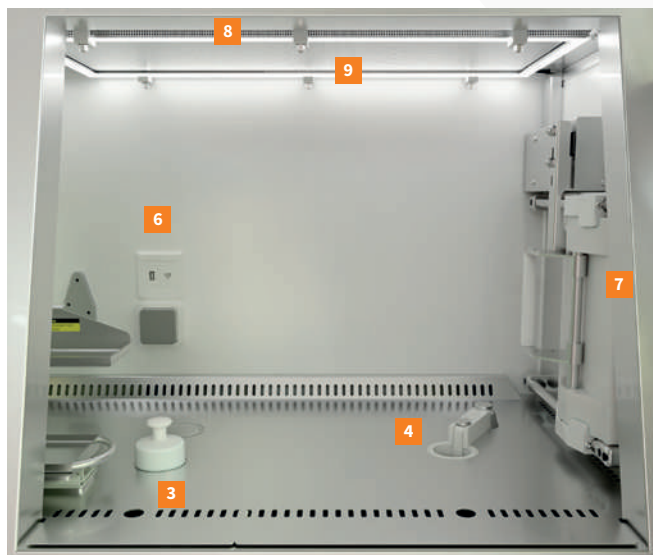
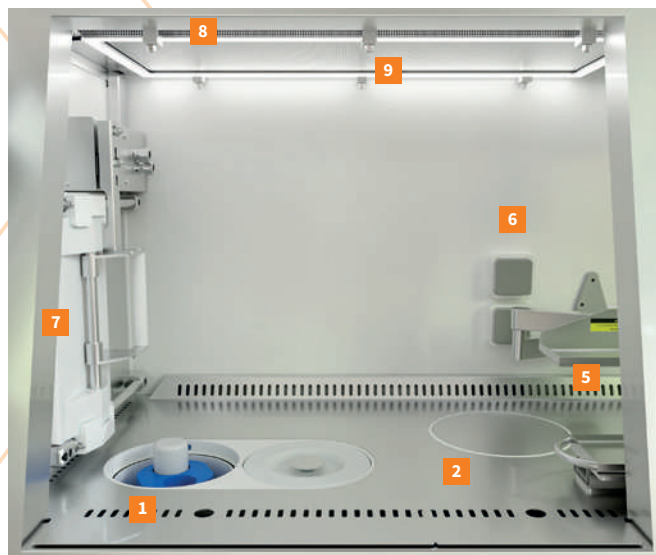
It ensures compliance with **Good Preparation Practices (GPP) and Good Manufacturing Practices (GMP)** for radiopharmaceuticals, provided the customer also implements appropriate procedures. The Medi 9000 PET 4R meets the **European Directive 96/29/EURATOM of 29 June 1996** regarding radiation protection. It guarantees a dose rate of less than **25 µSv/h at a distance of 5 cm from the walls**.

To comply with the requirements of the **French Nuclear Safety Authority (ASN) order of 16 January 2015** approving Decision 2014-DC-0463 which primarily addresses the ventilation and negative pressure of the shielded hot cell, the Medi 9000 PET 4R can be immediately connected to the ventilation network, independently of the building's

main system, via a 125 mm diameter suction outlet located on the ceiling of the room. It is also equipped with an extraction fan (with an airflow rate of 120 m³/h and a velocity of 1.7 m/s, measured at the hot cell outlet), located downstream of the filtration system, which ensures a negative pressure between 100 and 250 Pa.

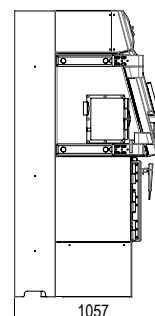
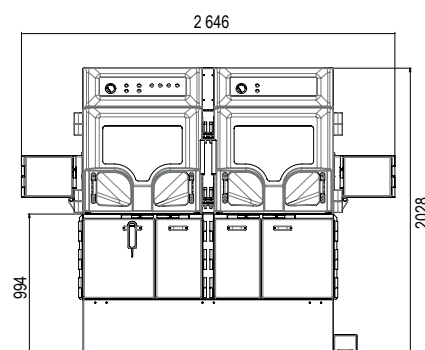
The hot cell features a self-contained ventilation and filtration system, including HEPA inlet filtration and aerosol and active carbon outlet filters.

A **Class A** controlled atmosphere (GMP criteria) under laminar flow is maintained across the entire work surface by two fans. The generator compartment and the airlock chambers are equipped with a ventilation/filtration system that ensures **Class C** air quality (GMP criteria), with an **option for Class B**. The different air classifications in the hot cell are measured per **ISO 14644**.



- 1 | Generator access 2 | Front airlock chamber access 3 | Waste bin access 4 | Dose calibrator access 5 | Articulated shelf (optional) 6 | Outlet blocks (electrical, USB, RJ45) 7 | Inner airlock chamber door with handle for manual opening and interlock system 8 | HEPA filter 9 | LED lighting 10 | Shielded generator compartment 50 mm 11 | Airlock chamber with front opening (optional) 12 | 40 mm shielded 2-bin compartment with mini decay storage below 13 | 40 mm shielded pot compartment 14 | Shielded lateral airlock chamber 15 | Pneumatic dose calibrator dipper raising and lowering system 16 | Mediflash airlock chamber in second airlock chamber to automate dose collection (optional) 17 | 4/3 or 16/9 built-in screen (optional)

EFFECTIVE DIMENSIONS (mm)



OPTIONS

SECOND GENERATOR	in place of the storage compartment.
FRONT AIRLOCK CHAMBER	in place of the storage compartment.
SECOND POT COMPARTMENT	in place of the storage compartment.
INTERLOCKING OF AIRLOCK CHAMBER	ensures the air quality class is maintained in the workspace when equipment is moved in and out.
MEDIFLASH AIRLOCK CHAMBER	allows for automated collection of patient doses.
ARTICULATED SHELF	allows convenient storage of accessories and consumables used routinely, keeping the work surface clear and organized.
BUILT-IN SCREEN	positioned at the rear of the hot cell, it provides optimal ergonomic positioning for the operator. Available in both 4/3 and 16/9 formats.
OUTLET PROGRAMMER	to control the operation of electrical accessories on the work surface.
PNEUMATIC DIPPER RAISING SYSTEM	operated by foot, reducing exposure to extremities by allowing measurements with just one hand.
ELECTRIC LOCK	on the generator compartment door.

General

Exterior dimensions* (1/2 airlock chambers): L 2,500/2,820 x D 1,050 x H 2,040 mm
Hot cell tare weight (1/2 airlock chambers): 7,300/7,500 kg
Exterior finish: Painted steel RAL 9010 + ABS
Interior finish: Corian® + stainless steel 316 L
Standard equipment: - 1 airlock chamber - 1 shielded compartment with 2 generators - 1 shielded pot compartment with elevator - 1 shielded dose calibrator compartment - 1 shielded compartment with 2 bins - 1 shielded storage compartment
Luminosity: > 1,000 Lux (adjustable via remote control)
UV Germicides: 2 x G23 9W UV bulbs
Noise level: < 60 dB(A)
Shield thickness: 40 mm lead

Radiation protection

Maximum manipulable activities to maintain a dose rate of less than 25 µSv/h at 5 cm from the walls**	
Radionuclides	Maximum Manipulable Activities
¹⁸ F	97.9 GBq
¹³¹ I	71 GBq
⁶⁸ Ga	3.22 GBq
¹⁷⁷ Lu	5,55,10 ⁹ TBq
Calculation conditions: sources positioned in a 30 mm lead pot	

Work surface

Total Dimensions: L 1,700 x D 590 x H 550 mm
Effective dimensions: L 1,580 x D 550 x H 550 mm
Work surface height : 1,068 mm
Work surface finish: 316L stainless steel
Shielding thickness: 40 mm of lead
Number of glove rings: 4
Diameter of the glove ports: Ø 156 mm
Glove ports axis height: 1,170 mm
2 Diamond Glass lead glass viewing windows: L 563 x H 405 x Th. 130 mm each

Generator compartment

Internal dimensions of the component: L 413 x H 564 x D 437 mm
Maximum generator size: L 160 x H 328 x D 220 mm
Number of generators: 2
Security and closing of the compartment: Lockable
Shielding thickness: 50 mm of lead
Compatible generator models: Tekcis®, Ultra Technetow™ (others upon request)

Pot compartment

Total Dimensions: L 310 x D 437 x H 564 mm
Number of pots: 1
Max. pot size: Ø 160 x H 190
Shielding thickness: 40 mm of lead
Lift with sliding drawer: electric with 300 mm
Compatible pot models: Curium, AAA, PETNET, Posisafe®, Comecer (other on request)

Dose calibrator compartment

Effective dimensions: L 380 x D 437 x H 564 mm
Shield thickness: 40 mm of lead
Compatible Activimeter Brands: Lemer Pax, Capintec, others on request

Bin compartment

Total Dimensions: L 310 x D 437 x H 564 mm
Effective dimensions: L 235 X D 437 X H 463
Number of containers: 2
Shielding thickness: 40 mm of lead
Removal of the waste bins: on the front under the worksurface
Compatible waste container models: Dispo 2L - Septoeco PBS New 2L AP Medical

Airlock chamber

Internal dimensions: L 400 x D 170 x H 210 mm
Sliding tray: on slide - maximum load: 10 kg
Effective dimensions of the sliding tray: L 340 x D 130 x H 210 mm
Shielding thickness: 20 mm of lead

Options

Front airlock chamber (replacing the storage system)
Interlocking of airlock chamber doors (by electric latch)
Mediflash airlock chamber
Articulated shelf (maximum load 10 Kg) Effective dimensions: L 300 x D 100 mm
Built-in screen (inside the hot cell): 15 inches
Programmer: controls 1 socket
Pneumatic dipper raising system: Compatible with Lemer Pax dose calibrator
Electric lock for generator compartment door
Partition wall (40 mm of lead): sliding and airtight, with separate ventilation system
Isokinetic probe: real-time measurement of air quality
Aeraulic
Exhaust air flow rate: 120 m³/h
Extraction filtration: Activated carbon filter
Work surface air quality: Class A
Laminar flow filtration: HEPA filter
Negative pressure inside the hot cell: -160 Pa (+/- 20%)
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 / 2P+T 50Hz / 3 A
Interior power sockets: 2 electrical sockets + 1 RJ 45 / USB socket
Dry contact: for on/off status relay
Installation requirements
Floor load: 7.3 t/m²
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 option): Contact us
Ref: Contact us

*Dimensions must be confirmed by a layout drawing

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