# PHL SERIES
## STERILE ISOLATORS FOR CELLULAR LABELING


The Cellular Labeling in nuclear medicine are classified by Good Radiopharmacy Practice Standards in the Preparation of Radiopharmaceuticals in Nuclear Medicine as "extemporaneous preparations" and must be carried out in a laminar flow hood (Class A) located in a Class B environment, or within an isolator, which can maintain sterility, located in a Class D environment.

The second solution avoids having to set up a cleanroom within the Nuclear Medicine Department and guarantees full protection of the product and the operator.

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) for the main chamber to never be 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.

All the operations normally performed within an area in the Nuclear Medicine Department intended for cellular labeling are summarised inside the isolator.

All the production phases can be monitored closely with maximum protection through the large windows.

The cleaning operations at the end of the cycle can be performed with the gloves, whereas the front wall of the work chamber can be opened completely in order to facilitate maintenance operations.

The isolator is mounted on wheels, which facilitates the maintenance and cleaning operations.

Materials can be sanitised and entered in the work chamber through the inlet pre-chamber.

The pre-chamber has a front manually-opened tempered glass door with a closing sensor and tightness system with inflatable gaskets made of pharmaceutical grade FDA-approved silicone.

A second door, equipped with the same tightness system, connects the pre-chamber with the work chamber.

Both doors have an interlock that does not allow them to be opened simultaneously. This safety device prevents the work chamber from being connected directly with the external environment, thereby guaranteeing sterility within.

A tray mounted on sliding guides is set inside the pre-chamber to facilitate transferring the materials to the work chamber.

The inner part of the work chamber is large enough to allow the handling operations and fractioning of cytostatic drugs, while in a seated position and using gloved flanges. An electric socket can be found on the rear part.

The front wall can be opened completely and is equipped with an opening handle, gas springs to balance the weight and perimeter inflatable gaskets made of pharmaceutical grade FDA-approved silicone. The wall can be tilted 6° in order to have a better view of within.

The software regulates a number of interlocks, which prevents a number of doors being opened simultaneously.

2 oval glove flanges are found on the wall equipped with ambidextrous gloves (the type of material and glove size will be defined according to the customer requirements): they have a double groove for safe replacement (the glove can be replaced without connecting the chamber with outside).

**Features and Benefits**

- Modular design and flexible configuration
- Touch screen for hot cell and dispensing system
- DOP test connections (filter leakage test)

## Equipment lines

| Models / Main equipment | PHL RIGHT AIRLOCK | PHL RIGHT PHARMA PRE-CHAMBER | PHL DOUBLE PHARMA PRE-CHAMBER |
|---|---|---|---|
| Pre-chamber right side for materials introduction | S | - | - |
| Pharmaceutical pre-chamber right side for the introduction and manipulation of materials | - | S | S |
| Pharmaceutical pre-chamber left side for the introduction and manipulation of materials | - | - | S |
| Sliding tray for transferring materials | S | S | S |
| European Power Supply | R | R | R |
| American Power Supply | R | R | R |

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

## Technical data

| | | |
|---|---|---|
| Frame support material | | Tubular AISI 304 |
| External casing material | | AISI 304 - Scotch Brite™ |
| Working chamber material | | AISI 316L - Mirror Bright |
| Lead purity | Title | Pb 98% + Sb 2% |
| Electrical panel protection rating | IP | 54 |
| Shielding (if present) (Pb) | mm | 3 |
| Shielded glass window dimensions (if present) | mm | 180 x 120 (w x h) |
| Weight | kg | 650 |
| Working chamber internal dimensions | mm | 1200 x 520 x 730 (w x d x h) |
| Internal pre-chamber dimensions (if applicable) | mm | 505 x 590 x 505 (w x d x h) |
| External dimensions with pre-chamber | mm | 1895 x 930 x 2140 (w x d x h) |

## Ventilation and Filters

| | |
|---|---|
| Working chamber | Air Quality: Class A with laminar flow (LAF) on the entire area<br>Air inlet: F9 pre-filter and U15 absolute filter<br>Air outlet: active carbon filter (on customer request)<br>Air flow rate: 100 $m^3/h$ |
| Pre-chamber side for materials introduction (if present) | Air Quality: Class B<br>Air inlet: H14 absolute filter<br>Air outlet: H14 absolute filter<br>Air flow rate: 20 $m^3/h$ |
| Pre-chamber side for handling materials (if present) | Air Quality: Class B<br>Air inlet: H14 absolute filter<br>Air outlet: H14 absolute filter<br>Air flow rate: 20 $m^3/h$ |

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