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# **BBST COMBO SERIES**

### SHIELDED ISOLATORS FOR SYNTHESIS AND DISPENSING



- Modular design and flexible configuration
- Work chamber for dispensing with air quality complying with Class A "At rest" (EEC-cGMP) and equipped with laminar flow over the entire area
- Synthesis and dispensing in a single cell
- Product extraction system in shielded container by means of specific drawer.
- Dose calibrator compartment equipped with pneumatic system to move the vial in the well

The BBST COMBO shielded isolator has been designed specifically to combine a shielded housing for synthesis modules and a fractioning area in sterile conditions (A LAF Class) 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).

#### Features and Benefits

- Material introduction chamber (airlock) with air quality complying with Class B "At rest" (EEC-cGMP) and equipped with handling gloves
- Synthesis chamber with air quality complying with Class B "At rest" (EEC-cGMP)
- Waste compartment with air quality complying with Class B "At rest" (EECcGMP) and removable tray
- Duct passing between dispensing chamber and waste area equipped with airtight door
- Duct passing between the synthesis camber and waste area, equipped with airtight connections to discharge liquid waste
- Possibility of installing a product extraction system equipped with "Passthrough dose calibrator"
- Automatic Bubble Point Test

- Possibility of setting up connection and integration with COMECER automatic dispensers
- Shielded and hinged front doors
- Shielded chambers under constant negative pressure
- Possibility of installing a Geiger-Muller probe to detect radioactivity inside the synthesis and dispensing cell and door interlock management
- Possibility of connecting the hot cell to the contaminated Air Compressing Station (ACS)
- Possibility of installing ventilation isolation valves and connection to hydrogen peroxide solution generators (AVC LIGHT) for the dispensing chamber and the material introduction chamber
- Possibility of arranging a system for automatic leak tests on the dispensing chamber, the material introduction chamber, and the synthesis chamber

#### **Equipment lines**

The machine is available in different equipment lines to fulfil the requirements of any production centre.

| Models  |            |   |
|---|------------|---|
|   | BBST COMBO | BBST COMBO WITH PASS THROUGH DOSE<br>CALIBRATOR |
| Main equipment  |            |   |
| Dispensing chamber  | S          | S   |
| Synthesis chamber   | S          | S   |
| Side pharmaceutical pre-chamber for materials introduction                    | S          | S   |
| Solid waste compartment   | S          | S   |
| Dose calibrator   | S          | S   |
| Pass through dose calibrator  | -          | S   |
| Smart Geiger (internal environmental monitoring system)                       | 0          | 0   |
| Automatic Bubble Point Test   | S          | S   |
| Drawing system  |            |   |
| Drawing System for vials and syringes   | S          | -   |
| Drawing System for vials and syringes with integrated pass through calibrator | -          | S   |
| Dispenser set-up  |            |   |
| GET dispensing system set-up  | 0          | 0   |
| TIMOTHEO LT dispensing system set-up  | 0          | 0   |
| ARGO dispensing system set-up   | 0          | 0   |
| Shielded container  |            |   |
| Vial shielded container mod. CF18   | S          | S   |
| Vial shielded container mod. CF18-T   | 0          | 0   |
| Syringe shielded container mod. CTS   | 0          | 0   |

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

#### **Technical data**

|       | Carbon steel treated with epoxy paints                |
|-------|---|
|       | AISI 304 - Scotch-Brite™                              |
|       | AISI 316L - Mirror-Bright                             |
| Title | Pb 98% + Sb 2%  |
| IP    | 54  |
| mm    | 75  |
| mm    | 200 x 200 (w x h)                                     |
| kg    | 10000   |
| mm    | 559 x 742 x 499 (w x d x h)                           |
| mm    | 634 x 682 x 674 (w x d x h)                           |
| mm    | 594 x 587 x 662 (w x d x h)                           |
| mm    | 2040 x 1090 x 2549 (w x d x h)                        |
|       | Title<br>IP<br>mm<br>mm<br>kg<br>mm<br>mm<br>mm<br>mm |

#### **Ventilation and Filters**

| Dispensing chamber                     | Air classification: Class "A" with laminar flow (LAF) on the entire area |
|--|--|
|  | Air inlet: F9 pre-filter and U15 absolute filter                         |
|  | Air outlet: Active carbon filter   |
|  | Air flow rate: 100 m3/h  |
| Pre-chamber for materials introduction | Air classification: Class "B"  |
|  | Air inlet: H14 absolute filter   |
|  | Air outlet: H14 absolute filter  |
|  | Air flow rate: 20 m3/h   |
| Synthesis chamber                      | Air classification: Class "B"  |
|  | Air inlet: H14 absolute filter   |
|  | Air outlet: active carbon filter   |
|  | Air flow rate: 20 m3/h   |

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