

UniFill - Dispensing System for PET radiopharmaceuticals

Automatisiertes Abfüllsystem zur Befüllung von offenen und geschlossenen Vials

The automated dispensing system UniFill consists of the lead shielded class A dispensing cell and the directly connected class B pre-chamber. The dispensing system is installed inside the dispensing cell. The shielding at the front side can be lowered for the inactive preparation of the dispensing system through the glove ports. Lead plugs are available to perform the preparation under active conditions. Dispensing cell and pre-chamber are equipped both with LAF units and each have separate ventilation and filter systems. The complex is working under negative pressure. The pressure in the pre-chamber is lower than the pressure in the dispensing cell. The dispensing system enables the filling in open and/or closed vials of different sizes. A rotary plate is positioning the vials under each module of the dispensing system. A syringe pump is transferring the product solution through a sterile filter. Afterwards the vials are automatically dropped into the ventilated bottom lock, in which also the activity will be determined. The extraction is done directly into a lead container. The lid of the container will be automatically handled. All vials of a batch are filled consecutively according a preparation list. The determination of the activity and weight of the bulk solution and the dilution are performed in advance of the dispensing process. Significant parameters are monitored and logged.



Features Dispensing System

Automated dispensing process¹
Cycle time closed filling < 1 min/vial
Cycle time open filling < 2 min/vial

Solely use of sterile disposable material for all components which get in contact with the product solution; sterile sets are available (customized sets with any sterile filter³ possible)

Gravimetric determination of the activity concentration of the bulk solution; Dilution of the bulk solution and mixing; diluted product solution with max. 100 ml and max. 590 GBq (F-18)⁵

Activity probes for the determination of the activity of the vials Activity range: 10 MBq – 50 GBq (F-18)

Dispensing with sterile filtration in open and/or closed vials (size between 10 ml and 25 ml)²
Maximum batch size 25 vials (10 ml), 24 vials (20 ml)

Dispensing by volume with an accuracy of $\pm 2\%$ ⁴

Bar code reader to trace the pre-labeled vials

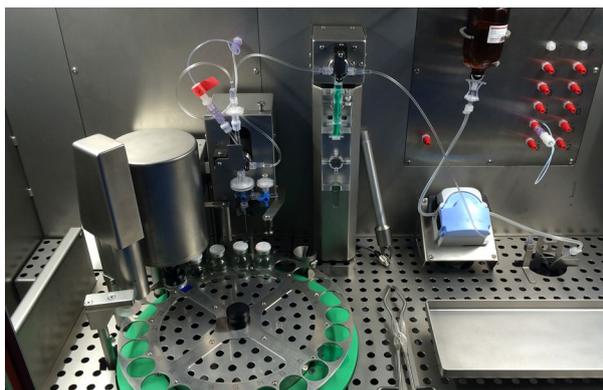
Extraction of the vials after determination of the activity directly in the lead container

¹ cycle time depends on the product solution and filled volume, cycle time may differ
² dispensing system is preset for a specific vial size, other sizes on request
³ sterile filter on request
⁴ accuracy depends on syringe, filled volume and product solution, accuracy may differ
⁵ bigger volume and activity range on request

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Technical Data

Overall dimensions (W x H x D) [mm]	ca. 2500 x 2600 x 1100
Inner dimensions isolator (working area) (WxHxD) [mm]	ca. 995 x 1000 x 495
Total weight	ca. 6500 kg
Shielding, all sides	75 mm lead
Covering	Powder-coated steel sheets
Material inner containment	AISI 304, Ra ≤ 3.2 µm
Air quality dispensing cell	Class „A“, LAF in working area LAF velocity: 0.54-0.36 m/s, digital
Air quality pre-chamber	Class „A“, LAF in working area LAF velocity: 0.54-0.36 m/s, digitally displayed
In-air filter	H13 (DIN EN 1822)
LAF filter	H14 (DIN EN 1822)
Exhaust-air filter	H13 (DIN EN 1822)
Power supply	230/400 V N/PE 50 Hz 32 A
Compressed air	min. 6 bar
Exhaust air	- 500 Pa, 20 m ³ /h



Isotope Technologies Dresden GmbH

Rosendorfer Ring 42
01328 Dresden
Germany

Tel.-Nr.: +49 351 266 34 0
Fax-Nr.: +49 351 266 34 10
itd-info@ezag.com
www.itd-dresden.de



Eckert & Ziegler

Isotope Technologies Dresden