



VON GAHLEN
FOR SURE

DOSE DIVIDERS

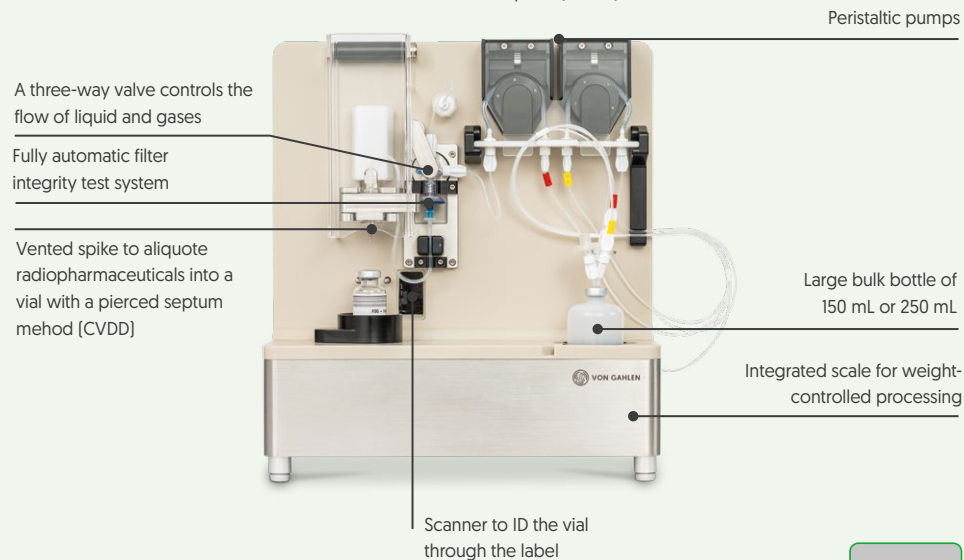
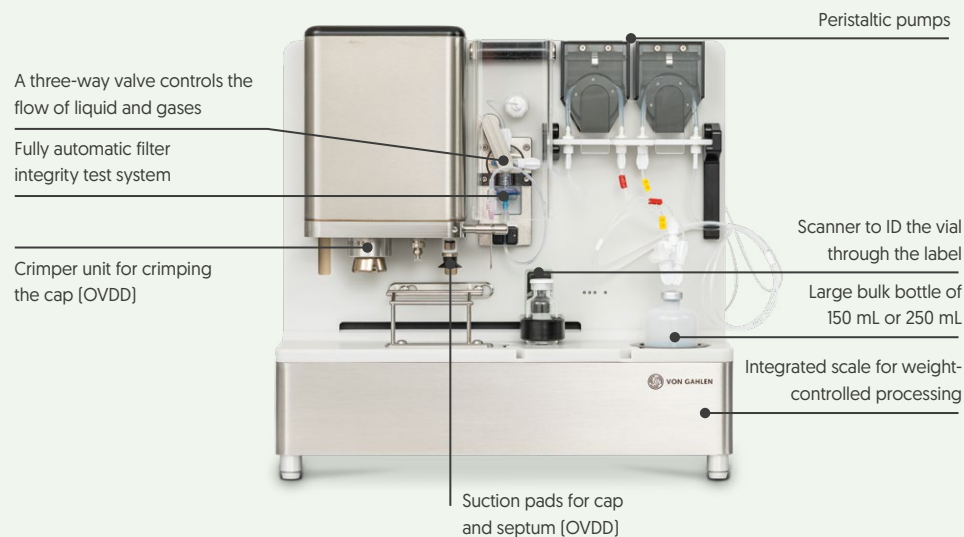
Our compact, GMP Annex 1-compliant dose dividers have a proven track record of more than 10 years in the market and are available in both Open Vial [OVDD] and Closed Vial [CVDD] dosing variants. To divide the bulk product into vials, use open-vial dosing with the OVDD and the pierced-septum method with the CVDD, respectively. When placed inside our dispensing hot cell, they provide a complete solution for aseptic manipulation and dispensing of radiopharmaceuticals into a patient dose.

The dispensing process includes batch production and the filling of pre-sterilized vials. The disposable set is specifically designed for the dose divider in accordance with GMP Annex 1 Single Use Systems and is available from Von Gahlen.

The filling procedure is automatic, with only vial measurement, input, and output done manually. When activity is present inside the hot cell, the dose dividers are remotely operated by tongs. When the hot cell is in "cold condition", the glove ports in the airtight acrylic door can be used.

The package includes a complete solution with a dose divider, an industrial controller with a large screen, intuitive user software, and two label printers. Optionally, a dose calibrator can be provided.

Variant	OVDD-CAN	CVDD-CAN
Filling method	open vial	pierced septum
Filling capacity	1 to 25 mL	1 to 25 mL
Cycle time (@5 mL)	55 s	55 s
Vial type acc. ISO 8362	R10 to R20	R10 to R20
Outside dimensions (mm) [W*D*H]	470*340*440	400*340*440
Floor space	420*270	350*270
Weight [Kg]	25	22



STANDARD FEATURES

Radiation protection

- Internal Tungsten shields for enhanced life.
- Fits best in Von Gahlen hot cells for optimal work flow and maximum operator safety.

Sample & product handling

- Automated filling.
- Easy manipulation of vials using one or two ball tong manipulation units.
- Glove ports in acrylic front door required for aseptic, cold preparation, like installing the disposable set.
- Complete integration with Product Retrieval Drawer system.

Air handling & distribution

- Designed for laminar downflow with an acrylic cover for air guidance.
- Optimal air conditions when placed in a Von Gahlen hot cell.
- The acrylic cover for air guidance ensures a sterile environment, designed in compliance with GMP standards.

Cleaning

- Housing made out of a combination of Corian and a high-grade 316L stainless steel with special micro-surface treatment.
- Exterior smooth surface finish for easy cleaning.
- Unit is compatible with 35% hydrogen peroxide vapor decontamination, generator not included.

Sensors

- Compatible with dose calibrators.
- Activity accuracy: max 10% deviation of the dispensed activity relative to the requested activity.
- Weight-based filling.
- Sensor for in-line Filter Integrity Test [FIT].
- Scanner for vial ID recognition.

System operation & control

- User-friendly and intuitive user software.
- Software-guided dosing is based on dose calibrator and recipe data.
- Create recipes to customize the workflow for each product
- Batches can contain vials for Quality Control, customers, or draining and flushing the system.
- The data of each batch is logged and stored in the database. Pre-batch reports and batch reports can be printed or paperless.
- Integrated vial and container label printing with supplied label printers.
- Reports and vial- and container labels are customizable by authorized users.
- Audit Trail logs system events and all data acquisitions, deletions, overwrites, and auditing changes, in line with risk management principles.
- The high-level system components, including the dose divider, dose calibrator and printers, are connected to the supplied controller.
- Implementation of software conforms to the Software Development Life Cycle [SDLC].
- Development and validation of software according to GAMP and is compliant with EudraLex V4 Annex 11 and 21 CFR Part 11.

Utilities

- Fully automatic in-line FIT system for pre- and post-batch inspection.
- Two label printers.
- Additional dilution, top-off, and flushing cycles available.
- Cassette-based, double-packed, sterile disposable set; see separate product sheet.
- Multiple runs are possible without waiting for decay.
- Products can be switched within 15 minutes without cross-contamination.

OPTIONAL FEATURES

- Tube cutter
- Diluent bag holder
- Various vial racks of stainless steel 316L or PEEK
- Manually exchangeable vial holders for various vial sizes, ranging from a height of 45 mm to 60 mm
- Micro suction cup system for open center caps
- Crimper for flip-off caps or regular aluminum caps

