

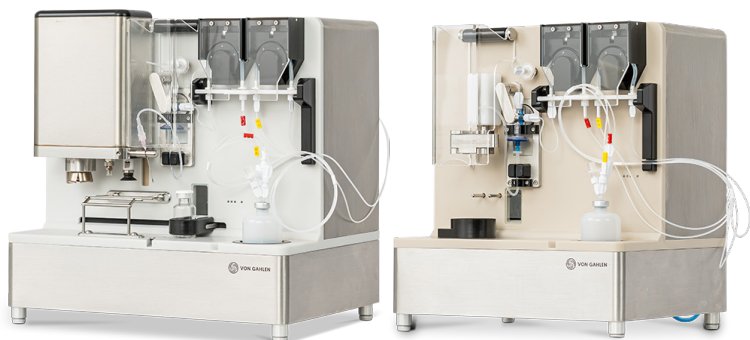


VON GAHLEN
FOR SURE



Dose Dividers

Compact dispensing solutions for sterile filling of radiopharmaceuticals that fit your needs



Dividing radiopharmaceuticals into multi-dose or unit-dose vials

Strictly controlled sterile environments

Sterile manufacturing and filling of radiopharmaceuticals in strictly controlled sterile environments are a crucial requirement outlined in Annex 1 of the EU GMP guidelines. Von Gahlen offers the advantages of automated dose dividing from regular GMP processes to the challenging environments of radiopharmaceuticals.



Challenges when dividing radiopharmaceuticals into small vials

In radiopharmacy, numerous isotopes can be used to diagnose and treat patients. All these different isotopes must be divided into bulk doses or patient-specific doses. Due to the short half-life of most radiopharmaceuticals, efficient aliquoting is essential.

Annex 1 compliance and sterile dosing

Our solutions are GMP Annex 1 compliant for sterile dosing without exposing operators to radiation or compromising process efficiency. The used technology and Von Gahlen's expertise in shielding and automation come together to ensure consistent quality, reproducibility, and safety in every batch.

Safe, efficient, sterile, and consistent **working**

Batch production and dosing of pre-sterilized vials

The two dose dividers are specifically designed for the fast dosing of radiopharmaceuticals into multi- or unit-dose vials. Their ergonomic design requires fewer actions, allowing you to work efficiently. Multiple runs can be performed without waiting for the activity to decay between batches.

Closed Vial Dose Divider (CVDD)



Our remotely operated solution for dosing with the pierced septum method.

During dosing, the ventilated spike pierces the septum of the sterile vial to fill it with the radiopharmaceutical while preventing over-pressurization.

Open Vial Dose Divider (OVDD)



Our remotely operated solution for open vial dosing.

Dose dividing process: opening, dosing, capping, and crimping of the pre-sterilized vial. The critical 'vial open' time is max 8 seconds.

Proven Performance

- ⦿ Reliable system, +10 years on the market
- ⦿ Designed according to GMP regulations
- ⦿ Well-developed hardware and evolved user-friendly software
- ⦿ Pierced septum method (CVDD) / open vial dosing (OVDD)
- ⦿ Remotely operated, aseptic manipulation and aliquoting
- ⦿ Safe and high-precision filling
- ⦿ Multi-dose or single-dose vials
- ⦿ Opening, filling, capping, and crimping of the pre-sterilized vial (OVDD)
- ⦿ Vented spike prevents vial over-pressurization during dosing (CVDD)
- ⦿ Dispense 1 up to 25 mL of the diluted radiopharmaceutical
- ⦿ Sterile disposable set – easy transition between batches
- ⦿ Supports sterility and aseptic production

To optimally serve locations with patient scheduling

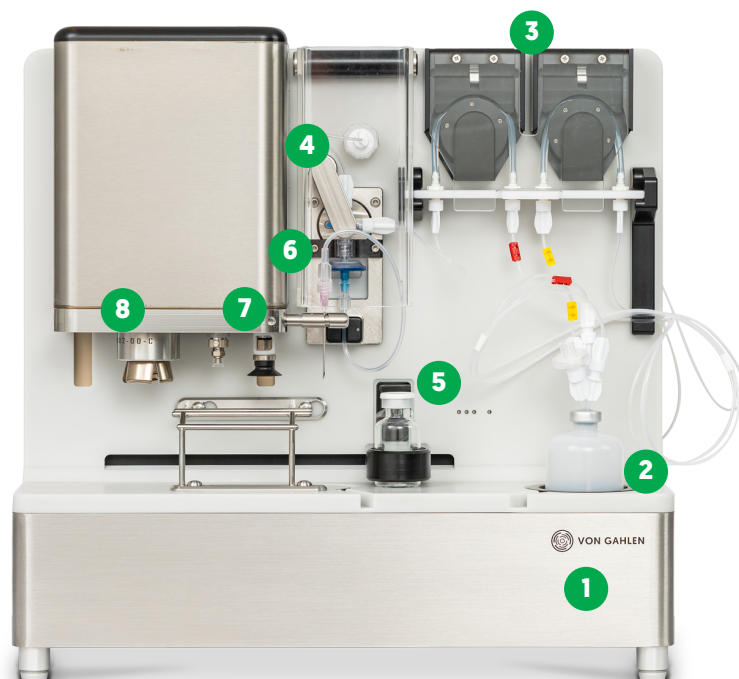


Vial handling

For both models, vial handling between the automatic Dose Divider and the hot cell is performed using the ball-tong manipulators; therefore, unnecessary automation risks are eliminated.

Advanced **Technical** features:

- 1 Integrated scale for weight-controlled processing**
Dosing radiopharmaceuticals requires high accuracy. To ensure each vial contains the correct volume, our dose dividers use weight and dose controlled filling. By measuring both the bulk bottle and the vial, a weight deviation of max 5% is achieved.
- 2 Large bulk bottle of 150 ml or 250 ml**
- 3 Peristaltic pumps**
Two pumps are used to dilute and pump the radiopharmaceutical from the bulk bottle
- 4 A three-way valve controls the flow of liquids and gases**
- 5 Scanner to ID the vial through the label**
- 6 Fully automatic in-line filter test system**
- 7 Suction pads for cap and septum (OVDD)**
- 8 Crimper unit for crimping the cap (OVDD)**
- 9 Vented needle to aliquote radiopharmaceuticals into a vial with a pierced septum method (CVDD)**



Dispensing capabilities

Cycle time

Both Dose Dividers have a cycle time of dispensing 5 ml in less than 55 seconds.

Accuracy

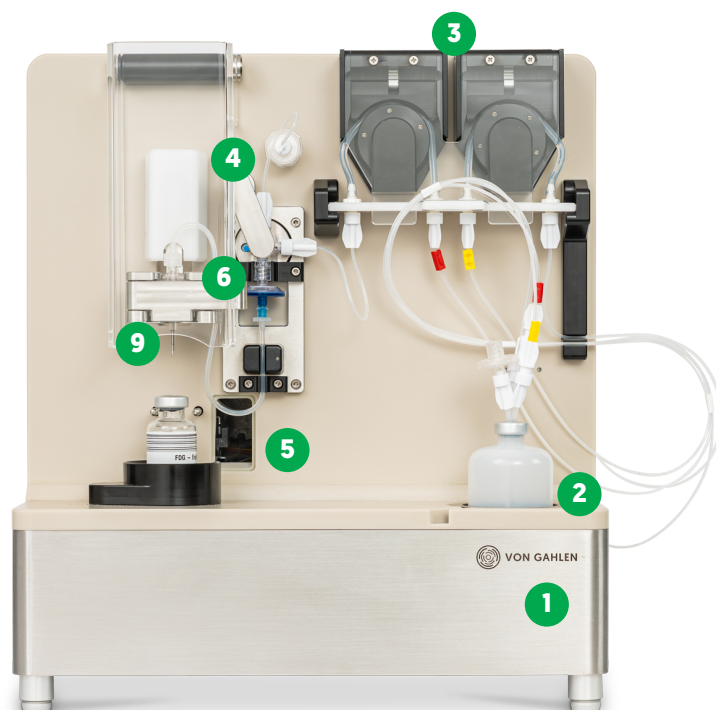
Activity accuracy: max. of 10% deviation of the dispensed activity relative to the requested activity.

Automatic lift system

The lift system and dose calibrator is fully controlled through the user software

Different products

Switching between products is easy; the maximum time is 15 minutes, with no risk of cross-contamination. It is possible to perform multiple runs without waiting for the radiation to decay between batches.



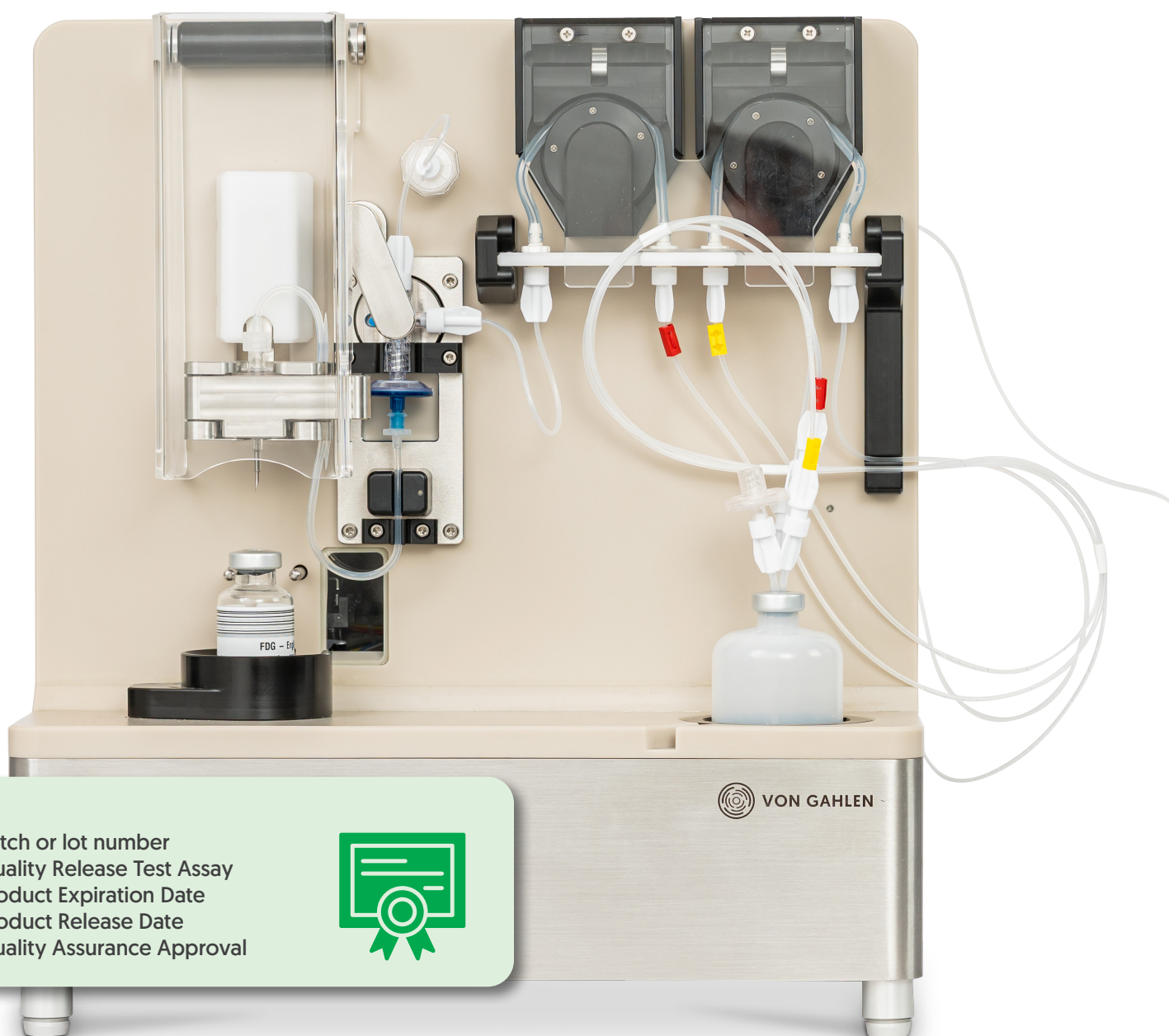
Disposable set designed to minimize the risk of contamination

The OVDD and CVDD systems use dedicated single-use sterile disposable sets, designed to support aseptic filling processes while minimizing the risk of cross-contamination between batches.

The disposable sets are specifically developed for radiopharmaceutical dosing applications and enable fast batch changeovers, efficient workflows, and consistent GMP-compliant operation.

The sets include all necessary components for handling and transferring radioactive solutions in clinical or laboratory settings. They contain standard luer locks, offering the possibility to exchange product-specific parts like the sterility filter. Other disposable sets are also available upon request.

All batches are delivered with a Certificate Of Analysis (COA) and Leachable and Extractable data is available upon request.



COA

- Batch or lot number
- Quality Release Test Assay
- Product Expiration Date
- Product Release Date
- Quality Assurance Approval



Optimize your daily workflow

Fewer actions, greater efficiency

The disposable sets are ETO sterilized and come double pouched to ensure sterility. After a batch, the set can be removed and thrown into the hot cell waste compartment. Optionally, a flushing step can be used before removal to minimize the residual activity in the set. This allows for fast switching between batches or products without waiting for the activity to decay and without risk of cross-contamination. Down time between batches is less than 15 minutes.

Using a standard luer lock connection, the disposable set can be connected directly to the target line from the synthesis unit to create a closed system. The standard disposable set contains a .22 micron sterility filter. The filter is automatically tested at the end of each batch to ensure all product is delivered sterile.



Sterility assurance

- ⦿ Single-use EtO sterilized in accordance with ISO 11135
- ⦿ Double pouched
- ⦿ Delivered with Certificate of Analysis (COA)
- ⦿ Integrated sterility filter
- ⦿ Automatic filter integrity test after each batch

Optimized dispensing efficiency

- ⦿ Fast and easy batch transition
- ⦿ Minimal downtime between productions
- ⦿ Supports multiple dispensing runs without waiting for isotope decay in between
- ⦿ Flush functionality minimizes residual activity

Designed for radiopharmaceutical applications

- ⦿ Cone-shaped bulk bottle minimizes product loss
- ⦿ Materials selected for compatibility with radiopharmaceutical processes
- ⦿ Separate disposable sets available for OVDD and CVDD configurations



Safe waste handling

After completion of the dispensing batch, the disposable set can be safely removed using ball-tong manipulators and discarded directly into the waste compartment below the hot cell, minimizing operator exposure.

Complete solution to optimize lead time and reduce manual operations

The Dose Dividers are delivered with all the necessary accessories to provide a fully functional system. A screen, keyboard and label printers for vials and lead containers are part of the standard package. Other optional accessories include:

- 🌀 vial trays
- 🌀 customizable vial holder
- 🌀 hook to hang a bag with diluent
- 🌀 cutters to quickly sever the connection with the target line and minimize down time between batches
- 🌀 For activity measurements the dose dividers can work together with various dose calibrators



Enhanced operator comfort

The OVDD and CVDD come with a dedicated electrical cabinet. This allows the machine to work completely stand-alone, only a power socket is needed to plug in the cabinet. In Von Gahlen hot cells the system can be fully integrated, so it works together with the rest of the systems.

Designed for ergonomic efficiency

- 1 Dose calibrator
- 2 Dose divider
- 3 Electrical cabinet



Seamless integration within the hot cell

Fully integrated hot cell production lines

With decades of expertise in radiation protection and GMP compliance, we design and build hot cells for both research and production. Our integrated solutions combine proven technology with innovation to meet the highest international standards.



Seamlessly integrated in our Dispensing Hot Cell (DPB)*, Modular Hot Cell (MHC), or Shielded Glove Box (SGB)*

*Our hot cells have an integrated laminar down-flow providing a GMP Class A environment for aseptic filling. Designed for seamless integration of dose dividers, it ensures safe, accurate, and efficient workflows.



Automatic dispensing system

Our OVDD and CVDD systems integrate seamlessly into your daily workflow, enabling you to precisely and quickly prepare patient doses. The integrated dose calibrator is operated via the dispensing software.

The software calculates optimal doses, scans vial labels, and generates customized identification to ensure safety and traceability. The entire dispensing process runs smoother, more efficiently, and is optimized.

Our dose dividers also offer the opportunity to optimize your daily work processes, volume based or concentration based processing, multiple label layouts per batch and different ART's (Activity Reference Time) possible per batch.

Optimizing your daily workflow and production efficiency

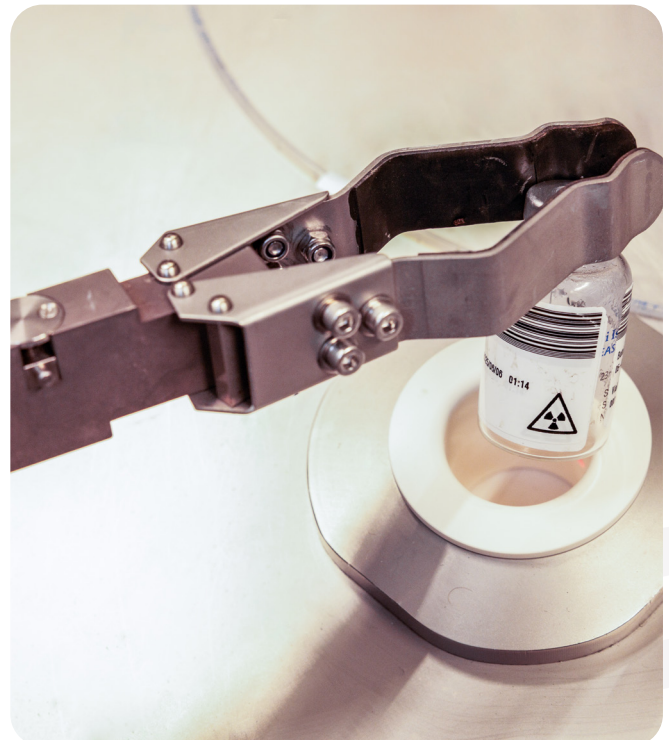


Designed for efficient daily production, the OVDD and CVDD support a smooth dispensing workflow inside the hot cell environment.

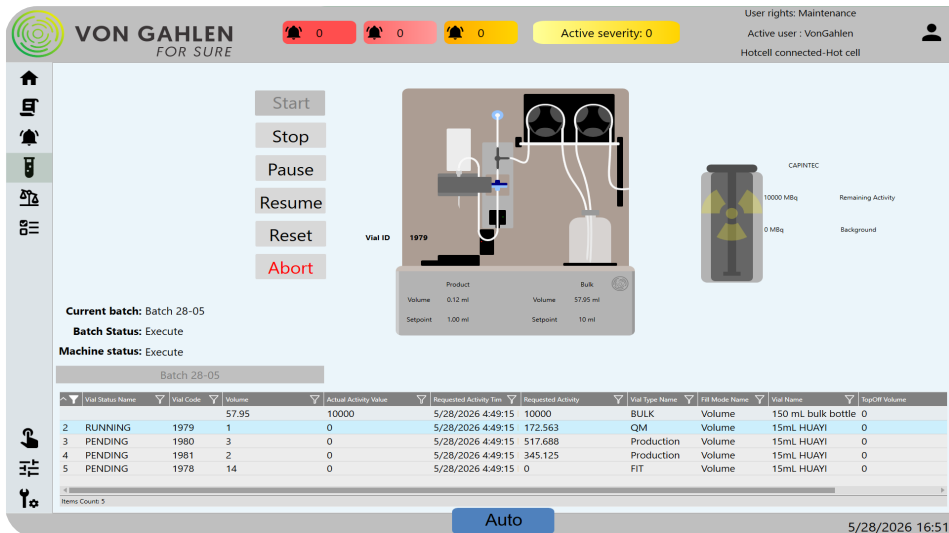
The ergonomic setup enables operators to safely perform dispensing operations using ball-tong manipulators while maintaining clear visibility and controlled handling throughout the process.

Efficient workflow integration

- ⦿ The dose dividers work optimally when placed inside our hot cells.
- ⦿ Designed for aseptically dispensing sterile radiopharmaceutical solutions.
- ⦿ Integrated laminar down flow providing a GMP class A environment.
- ⦿ Ergonomically placed ball-tong manipulators enable safe operation.
- ⦿ Easily position a fresh vial, and after filling, transfer it with minimal effort to the dose calibrator and drop tube.
- ⦿ Gently release the vial into a lead container, inside the Product Retrieval Drawer (PRD).
- ⦿ Ready to be packed in the Certified Type A packaging solution and prepared for safe transport.



Full process control, software guiding every step



A batch is a selection of several types of vials (QA, production, cleaning, test etc.) produced according to a specific recipe

Supporting your dispensing process

The included Fractionator user software was developed according to GAMP 5, and is compliant with the latest GMP Annex 11 and 21 CFR part 11 standards.

- ② Data from each batch is logged and stored in the database for the required retention time.
- ② Detailed batch reports are automatically generated at the end of each batch.
- ② A separate audit trail is available for logging all activities.
- ② The software supports automatic backups.

In Von Gahlen hot cells the software can also work together with the hot cell to operate the dose calibrator lift and the Product Retrieval Drawer for full vial traceability throughout the filling process.

Equipment

- Industrial controller
- Two label printers
- Running on a Windows application

Software requirements

We follow the guidelines for meeting the software requirements for pharmaceuticals: the GMP Annex 11 standard for Europe and its American counterpart, 21 CFR Part 11.



Complete dispensing workflow

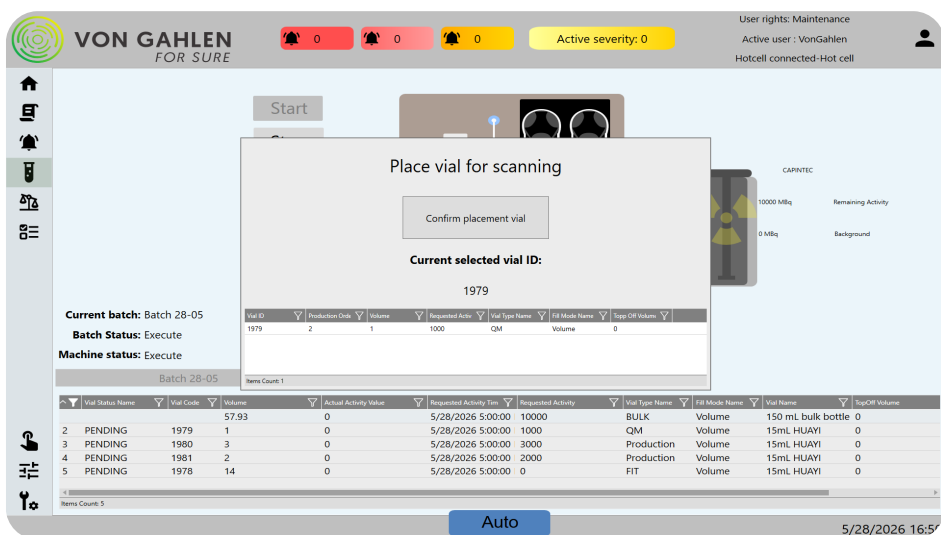
Flexible recipe and batch management

The software is built around configurable recipes, allowing the complete production process for each product to be defined while ensuring a consistent workflow. The software can also perform cold batches for validation of the device and development of production processes.

Recipe configuration

Each recipe defines the production parameters for a specific product, including:

- Base product and diluent
- Vial size
- Flushing requirements
- Product-specific settings
- customizable filter test settings for non-standard filters



Batch setup

Based on the selected recipe, a batch is created by defining the required product and diluent volumes, the number of vials, and their purpose (quality control, customer, or flushing). The software can also calculate the optimal bulk composition based on the desired activity concentration.

Automated filling

During production, the system measures the bulk volume and activity, performs automatic dilution, and fills each scanned vial according to the requested activity or volume. After filling, the vial activity is verified and the corresponding container label is printed automatically.

Batch completion

After production, the system performs an in-line filter integrity test and, if enabled, a flushing cycle. A batch report is then generated automatically and can be printed or stored digitally.

Customizable output

Vial labels, container labels, batch reports, and calibration reports are fully customizable.

Quality control & documentation

With decades of expertise in radiation protection and GMP compliance, we design and build hot cells worldwide for both research and production. Our integrated solutions combine proven technology with innovation to meet the highest international standards. For Sure!

Safe production

The radiation safety principles are built into the hot cells; alongside our dose dividers. They create a secure working environment. Product integrity is ensured by using a sterile disposable set that complies with Annex 1 single-use systems.



Audit Trail system

In accordance with risk management principles and in compliance with 21 CFR part 11 and GMP Annex 11, the audit trail function is integrated into our software.

The Audit Trail system automatically records and stores all activities performed within the dispensing process in detail, step by step. Besides traceability, which allows the retrieval and verification of the history and integrity of electronic data, it also ensures data integrity. Logs are retained for as long as the records themselves need to be retained, for potential inspections. All data is easily accessible to authorized users.

To establish GMP compliance;



The dispenser is easy to clean and resistant to common laboratory cleaning agents, including hydrogen peroxide vapor.



To prevent contamination between batches, a single-use, ETO-sterilized disposable set with a sterility filter is used.



After each batch, the integrity of the sterility filter is assessed with a bubble-point test.



Additionally, the specific design of the acrylic airflow guide ensures laminar downflow over the vial during filling when used in a GMP grade A environment.

Long-term partnership and support

We ensure that our solutions fully meet your requirements, while our in-house experts provide guidance to you and the product to ensure optimal performance in your daily workflow.

Service & Support for dose dividers

- 🌀 Advise on questions, needs, and possibilities
- 🌀 Before we ship, the in-house performance tests take place
- 🌀 Software performance test
- 🌀 Full dispensing tests with water
- 🌀 Training at the customer's site
- 🌀 Execution of Site Acceptance Test (SAT) together at your site
- 🌀 After-care: validation and maintenance services



Our OVDD and CVDD are reliable, flexible solutions for dispensing radiopharmaceuticals. Together, we develop the most durable and safest solutions. For Sure!



For more than 50 years, Von Gahlen has been a trusted family-owned company, developing advanced radiation shielding solutions for the radiopharmaceutical industry. Safety, quality and reliability are the foundation of everything we do.

Every day, we are committed to delivering the right solution for every customer. With confidence, dedication and pride, we enable our customers to develop, produce and transport life-saving radiopharmaceuticals safely in controlled and protected environments.

What sets us apart is our ability to combine proven technologies with continuous innovation. Backed by a highly skilled and experienced team, we understand complex challenges and work closely with our customers to develop advanced products and tailor-made solutions.

As a reliable long-term partner, we continuously refine our technologies based on new insights and evolving industry requirements. The result is a portfolio of high-quality solutions that protect people, their working environment and their products, helping our customers operate with confidence today and in the future.

Interested in our dose dividers?

Contact us:  sales@vongahlen.com |  +31 316 528 275

Do you need support with operating or maintenance of the dose dividers?

Contact us:  service@vongahlen.com |  +31 316 581 817

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