



DOSE DIVIDERS

DIVIDING RADIOPHARMACEUTICALS
INTO MULTI DOSE OR
UNIT DOSE VIALS



VON GAHLEN
FOR SURE

CHALLENGES WHEN DIVIDING RADIOPHARMACEUTICALS INTO PATIENT DOSES

In the field of radiopharmacy there are numerous isotopes that can be used to diagnose and treat patients. All these different isotopes must be divided in patient specific doses. Due to the short half-life of most radiopharmaceuticals efficient aliquoting is essential.

At Von Gahlen we have designed dose dividers specifically for fast dispensing of radiopharmaceuticals into multi or unit dose vials. In this whitepaper we will focus on two dose dividers: the Open Vial Dose Divider – Semi Automatic [OVDD -SA] and the Closed Vial Dose Divider – Semi Automatic [CVDD-SA]. For both models the vial handling between device and tray will occur by ball tong manipulators, therefore the devices are considered semi-automatic.

The dose divider hardware and software are designed for GMP compliant dispensing.





RADIOPHARMACEUTICAL DISPENSING SOLUTIONS THAT FIT YOUR NEEDS

Dispensing radiopharmaceuticals into vials needs to occur with high accuracy. To ensure that each vial contains the accurate dose, our dose dividers work based on weight-controlled filling. The software offers the option to generate batch protocols which enable efficient aliquoting of patient specific doses within one batch. The accuracy of the final activity dose per vial is 10%.

By measuring both the bulk bottle and the vial, a weight deviation of maximum 5% is achieved. The dose dividers have a cycle time of 55 seconds to dispense 5 mL of product.

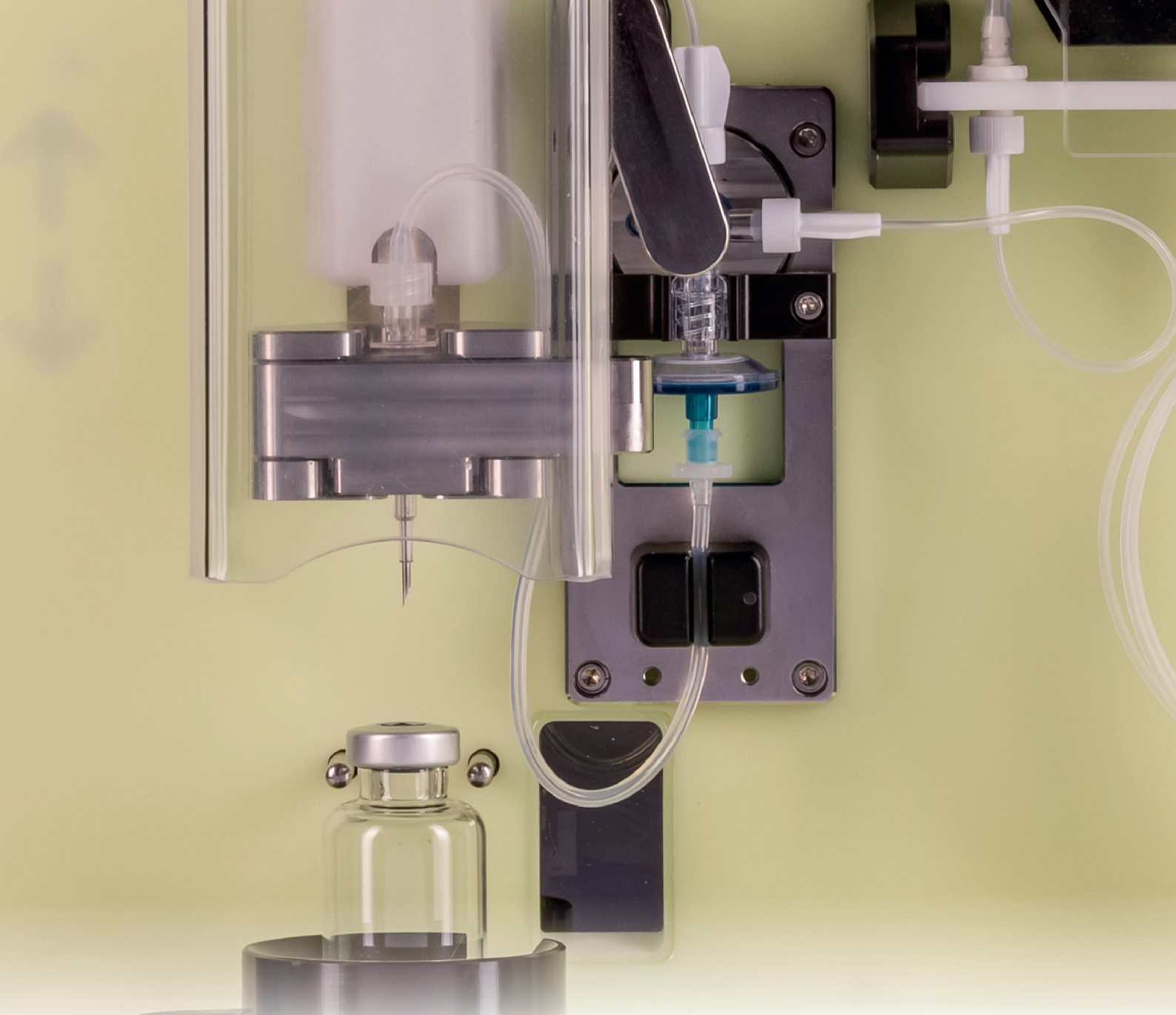
To establish GMP compliance, the dispenser is easy to clean and resistant to common laboratory cleaning agents, including hydrogen peroxide vapor. To prevent contamination between batches a single-use, ETO sterilized disposable set with sterility filter is used. After each batch the integrity of the 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.



OPEN VIAL DOSE DIVIDER

The Open Vial Dose Divider (OVDD) is a remotely operated semi-automatic dispensing system for safe and accurate dispensing inside a shielded hot cell. The dispensing process includes opening, filling, capping and crimping of the pre-sterilized vial. The vial is open for only 8 seconds plus the dispensing time. The OVDD is suitable for vials between 10 and 25 ml and can be customized for use with different types of caps. The device has an integrated scale for weight controlled filling. Multiple runs are possible with the OVDD without waiting for the activity to decay.





CLOSED VIAL DOSE DIVIDER

The Closed Vial Dose Divider (CVDD) is a remotely operated semi-automatic dispensing system that uses the pierced septum method. During the dispensing process the ventilated spike pierces through the septum of the sterile vial to fill it with the radiopharmaceutical. During filling the air pressure in the vial is maintained. The CVDD is suitable for vials between 10 and 25 ml and has an integrated scale for weight controlled filling.





COMPLETE DISPENSING SOLUTION WITH DISPENSING HOT CELL

For a complete dispensing solution, the dose dividers can be placed inside our dispensing hot cell. The dispensing hot cell model with laminar down flow (DPB-LDF) is designed for safe and aseptic dispensing of radiopharmaceuticals.

The integrated laminar down flow with HEPA filter provides for a GMP class A environment. Additionally, the integrated dose calibrator can be operated via the dispensing software or independently. The dose calibrator fits both the patient vial and the bulk bottle.

The hot cell has ergonomically placed ball tong manipulators which allow for safe operation of the dose divider in 'hot' conditions. Using these ball tongs, the operator can easily position a new vial and, once filled, transfer it to the dose calibrator and drop tube, which gently releases the vial into a lead container. When a batch is finished, the disposable set can be removed using the ball tong manipulators and safely discarded in the waste compartment below the hot cell.

DISPENSING SOFTWARE TO MEET YOUR DISPENSING NEEDS

The dose dividers are remotely operated with an industrial PC with a large screen and comes with two label printers. The in-house developed software runs on Windows and communicates with the dose divider, label printers and hot cell.

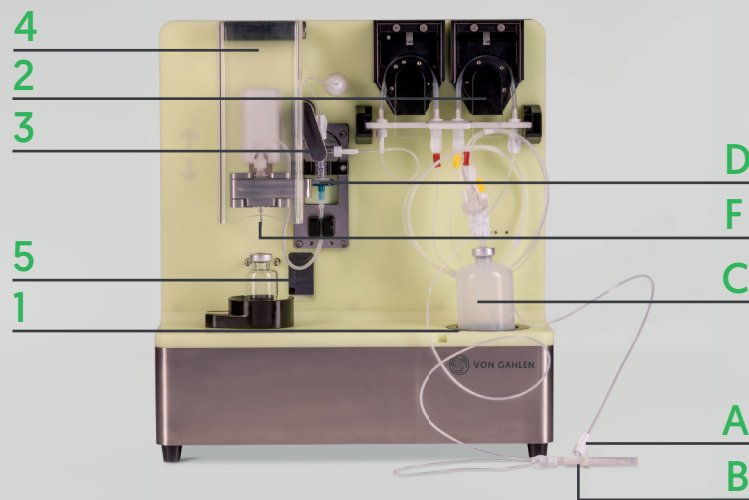
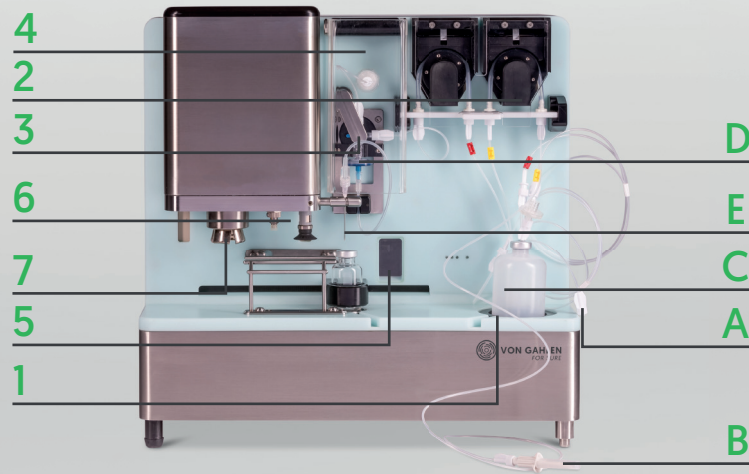
The dose divider software offers the option to generate batch protocols that enable efficient aliquoting of patient specific doses within one batch. By first measuring the activity per volume of the bulk bottle the software automatically calculates the volume per patient vial according to the prescribed activity. Alternatively, a protocol based on volume can be made. In this case the software automatically calculates the activity per vial.

The software is designed to allow for a GMP-compliant work flow. Every user has a password protected account and a specific level of access.

For quality control (QC) purposes, a new batch always starts with the dispensing of a QC sample followed by dispensing of the patient specific vials. The dose and volume of each patient are printed on the vial labels together with a barcode. This barcode is automatically scanned by the dispenser and the software ensures dispensing of the predefined patient dose or volume. After dispensing, the vial is measured and consecutively extracted from the hot cell through the drop tube. The software automatically prints the corresponding label with measured activity for the lead container.

Additional features of the dispensing software include an optional cleaning protocol for the disposable set. Furthermore, the software can work with a protocol that sterilizes vials with an autoclave after dispensing.





DOSE DIVIDER FEATURES

1. Sterile PE/silicon disposable set.
2. Two peristaltic pumps for dilution and filling.
3. Threeway valve to control the flow of liquid and gasses.
4. Acrylic airflow guide.
5. Barcode scanner to scan vial label.
6. Suction pad for vial cap & septum.
7. Crimper unit for crimping the cap.

DISPOSABLE SET FEATURES

- A. Luer lock connection to connect lines from synthesis module.
- B. Spike for connection with diluent bag.
- C. Bulk bottle, 150 mL.
- D. Sterility filter, 0.22 μm .
- E. Stainless steel needle.
- F. Dispensing spike.

YOUR LONG TERM DISPENSING PARTNER

Our R&D engineers are the product specialists for our dose dividers. They configure the software to customer specific needs, followed by testing of the system in our factory and on site. When the dose divider is installed and tested, an optional supervisor training can be provided. After this training the supervisor is able to:

- Understand the general structure of the software.
- Formulate a new product recipe.
- Create a batch protocol.
- Run a batch.
- Instruct junior and operator level employees.

At Von Gahlen we support your dispensing process. Please contact us for advise and questions. *For sure!*





WHAT IS YOUR CHALLENGE?

Thank you for your interest and your time. We would welcome the opportunity to meet you and discuss the challenges you come across in your daily work. Please feel free to contact us if you have questions about this article, our products or the optimization of your dispensing process. We will gladly think along with you.

[Share your challenge with us.](#) *For Sure!*



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