CLOSED VIAL DOSE DIVIDER

The closed vial dose divider is designed for automated filling making use of the pierced septum method.

The CVDD-SA is an automatic vial dispensing system for safe and accurate dispensing inside a shielded hot cell. The dispensing process includes batch production and filling of the pre-sterilized vial. This automated vial filling process has a total cycle time of less than 55 seconds, dispensing 5 ml.

The CVDD-SA is remotely operated. The package includes the dose divider, a calibrated ion chamber with automatic lift system, an industrial PC with large screen and two label printers.

Model VG-CVDD-SA

KEY FEATURES

- Dispensing volume: 1-20 ml
- Uses standard 20 ml vacuum vials, but can be easily adapted for different vial types
- Cassette based, double packed, sterile disposable set
- Activity accuracy: max 10% deviation of the dispensed activity relative to the requested activity
- Cycle time: < 55 seconds, dispensing 5 ml
- Fully automatic in-line filter integrity test system
- Additional dilution and cleaning cycles available
- The weight of the product vial is measured during filling cycle
- It is possible to perform multiple runs without waiting untill the radiation has decayed
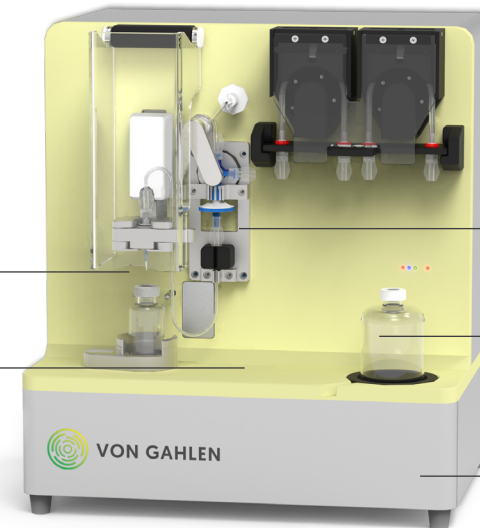- Switching between different products is easy, max time is 15 minutes without the risk of cross contamination

FOR ALL VIALS BETWEEN 10 AND 25 ML

HIGH PRECISION FILLING

FULLY AUTOMATIC FILTER TEST SYSTEM
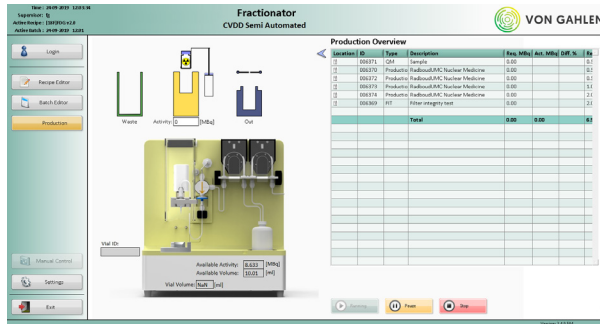
LARGE BULK BOTTLE OF 150 ML

WEIGHT CONTROLLED FILLING PROCEDURE

VON GAHLEN

YOUR GUARANTEE FOR QUALITY. FOR SURE.

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FOR SURE

DISPOSABLES / CONSUMABLES

- Standard disposable set based upon PE/silicone material
- Other disposable sets available upon request

QUALITY CONTROL

- ETO sterilized in accordance with ISO11135
- Sterility is tested and approved according to 21 CFR 212 media fill test and ISO 13408-1 (2015)
- ETO residual tested (1 PPM)
- LAL-Endotoxins
- Shelf-life 5 years (determined according to ISO 11607)
- Leachables and Extractables tested and approved according to ISO 10993-18
- Components have no origins that could result in contamination by Transmittable Spongiform Encephalitis (TSE), Bovine spongiform encefalopathie (BSE) or melamine
- Every batch will be delivered with a Certificate Of Analysis (COA) which contains at least:
  - Lot or batch number
  - Quality Release Testing Assay (Sterility, Bacterial Endotoxin test)
  - Product Expiration Date
  - Product Release Date including quality Assurance Approval

TECHNICAL DATA

- Overall space required: ± 400*340*440 mm (W*D*H)
- Floor space: ± 350*270 mm (W*D)
- Height: ± 390 mm
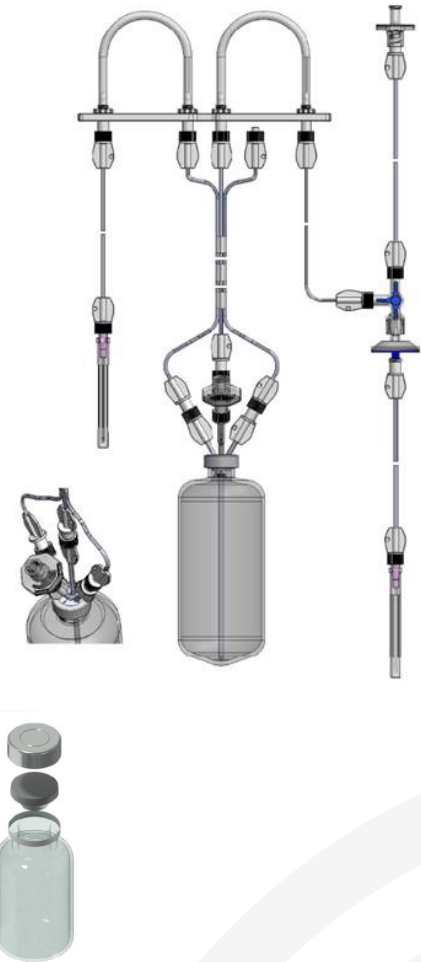- Weight: ± 20 kg

SOFTWARE

- To operate the dispenser a user friendly, intuitive interface is provided.
- The software guided dispensing is done based upon input from the ion chamber and user data based upon recipe management.
- A pre-production record can be created remotely. The data of each batch is logged and stored in the database. Batch reports and vial labels can be printed.
- The high level system components (dose divider, ion chamber, printers etc.) are controlled by an industrial PC running a Windows application.
- Vial- and container labels are fully customizable by authorized user.
- Implementation of software and firmware are conform SDLC (software development life cycle).
- Development and validation of software according to GAMP and is technically compliant with Eudralex V4 Annex 11 and 21 CFR Part 11.