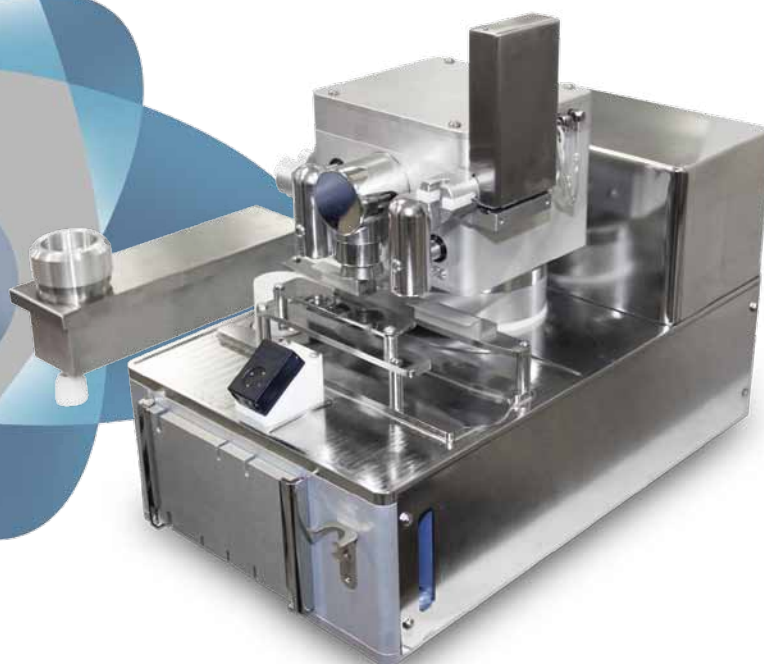


# CRP

## VIAL FILLING UNIT



CRP is a precise and compact system for dispensing both open and closed vials of radiopharmaceuticals in sterile conditions. The unit (Image 1) allows safe and rapid radiopharmaceutical dispensing into vials, minimizing the operator's tasks. It is suitable for any laminar flow hot cell with a dose calibrator pit and tele-pliers.

**The main parts of the unit are:**

- Opening/Closing/Crimping unit (Image 2) with:
  - . station for rubber cap removing/positioning;
  - . station for aluminum ring removing/positioning;
  - . station for aluminum ring crimping;
  - . actuated arm for vial moving among the above listed stations.
- A diluting/filling unit
- A piercing unit (optional)
- Additional stand-alone balance for faster activity concentration calculation (optional)

**The system automatically performs the following functions:**

- Measuring both total and specific activity delivered by the synthesis module
- Diluting the main vial to the required specific activity
- Filling open or closed vials, controlling the volume, using a built-in high precision electronic scale
- Plugging and crimping the filled vial (if using open vials)
- Performing a filter integrity test (instrument not included) without touching the contaminated filter

A computer and operating software, compliant with GAMP5 and CFR21 (Image 3), are supplied together with a touch screen monitor, an optional dose calibrator and a printer for lead container labels and reports.

## DIMENSIONS

- Overall dimensions: 280 x 520 x 400(h) mm

## ACTIVITY MEASUREMENT SYSTEM

- 1 dose calibrator (optional)

## VOLUME MEASUREMENT SYSTEM FOR VIALS

- 1 built-in high precision electronic scale

## VOLUME TRANSFER SYSTEM

- 1 high precision micro peristaltic pump
- Zero dead volume pneumatic pinch valves

## PERFORMANCES

- **Volume precision: < 1% for volumes > 1ml**
- Filling time: 60 sec. for one 10 ml vial

## STERILITY

- Smooth and easily cleanable surfaces
- VHP resistant materials
- Sterile daily disposable kits

## SOFTWARE (Image 3)

- GAMP5 and FDA 21 CFR part. 11 compliant
- N. 3 safety passwords (programmable): user, maintenance and RSO password
- Customizable user accounts
- Reports and Statistics: end of dispensing cycle, alarms & events (Audit Trail), operator actions. Auto saving into a neither corruptible nor modifiable file (encrypted)
- Automatic periodical back-up
- Daily or weekly work schedule (i.e. Patient list) can be imported from USB pen drive (or from Hot Lab Management software if interfaced)
- Online downloadable database (excel and encrypted files)

## FEATURES

- Built-in barcode reader (for vial identification and traceability)
- Total activity concentration assessment and automatic dilution up to the preset final concentration
- Automatic cap removal, vial filling and vial crimping
- Piercing station for closed vials (optional) (Image 2)
- Stand-alone high precision scale for faster concentration calculation (optional) (Image 4)



1



2



3



4