

μDDS-A

AUTOMATIC DISPENSER
CLASS 1M MEDICAL DEVICE

CE
0476



Engineered to fulfill all GMP guidelines for PET, SPECT γ and β radiopharmaceutical dispensing, the μ DDS-A is a stand-alone automatic dispenser which can be positioned inside different types of hot cells, fume hoods, etc.

It has been developed specifically for syringe dispensing but it can be used for vial dispensing as well. Its small and compact shape makes it a very flexible and easy-to-handle device.

The dispenser can be connected to a wide range of commercial dose calibrators.

Empty tube dispensing philosophy: the tubes are completely free of radioactive liquid whenever the operator is approaching the system to connect-disconnect the shielded syringe.

The "**DFC - Dual Fiber Calibration**" technology, developed and patented by Tema Sinergie, makes the system fit dynamically to the specific characteristics of each mounted disposable set, helping the operator to prevent potential troubles before starting the dispensing process.

Software is GAMP5 and FDA 21 CFR Part 11 compliant. It can also be interfaced with Hot Lab Management software: compatibility needs to be checked in advance.

The μ DDS-A dispenser can be upgraded with Tema Sinergie **RAD-INJECT**, the fully automated mini injector for radiopharmaceuticals.

PERFORMANCES

- Average filling time (per syringe): <50"
- Volume accuracy: (Examples of activity accuracy in typical Radiopharmacy conditions)

| EOS(*) mCi/ml | Syringe Requested Activity mCi | FDG Volume mL | Degree of Accuracy% |
|---------------|--------------------------------|---------------|---------------------|
| 120 | 10 | 0.083 | 90,4% |
| 30 | 10 | 0.333 | 97,6% |

* EOS: End of Synthesis specific activity

MAIN OPERATIONS

- Measurement of total activity and concentration coming from synthesis module or from external vial
- Dilution of the bulk activity at the required concentration
- Shielded syringe dispensing and dilution at the required volume and activity
- Syringe residual activity measurement after the injection
- Vial dispensing to the required volume and activity

DIMENSIONS (Image 1)

- Width 200 mm
- Depth 260 mm
- Height 165 mm
- Weight 16 Kg

SHIELDING

- Built-in lead container for main vial: 40 mm thickness (Image 2)

SAFETY

- Stainless steel medical grade finishing for easy cleanable surfaces
- Easy-to-install sterile daily **disposable set - medical device CE 0476**. Supplied in a sterile double bag with 5 years expiry time
- **Class 1m medical device CE 0476**

DISPOSABLE SET

- µDDS-A is a very flexible dispenser: it can dispense both syringes and vials, and can also receive the radiopharmaceutical bulk either directly from the Synthesis module or from an external vial. Each of these configurations requires a different disposable set. For further details please refer to µDDS-A Technical Specification.

VOLUMES TRANSFER SYSTEM

- Zero-dead volume 4 rollers micro-pump. Encoder controlled to grant the highest precision
- Pneumatic pinch valves for liquid flow control

SOFTWARE (Image 3)

- GAMP5 and FDA 21 CFR part. 11 compliant
- N. 3 safety level passwords (programmable): user, maintenance and RSO
- 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)
- On-line downloadable database (excel and encrypted files)

ACTIVITY MEASURE SYSTEM

- N. 1 dose calibrator (excluded) and up/down elevator for dose calibrator. µDDS-A is compatible with a wide range of commercial models available on the market

CALIBRATOR VIEWER

- The integrated software includes the "**Calibrator Viewer**" feature for a complete management of the dose calibrator from the dispenser software. No need for a direct access to the dose calibrator unit

LABELS

- Customized labels available on request

EQUIPMENTS

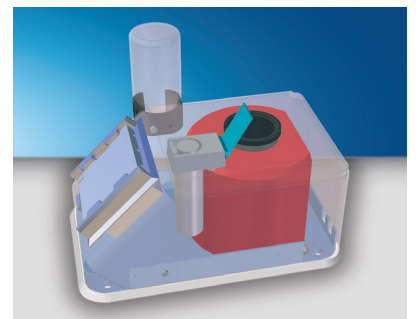
- **OPTION: SSI-T/SPEC** - Tungsten shielding for 5ml commercial syringe: 8 mm thickness
- **OPTION: µShield** - additional external shielding (Image 4): This stand-alone configuration grants a correct protection for the operator during all phases of manipulation and dispensing of the radiopharmaceutical
- **OPTION: Rad Inject** - see relevant brochure

µDDS-A

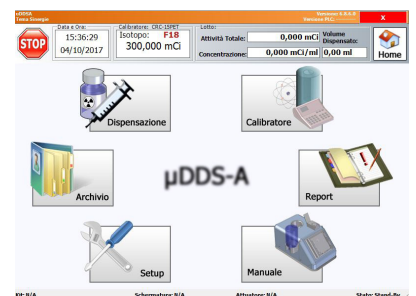
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