

THEODORICO 2

ROBOTIC DISPENSING ISOLATOR FOR VIALS



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Theodorico 2 is an automatic shielded system for dispensing radiopharmaceuticals into open and closed vials. Its flexible system configuration allows it to handle a variety of production needs.

Theodorico 2 was designed in compliance with GMP requirements: It is equipped with a Class B pre-chamber to introduce materials and an automatic and ventilated transfer system from the dispensing chamber (Class A) to the shielded container located in the drawing system (Class B) for dispensed vial removal. The dispenser receives the radiopharmaceutical from a parent vial (bulk) and calculates its concentration thanks to the integrated calibrator and scale. Dispensing

of the final product is based on the measurement of the weight/volume ratio with final verification of the activity dispensed in a second dose calibrator.

The patented gas dispensing technology is extremely precise and highly reliable: this is possible thanks to a simple and easy to install disposable kit.



- ✓ *Modular design and flexible configuration*
- ✓ *cGMP compliant*
- ✓ *Zero operator exposure to doses*
- ✓ *Fully automatic dispensing process thanks to the robotic arm*
- ✓ *Final aseptic or sterilization operations with autoclave*

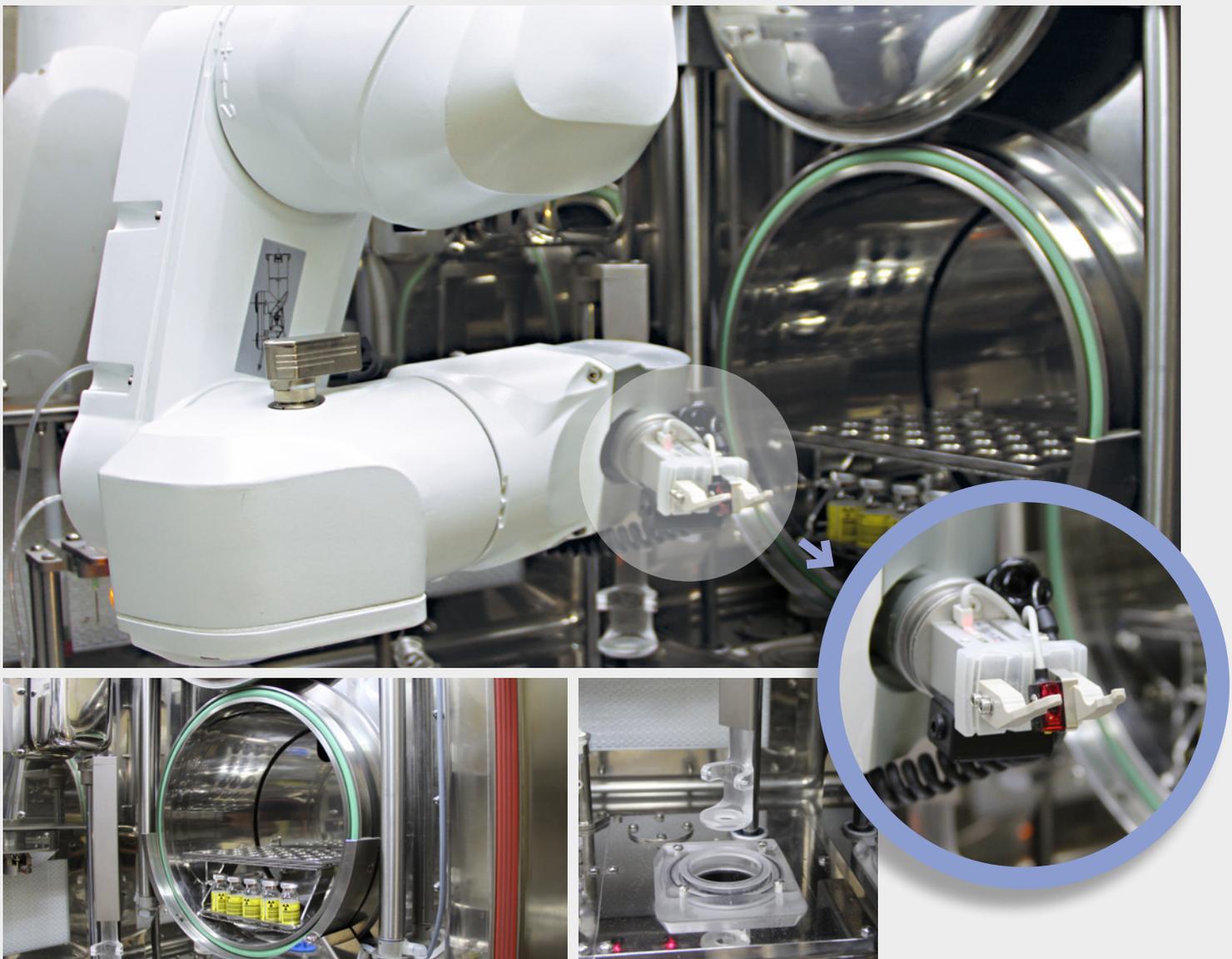
The dispensing chamber is equipped with a robot for vial handling throughout all dispensing phases. This considerably reduces operator exposure to radiation.

Theodorico 2 is equipped with features such as the Bubble Point Test (BPT) for the dispensing filter, the main chamber leak test, the bio-burden sample collection and the filling speed test.

The device is equipped with a system for dynamic air sampling, for particle counting, and for the VPHP sterilization cycle. The critical chamber

parameters are constantly monitored and displayed in real time on the operator panel at the front of the machine and the chronology is recorded in the integrated data logger database.

The shielding for Theodorico 2 is available in two thickness types: 75 or 100 mm of lead (present on all sides of the machine).

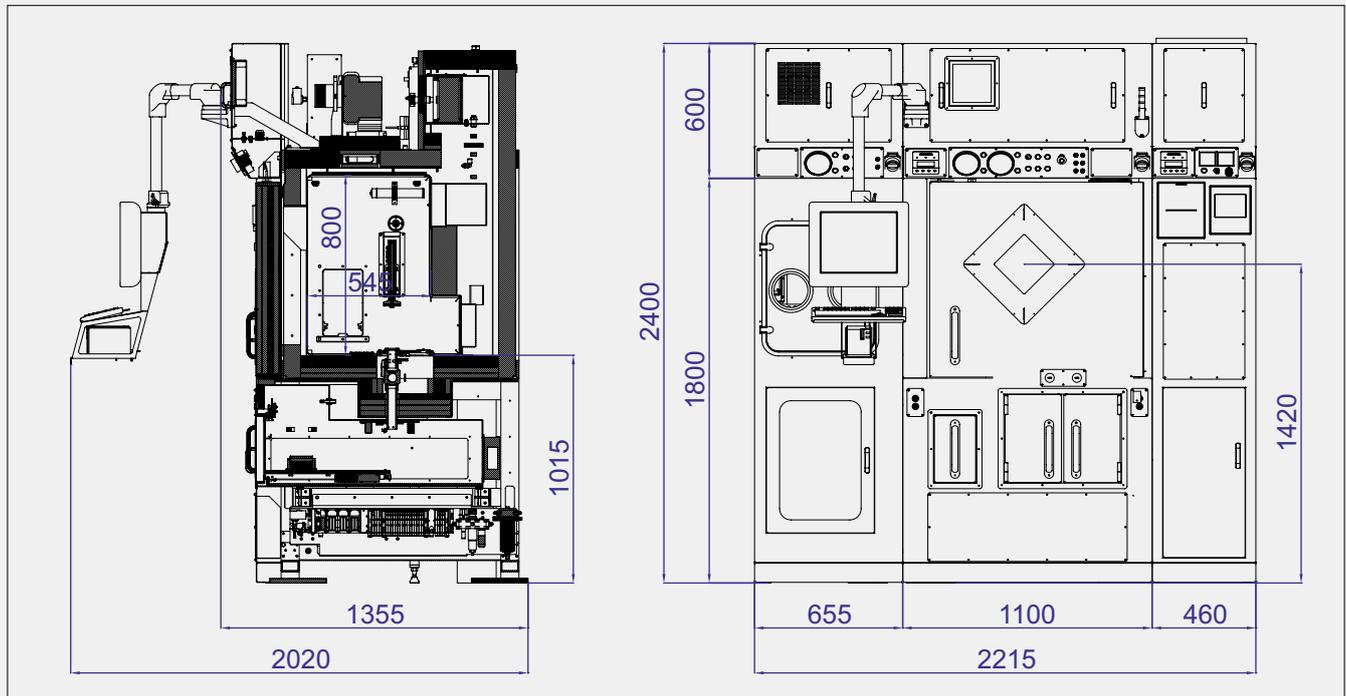


MAIN FEATURES

- Available with 75 or 100 mm Pb shielding
- RAC (radio concentration) calculation with scales and calibrators
- Integrated Bubble Point Test (BPT)
- Set-up for dynamic air sampling, particle counting, VPHP cycle
- Integrated bio-burden sample collection and filling speed test
- Pressure, temperature and humidity monitoring
- Optional ethanol line flushing for kit activity reduction
- Greater machine usability (verification of correct crimping, detection of vial presence in the shielded container).

Technical data

Support frame material		Carbon steel treated with epoxy paints
External casing material		AISI 304 - Scotch-Brite™
Working chamber material		AISI 316L - Mirror-Bright
Lead purity	Title	Pb 98% + Sb 2%
Electrical panel protection rating	IP	54
Weight with Autoclave	kg	14500
Working chamber internal dimensions	mm	725 x 545 x 800 (l x w x h)
Total external dimensions	mm	1755 x 1355 x 2400 (l x w x h)
Total external dimensions with Autoclave	mm	2215 x 1355 x 2400 (l x w x h)
Mains power supply	For Europe and similar systems	230V (1Ph+N+PE) 50/60Hz 16A TN-S
Mains power supply	For North America & similar systems	208/120V (2Ph+N+PE(GND)) 60Hz 15A



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