UNIDOSE

THE ART OF RADIOPHARMACEUTICALS:
DEDICATED PET RADIOTRACER PREPARATION AND INJECTION

- Controlled dosimetry
- Fast and accurate process
- Versatile and easy to use
- Robust and reliable
- Meets the highest standards

LEADING THE WAY IN RADIOPHARMACY
UNIDOSE is a highly compact (1m² floor space), fully automated dose dispensing system, contained in a hot cell that meets the most demanding radiopharmaceutical standards (class A - ISO 4.8, sterilising filtration).

The outcome of four years of research and development, UNIDOSE enables fast and precise preparation of all PET radiotracers, in optimal aseptic conditions.

Its bidirectional software means that your radiopharmaceutical procedures are completely traceable, and there are powerful tools dedicated to safety and dosage control.

UNIDOSE dispenses doses precisely in aseptic conditions, using combined weight and activity measures, tailored to the patient’s details.

Managing injections with the UNIDOSE system is easy for hospital staff, and their exposure to radiation is controlled.

The **UNIDOSE automatic dose dispensing system** consists of:

- an automated dispenser
- a hot cell
- a kit for handling in simplified mode
- an injection system shielded with 23 mm of tungsten

**Within the hot cell:**

- a multidose vial transfer zone
- an automated preparation zone, class A, sterilising filtration
- an airlock enabling manual use of the hot cell
- an airlock for collecting doses from their dose shield
- a compartment for the printer, storage space, and a mini-compressor if required
- a hopper for retrieving syringes outside the hot laboratory (optional)

*Catherine Le Meur*
Radiopharmacist Hopital Privé d’Antony. (Antony - FRANCE)

*‘When dispensing, UNIDOSE has a 5% precision which is very low compared to a manual system.’*
The Unidose hot cell type ISO 4.8 (class A) has 50 mm of lead shielding on all surfaces. It houses the automated dose dispenser and ensures that transfer from the multidose vial, preparation of individual doses, checking of each patient dose and transfer of the dose into the injection shield are safe processes.

**CONTROLLED DOSIMETRY**

The shielding of the hot cell, combined with the distance maintained and speed of preparation, means that hospital staff receive negligible exposure.

Several studies of preparation and injection using a Unidose automated dispensing system have shown up to 95% reduction in exposure.

With its dual H13 and H14 ventilation system, Unidose uses 0.22 μm filters, providing sterilising filtration, and a weighing membrane to measure each patient dose. The two calibrators (one on entry, one on exit) give constant information about system activity, and rigorously control doses to be given to patients.

Round glove ports, a wide shielded window, airlock and integrated step mean that the hot cell can be used manually as part of a simplified procedure.

The dose for the patient is placed into a cartridge, which is opened and filled entirely in a controlled atmosphere and in sterilising filtration conditions.

Once the patient dose is measured, the Unidose printer prints a 3-part label, customised by the radiopharmacist and containing information about the patient and the tracer. One part is for the patient’s medical record, the other for the request form, and the last is affixed to the dose shield (Fig. 1). This ensures that the whole process is traceable, from transfer of the stock solution to injection into the patient.
CONSUMABLES

Thanks to the disposable sterile kit (Fig. 1), which takes less than 2 minutes to install, radiopharmaceuticals never come into contact with the dispenser, which significantly reduces the risk of microbial contamination, while adhering to the most demanding radiopharmaceutical standards.

The patient doses are contained in cartridges. These are produced and assembled in a clean room. They are packaged in boxes of 295, delivered under sterile conditions using double packaging.

Labels, which can be customised using the user interface, are delivered in three parts in packs of 1000 labels; they can easily be detached from the dose shield after administration to patients.

SOFTWARE

The graphic interface of UNIDOSE’s inbuilt software is easy and intuitive to use, which means you can get up and running quickly.

It is completely compatible with the main hospital management software packages used in nuclear medicine. The interface can be used to fetch a patient list from the centralised software, prepare patient doses, perform daily, weekly and monthly checks, and export data to the centralised software.

It can also be used to see the interior of the hot cell with the integrated camera, which is also helpful to our service team when offering remote support.
ACCESSORIES

The « CHOPE » - Trasis dose shield

When doses are prepared and administered on the ward, patient doses are injected behind a 24 mm tungsten shield on all surfaces, and can be administered directly by a member of hospital staff. The operation is done by clipping on a tungsten plunger on one side and connecting the shielding to the patient’s line, using a Luer lock adaptor, on the other side.

INJECTION KIT

When doses are used directly in the hospital, calibrated shields are themselves inserted into an additional shield, which is designed to be moved around the hospital and to be suitable for injection. The dose is surrounded by a total of 24 mm of tungsten, and can be injected directly by a medical professional using a piston and injection kit.

INJECTION TOOL

The tungsten-shielded plunger is used to push the cartridge’s piston. It clips onto the dose shield and transforms it into a shielded syringe. This can be used to give injections and rinse the patient’s line. After rinsing, residual activity in the cartridge is negligible, and it can easily be disposed of into the shielded bin.

The plunger is never in contact with fluids or with surfaces that can touch fluids. It can therefore be used for several patients. One injection tool per dose shield is therefore sufficient.
**TRANSFER TUNNEL**

Specially designed to avoid untimely back and forth in the hotlab, the tunnel is an optional complementary UNIDOSE equipment that delivers the patient dose straight in its injection shielding outside from the hotlab.

Using this connection system, the control screen and label printer can be installed outside the hot laboratory, saving time and reducing exposure when starting the dispensing process.

“UNIDOSE is the guarantee of a complete trace-ability of the dispensing from radiopharmaceutical prescription to the patient injection.”

**Philippe Gervais**  
Radiopharmacist SHFJ (Orsay)
ACCOMPANYING EQUIPMENT: SHIELDED SCREEN

The Trasis mobile shielded screen has been specially designed in accordance with ALARA principles. It increases radioprotection for care staff when injecting patients with radiotracer doses.

It consists of an elevated shelf with three adjustable positions, and casters to ensure that the screen is easy to move. Two thicknesses of lead are available (15 and 30 mm).

It is easy to maintain, as it can be cleaned using the usual cleaning and decontamination products.

The Unidose ergonomic shelf (Fig.1) is an accessory that is designed to make the injecting process easier. It ensures the procedure is safe, and stabilises the connection between the injection kit and the injection shield containing the cartridge.

The shelf can be used by right-handed and left-handed users, and can be fixed to a mobile screen or placed on a small mobile table or trolley.

Fig.1 Ergonomic shelf
**SUPPORT**

**CUSTOMER SUPPORT**

Our support team consists of IT, electromechanical engineers, design engineers, chemists, and highly qualified technicians. They provide remote (online and telephone) and on-site assistance.

**Telephone support**

Our team is available 7am to 6pm (CET) to offer telephone assistance.

**Online support**

Automated dose dispensers can be controlled remotely, if the user requests this. Our support team will take control of the equipment remotely to diagnose the problem and repair it as required. Over 90% of problems can be resolved online.

**On-site help**

Our internal support team and network of designated regional agents provide on-site help.

**TRAINING**

In addition to training for new users, we organise training sessions for existing customers whose needs have changed or who want more detailed knowledge. This personalised training covers equipment and software, good practice in using the system, design of the synthesis process, and any other content our customers need in order to get the best from this system.

Training can be on-site, at our premises, or remote.
ABOUT TRASIS

At Trasis our primary focus is allowing the medical community to access new radiolabeled therapeutic and diagnostic substances easier and faster. For this purpose, we design, manufacture, sell and support high performance synthesizers, dose preparation equipment, their shielding and accessories. We also develop customized synthetic methods, instruments and consumables. We can provide GMP Active Pharmaceutical Ingredients (API) and assist our customers with their regulatory affairs.

Our proven radiopharmaceutical expertise, coupled with our high-end instruments allows us to provide fully integrated solutions for effective tracer production and faster transition from drug development to marketing authorization. Our equipment is used worldwide in nuclear medicine departments, research centers, radiopharmaceutical production facilities and pharmaceutical companies.

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