TRASIS

PHARMACY INSTRUMENTS

Unidose

The first patient dose preparation system for PET and SPECT combining

- V Safety for technologist and patient
- V Speed
- V Flexibility
- V Accuracy

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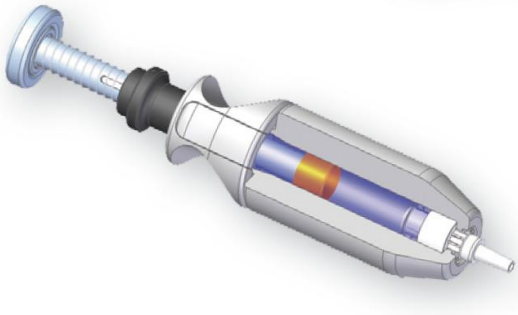
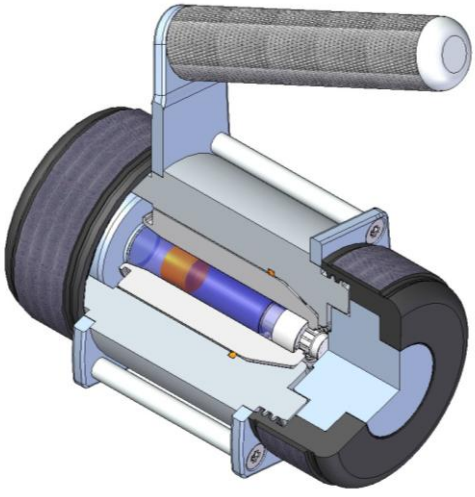
Syringe-like cartridges

The packaging system of Trasis is designed for the preparation and the administration of unit patient doses for PET and SPECT radiopharmaceuticals. This solution addresses in a global way the needs of the hospitals and of the radiopharmaceutical industry for fast and safe preparation, for reduced shipping weight, and for a drastic reduction of the exposure of the personnel.

The system is based on a syringe-like cartridge, and an aseptic filling machine. This dedicated packaging allows preparing ready for use patient doses automatically, in a compact and perfectly sealed container (which is not the case of syringes). The cartridge converts into a shielded syringe at the time of injection, requiring no special change in the usual injection procedure.

The machine delivers the cartridges directly in their injection shield. The technologist only needs to snap on the plunger and place a Luer adapter (such as in the vacutainer system, used for sampling blood). If required, the dose can be measured through its shielding. All the shields are calibrated. The dose is ready for injection.





Shielding of the doses :
Unequalled protection and ease of use

An aseptic filling machine for hospitals

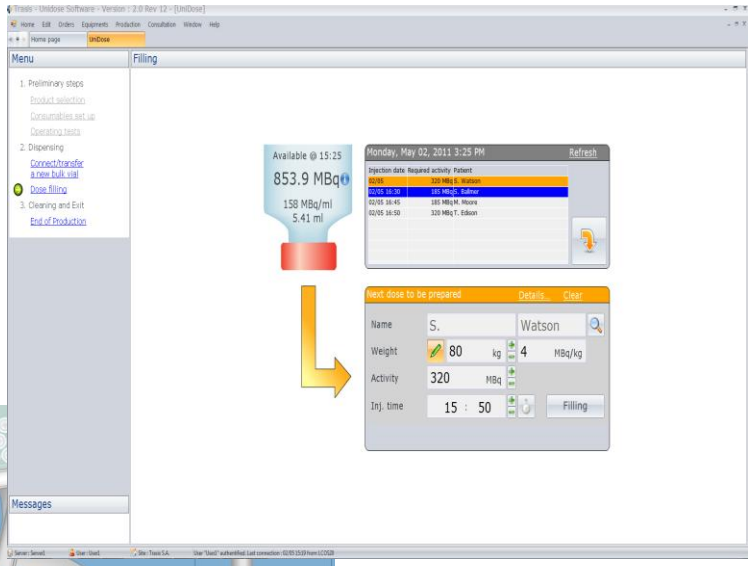
The machine ensures an accurate filling under aseptic conditions, by combined measurement of weight and radioactivity. The machine includes:

- An area where the fluids are handled, within a sterile and disposable set, to be replaced once a day.
- An area where the cartridges are manipulated, and where the cartridge filling, closing and crimping operations are carried out ,
- A delivery area, including a double air lock, a dose calibrator and the delivery into a shielded container.

The labels, which can be customized, are printed online, and show the actually measured activity and volume. The machine can be connected on the local Ethernet network and can be operated remotely, using a graphical user interface.

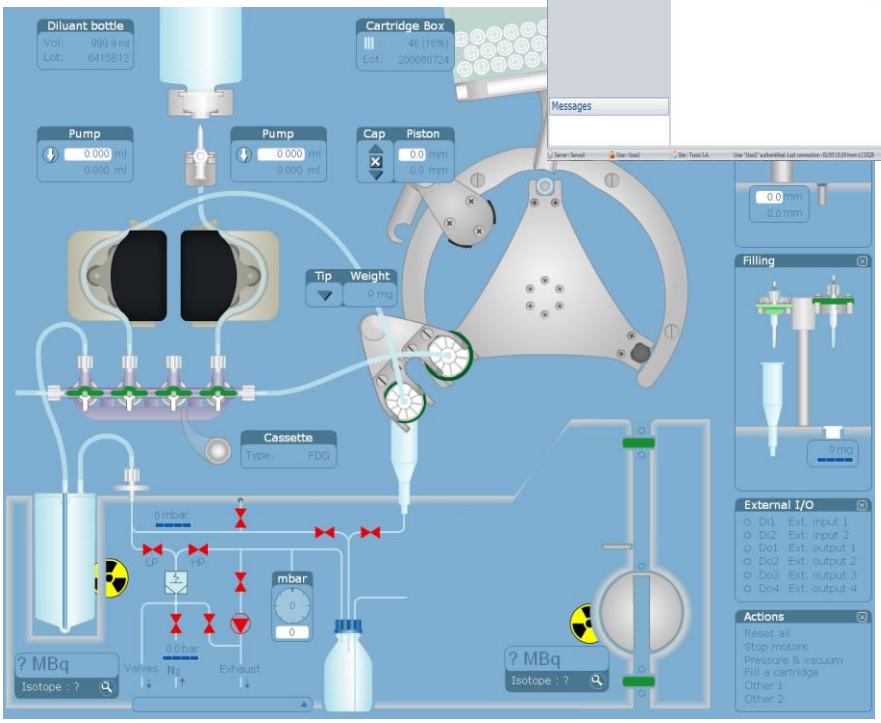
Main components

The machine includes two peristaltic pumps for the radioactive solution and for saline, actuators for the stopcock valve manifold, two ionization chambers for the incoming activity and for the unit doses, an RFID reader to track the starting materials, a scale, a system to locate the piston appropriately in the catridges, a gripper for closing and crimping the caps, a carrousel to move the cartriges, an airlock to keep the dispensing area isolated, and a label printer, outside the shielded enclosure. The system is PLC operated, and controlled with a graphical user interface on PC.



Control system

The user interface allows creating or importing orders. It helps the technologist throughout his tasks. The production repports are saved in a data base and can be edited. The system can exchange data with other applications.



Consumables and accessories

The Tubing set

All fluid handling operations such as diluting, mixing and filling are performed within disposable sterilized "tubing set". This set includes a transfer line for the incoming activity, a line for saline, stopcock valve manifold, a reservoir and filters. Setting up the machine with the tubing set takes half a minute. The tubing set is available in a double wrapping

The cartridges

The cartridges are plunger-less capped syringes. They are made of three parts: the barrel, the piston and the cap. The cap connects with a Luer adapter as used for blood sampling. The piston can connect to a shielding plunger in such way that one can pull to draw and push to inject. This allows rinsing the cartridge and transferring all the activity to the patient. The plunger can also disconnect. When the Luer adapter and the plunger are connected onto the shield, this convert the cartridge into a shielded syringe. The cartridges are supplied in boxes of 295 cartridges each, which fit on the Unidose dispenser. These consumables are produced and assembled in clean room and delivered in double wrapping. RFID tags make traceability easier.

Calibrated shields

Once filled and closed, the cartridge is dropped into its injection shield used for both transportation and injection. All the shields designed for a given isotope have the same attenuation factor. Therefore, the activity can be assayed through the shields, reducing the exposure of the personnel. These shields can be delivered with the logo of the institution and a unique bar-code identifier.

Hospital shield

When the doses are at the hospital, the calibrated shields described above can be themselves inserted into an additional "hospital shield", adapted for moving the doses within the hospital, and for injecting. Once placed in the hospital shield, the dose is surrounded by 24 mm of tungsten on all sides. The exposure on the hand at the level of the handle is <30 µSv/hr for 10 mCi (370 MBq) inside. When the Unidose dispenser is
operated at the hospital the doses are delivered directly into this hospital shield.

Shipping container

When doses need delivering to another hospital, a transport container for two unit doses can be used. The compactness of the design allows limiting the weight of these containers. For the sake of comparison, these containers are nearly half the weight of their counterpart for standard syringes.

The injection tool (the plunger)

This accessory is a shielded plunger allowing moving the piston and reducing hand exposure. It is made of tungsten. It snaps onto the calibrated shield and converts it into a shielded syringe. It allows injecting and drawing of saline into the cartridge for rinsing. A mechanism allows the plunger to release from the piston. The plunger is never in contact with any fluid nor in contact with any surface that might be in contact with the fluids. The same plunger can be used for all patients.

Operating the dispenser

The doses can be produced one by one on demand according to the need. They can also be listed ahead of time in a table, edited in the user interface, or imported from another application.

The shielded container holding the multi-dose vial is placed on a shelve, about 3 ft (~1m) high in a shielded compartment. The container is tilted backwards in such a way that when the withdrawal needled is inserted vertically through the septum, the tip of the needle reaches the bottom of the vial at its lowest point. The withdrawal needle is placed on mobile support that can slide vertically along a rail. This allows punching the vial at a fair distance. The tilt of the container also keeps the operator out of the direct shine of the vial at the time he removes the lid.

The operator places the tubing set on the dispenser and connects a small pouch of saline. He makes a visual check that the cartridge box still contains enough cartridges and closes the door. On the side compartment, He connects on the mobile support the withdrawal needle of transfer line (which is part of the tubing set that was just put in place) emerging from the main enclosure. He checks the alignment of the container under the needle and with the handle, moves the needle down through the septum, into the vial. For vials with small head space, it is recommended to also place a vent needle. He closes the door of the compartment.

When the user interface invites him to do so, the operator enters the information about the multi-dose vial such as the lot number, the activity, the volume or the concentration and the reference time. This information will be used when drawing the first dose.

The system is ready to produce the patient doses. In the production mode of the user interface, the operator either selects or defines the dose to be produced.

Less than 30 seconds later, a sticker pops out of the printer, indicating that the dose is ready. The operator puts the sticker on an empty shield and pushes the shield into the delivery position below the enclosure. As soon as the shield is detected, the dose falls into it. The operator pulls it out from below the enclosure and screws the lid onto it.

Connecting a vial:
The operator's hand remains at fair distance.
A shielding ring is placed on the crimp cap of the vial

Administering the doses

A drip has been placed, with a three way stopcock valve along the the line to the patient.
The components necessary for injecting are:
- The injection tool (shielded Plunger)
- Tweezers
- A Luer adapter (such as vacutainer from B-D)

To proceed with the injection of the radiopharmaceutical solution, the technologist removes the lower cap of the hospital shield. With tweezers, he peels off the tyvek protection disc, then screws in a Luer adapter.
He removes the upper cap and snaps on the shielded plunger.

The system is connected onto the three-way valve along the patient line. The technologist rotates the valve appropriately and injects the product. The syringe can be rinsed by aspirating saline and injecting back to the patient.
This requires repositioning the valve in between each change of direction when actuating the plunger.

If an injection line from Trasis (see below) is used instead of a standard drip, there is no need any more to rotate any valve by hand. The technologist simply connects the dose onto the line and injects the product. The plunger snaps automatically onto the piston. The technologist draws saline into the cartridge just by pulling out the plunger. As he pushes it in again, the content of the syringe is directed to the patient.
An additional cycle ensures the full transfer of the activity to the patient
The self-obturating Luer allows disconnecting the syringe as soon as the injection cycle is done.

The efficiency of the rinsing makes any measurement of the residual activity unnecessary. The activity is injected without loss. Each back and forth cycle causes the injection of 3 mL of solution. The whole process takes less than 30 seconds.

The injection set (optional)

The automatic injection port of Trasis merges 2 check valves and a self-obturating female Luer into a single component. It is supplied with a tube and a spike to connect on most saline bags.
This optional injection set eases the work and reduces hand exposure of the technologist by suppressing any actuating of a three way valve.

Specifications and Performances

Shielded enclosure:

Dimensions (width x depth x height)	120 x 70 x 200 cm
Lead thickness	(2 inch) 5 cm
Weight	< 2T
Inside liner:	Stainless steel

Air quality:

Iso -5 (class 100) on less than 5 minutes

Pressure in the enclosure: positive or negative on request

Connection to stack	OD 50 mm

Preparation

Aseptic filling	
Traceability: automatic identification of starting materials:	by RFID Tag
Time to set up the dispenser, including self test (once a day)	<5 min
Time to prepare a dose	<40 s
Filling range :	0,3 à 3 mL
Filling accuracy :±0,02	mL

Ionization chambers: Two. One for inlet activity, the other for each delivered dose

Shielding for injection

Tungsten thickness, at choice	9 or 23 mm
Weight for 9mm ("calibrated shield"):	450 gr.
Weight for 23mm ("calibrated shield" inside "hospital shields"):	4,0 kg

Exposure of a technologist per 370 MBq dose prepared and injected

Body (Chest)	~1 µSv
Hand (most exposed finger):	< 20 µSv

EXPOSURE OF A TECHNOLOGIST (*)	Time of the step	Activity		**Body dose**	**Hand dose**
	(s)	(mCi)	(MBq)	**(µSv)**	**(µSv)**
Preparation (for 5 doses on average) :					
Sub-Total: Placement of a multi-dose vial container	***90***	***150***	***5550***	***1.276***	***29.596***
Administration of one dose to one patient					
From the filling machine to the patient	35	10	370	0.095	2.057
Preparing the injection, connection to the drip	15	10	370	0.012	8.147
Injection and rinsing	23	10	370	0.083	2.412
Disconnection from the patient line, and discarding empty cartridge	7	10	370	0.000	0.011
From patient, during complete administration process	25	10	370	0.486	0.486
Sub-Total: Administration of one dose to one patient	***105***	***10***	***370***	***0.677***	***13.113***
Total technologist exposure per patient, including 1/5th of preparation and 1 administration				**0.932**	**19.032**

(*) measurements performed in collaboration with the radiation safety dpt. of the University of Liege (Belgium)

Use your activity to the last drop

From one or several multi-dose vials, prepare your patient doses on the fly, accurately with all markings and complete traceability… to the last drop of the available solution.

The same dispenser will allow the preparation of different compounds.

Automated dispensing of the patient doses

Inject safely

The doses remain shielded at all times, even while measuring them.

You keep the feeling and the control needed for delicate injections.

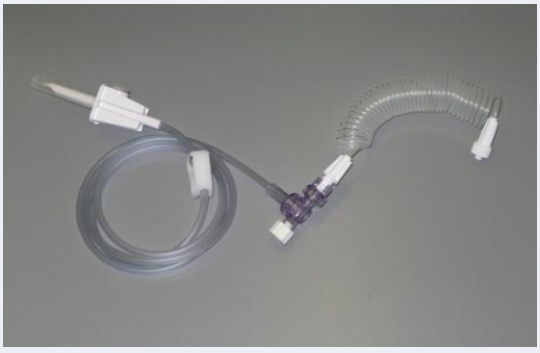
The sterilised Injection Set makes rinsing easier than ever.

Shielded and labelled patient dose

Safe and commonly accepted practice

The preparation of the patient doses, separated from their injection, makes any cross contamination impossible.

The environment and the traceability are in line with the standards of the pharmaceutical industry.



The Injection Set allows injecting and rinsing the syringe and the line

Radiopharmacy instrumentation specialists

Trasis, specialised in professional and innovative solutions for the radiopharmaceutical industry, also invests in nuclear medicine's future, through the development and implementation of miniaturised radiolabelling technology.