OUR VISION FOR DESIGN

Posijet® was initially designed for **fractionating and intravenous administration of multidose PET radiopharmaceuticals**, and is constantly upgrading to **adapt to new applications and new tracers**. In addition to the development of its **dedicated paediatric version (> 1 year old)**(specific packaging, application and safety parameters), Posijet® now features a **new innovative feature: administration of therapeutic radiopharmaceuticals**.

It **can be customised** according to the service's practices, making it the **most versatile shielded preparation and injection unit** currently available on the market.

POSIJET®

SHIELDED RADIOPHARMACEUTICAL INJECTION AND PREPARATION UNIT

ALL **ENERGIES**

SPECT PET

TRT

PATENTED

EU-MDR CERTIFIED

OPTIONS

- Therapy Application
- Radiopharmacy software interface
- COFRAC (French Accreditation Committee) preset dose calibrator
- Peripheral injection with Minijet

Posijet® is a compact, self-contained, radiation protected radiopharmaceutical (high-energy) fractionating and injection unit that **collects, measures and injects** the required patient dose in maximum safety and reliability conditions for both the user and the patient, while guaranteeing the integrity of the radioactive drug. Posijet® supports all multi-dose fluorinated tracers (**^{18}F**) including ^{18}F-FDG, ^{18}F-DOPA, ^{18}F-CHOLINE, ^{18}F-FNA, ^{18}F-PSMA, etc. and also tracers labelled with **^{68}Ga**, as well as Ammonia labelled with ^{13}N for cardiac PET examinations.

With its new "Therapy" application, it is also able to perform slow administrations in 30 minutes, for Vectorised Internal Radiation Therapy (VIR) treatments with **^{177}Lu** labelled radiopharmaceuticals (^{177}Lu octreotate or ^{177}Lu DOTA-TATE, ^{177}Lu-PSMA-617, etc.). It is also possible to perform fractionating and intravenous administration of **^{99m}Tc-labelled** SPECT radiopharmaceuticals.
For routine diagnostic applications, Posijet® features a very fine sampling capacity of 100 µL of the stock solution with an average dose preparation time of 50 seconds and an accuracy of around 2 %. The average injection time, including rinsing operations, is less than 1 minute 30 seconds.

1 | Manual injection plunger **2** | Dose calibrator for real-time measurement of radiopharmaceutical dose **3** | Secure automatic preparation and controlled injection system in automatic or manual mode **4** | Touch screen for control and command **5** | Secure shielded door accommodating the multi-dose vial in its shielded transport container **6** | Air bubble detector **7** | Saline solution holder connected to the stock solution kit **8** | Removable de spill containment tray **9** | Mains outlet **10** | Motorised rotary assistance control (independent battery) **11** | Bar code reader for kit traceability **12** | Printer for customisable injection and quality control reports **13** | Ethernet connection if no Wifi **14** | Castor braking system **15** | Optional RIS (Remote Injection System) allows preparation and packaging of a patient dose for manual injection **16** | Maintenance hatch

Focus on features

GENERAL

- **The user-friendly and intuitive user interface** is controlled by a touch screen.
- **The application** is available in a choice of languages: French, English, Russian, Chinese, German and Italian.
- **The units of measurement** can also be set as required: MBq or mCi
- **Operating time** of 8 hours on battery, possibility of mains operation
- **Charging time:** 3h
- **Lexan trim** is customisable in a choice of colours and patterns.
- **Radiation protection** guarantees a dose rate of less than 25 µSv/h at 5 cm from the walls during preparations, when the operator is standing behind the control console for ^{18}F stock solution activities of 37 GBq when the vial is held in a 30 mm lead pot.
- **Connectivity:** Wifi and Ethernet
- Idle mode allows the dose calibrator chamber to be closed at the end of the day.
- **The web application** allows monitoring and control over: the schedule of the day's injections, the follow-up of the injections carried out as well as the exportable log in CSV or XML format, the traceability of the activity concentration checks, the list of drugs, management of the various isotopes (creation, deletion, addition), the management of the users as well as their rights (simple users, administrators), the quality control log, etc.

MEASUREMENTS & DOSE PREPARATION

- **Settings and calibration** of the different isotopes and constancy sources are accessible and can be carried out by radiophysicists or service personnel as well as certified organisations, in order to check or adapt Posijet® in accordance with the requirements and practices of the services and their developments.
- **The real-time update of the stock solution information** on the application screen (minimum dose, activity concentration, vial volume and total activity of the vial) allows for permanent follow-up and control of the users.
- **The dilution**, available at any time during the cycle, guarantees the full use of the stock solution. It can be customised (target volume set point selected by the user) or optimised (target volume set point calculated automatically by the injection unit), and allows the concentration of the vials to be adapted for improved user comfort and facilitates the collection of the end-of-vial activity.
- **The "Mixing" function**, when activated, allows the radiopharmaceutical drug to be homogenised with saline solution following high dilution.
- **The automatic** vial **pressure adjustment function** was developed to improve the accuracy of patient dose preparation.
- **The prescription calculation** allows to automatically determine a prescription based on weight, surface area or BMI, etc.
- **The patient schedule** according to the activity of the stock solution vial, allows to optimise the use of the vials and to view the forecast consumption of activity in order to anticipate the unloading and loading of the next vial.
- **The "Chrono" function** allows the preparation of the patient dose in advance (from 0 to 10 minutes max). Optimal anticipation function during the day when performing simultaneous patient transfer actions under the PET camera, successive injections, as well as deperfusions.
- **The end-of-vial measurement** takes a total sample of the residual activity present in the vial in order to optimise the sampling of the last doses.

INJECTIONS

- **The automatic venting** upon start-up as well as the automatic inter-patient venting on all kits, ensure that no air bubbles can be injected into the patient.
- **The "Test vein" function** before a dose preparation, ensures a verification of the venous line before injection in order to anticipate any possible problem relating to obstructed veins for example.
- **Three injection profiles** (configured according to the application required by the service) are available to take into account the injection location as well as the catheter used to prevent the risk of extravasation.
- **Automatic or manual injection** with plunger.
- **Rinsing** after the injection can be set in volume from 10 to 30 mL directly by the user.
- **A force sensor** is located in the sampling head with an injection rate control and a visual gauge on the application screen, allowing the user to vary the injection speed.
- **The air bubble detector** checks for air bubbles in real time and alerts the user if necessary.
- **Injection reports** in the form of labels with configurable information and size are issued at the end of each radiopharmaceutical dose administration.

SAFETY & CONTROL

• **Contextual help** is available throughout the user cycle to assist users in their handling operations.
• **The loading aid** is presented in the form of a photo slide show for each step and the positioning of the various accessories required to load the machine.
• **The activity concentration control** allows to check the information of the stock solution (configurable, duration 1 min 30) and increases the accuracy of the samples.
• **The barcode reader** for stock solution kits and patient kits ensures the traceability of the consumables used.
• **Management of the volume of the NaCl** bag necessary for venting, rinsing and diluting prevents insertion of air into the system and allows the user to anticipate the bag change.
• **The rinsing function of the stock solution kit** at the end of the vial allows the machine to be unloaded without any activity in the tubing.
• Daily and regulatory **quality checks** of the dose calibrator ensure reliable measurements.
• **The interoperability** between Posijet® and the radiopharmacy software ensures complete and secure traceability of information concerning radiopharmaceuticals and patients. The software compatible with this two-way communication interface is: Venus (Nicesoft), PharmaManager (Softway Medical), Gera (Thélème) and Xplore (EDL). The Sectra RIS (Sectra) and IBC NM (Comecer) software via the HL7 protocol feature a two-way connection for the reception of patient worklists by the LPDose software and the return of prepared doses. As for the other PACS via DICOM protocol, they can also be interfaced with the LPDose software, in one direction, and allow the simple reception of appointments or patient worklists.
• **The prepared dose** is controlled by a configurable system with threshold rules determined by the service, according to specific applications. For example, patient doses for paediatric use (> 1 year old) may be subject to a stricter threshold rule depending on the age of the patient. A colour code as well as warning messages in case of over- or under-dosing in relation to these thresholds, guarantee conformity between the prescription and the patient dose.
• **Logging**, or real-time recording of data for monitoring, creates log files stored in the machine, which are required for analysis in the event of a malfunction.
• **Remote control** is possible and allows problems to be solved without the need for a technician to be dispatched.
• **An air bubble detector** and a **force sensor** ensure safe injections.

TOOLS & DOWNGRADED CASES:

A menu in the application has been specially designed and made available to users to allow many features to be activated outside the nominal usage cycle. The aim of this programme is to help and support users and thus guarantee the continued use of the Posijet® preparation and injection unit regardless of the uncertainties of patient organisation and management (late delivery of radiopharmaceutical, late or cancelled patient, higher dose required, delayed administration, etc.) as well as potential malfunctions that may occur during a day of PET activity. Therefore, a dose that has already been prepared but cannot be injected into the patient, for example, can be reallocated to another patient of a similar weight or diverted into a specific bin without interfering with the use of the injection unit.

The activity simulator developed by Lemer Pax's R&D team allows the service teams to handle and operate the device in real conditions without unnecessary exposure since there is no activity.

ADAPTATION 13N-AMMONIA:

Building on its **collaborative work** with user services worldwide, Lemer Pax once again provides technical expertise for innovation by developing in 2019 a **Posijet® programme for fractionating and administration of the ^{13}N-Ammonia radiopharmaceutical**. Mainly indicated for cardiac PET diagnostic imaging, when coronary artery disease is suspected or developed, this **new specific application** makes Posijet® the **first preparatory injection unit capable of handling ^{13}N**. Despite an extremely short half-life (10 minutes), Posijet® accurately prepares the patient dose and administers it according to the strict protocol required for the success of this specific PET examination.

Exchanges between the **Geneva University Hospitals (HUG)** and the Lemer Pax development teams have enabled the routine use of ^{13}N-Ammonia dose preparations with Posijet® since 2019. The hospital currently performs approximately 1,600 examinations per year, while ensuring a considerable reduction in exposure for medical staff. Collaboration with the **University Hospital of Zurich** from 2020 onwards, has allowed the Posijet® Ammonia version to be further developed in two areas: optimisation of the accuracy of patient dose preparation and automatic injection from the Posijet®, in accordance with the restricted timing criteria imposed by the administration protocol for this examination.

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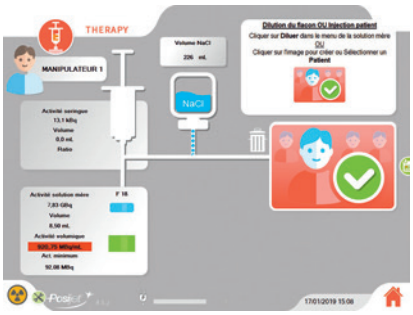
THERAPY APPLICATION

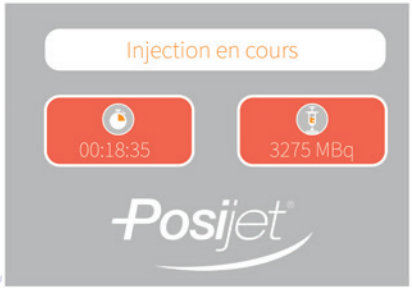
Theranostics is a new medical approach aiming to promote simultaneous development of diagnostic and therapeutic aspects in nuclear medicine, and visualise for improved cancer treatment by associating a diagnostic test and an adapted targeted therapy.

In this new context, Lemer Pax has invested in Research and Development to include Posijet® in this theranostic use, thus opening up parallel access to **diagnostic PET injections and therapeutic TRT (Targeted Radiation Therapy) injections** in secure conditions. With the launch of new ^{177}Lu labelled molecules on the market, such as **^{177}Lu-DOTATATE** for the treatment of inoperable neuroendocrine tumours, as well as **^{177}Lu-PSMA** for specific prostate indications, the Lemer Pax teams aimed to support these developments by offering healthcare professionals the opportunity to improve their administration methods for these new radiopharmaceutical drugs with an **ultra-secure** industrial solution adapted to these **Targeted Radiation Therapy (TRT)** treatments.



This new development is mainly focused on **complete and secure automation** of radiopharmaceutical administration, while **respecting the constraints of pharmacological protocols**. The “Diagnosis” and “Therapy” menus feature the **same graphical structure** of the application, however, they are differentiated by a distinct coloured frame to improve user **ergonomics**. In order to preserve the exposure gain for users, the single-dose vial of VIR radiopharmaceuticals and its shielded transport container are positioned directly in the Posijet® regardless of the selected application: “Diagnosis” or “Therapy”. The Therapy injection menu includes **specific radiopharmaceutical checks (concentration and radioisotope verification) and kits** to ensure safe administration.

In accordance with the administration conditions required in the Summaries of Product Characteristics (SCP) of radiopharmaceuticals, the user only enters the total administration time required and the rinse volumes. The Posijet® will automatically execute the recorded protocol of the drug, guaranteeing an **injected dose accuracy of more than 99 %** of the prescription. With the dose calibrator integrated in Posijet®, the operator can monitor the activity administered in real time, in addition to the remaining injection time. The injection unit also allows **partial administration** of single-dose vials to suit individual patient prescriptions. **An injection report in the form of labels** with configurable information and size is issued at the end of each radiopharmaceutical dose administration.



In addition to the intuitive interface of the Posijet® integrated screen, a **remote injection monitoring interface** is available, combining information on injected activity, remaining administration time, as well as alerts in case of patient problems. This interface is accessible via the Posijet® embedded website and therefore available on the service control screens.

FEATURES

General

Languages: French, English, Italian, Russian, Chinese. Other on request.

Units: Bq/MBq or Ci/mCi

"Diagnosis" application:
^{18}F - ^{68}Ga - ^{13}N- ^{99m}Tc

"Therapy" application: ^{177}Lu

Insertion of the stock solution:
shielded transport supplier pot fitted directly

Max. vial volume: depending on vial packaging adaptation

Accessibility to the injection unit internal data:
built-in web site to monitor use of the device in real time and consultation of QCs (remotely on PC and tablet)

Battery autonomy management:
indicator cartridge permanently displayed on screen and indicator light on control panel

Injections

Purge of system and kits:
automatic and manual purging

Injection modes:
automatic or manual,
can be changed during injection

Test vein before injection: yes,
with configurable NaCl volume

Injection rate management:
3 rates can be selected and configured:
"slow" (approx. 25 mL/min)
"normal" (approx. 33 mL/min)
"fast" (50 mL/min)
depending on the various catheters (yellow, blue, pink), and to take into account the specific features of the patient injection site.
The speed can be changed during injection (within the selected profile).
The rate is visible during injection.

Possibility of making 2 simultaneous injections: yes, with the RIS option

Total injection volume with rinsing:
10 mL injection dose + rinsing volume configurable from 10 to 30 mL

Details concerning rinsing with NaCl:
Rinsing volume as required for each injection from 10 to 30 mL after injection.
Possibility of other rinsing operations in downgraded mode if necessary.

Injection report:
Label printout (2 possible dimensions) after validating the configurable injection, info, number and size.
Possibility of printing out more labels at any time.

Injection site validation: yes

Measurements & dose preparation

Max. activity of a patient dose:
500 MBq (configurable value)

Integrated measuring instrument:
Scintidose dose calibrator (class Im medical device) always operational without warm-up time

Check report: customisable label
+ consultation possible on web site

Dilution: yes, function available at all times, with possibility of diluting as required or according to the device recommendations (always with a safety limit taking into account the total permitted volume of the vial)

Vial management: automatic vial pressure adjustment function to improve patient dose preparation

Maximum vial activity concentration:
max 3 GBq/mL

End-of-vial management: dilution possible and automatic measurement of remaining activity

Patient dose measurement method:
the activity sampled is measured directly in a 10 mL syringe filled up with saline solution to obtain identical measurement geometry for each measurement.

Max. volume of the sampling syringe: 10 mL

Minimum radiopharmaceutical sampling volume: 100 µL

Deferred preparation: yes, possibility of preparing the dose 0 to 10 min before the required injection time with automatic adjustment of the dose according to the decay

Calculation method: automated dose calculation according to the weight to be configured

Injection schedule: yes, to view the number of injections possible and change the patient order if necessary to optimise the vial and/or reassign a prepared dose
+ possibility of cancelling a patient.

Tools & downgraded cases

Management of a non-injectable prepared dose: reassign the dose to another patient using the schedule or redirect the dose to the portable bin

Customer support:
yes, remote maintenance + hotline
Real-time internal data log files saved for diagnosis in case of problem

Management of downgraded modes: yes, numerous downgraded modes are proposed to ensure that you never remain blocked:
"Utilities" menu - one tab is dedicated to downgraded actions
Fully downgraded mode with a "posi block" system allowing manual sampling

Safety & controls

Removing the flip off and hygiene of the septum: removal and manual disinfection of the septum after fitting the pot in its housing

Check of vial activity:
check of the vial activity concentration. The measured sample is then put back in the vial.

View of vial activity:
permanently on application screen

Safety & dose thresholds:
Max. 2 configurable doses (one for adults and one for children) protected by password.
Colour code to help the operator assess reliability of the dose prepared with respect to the prescription with admin password setting in case of over- and under-dosing.

Injection safety features:
Built-in air bubble detector.
Force detector to stop the injection in case of back-pressure.

Interoperability:
RIS or radiopharmacy software + DICOM

Compatibility with the following software: Venus, Pharma2000, Pharma Manager, Gera, DICOM protocol, HL7 Protocol (IBC NM, SECTRA, etc.) and others on request

RIS connection type:
one-way or two-way
wifi or ethernet

Software wizard:
Complete wizard: context help permanently available when using the device + photos for the loading process as well as complete step by step help for the user

NaCl bag management:
yes, with alert when replacement required (alert volume can be configured).
Several bag volumes can be configured.

Traceability:
each kit is canned before being positioned, thereby ensuring rigorous traceability in case of incident

Built-in safety on the kits:
bionector - mother solution kit
non-return valves - patient kit
bubble trap - patient kit

Medication integrity:
0.22 µm filter at patient kit output guarantees that the medication injected in the patient is sterile

Rinsing of stock solution kit after use: yes

Paediatric design

REGULATORY FRAMEWORK

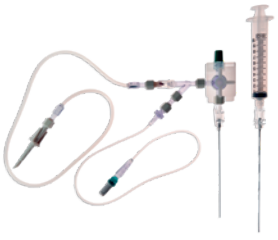
The Posijet® preparation and injection units meets the requirements of **EU regulation 2017/745** as a **class IIb medical device**. Electromedical device, compliant with **IEC 60601-1:2005 (+ A1/2012)(+ A2/2020)** for general safety requirement and **IEC 60601-1-2:2014 (+ A1/2020)** for electromagnetic compatibility. The control software for the LPDose dose calibrator meets the requirements of **IEC 62304:2006 (+ A1/2015)** for the software life cycle process. It is equipped with the necessary safety features for integration into a hospital network and is GDPR compatible. The Scintidose dose calibrator integrated in Posijet® meets the requirements of **EU regulation 2017/745** as a **class Im medical device** for its measurement function. It features inspection functions regulated by the **French decree of 25 November 2008** and **international standard IEC 61948-4**. Posijet® is also **certified for paediatric use (>1 year old)**.

Calibration and Presetting:

Factory calibration of ^{18}F and ^{68}Ga for the 10 mL syringe package (Posijet® dose measurement conditions) can be integrated into the software as required by the service. The Posijet® preparation and injection unit can also be calibrated on site by the Medical Physics Service of the hospital. Calibration by a certified body can be carried out in accordance with the requirements of the **COFRAC ISO 17025 accreditation standard** as an option.

CONSUMABLES

Patient kit
Ref: POSIKIT® 2



Stock solution kit
Ref: POSIKIT® 1B

CHARACTERISTICS

ALL **ENERGIES**

General

Overall dimensions:
L 616 x D 932 x H 1 261 mm

Weight: 380 kg

Frequency: 50/60 Hz

Supply voltage: 110 V - 240 V

Power supply: mains or battery

USB : yes

Screen type: touch screen

Shielding thickness:
25 mm around the sampling syringe
12 mm to 16 mm around the shielded drum of the radiopharmaceutical solution

Battery life: 8h

Outfitting:
15 colours and patterns to choose from possibility to integrate the service's logo

Presence of a bin:
Specific 20 mL syringe shield

Operator protection during injection:
shielding by injection unit

List of radioisotopes claimed by the manufacturer:
^{18}F (all fluorinated tracers: FDG, FNA, FDOPA, FCHOLINE, etc.)
^{13}N
^{68}Ga
^{177}Lu

Built-in measuring instrument:
Scintidose dose calibrator (class Im medical device) always operational without warm-up time

Measurement accuracy: +/– 2%

Quality controls: Auto programme of daily checks: zero, background noise, high voltage and shift + linearity, repeatability and reproducibility checks accessible via specific tabs

Motorised assistance: Motorised assistance with independent battery power supply, one-hand rotary control, progressive speed variation up to 2 km/h, forward and backward movement.
Automatic switching to standby if not used for 5 min or by pressing the special switch located on the machine control panel.

Manual operation: possible at all times

Brakes: by foot control

Accessories & Consumables

Consumables:
POSIKIT® 1B mother solution kit
POSIKIT® 2 patient kit

Accessories: top + bottom guide cones to guarantee perforation of the vial and kit connections

Compliances: Complies with EU regulation 2017/745 Class IIb medical device by notified body (0459)
Complies with international standard IEC 60601-1:2005 (+ A1/2012) (+ A2/2020)
IEC 60601-1-2:2014 (+ A1/2020)
IEC 62304:2006 (+ A1/2015)
Complies with the French decree of 25 November 2008
Complies with international standard IEC 61948-4
Complies with EU regulation 2016/679 (GDPR)
COFRAC calibration service on request (ISO 17025)
Certified for paediatric use (>1 year old)

Maintenance contract: yes

Radiation protection:

Maximum radioactivity that can be handled to obtain a dose rate less than 25 µSv/h at 5 cm from the walls*

Radionuclide	Maximum radioactivity that can be handled
^{18}F	37 GBq if the source is in its 30 mm lead transport pot

Calculation conditions: the user is positioned behind the Posijet® control panel

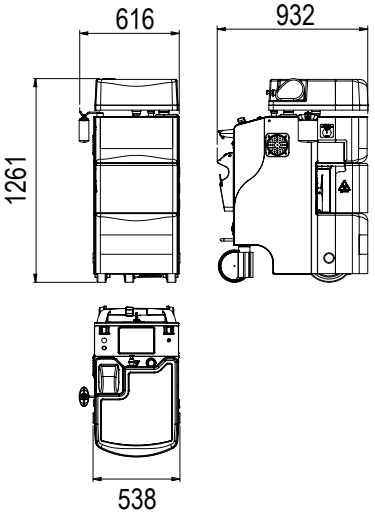
Package

Package dimensions:
L 850 x D 1 500 x H 1 580 mm

Package weight: 520 kg

Ref.: 00019530-CALPosijet®
with calibrated dose calibrator
00019530-ET Posijet®
with calibrated dose calibrator

EFFECTIVE DIMENSIONS (mm)



Paediatric version

AVAILABLE COLOURS (ALSO AVAILABLE FOR PAEDIATRIC DESIGN)

Dark blue | Light blue | Light grey | Yellow | Lilac | Orange | Pink | Red | Light green | Dark green | Antique pink | Violet

*Regulations in ASN Guide No.32 "In vivo nuclear medicine facilities: minimum technical rules for design, operation and maintenance"

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