



Viva Medical, UAB

Santariškių 5, LT-08406 Vilnius Tel.: +370 658 34334 info@vivamedical.lt Įmonės kodas 302820861, Įmonės
PVM kodas: LT100007018811

Registro tvarkytojas: VĮ Registrų centras Vilniaus filialas

LIETUVOS SVEIKATOS MOKSLŲ UNIVERSITETO LIGONINĖ

KAUNO KLINIKOS

(Adresatas (perkančioji organizacija))

PASIŪLYMAS

**DĖL AUTOMATINIO MULTIDOZIŲ INJEKTORIAUS PET RADIOFARMACINIŲ PREPARATŲ INJEKTAVIMUI
PIRKIMO**

2025-03-26 Nr.26/03/2025-1

(Data)

Vilnius

(Sudarymo vieta)

1 lentelė

TIEKĖJO REKVIZITAI

Tiekėjo pavadinimas /Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių pavadinimai/	Viva Medical, UAB
Tiekėjo adresas /Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių adresai/	Santariškių 5, Vilnius
Įmonės kodas, PVM mokėtojo kodas	302820861, LT100007018811
Atsiskaitomosios sąskaitos numeris, bankas, banko kodas	
Įmonės vadovo pareigos, vardas, pavardė	Direktorius Antanas Juška
Už pasiūlymą atsakingo asmens vardas, pavardė	
Už sutarties vykdymą atsakingo asmens pareigos, vardas, pavardė, el. pašto adresas, telefono numeris	
Telefono numeris	069932161
Fakso numeris	-
el. pašto adresas	info@vivamedical.lt

Šiuo pasiūlymu pažymime, kad sutinkame su visomis pirkimo sąlygomis, nustatytomis:

- 1) atviro konkurso skelbime, paskelbtame Viešųjų pirkimų įstatymo nustatyta tvarka;
- 2) kituose pirkimo dokumentuose (jų paaiškinimuose, papildymuose).

Pasirašydamas CVP IS priemonėmis pateiktą pasiūlymą, parašu patvirtinu, kad dokumentų skaitmeninės kopijos ir elektroninėmis priemonėmis pateikti duomenys yra tikri.

2 lentelė

SUBTIEKĖJO REKVIZITAI

Eil. Nr.	SubtiekJo (-ų) pavadinimas (-ai), adresas (-ai)

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*Pastaba: pildoma, jei tiekėjas ketina pasitelkti subtiekęją (-us)

3 lentelė

PASIŪLYMO KAINA

Kainų pasiūlymą užpildyti pirkimo dokumentų 6 priede „Kainų pasiūlymo lentelė“
(dokumentas turi būti pateikiamas redaguojamu formatu)

4 lentelė

PATEIKIAMŲ DOKUMENTŲ SĄRAŠAS

Eil. Nr.	Pateiktų dokumentų pavadinimas	Dokumento puslapių skaičius	Failo, kuriame yra dokumentas, pavadinimas
1	Gamintojo įgaliojimas	1	LETTER OF AUTHORIZATION_signed.pdf
2	CE sertifikatas	3	6_6 priedas KAINŲ PASIŪLYMO LENTELĖ.xls
3	Techninė specifikacija	4	Techninė specifikacija.docx
4	Kainų pasiūlymo lentelė	1	6_6 priedas KAINŲ PASIŪLYMO LENTELĖ.docx
5	Deklaracija dėl tiekėjo atsakingų asmenų	1	7_7 priedas DEKLARACIJA DĖL TIEKĖJO ATSAKINGŲ ASMENŲ.docx
6	Tiekėjo deklaracija dėl tarybos reglamente (es) 2022/576 nustatytų sąlygų nebuvimo	1	8_8 priedas Tiekėjo deklaracija.docx
7	EBVPD	15	espd-response.pdf ir espd-response.xml
8	Posijet_catalogue	8	Posijet_catalogue.pdf
9	POSIJET_Instructions Manual	172	POSIJET_Instructions Manual.pdf
10	Scintidose_manual	6	Scintidose_manual.pdf
11	Manufacturer declaration	1	Manufacturer declaration.pdf

Pasiūlymas galioja iki termino, nustatyto pirkimo dokumentuose.

Primintina, kad pasiūlyme nurodytos kainos bei įkainiai, taip pat nuolaidos dydis ar įkainio bazė, tiekėjo siūlomų prekių gamintojai, pavadinimai, modeliai, tiekėjo siūlomų prekių techninės specifikacijos, nurodomos užpildant perkančiosios organizacijos pateiktas lenteles, gaminio naudotojo instrukcija, tiekėjo siūlomų prekių atitiktį techninės specifikacijos reikalavimams įrodantys dokumentai - brošiūros, aprašymai, instrukcijos - nėra konfidenciali informacija (plačiau skaityti¹).

Pasiūlymo konfidencialią informaciją sudaro: (tiekėjai turi nurodyti, kokia pasiūlyme pateikta informacija yra konfidenciali. Jei pasiūlyme nėra konfidencialios informacijos, tiekėjas turi nurodyti, kad konfidencialios informacijos pasiūlyme nėra.):

Pasiūlyme konfidencialios informacijos nėra.

(Tiekėjo arba jo įgalioto asmens
pareigų pavadinimas)

(Parašas)

Vardas, pavardė

¹ https://vpt.lrv.lt/uploads/vpt/documents/files/mp/konfidenciali_informacija.pdf

Tiekėjo pavadinimas (nurodyti): Viva Medical, UAB

[illegible]

**Automatinio multidozių įjektoriaus PET radiofarmacinių preparatų injekavimui techninė
specifikacija (kiekis 1 vnt.)**

Eil. Nr.	Parametrai (specifikacija)	Reikalaujamos parametrų reikšmės	Siūlomos parametrų reikšmės
1.	Paskirtis	Įranga turi būti skirta automatiniam PET (pozitronų emisijos tomografijos) radiofarmacinių preparatų dozavimui ir injekavimui.	Įranga skirta automatiniam PET (pozitronų emisijos tomografijos) radiofarmacinių preparatų dozavimui ir injekavimui. Posijet catalogue (1p, 3p.)
2.	Radiofarmacinių preparatų dozavimo ir injekavimo sistema	<ol style="list-style-type: none"> Radiofarmacinio preparato dozavimas ir injekavimas vyksta naudojant vieną įrenginį; Sistema turi būti tinkama naudoti su populiariausiais PET radioizotopais (18F, 68Ga ir pan.) bei 177Lu; Reguliuojamas injekavimo greitis ne siauresnėse nei 7,5 ml/min - 27 ml/min ribose; Vieta fiziologinio tirpalo talpai (≥ 250 ml); Galimybė praskiesti radiofarmacinį preparatą; Praskiestas radiofarmacinio preparato aktyvumas turi būti nuolat matuojamas; Galimybė bet kurio metu sustabdyti injekavimą. 	<ol style="list-style-type: none"> Radiofarmacinio preparato dozavimas ir injekavimas vyksta naudojant vieną įrenginį; Posijet_catalogue (3p.) Sistema turi būti tinkama naudoti su populiariausiais PET radioizotopais (18F, 68Ga ir pan.) bei 177Lu; Posijet_catalogue (2p.) Reguliuojamas injekavimo greitis ne siauresnėse nei 7,5 ml/min - 27 ml/min ribose; Manufacturer declaration (1p.) Vieta fiziologinio tirpalo talpai 250ml, 500ml, 1000ml; POSIJET_Instructions Manual (44p.) Galimybė praskiesti radiofarmacinį preparatą; Posijet_catalogue (2p.) Praskiestas radiofarmacinio preparato aktyvumas nuolat matuojamas; Manufacturer declaration (1p.) Galimybė bet kurio metu sustabdyti injekavimą. POSIJET_Instructions Manual (17p.) POSIJET_Instructions Manual (6
3.	Ryšio protokolai	DICOM protokolas tiesioginiam RIS/PACS ryšiui ir darbų sąrašo importavimui	DICOM protokolas tiesioginiam RIS/PACS ryšiui ir darbų sąrašo importavimui POSIJET_Instructions Manual (28p.)

4.	Sistemos mobilumas	Sistemos mobilumas užtikrintas elektrinės pavaros pagalba	Sistemos mobilumas užtikrintas elektrinės pavaros pagalba Posijet_catalogue (8p.)
5.	Radiofarmacinio preparato buteliukai ir transportiniai konteineriai	<ol style="list-style-type: none"> 1. Galimybė naudoti buteliukus, kurių talpa ne mažesnė nei 10 ml ir ne didesnė nei 20 ml; 2. Suderinamas su kelių tipų radiofarmacinio preparato buteliukais; 3. Suderinamas su kelių tipų radiofarmacinio preparato transportiniais konteineriais; 4. Įrenginys instaliavimo metu turi būti pritaikytas naudoti su Comecer CF18T transportiniais konteineriais. 	<ol style="list-style-type: none"> 1. Galimybė naudoti buteliukus, kurių talpa ne mažesnė nei 10 ml ir ne didesnė nei 20 ml; Manufacturer declaration (1p.) 2. Suderinamas su kelių tipų radiofarmacinio preparato buteliukais; Manufacturer declaration (1p.) 3. Suderinamas su kelių tipų radiofarmacinio preparato transportiniais konteineriais; Posijet_catalogue (8p.) 4. Įrenginys instaliavimo metu turi būti pritaikytas naudoti su Comecer CF18T transportiniais konteineriais. Manufacturer declaration (1p.)
6.	Dozių kalibratorius	<ol style="list-style-type: none"> 1. Energijų diapazonas ne siauresnis nei 30 keV - 2 MeV; 2. Bendras tikslumas (paklaida) $\leq \pm 5 \%$; 3. Didžiausias naudojamas aktyvumas (18F): ≥ 30 GBq. 	<ol style="list-style-type: none"> 1. Energijų diapazonas 30 keV - 2 MeV; Scintidose_manual (6p.) 2. Bendras tikslumas (paklaida) $\pm 2 \%$; Posijet_catalogue (8p.) 3. Didžiausias naudojamas aktyvumas (18F): 37 GBq. Posijet_catalogue (8p.)
7.	Įrangos valdymas	Įranga valdoma jutiklinio ekrano pagalba	Įranga valdoma jutiklinio ekrano pagalba Posijet_catalogue (2p.)
8.	Saugumo savybės	<ol style="list-style-type: none"> 1. Apsaugos sistema, kuri neleis dozavimo, jei durys neuždarytos; 2. Prietaiso aplinka apsaugota nuo jonizuojančiosios spinduliuotės poveikio – dozės galia $\leq 10 \mu\text{Sv/h}$ (10 cm atstumu) arba $\leq 25 \mu\text{Sv/h}$ (5 cm atstumu); 3. Vieta ekranuotai talpyklai su radiofarmacinio preparato buteliuku įdėti; 4. Burbulų detektorius. 	<ol style="list-style-type: none"> 1. Apsaugos sistema, neleidžianti dozavimo, jei durys neuždarytos; Manufacturer declaration (1p.) 2. Prietaiso aplinka apsaugota nuo jonizuojančiosios spinduliuotės poveikio – dozės galia $\leq 25 \mu\text{Sv/h}$ (5 cm atstumu); Posijet_catalogue (8p.) 3. Vieta ekranuotai talpyklai su radiofarmacinio preparato buteliuku įdėti; Posijet_catalogue (2p.) 4. Burbulų detektorius. Posijet_catalogue (3p.)

9.	Bendra sistemos masė	≤ 380 kg	380 kg Posijet catalogue (8p.)
10.	Maitinimo įtampa	230 VAC (50 Hz)	230 VAC (50 Hz) Posijet catalogue (8p.)
11.	Akumuliatorius	Garantuojamas veikimo autonomiškumas ≥ 8 val. standartiniam naudojimui.	Garantuojamas veikimo autonomiškumas 8 val. standartiniam naudojimui. Posijet catalogue (8p.)
12.	Garantinis terminas	≥ 24 mėnesiai	24 mėnesiai
13.	Žymėjimas CE ženklu	Būtinas (kartu su pasiūlymu būtina pateikti žymėjimą CE ženklu liudijančio galiojančio dokumento (CE sertifikato arba EB atitikties deklaracijos) kopiją)	Pateikiamas CE sertifikatas
14.	Įrangos pristatymas ir instaliavimas	Įrangos pristatymo, iškrovimo, pervežimo į instaliavimo vietą, instaliavimo, po instaliavimo likusių įpakavimo medžiagų išvežimo (utilizavimo) išlaidos įskaičiuotos į pasiūlymo kainą.	Įrangos pristatymo, iškrovimo, pervežimo į instaliavimo vietą, instaliavimo, po instaliavimo likusių įpakavimo medžiagų išvežimo (utilizavimo) išlaidos įskaičiuotos į pasiūlymo kainą.
15.	Įrangos testavimas / priėmimo bandymai	Būtina (įrangos tiekėjas ar gamintojo atstovas po įrangos sumontavimo ir suderinimo įsipareigoja atlikti arba organizuoti priėmimo testus (angl. site acceptance tests), remiantis gamintojo rekomendacijomis).	Įrangos tiekėjas ar gamintojo atstovas po įrangos sumontavimo ir suderinimo įsipareigoja atlikti arba organizuoti priėmimo testus (angl. site acceptance tests), remiantis gamintojo rekomendacijomis).
16.	Metrologinė patikra	Būtina (įrangos tiekėjas ar gamintojo atstovas po įrangos sumontavimo ir suderinimo įsipareigoja atlikti arba organizuoti dozių kalibratoriaus metrologinę patikrą 18F, 68Ga, 177Lu radioizotopams).	Metrologinė patikra (įrangos tiekėjas ar gamintojo atstovas po įrangos sumontavimo ir suderinimo įsipareigoja atlikti arba organizuoti dozių kalibratoriaus metrologinę patikrą 18F, 68Ga, 177Lu radioizotopams).
17.	Vartotojų apmokymas	Vartotojų apmokymas naudoti įrangą įskaičiuotas į pasiūlymo kainą.	Vartotojų apmokymas naudoti įrangą įskaičiuotas į pasiūlymo kainą.
18.	Priemonės periodiniams kokybės kontrolės bandymams atlikti	Būtina (įskaitant radioaktyvųjį šaltinį periodiniams kokybės kontrolės bandymams atlikti).	Priemonės periodiniams kokybės kontrolės bandymams atlikti (įskaitant radioaktyvųjį šaltinį periodiniams kokybės kontrolės bandymams atlikti).
19.	Kartu su įranga pateikiama dokumentacija	1. Naudojimo instrukcija lietuvių ir anglų kalba; 2. Serviso dokumentacija lietuvių arba anglų kalba: a) Struktūrinė schema ir/arba atskirų blokų funkcijų aprašymas;	Kartu su įranga pateikiama dokumentacija: 1. Naudojimo instrukcija lietuvių ir anglų kalba; 2. Serviso dokumentacija lietuvių arba anglų kalba:

		b) Instaliavimo instrukcijos; c) Funkcionalumo patikrinimo instrukcijos; d) Aptarnavimo instrukcijos; e) Gedimų nustatymo instrukcijos; f) Išardymo-surinkimo instrukcijos; g) Atsarginių dalių katalogas; h) Periodinio techninės būklės tikrinimo instrukcijos; i) Derinimo/kalibravimo instrukcijos (taikoma, jei šios procedūros yra numatytos siūlomos įrangos gamintojo); j) Programinė įranga, serviso slaptažodžiai bei aparatūriniai „raktai“ b), c), d), e), h) ir i) punktuose nurodytiems darbams atlikti (taikoma, jei šios priemonės yra numatytos siūlomos įrangos gamintojo).	a) Struktūrinė schema ir/arba atskirų blokų funkcijų aprašymas; b) Instaliavimo instrukcijos; c) Funkcionalumo patikrinimo instrukcijos; d) Aptarnavimo instrukcijos; e) Gedimų nustatymo instrukcijos; f) Išardymo-surinkimo instrukcijos; g) Atsarginių dalių katalogas; h) Periodinio techninės būklės tikrinimo instrukcijos; i) Derinimo/kalibravimo instrukcijos (taikoma, jei šios procedūros yra numatytos siūlomos įrangos gamintojo); j) Programinė įranga, serviso slaptažodžiai bei aparatūriniai „raktai“ b), c), d), e), h) ir i) punktuose nurodytiems darbams atlikti (taikoma, jei šios priemonės yra numatytos siūlomos įrangos gamintojo).
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Europos bendrasis viešųjų pirkimų dokumentas (EBVPD)

I dalis. Informacija apie pirkimo procedūrą ir perkančiąją organizaciją ar perkantįjį subjektą

Informacija apie paskelbimą

Skelbimo numeris OL S (tik tarptautiniams pirkimams):

-

Skelbimo numeris CVP IS (kur rasti?):

-

Perkančiosios organizacijos / Perkančiojo subjekto tapatybė

Oficialus pavadinimas:

LSMUL KAUNO KLINIKOS

Šalis:

Lietuva

Informacija apie pirkimo procedūrą

Procedūros tipas

Nepasirinkta

Pavadinimas:

AUTOMATINIS MULTIDOZIŲ INJEKTORIUS PET RADIOFARMACINIŲ PREPARATŲ
INJEKTAVIMUI

Trumpas aprašymas:

AUTOMATINIS MULTIDOZIŲ INJEKTORIUS PET RADIOFARMACINIŲ PREPARATŲ
INJEKTAVIMUI

**Perkančiosios organizacijos ar perkančiojo subjekto (jei taikoma)
priskirtas dokumento numeris:**

-

II dalis. Informacija apie ekonominės veiklos vykdytoją

A. Informacija apie ekonominės veiklos vykdytoją

Tiekėjo pavadinimas arba vardas ir pavardė (jei fizinis asmuo):

Viva Medical, UAB

Gatvė ir namo numeris:

Santariškių 5, Vilnius

Pašto kodas:

08406

Miestas:

Vilnius

Šalis:

Lietuva

Interneto adresas (jei yra):

-

E. paštas:

info@vivamedical.lt

Telefonas:

+37069932161

Asmuo ar asmenys ryšiams:

Viva Medical, UAB

PVM mokėtojo kodas, jei yra:

LT100007018811

Jei PVM mokėtojo kodo nėra, nurodykite kitą nacionalinį identifikacinį numerį (Lietuvoje - įmonės kodą)

-

Ar ekonominės veiklos vykdytojas yra labai maža, mažoji ar vidutinė įmonė?

☒ Taip

☐ Ne

Tik tuo atveju, kai pirkimas rezervuotas: ar ekonominės veiklos vykdytojas yra globojama darbo grupė (neįgaliųjų socialinė įmonė), socialinė įmonė? Ar jis vykdys sutartį pagal globojamų darbo grupių (neįgaliųjų socialinių įmonių) užimtumo programas?

☐ Taip

☒ Ne

Jei taikoma, ar ekonominės veiklos vykdytojas įtrauktas į oficialų patvirtintų ekonominės veiklos vykdytojų sąrašą arba ar jis turi lygiavertį sertifikatą (pvz., pagal nacionalinę (išankstinę) kvalifikacijos vertinimo sistemą)? Lietuvos tiekėjai renkasi „ne“

☐ Taip

☒ Ne

- Be to, užpildykite trūkstamą informaciją IV dalies A, B, C arba D skirsniuose, atsižvelgdami į konkretų atvejį TIK jei to reikalaujama atitinkamame skelbime arba pirkimo dokumentuose:

e) Ar ekonominės veiklos vykdytojas galės pateikti sertifikatą dėl socialinio draudimo įmokų ir mokesčių mokėjimo arba pateikti informaciją, kuri leistų perkančiajai organizacijai ar perkančiajam subjektui jį gauti tiesiogiai naudojantis prieiga prie bet kurios iš valstybių narių nemokamos nacionalinės duomenų bazės?

☒ Taip

☐ Ne

Jei atitinkami dokumentai prieinami elektroniniu būdu, nurodykite:

-

Ar ekonominės veiklos vykdytojas pirkimo procedūroje dalyvauja kartu su kitais? Žymima TAIP, jei pasiūlymą teikia ūkio subjektų grupė (konsorciumas) pagal jungtinės veiklos sutartį

☐ Taip

☒ Ne

Jei pirkimas padalintas į dalis, nuoroda į pirkimo dalį (-is), dėl kurios (-ių) ekonominės veiklos vykdytojas nori dalyvauti konkurse:

-

B. Informacija apie ekonominės veiklos vykdytojo teisinius atstovus #1

- Šis skirsnis pildomas, jeigu tiekėjo vadovas įgalioja kitą asmenį pasirašyti pasiūlymą, bendrauti su pirkimo vykdytoju, įgalioja atstovauti ir pasirašyti EBVPD, bendrauti su pirkimo vykdytoju dėl EBVPD pateiktos informacijos, teikiamų kvalifikaciją ir pašalinimo pagrindų nebuvimą pagrindžiančių dokumentų, dėl pasiūlymo ir pan.

Jei taikytina, nurodykite asmens (-ų), įgalioto (-ų) atstovauti ekonominės veiklos vykdytojui šios pirkimo procedūros tikslais, vardą ir pavardę ir adresą:

Vardas

[Redacted]

Pavardė

[redacted]
Gimimo data

[redacted]
Gimimo vieta

[redacted]
Gatvė ir namo numeris:

[redacted]
Pašto kodas:

08113

Miestas:

Vilnius

Šalis:

Lietuva

E. paštas:

[redacted]
Telefonas:

[redacted]
Pareigos arba statusas:

[redacted]
Prireikus pateikite išsamią informaciją apie atstovavimą (formą, aprėptį, paskirtį ir t. t.):

-

C. Informacija apie rėmimąsi kitų subjektų pajėgumais

Ar siekdamas patenkinti IV dalyje nurodytus atrankos kriterijus ir V dalyje nurodytus kriterijus bei taisykles (jei tokių yra) ekonominės veiklos vykdytojas remiasi kitų subjektų pajėgumais?

☐ Taip

☒ Ne

D. Informacija apie subrangovus, kurių pajėgumais ekonominės veiklos vykdytojas nesiremia

- (Skirsnį reikia pildyti, tik jei šios informacijos aiškiai reikalauja perkančioji organizacija ar perkantysis subjektas.)

Ar ekonominės veiklos vykdytojas ketina kurias nors sutarties dalis subrangos sutartimi pavesti atlikti trečiosioms šalims?

☐ Taip

☒ Ne

- Jei perkančioji organizacija ar perkantysis subjektas aiškiai prašo šios informacijos, šalia informacijos pagal šį skirsnį, pateikite pagal šios dalies A ir B skirsnius ir III dalį reikalaujamą informaciją apie kiekvieną susijusį subrangovą (subrangovų kategorijas).

III dalis. Pašalinimo pagrindai

A. Su baudžiamaisiais nuosprendžiais susiję pagrindai

Direktyvos 2014/24/ES 57 straipsnio 1 dalyje nustatyti šie pašalinimo pagrindai

A1. Dalyvavimas nusikalstamos organizacijos veikloje (VPĮ 46 str. 1 d. 1 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už dalyvavimą nusikalstamos organizacijos veikloje, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2008 m. spalio 24 d. Tarybos pamatinio sprendimo 2008/841/TVR dėl kovos su organizuotu nusikalstamumu 2 straipsnyje (OL L 300, 2008 11 11, p. 42).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A2. Korupcija (VPĮ 46 str. 1 d. 2 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už korupciją, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo

laikotarpis tebesitęsia? Kaip apibrėžta Konvencijos dėl kovos su korupcija, susijusia su Europos Bendrijų pareigūnais ar Europos Sąjungos valstybių narių pareigūnais, 3 straipsnyje (OL C 195, 1997 6 25, p. 1) ir 2003 m. liepos 22 d. Tarybos pamatinio sprendimo 2003/568/TVR dėl kovos su korupcija privačiame sektoriuje 2 straipsnio 1 dalyje (OL L 192, 2003 7 31, p. 54). Į pašalinimo pagrindus taip pat įtraukta korupcija, kaip apibrėžta perkančiosios organizacijos (perkančiojo subjekto) arba ekonominės veiklos vykdytojo nacionalinėje teisėje.

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A3. Sukčiavimas (VPĮ 46 str. 1 d. 3 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už sukčiavimą, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Pagal Europos Bendrijų finansinių interesų apsaugos konvencijos 1 straipsnį (OL C 316, 1995 11 27, p. 48).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A4. Teroristiniai nusikaltimai arba su teroristine veikla susiję nusikaltimai (VPĮ 46 str. 1 d. 5 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už teroristinius nusikaltimus arba

su teroristine veikla susijusius nusikaltimus, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2002 m. birželio 13 d. Tarybos pamatinio sprendimo dėl kovos su terorizmu 1 ir 3 straipsniuose (OL L 164, 2002 6 22, p. 3). Į pašalinimo pagrindus taip pat įtrauktas nusikalstamos veikos kurstymas, pagalba ar bendrininkavimas ją vykdant arba kėsiniimasis ją įvykdyti, kaip nurodyta to pamatinio sprendimo 4 straipsnyje.

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A5. Pinigų plovimas arba teroristų finansavimas (VPĮ 46 str. 1 d. 6 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už pinigų plovimą arba teroristų finansavimą, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2005 m. spalio 26 d. Europos Parlamento ir Tarybos direktyvos 2005/60/EB dėl finansų sistemos apsaugos nuo jos panaudojimo pinigų plovimui ir teroristų finansavimui 1 straipsnyje (OL L 309, 2005 11 25, p. 15).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

A6. Vaikų darbas ir kitos prekybos žmonėmis formos (VPĮ 46 str. 1 d. 7 p.)

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo,

sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo nuteistas galutiniu teismo sprendimu už vaikų darbą arba kitas prekybos žmonėmis formas, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia? Kaip apibrėžta 2011 m. balandžio 5 d. Europos Parlamento ir Tarybos direktyvos 2011/36/ES dėl prekybos žmonėmis prevencijos, kovos su ja ir aukų apsaugos, pakeičiančios Tarybos pamatinį sprendimą 2002/629/TVR, 2 straipsnyje (OL L 101, 2011 4 15, p. 1).

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

B. Su mokesčių ar socialinio draudimo įmokų mokėjimu susiję pagrindai **Direktyvos 2014/24/ES 57 straipsnio 2 dalyje nustatytos šios pašalinimo priežastys**

B1. Mokesčių mokėjimas VPĮ 46 str. 3 d.

Ar ekonominės veiklos vykdytojas pažeidė savo pareigas, susijusias su mokesčių mokėjimu, tiek šalyje, kurioje yra įsisteigęs, tiek perkančiosios organizacijos ar perkančiojo subjekto valstybėje narėje, jei tai nėra jo įsisteigimo šalis?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

B2. Socialinio draudimo įmokų mokėjimas VPĮ 46 str. 3 d.

Ar ekonominės veiklos vykdytojas pažeidė savo pareigas, susijusias su socialinio draudimo įmokų mokėjimu, tiek šalyje, kurioje yra įsisteigęs, tiek perkančiosios organizacijos ar perkančiojo subjekto valstybėje narėje, jei tai nėra jo įsisteigimo šalis?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☒ Taip

☐ Ne

URL

https://draudejai.sodra.lt/draudeju_viesi_duomenys/

Kodas

2171927

Emitentas

Valstybinio socialinio draudimo fondo valdyba prie Socialinės apsaugos ir darbo ministerijos

C. Su nemokumu, interesų konfliktu ar profesiniais nusižengimais susiję pagrindai

Direktyvos 2014/24/ES 57 straipsnio 4 dalyje nustatyti šie pašalinimo pagrindai

C10. Su kitais ekonominės veiklos vykdytojais sudaryti susitarimai, kuriais siekta iškreipti konkurenciją (VPĮ 46 str. 4 d. 1 p.)

Ar ekonominės veiklos vykdytojas su kitais ekonominės veiklos vykdytojais yra sudaręs susitarimų, kuriais siekta iškreipti konkurenciją atliekamame pirkime?

Jūsų atsakymas

☐ Taip

☒ Ne

C11. Rimti profesiniai pažeidimai VPĮ 46 str. 4 d. 7 p., VPĮ 46 str. 6 d. 3 p.

Pirkimams pradėtiems nuo 2022-01-01: Ar ekonominės veiklos vykdytojas yra padaręs rimtą profesinį pažeidimą, kaip nurodyta žemiau?:

a) yra padaręs finansinės atskaitomybės ir audito teisės aktų pažeidimą ir nuo jo padarymo dienos praėjo mažiau kaip vieni metai; **Nuo 2022-08-12 pildydamas EBVPD tiekėjas yra informuotas ir supranta, kad finansinės atskaitomybės ir audito teisės aktų pažeidimu taip pat gali būti laikomi atvejai, kai tiekėjas nepateikia privalomų finansinės atskaitomybės dokumentų Registrų centrui ar juos pateikia nesilaikydamas privalomų teisės aktų reikalavimų. Išsamiau: <https://vpt.lrv.lt/lt/naujienos-3/>**

finansiniu-ataskaitu-nepateikimas-gali-tapti-kliutimi-dalyvauti-viesuosiuose-pirkimuose

b) neatitinka minimalių patikimo mokesčių mokėtojo kriterijų, nustatytų Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje. Taikant šį tiekėjo pašalinimo iš pirkimo procedūros pagrindą, vadovaujamosi Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje nustatytais terminais, juos skaičiuojant nuo Mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje nurodytų pažeidimų padarymo dienos, tačiau visais atvejais šie terminai negali būti ilgesni negu 3 metai;

c) yra padaręs draudimo sudaryti draudžiamus susitarimus, įtvirtinto Lietuvos Respublikos konkurencijos įstatyme ar panašaus pobūdžio kitos valstybės teisės akte, pažeidimą ir nuo jo padarymo dienos praėjo mažiau kaip 3 metai;

d) yra padaręs bet kokią kitą rimtą profesinį pažeidimą, nenurodytą aukščiau, nuo kurio padarymo dienos praėjo mažiau kaip vieni metai?

Pirkimams pradėtiems iki 2022-01-01: Ar ekonominės veiklos vykdytojas yra pripažintas kaltu dėl sunkaus profesinio nusižengimo kaip nurodyta žemiau?

I. ar ekonominės veiklos vykdytojas yra padaręs profesinį pažeidimą, kai už finansinės atskaitomybės ir audito teisės aktų pažeidimus ekonominės veiklos vykdytojui ar jo vadovui paskirta administracinė nuobauda ar ekonominė sankcija, nustatytos Lietuvos Respublikos įstatymuose ar kitų valstybių teisės aktuose, ir nuo sprendimo, kuriuo buvo paskirta ši sankcija, įsiteisėjimo dienos arba nuo dienos, kai asmuo įvykdė administracinį nurodymą, praėjo mažiau kaip vieni metai?

II. Ar ekonominės veiklos vykdytojas yra padaręs kurį nors vieną iš žemiau nurodytų rimtų profesinių pažeidimų(taikoma tik tada kai, ir tik tiek, kiek apibrėžta kituose pirkimo dokumentuose):

a) profesinės etikos pažeidimas, kai nuo ekonominės veiklos vykdytojo pripažinimo nesilaikančiu profesinės etikos normų momento praėjo mažiau kaip vieni metai;

b) konkurencijos, darbuotojų saugos ir sveikatos, informacijos apsaugos, intelektinės nuosavybės apsaugos pažeidimas, už kurį ekonominės veiklos vykdytojui ar jo vadovui yra paskirta administracinė nuobauda ar ekonominė sankcija, nustatytos Lietuvos Respublikos ar kitų valstybių įstatymuose, kai nuo sprendimo, kuriuo buvo paskirta ši sankcija, arba nuo dienos, kai asmuo įvykdė administracinį nurodymą, įsiteisėjimo dienos praėjo mažiau kaip vieni metai;

c) draudimo sudaryti draudžiamus susitarimus, įtvirtinto Lietuvos Respublikos konkurencijos įstatyme ar panašaus pobūdžio kitos valstybės teisės akte, pažeidimas, kai nuo sprendimo paskirti Konkurencijos įstatyme ar kitos valstybės teisės akte nustatytą ekonominę sankciją įsiteisėjimo dienos praėjo mažiau kaip 3 metai;

d) ekonominės veiklos vykdytojas, kuris yra fizinis asmuo, arba ekonominės veiklos vykdytojo, kuris yra juridinis asmuo, kita organizacija ar jos padalinys, vadovas, kitas valdymo ar priežiūros organo narys ar kitas asmuo, turintis (turintys) teisę atstovauti ekonominės veiklos vykdytojui ar jį kontroliuoti, jo vardu priimti sprendimą, sudaryti sandorį, arba dalyvis, turintis balsų daugumą juridinio asmens dalyvių susirinkime, yra pripažintas kaltu dėl tyčinio bankroto, kaip jis apibrėžtas Lietuvos Respublikos įmonių bankroto įstatyme ar panašaus pobūdžio kitų valstybių teisės aktuose, kai nuo teismo sprendimo įsiteisėjimo dienos praėjo mažiau kaip 3 metai?

Jūsų atsakymas

☐ Taip

☒ Ne

C12. Interesų konfliktas dėl dalyvavimo pirkimo procedūroje (VPĮ 46 str. 4 d. 2 p.)

Ar ekonominės veiklos vykdytojas žino apie kokius nors [interesų konfliktus](#), kaip nurodyta nacionalinėje teisėje, atitinkamame skelbime ar pirkimo dokumentuose, kylančius dėl jo dalyvavimo pirkimo procedūroje?

Jūsų atsakymas

☐ Taip

☒ Ne

C13. Tiesioginis arba netiesioginis dalyvavimas rengiant šią pirkimo procedūrą (46 str. 4 d. 3 p.)

Ar ekonominės veiklos vykdytojas arba su juo susijusi įmonė konsultavo perkančiąją organizaciją ar perkantįjį subjektą arba kitaip dalyvavo rengiant pirkimo procedūrą?

Jūsų atsakymas

☒ Taip

☐ Ne

Pateikite išsamią informaciją apie tai

Konsultacija rengiant techninius reikalavimus.

C14. Sutarties nutraukimas anksčiau laiko, žala ar kitos panašios sankcijos (VPĮ 46 str. 4 d. 6 p.)

Ar ekonominės veiklos vykdytojas turėjo tokios patirties: ankstesnė viešoji sutartis, ankstesnė sutartis su perkančiuoju subjektu arba ankstesnė koncesijos sutartis buvo nutraukta anksčiau laiko; arba buvo pareikalauta atlyginti su ankstesne sutartimi susijusią žalą ar skirtos kitos panašios sankcijos?

Lietuvoje (be kita ko) - ar ekonominės veiklos vykdytojas yra įtrauktas į nepatikimų tiekėjų sąrašą ?

Jūsų atsakymas

☐ Taip

☒ Ne

C15. Pripažinimas kaltu dėl faktų iškraipymo, informacijos nuslėpimo, negalėjimas pateikti reikalaujamų dokumentų ir su šia procedūra susijusios konfidencialios informacijos gavimas (46 str. 4 d. 4 p. ir 46 str. 4 d. 5 p.)

Ar ekonominės veiklos vykdytojas yra susijęs su vienu iš šių atvejų, kai jis :

- a) buvo labai iškreipęs faktus pateikdamas informaciją (**pateikęs melagingą informaciją**), reikalingą patikrinti, ar nėra pagrindų pašalinti, arba patikrinti atitiktį atrankos kriterijams;
- b) slėpė tokią informaciją;
- c) delsė pateikti patvirtinamuosius dokumentus, kurių reikalavo perkančioji organizacija ar perkantysis subjektas,
- d) siekė daryti neteisėtą įtaką perkančiosios organizacijos ar perkančiojo subjekto sprendimų priėmimo procesui, kad gautų konfidencialios informacijos, dėl kurios per pirkimo procedūrą įgytų nepagrįstą pranašumą, arba tyčia teikti klaidinančios informacijos, kuri gali turėti esminės įtakos sprendimams dėl pašalinimo, atrankos ar sutarties skyrimo?

Jūsų atsakymas

☐ Taip

☒ Ne

D. Išimtinai nacionaliniai pašalinimo pagrindai

Išimtinai nacionaliniai pašalinimo pagrindai, nurodyti atitinkamame skelbime ar pirkimo dokumentuose.

D1. Išimtinai nacionalinis pašalinimo pagrindas dėl nusikalstamo bankroto (VPĮ 46 str. 1 d. 4 p.)

Pirkimams pradėtiems nuo 2022-01-01:

Ar pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo **nuteistas galutiniu teismo sprendimu už nusikalstamą bankrotą**, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia?

Pirkimams pradėtiems iki 2022-01-01:

Ar ekonominės veiklos vykdytojas yra susijęs su vienu iš šių atvejų, kai:

a) jis **neatitinka minimalių patikimo mokesčių mokėtojo kriterijų**, nustatytų Lietuvos Respublikos mokesčių administravimo įstatymo 40¹ straipsnio 1 dalyje ir dėl to laikomas padariusiu šiurkštų profesinį pažeidimą.

b) pats ekonominės veiklos vykdytojas ar bet kuris asmuo, kuris yra jo administracijos, valdymo ar priežiūros organo narys arba turi atstovavimo, sprendimo ar kontrolės įgaliojimus to ekonominės veiklos vykdytojo atžvilgiu, buvo **nuteistas galutiniu teismo sprendimu už nusikalstamą bankrotą**, o nuosprendis priimtas prieš ne daugiau kaip penkerius metus arba kai nuosprendyje aiškiai nustatytas pašalinimo laikotarpis tebesitęsia?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

D2. Išimtinai nacionalinis pašalinimo pagrindas dėl paskirtos

baudžiamojo poveikio priemonės (VPĮ 46 str. 2¹ d.)

Pirkimams pradėtiems nuo 2025-02-01:

Ar ekonominės veiklos vykdytojui yra taikoma sąlyga, kad jis yra neatlikęs jam paskirtos baudžiamojo poveikio priemonės – uždraudimo juridiniam asmeniui dalyvauti viešuosiuose pirkimuose?

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

IV dalis. Atrankos kriterijai

α. Visų atrankos kriterijų bendra nuoroda

Dėl atrankos kriterijų ekonominės veiklos vykdytojas pareiškia, kad

Jis atitinka visus reikalaujamus atrankos kriterijus

Jūsų atsakymas

☒ Taip

☐ Ne

Baigti

IV dalis. Kandidatų, kurių kvalifikacija tinkama, skaičiaus sumažinimas

Ekonominės veiklos vykdytojas pareiškia, kad:

Tais atvejais, kai pirkimo dokumentuose perkančioji organizacija ar perkantysis subjektas yra nustatęs objektyvius ir nediskriminacinius kriterijus ar taisykles, taikytinus siekiant sumažinti kandidatų skaičių ir kai reikalaujama tam tikrų sertifikatų ar kitų formų įrodomųjų dokumentų, ekonominės veiklos vykdytojas pareiškia, jog turi kiekvieną reikiamą dokumentą.

Jei kai kurie iš šių sertifikatų ar įrodomųjų dokumentų formų prieinami elektroniniu būdu, nurodykite kiekvieno iš jų:

Jūsų atsakymas

☐ Taip

☒ Ne

Ar ši informacija ES valstybės narės duomenų bazėje nemokamai prieinama valdžios institucijoms?

☐ Taip

☒ Ne

IV dalis. Baigiamieji pareiškimai

Ekonominės veiklos vykdytojai oficialiai pareiškia, kad II–V dalyse pateikta informacija yra tiksli ir teisinga ir kad ji pateikta visiškai suvokiant didelio faktų iškreipimo padarinius.

Ekonominės veiklos vykdytojai oficialiai pareiškia, kad pareikalavus gali nedelsdami pateikti nurodytus sertifikatus ir kitų formų įrodomuosius dokumentus, išskyrus tuos atvejus, kai:

a) perkančioji organizacija ar perkantysis subjektas turi galimybę atitinkamus patvirtinamuosius dokumentus tiesiogiai gauti naudodamiesi prieiga prie bet kurios iš valstybių narių nemokamos nacionalinės duomenų bazės (su sąlyga, kad ekonominės veiklos vykdytojas pateikė reikalingą informaciją (interneto

adresą, išduodančiąją instituciją ar įstaigą, tiksliai dokumentų nuorodas), kuri perkančiajai organizacijai ar perkančiajam subjektui leidžia tai padaryti (pareikalavus dėl tokios prieigos turi būti pridėtas atitinkamas sutikimas), arba b) perkančioji organizacija ar perkantysis subjektas yra gavusi ir turi aktualius susijusius dokumentus iš ankstesnių (kitų) pirkimo procedūrų.

Ekonominės veiklos vykdytojai oficialiai sutinka perkančiajai organizacijai ar perkančiajam subjektui, nurodytam I dalyje, leisti susipažinti su dokumentais, kuriais patvirtinama informacija, pateikta šio Europos bendrojo viešųjų pirkimų dokumento III ir IV dalyse, kiek tai susiję su pirkimu, nurodytu I dalyje.

Data, vieta ir, jei reikia ar būtina, parašas (-ai):

Data

04-04-2025

Vieta

Vilnius

Parašas

VALSTYBĖS ĮMONĖ REGISTRŲ CENTRAS

Studentų g. 39, 08106 Vilnius, tel. +370 5 268 8262, el. p. info@registrucentras.lt

**KOMPETENTINGŲ INSTITUCIJŲ TVARKOMŲ JUNGTINIŲ DUOMENŲ APIE VIEŠŲJŲ
PIRKIMŲ PROCEDŪROJE DALYVAUJANTĮ TIEKĖJĄ (JURIDINĮ ASMENĮ)
PAŽYMA**

2025-03-12 Nr. 761385

Tiekėjo pavadinimas	Viva Medical, UAB
Tiekėjo kontaktinė informacija:	
mobilusis telefonas	+37069932161
elektroninio pašto adresas	info@vivamedical.lt
interneto svetainės adresas	www.vivamedical.lt
Buhalterio (buhalterių) ar kito (kitų) asmens (asmenų), turinčio (turinčių) teisę surašyti ir pasirašyti tiekėjo apskaitos dokumentus, vardas, pavardė	
<u>Juridinių asmenų registras:</u>	
kodas	302820861
teisinė forma	Uždaroji akcinė bendrovė
teisinis statusas	Teisinis statusas neįregistruotas
buveinė (adresas)	Vilnius, Pramonės g. 97, LT-11115
Vadovo, kito valdymo ar priežiūros organo nario ar kito asmens, turinčio (turinčių) teisę atstovauti tiekėjui ar jį kontroliuoti, jo vardu priimti sprendimą, sudaryti sandorį, vardas, pavardė	ANTANAS JUŠKA
įregistravimo data	2012-07-16
<u>Valstybinė mokesčių inspekcija prie Lietuvos Respublikos finansų ministerijos:</u>	
duomenys apie tiekėjo atsiskaitymą su valstybės, savivaldybių biudžetais ir valstybės pinigų fondais	Atsiskaitęs
Duomenų suformavimo data	2025-03-10
<u>Valstybinio socialinio draudimo fondo valdyba prie Socialinės apsaugos ir darbo ministerijos:</u>	
duomenys apie tiekėjo atsiskaitymą su Valstybinio socialinio draudimo fondu	Neįsiskolinęs
Duomenų suformavimo data	2025-03-10
<u>Įtariamųjų, kaltinamųjų ir nuteistųjų registras:</u>	
duomenys apie tiekėją	Dėl UAB Viva Medical, kodas 302820861, per pastaruosius 5 metus nėra priimtas ir įsiteisėjęs apkaltinamasis teismo nuosprendis už nusikalstamas veikas, nurodytas Lietuvos Respublikos viešųjų pirkimų įstatymo 46 straipsnio 1 dalyje ir 3 dalyje. Nėra paskirta baudžiamojo poveikio priemonė - uždraudimas juridiniam asmeniui dalyvauti viešuosiuose pirkimuose pagal Viešųjų pirkimų įstatymo 46 straipsnio 2-1 dalį.
duomenys apie tiekėjo vadovą, kitą valdymo ar priežiūros organo narį ar kitą (kitus) asmenį (asmenis), turintį (turinčius) teisę atstovauti	Antanui Juškai [redacted] pastaruosius 5 metus nėra priimtas ir įsiteisėjęs apkaltinamasis teismo nuosprendis ir jis neturi

tiekėjui ar jį kontroliuoti, jo vardu priimti
sprendimą, sudaryti sandorį

duomenys apie tiekėjo buhalterį (buhalterius) ar
kitą (kitus) asmenį (asmenis), turintį (turinčius)
teisę surašyti ir pasirašyti tiekėjo apskaitos
dokumentus

Duomenų suformavimo data

**neišnykusio ar nepanaikinto teistumo už
nusikalstamas veikas, nurodytas Lietuvos Respublikos
viešųjų pirkimų įstatymo 46 straipsnio 1 dalyje.**

**pastaruosius 5 metus nėra priimtas ir įsiteisėjęs
apkaltinamasis teismo nuosprendis ir ji neturi
neišnykusio ar nepanaikinto teistumo už
nusikalstamas veikas, nurodytas Lietuvos Respublikos
viešųjų pirkimų įstatymo 46 straipsnio 1 dalyje.**

2025-03-12

Pažymą išspausdino:

Asmenų registravimo centro Juridinių asmenų registro
Kauno skyriaus Kauno 3 Juridinių asmenų registro
duomenų tvarkymo grupės
Registratorė

A. V.

Certificat/Certificate: N° 39347 rev. 1

Délivré le /Issued on: April 8th, 2024

Certificat délivré à /Certificate issued to: **LEMER PAX**

72 rue de Lorraine - ZA d'Erdre Active Malabry

44240 LA CHAPELLE SUR ERDRE FRANCE

SRN: FR-MF-000003579

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'audit du système de gestion de la qualité et le(s) rapport(s) d'évaluation de la documentation technique associé(s), le cas échéant, référencé(s) P603744, P603935, le système de gestion de la qualité est conforme aux dispositions pertinentes du règlement (UE) 2017/745 pour les produits suivants :

GMED certifies that, on the basis of the results listed in the quality management system audit report(s) and the associated technical documentation assessment report, where appropriate, referenced P603744, P603935, the quality management system complies with the relevant provisions of the regulation (EU) 2017/745 for the following products:

Injecteur de radiopharmaceutique

Radiopharmaceutical Injector

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché de dispositifs de classe III et/ou de dispositifs de classe IIb implantables à l'exception des sutures, agrafes, produits d'obturation dentaire, appareils orthodontiques, couronnes dentaires, vis, cales, plaques, guides, broches, clips et dispositifs de connexion, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/745 est requis.

La validité du présent certificat est conditionnée au respect des obligations qui découlent du système de gestion de la qualité approuvé et de la surveillance effectuée par l'organisme notifié prévue par le règlement. Ce certificat est lié par les conditions du contrat.

For the purpose of placing on the market class III devices and / or class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, another certificate issued in accordance with the provisions of the regulation (EU) 2017/745 is required.

The validity of this certificate is subject to compliance with the obligations arising from the approved quality management system and from the surveillance carried out by the notified body as required by the regulation. This certificate is bound by the conditions of the contract.

Début de validité /Effective date: April 8th, 2024 (included)

Valable jusqu'au /Expiry date: April 20th, 2027 (included)



1. Le cas échéant, le nom et l'adresse du mandataire / If applicable, the name and address of the authorised representative:

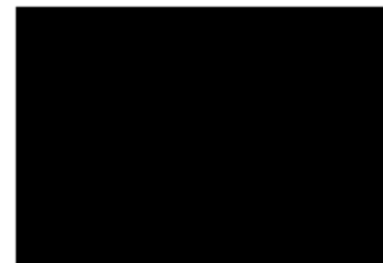
Non applicable / Not applicable

2. Identification des sites / Identification of sites:
LEMER PAX

- 72 rue de Lorraine - ZA d'Erdre Active Malabry - 44240 LA CHAPELLE SUR ERDRE - FRANCE
- 58 rue de Lorraine - 44240 LA CHAPELLE SUR ERDRE - FRANCE
- 3 rue de Lorraine - 44240 LA CHAPELLE SUR ERDRE - FRANCE

3. Identification des dispositifs / Identification of devices:

Nom du dispositif médical <i>Medical device name</i>	Nom commercial <i>Commercial name</i>	Destination (DM classe IIb uniquement) <i>Intended use (MD Class IIb only)</i>	Classe du DM <i>MD Class</i>	Référence au certificat requis pour la mise sur le marché (uniquement DM classe III et IIb implantable) <i>Reference to the certificate required for placing on the market (only DM class III and IIb implantable)</i>
Posijet	Posijet	Dispositif permettant d'injecter un radiopharmaceutique à des fins d'imagerie ou de thérapie en fonction du radiopharmaceutique administré	IIb	NA
Rubijet	Rubijet	Dispositif destiné à l'injection par voie intraveineuse de radiopharmaceutique à des fins d'imagerie	IIb	NA



4. Historique du certificat / Certificate history:

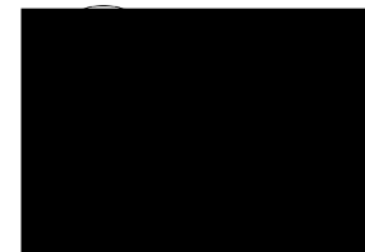
Référence au certificat précédent <i>Reference to the preceeding certificate</i>	Date de délivrance <i>Date of issue</i>	Modifications apportées <i>Identification of the changes</i>
39347 rev. 0	10 juillet 2023 <i>July 10th, 2023</i>	Ajout Rubijet <i>Addition of Rubijet</i>

5. Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat / If applicable, specific information relating to the limitations to the validity of the certificate:

Non applicable / Not applicable

6. Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat / If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate:

Non applicable / Not applicable



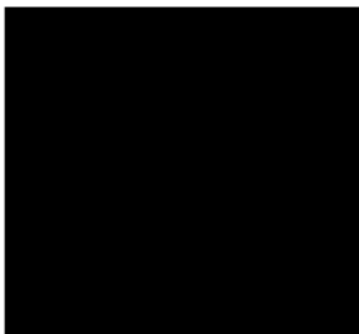
Letter of Authorization

To whom it may concern,

Subject: Letter of Authorization for Viva Medical Ltd

We, **Lemer Pax**, located 72 rue de Lorraine 44240 La Chapelle sur Erdre France (registration N° 870 801 594 RCS NANTES), hereby authorize: **Viva Medical, UAB**, registration code 302820861 (VAT no. LT100007018811), located at Santariškių g. 5, LT-08406 Vilnius, Lithuania as our partner for product sales, service, warranty and product delivery in Lithuania.

Signed on 12th March 2025



MANUFACTURER DECLARATION

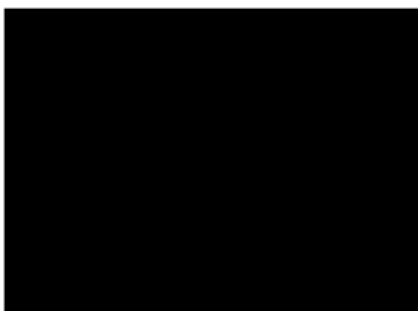
We, LEMER PAX, with our Head Office located at 72 Rue de Lorraine, ZA Erdre Active-Malabry, 44240 La Chapelle sur Erdre (France), certify that our injector Posijet is able to meet these below requirements:


- Injection rate: 7.5 mL/ min – 50 mL/ min
- Space for the saline bag: ≥ 250 ml
- Possibility to use bottles with a capacity of at least 10 ml and no more than 20 ml
- Compatible with several types of radiopharmaceutical vials
- The activity of the diluted radiopharmaceutical is continuously measured;
- A security system prevents dosing if the door is not closed (open);
- The device is adapted for use with Comecer CF18T transport containers during installation.
- The supplier or manufacturer's representative undertakes to perform or organize site acceptance tests after installation and adjustment of the equipment, based on the manufacturer's recommendations.
- The supplier or manufacturer's representative undertakes to perform or organize a metrological verification of the dose calibrator for ^{18}F , ^{68}Ga , ^{177}Lu radioisotopes after installation and adjustment of the equipment. (With a referred dose calibrator on site)

This document is issued to serve the purpose it might be required.

Yours sincerely,

La Chapelle sur Erdre, March 20th 2025



	Instruction manual	English version V8 June 2024
Dose calibrators		

I. Introduction

This document concerns Lemer Pax dose calibrators: scintiDOSE, microDOSE and cycloDOSE.

I.1. Regulatory obligations

The product that you have acquired is a Class I medical device with a measuring function as per rule 13 of Annex VIII of Directive (EU) 2017/745. Its placement on the European Union market requires CE marking by a notified body. Its design, manufacture and market placement must therefore comply with the general health and safety requirements stipulated by Regulation (EU) 2017/745.

I.2. Liabilities


The user may be held liable under a considerable range of circumstances. Lemer Pax cannot be held liable for any accidents that may occur if the unit is used in any way other than that described in this instruction manual.

Under no circumstances may the device be modified without written permission from Lemer Pax.

Similarly, just as the manufacturer may be held liable for non-compliance of the product, the user also shares liability if they do not practically verify that they are in possession of the conformity documents, even if the product concerned is administratively compliant. The user is also liable if they aggravate any defect with the product. The liability of the manufacturer may be mitigated or eliminated under certain circumstances, if the damage is caused jointly by a defect in the product and by error on the victim's part, or by a person for whom the victim is responsible ("General Product Safety" Directive 2001/95/EC and "Manufacturer's Liability for Defective Products" Directive 85/374/EC modified 1999/34/EC).

The Head of the Establishment must comply with the regulations referred to above, notably:

- The Head of the Establishment must appoint a department competent in radiation protection matters.
- Exposed personnel must be assigned category A or category B with medical surveillance and dose meter monitoring of internal and/or external exposure.
- User establishment personnel required to perform specific functions such as operating the dose calibrator in a monitored or controlled zone, and undertaking maintenance thereon, must be qualified and therefore trained and approved for working in a monitored and/or controlled zone (Directive 2013/59 Euratom, or equivalent national law).
- Exposed personnel must receive initial training and information on radiation protection, repeated at least every three years.
- A workstation analysis must be conducted taking note, in particular, of the operating procedures and activity handled (Directive 2013/59 Euratom, or equivalent national law).

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- The user must conduct the various routine checks, or have them conducted, and must keep a maintenance record ("Safety at Work" Directive 2009/104/EC, and Decree 2001-1154 of 5 December 2001 or equivalent national law).

The dose calibrator has not been designed for use in explosive atmospheres (ATEX Directive 94/9/EC dated 23 March 1994).

When used for medical purposes, including the software-measured injection of preparations, calibrations shall be conducted by an accredited body (ISO 17025 for the measured quantity). In the absence of official and valid referencing, measurement validity is the sole responsibility of the users.

The area in which the device is used must be within a restricted zone and comply with the statutory texts in force (Directive 2013/59 Euratom, or equivalent national law).

Lemer Pax cannot be held liable if an accident occurs resulting from improper use, negligence or dismantling of the device.


I.3. Warranty

Lemer Pax scintiDOSE, microDOSE and cycloDOSE dose calibrators are guaranteed for 1 year by the manufacturer (parts, labour and transport), as long as they are used as described herein.

The warranty does not apply to damages caused by the following:

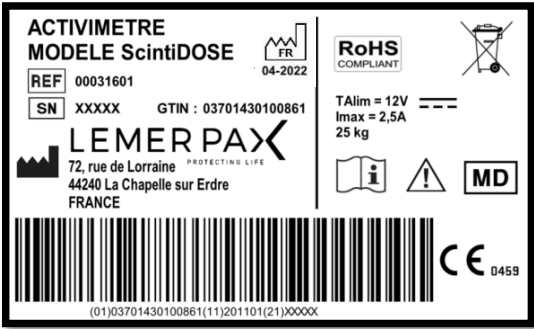

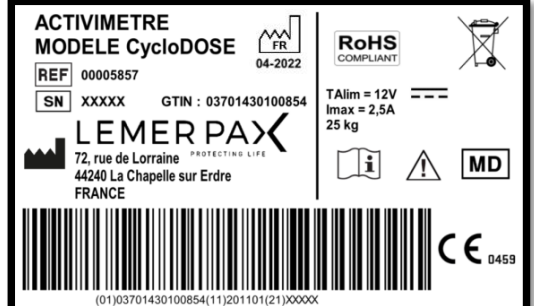











- Misuse, improper maintenance, incorrect adjustment or repair of the device within the scope of use described in this manual,
- Failure to comply with the device's general power supply voltage,
- Servicing by individuals not qualified nor certified by Lemer Pax,
- Incidents due to an external agent: fire, lightning, flood, humidity,
- Incorrect installation, adaptation or modification of the device or non-compliance with the technical or safety standards in force in the country of use,
- Incident occurring during transportation of the device, if the transport service is not managed by Lemer Pax.


No compensation may be claimed for losses resulting from unavailability of the device in case of repairs.

	<p>Instruction manual</p>	<p>English version V8 June 2024</p>
<p>Dose calibrators</p>		





I.4. Data plates and safety labels

I.4.a. Device® data plates

	Pictograms	Definition of symbols
		<p>Consult the user manual.</p>
		<p>This product is a medical device</p>
		<p>Electrical and electronic equipment must be disposed of selectively.</p>
		<p>Lemer Pax is the manufacturer.</p>
		<p>Device year of manufacture</p>
		<p>The device bears the CE mark by the notified body 0459</p>
		<p>The device contains no hazardous substances</p>
		<p>Make sure to consult the user instructions for any safety-related information (warnings and precautions to take)</p>
		<p>Catalogue reference</p>
		<p>Serial number</p>

	<p>Instruction manual</p>	<p>English version V8 June 2024</p>
<p>Dose calibrators</p>		

I.5. Dose calibrator specific labels

	<p>Risk of contamination and risk of external exposure due to the introduction of radioactive products used by the operator in order to measure radioactivity.</p>
	<p>CAUTION high voltage present: U = 160 V</p>
	<p>CAUTION DANGER</p>
	<p>Earthing mandatory</p>

II. Product overview

Lemer Pax has developed a range of dose calibrators in order to make radioactivity measurements in medical, research and industrial applications simpler and safer.

This range consists of 3 dose calibrator references, allowing you to measure low, medium and high activity levels:


- microDOSE: 15.10⁻³ to ~100 MBq
- scintiDOSE: 15.10⁻³ to ~37.10³ MBq
- cycloDOSE: 15.10⁻³ to more than 500.10³ MBq

Values given for guidance for Fluorine 18 or FDG.

Their simple, self-explanatory operation makes it easy to process activity measurements, conduct check tests and store essential data on files or labels.

The display and controls have been designed for visual comfort and to make them as easy as possible to read. Developed for use with a touchscreen, a user-friendly virtual keyboard allows the operator to make the alphanumeric entries required for regular use.

The device is compatible with radioisotope management software developed by Thélème, Segami and Waid.

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Dose calibrators		

II.1. Claimed use

The dose calibrator is aimed at measuring the activity of radiopharmaceutical substances to be administered to patients with a view to medical radiodiagnostics or radiotherapy.

The dose calibrator can be used for patients indicated for treatment for the purposes of imaging or radiopharmaceutical injection therapy.

Note: Given the wide variety of indications with regard to the device's intended use, it is not possible to define a target population. Indeed, there are no age, weight, gender or ethnic restrictions.

The dose calibrator must be used only by trained medical or paramedical personnel trained in and authorised for its use, for:

- Preparing and injection radiopharmaceuticals,
- Working in ionising radiation.

The dose calibrator itself is not in direct interaction with the patient.

The dose calibrator is used in nuclear medical departments, as well as in hospital environments. These centres take on average 40 measurements per day with a dose calibrator

The dose calibrator first came onto the market in 2008.

II.2. Clinical benefits

The dose calibrator ensures accurate dose preparation to adhere to the MRP medical prescription, but the device does not make any claims to improve therapy or imaging performance. Using the dose calibrator does not give the patients any clinical benefits.

II.3. Technical characteristics


Weight: 25 kg

External dimensions:

- Height (total): 420 mm
- External diameter: 220 mm
- Sample holder well diameter: 45 mm

Operating conditions:

- Temperature: between 18°C and 38°C
- Relative humidity: 5% < RH < 95% without condensation;
- Atmospheric pressure: 70 to 106 kPa
- Filling gas: argon (99%) in a volume of 4.3 dm³ at 1.5 bar

 <small>PROTECTING LIFE</small>	Instruction manual	English version V8 June 2024
Dose calibrators		

Service life: 7 years

Electrical characteristics:

- Nominal polarisation voltage: 160V ± 10%
- Consumption ≤ 2 W

Protection index: The dose calibrator is not protected against liquid ingress. It is designed for indoor use.

Shielding: Shielding lead thickness: 6 mm

Operating mode: AC

- Electrical class: Connected to mains 100 – 240 V, 1A, 50 – 60 Hz
- Patient contact: No patient contact

6.1 Energijos diapozonas

Measurable energy range: 30 KeV to 2 MeV

Isosensitivity zone at 2%: total height 90 mm / total diameter at centre 30 mm

Measurement range (Values given for guidance for Fluorine 18 or FDG):

- o Detection threshold: 15 kBq
- o Maximum activity measured: 100 MBq; 37 GBq; 500 GBq according to the reference
- o Maximum measurable activity (theoretical): 3700 GBq
- Counting time: 2 to 5 seconds
- Operating range:
 - microDOSE: 15.10⁻³ to ~100 MBq
 - scintiDOSE: 15.10⁻³ to ~37.10³ MBq
 - cycloDOSE: 15.10⁻³ to more than 500.10³ MBq

Values given for guidance for Fluorine 18 (e.g. FDG).

Repeatability (relative standard deviation/mean): ≤ ± 0.2%

Reproducibility (relative standard deviation/mean): ≤ ± 1%

II.4. Performance

- Measurement accuracy: Drift ≤ 5% (including standard source precision).
- Measurement range accuracy: Linearity: < 5%

II.5. Contraindications

There are no medical contraindications for using a dose calibrator.

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**

**EKRANUOTAS
RADIOFARMACINIŲ PREPARATŲ
INJEKTORIUS
IR PARUOŠIMO ĮRENGINYS**

1

ALL ENERGIES



CE
0459

**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 (**¹⁸F**) including ¹⁸F-FDG, ¹⁸F-DOPA, ¹⁸F-CHOLINE, ¹⁸F-FNA, ¹⁸F-PSMA, etc. and also tracers labelled with **⁶⁸Ga**, as well as Ammonia labelled with **¹³N** for cardiac PET examinations.

With its new “Therapy” application, it is also able to perform slow administrations in 30 minutes, for RadioPharmaceutical Therapy (RPT) treatments with **¹⁷⁷Lu** labelled radiopharmaceuticals (¹⁷⁷Lu octreotate or ¹⁷⁷Lu DOTA-TATE, ¹⁷⁷Lu-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.



2.6

Dozės kalibratorius, skirtas radiofarmacinės dozių matavimui realiuoju laiku

- 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 accommodation 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 Miniject (remote injection system) allows preparation and packaging of a patient dose for manual injection 16 | Maintenance hatch
- Saugios ekranuotos durys talpinančios kelių dozių buteliuką, esantį ekranuotame transportavimo konteineryje** **Jutiklinis ekranas valdymui**

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 $\mu\text{Sv/h}$ 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.



1, 2.1

MEASUREMENTS & DOSE PREPARATION

- **Settings and calibration** of the different isotopes and constancy sources are accessible and can be carried out by radio-physicists 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.

Matavimai ir
dozės paruošimas



INJECTIONS 2.1 Injekavimas

- **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. **Burbulų detektorius**
- **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.

8.4





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 inter-

face 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 ¹³N-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 ¹³N**. 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.

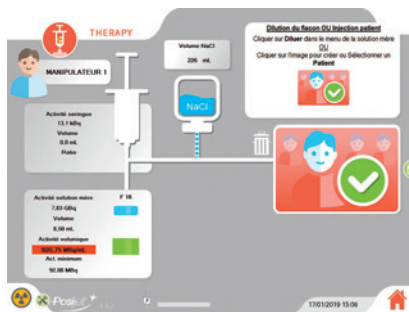
Exchanges between the **Geneva University Hospitals (HUG)** and the Lemer Pax development teams have enabled the routine use of ¹³N-Ammonia dose preparations with Posijet® since 2019. The hospital currently performs approximately 1,600 examinations per year, while ensuring a considerable reduction in 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.

Therapy Application

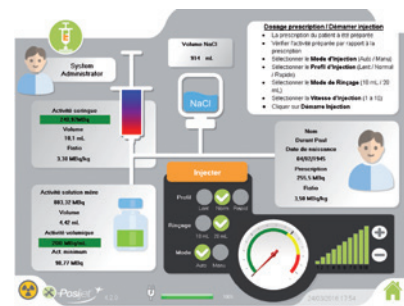
Theranostics is a new medical approach aiming to promote simultaneous development of diagnostic and therapeutic aspects in Nuclear Medicine, and visualise for improved cancer treatment by associating a diagnostic test and an adapted targeted therapy.



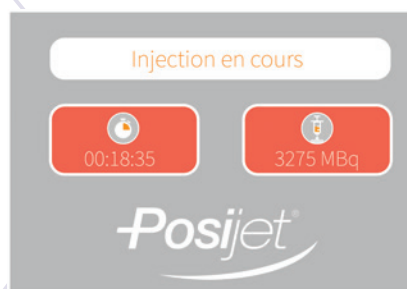
In this new context, Lemer Pax has invested in Research and Development to include Posijet® in this theranostic use, thus opening up parallel access to **diagnostic PET injections and therapeutic RPT (RadioPharmaceutical Therapy) injections** in secure conditions. With the launch of new ^{177}Lu labelled 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 **RadioPharmaceutical Therapy (RPT)** 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 RPT 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 - $^{99\text{m}}\text{Tc}$

“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 Minijet 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, SPECTRA, 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



REGULATORY FRAMEWORK

The Posijet® preparation and injection unit meets the requirements of **93/42/CEE directive 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**

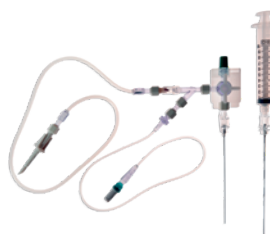
decree of 25 November 2008 and **international standard IEC 61948-4**. Posijet® is also **certified for paediatric use (>1 year old)**.

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

9 **Weight: 380 kg** **Bendra masė**

Ground load: 660 kg/m²

10 **Frequency: 50/60 Hz** **Dažnis**

Supply voltage: 110 V - 240 V **Įtampa**

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

11 **Battery life: 8h** **Baterijos veikimo laikas**

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

2.2 **List of radioisotopes claimed by the manufacturer:**

¹⁸F (all fluorinated tracers: FDG, FNA, FDOPA, FCHOLINE, etc.)

¹³N

⁶⁸Ga

¹⁷⁷Lu

Gamintojo nurodomas radioizotopų sąrašas

Built-in measuring instrument:

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

6.2 **Measurement accuracy: +/- 2%** **Matavimo tikslumas**

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

4 **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.

Motorizuota pagalba

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)

COFRAC calibration service on request (ISO 17025)

Certified for paediatric use (>1 year old)

Certified for paediatric use (>1 year old)

Maintenance contract: yes

5.3 **Compatible pot models:** Posisafe®

Cyclopharma, IBA/AAA, Biodex, PETNET,

Comcer, Capintec, Monrol, Tema sinergie,

Medrad, etc. **Suderinami konteineriai**

Radiation protection **Apsauga nuo radiacijos**

Maximum radioactivity that can be handled to obtain a dose rate less than

8.2 **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

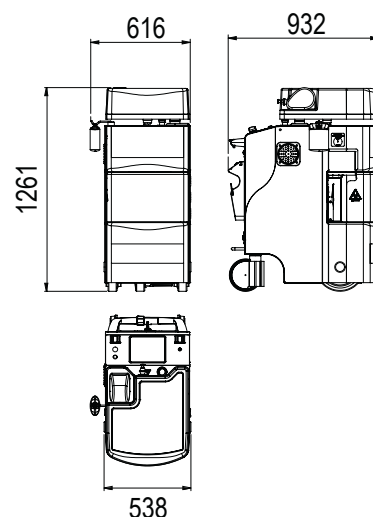
Ref.: 00019530-CALPosijet®

with calibrated dose calibrator

00019530-ET Posijet®

with calibrated dose calibrator

EFFECTIVE DIMENSIONS (mm)



Mažiau nei 25 µSv/h 5 cm atstumu nuo sienų

Maksimalus naudotinas radioaktyvumas

6.3



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

Paediatric version

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

Update 10/2024

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Instructions manual

 *Original English Version – V16-1– June 2024*

Posijet[®]



CE 0459



 <small>PROTECTING LIFE</small>	Instructions manual	English version V16-1 June 2024
Posijet® V3		

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I. Introduction

This document concerns a self-contained unit for calibration and injection of FDG: Posijet®.


I.1. Statutory obligations

The product you have purchased is a class IIb medical device according to rule 12 of annex VIII of the "Medical devices" Regulation (UE) 2017/745. Launching it onto the European Union market requires CE marking by a Notified Body. Its design, manufacture and marketing therefore comply with the general safety and performance requirements promulgated in regulation (UE) 2017/745. In addition, Posijet® complies with the essential health and safety requirements enacted by the Machinery Directive 2006/42.

Posijet® was designed to protect people against ionising radiation pursuant to Directive 2013/59 of 5 December 2013 laying down basic safety standards for the health protection against hazards resulting from exposure to ionising radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

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LEMER PAX / SAS WITH A CAPITAL OF 350 000 EUROS / 870 801 594 RCS NANTES / APE 3250 A
EXEMPT FROM VAT FOR INTRA-COMMUNITY SALES, ART / 262 TER-1 OF THE FRENCH TAX CODE / VAT: FR 18 870 801 594

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The device conforms to standard 60 601-1-2 associated with the references EN 60601-1-2 : 2015 et IEC 60601-1-2 : 2014 .
It does not create interferences with other devices, if they also conform to the same standard.

1.2. Liabilities

The user may be held liable under extreme circumstances. Lemer Pax cannot be held liable for any accidents that may occur if the unit is used in any way other than that described in these Instructions.

Under no circumstances may the apparatus be modified without written permission from Lemer Pax.

Similarly, just as the manufacturer may be held liable for non-conformity of the product, the user also shares liability if he does not tangibly verify that he has the documents testifying to conformity, even if the product concerned conforms administratively. The user is also liable if he himself accentuates the product's defect. The liability of the manufacturer may be reduced or eliminated under certain circumstances, when the damage is caused jointly by a defect in the product and by error on the victim's part or by a person for whom the victim is responsible ("General Product Safety" Directive 2001/95/EC and "Manufacturer's Liability for Defective Products" Directive 85/374/EC modified 1999/34/EC).


The Head of Establishment must comply with the regulations referred to above, notably:

- The Head of Establishment must appoint a department with authority for radiation protection matters.
- The personnel exposed must be assigned category A or category B with medical surveillance and dose meter monitoring of internal and/or external exposure.
- Personnel of the user Establishment required to perform specific functions such as operating the equipment in a monitored or controlled zone, and undertaking maintenance thereon, must be qualified and therefore trained and approved for working in a monitored and/or controlled zone (Decree N° 2003-296 dated 31 March 2003, or equivalent for other countries in the European Union).
- Personnel who are exposed must receive initial training and information on radiological protection, which must be repeated at intervals of no longer than three years.
- A workstation analysis must be conducted taking note, in particular, of the operating procedures and handling operations of Fluorine 18.
- The user must conduct, or have conducted, the various periodic checks and must keep a record of maintenance ("Safety at Work" Directive 2009/104/EC, and Decree 2001-1154 dated 5 December 2001 or equivalent for other countries in the European Union).

The equipment has not been designed for use in explosive atmospheres (ATEX Directive 94/9/EC dated 23 March 1994).

The room in which the device is used must be within a restricted zone and comply with statutory texts in force (Decree 2003-296 dated 31 March 2003).

Lemer Pax cannot be held liable if an accident occurs resulting from improper use, negligence or dismantling of the device.

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I.3. Warranty

Posijet® is guaranteed for 1 year by the manufacturer (parts, labour and transport), as long as it is used as described herein.

The warranty does not apply to damages caused by the following:













- Misuse, improper maintenance, incorrect adjustment or repair of the device within the operating limits described in this instruction manual,
- Failure to comply with the device general power supply voltage,
- Intervention of persons not qualified nor certified by Lemer Pax,
- Incidents due to an external agent: fire, lightening, flood, humidity,
- Incorrect installation, adaptation or modification of the device or non-compliance with the technical or safety standards in force in the country of use,
- Incident occurring during transportation of the device if the transport service is not performed by Lemer Pax.

No compensation may be claimed for damage resulting from unavailability of the unit for repairs.

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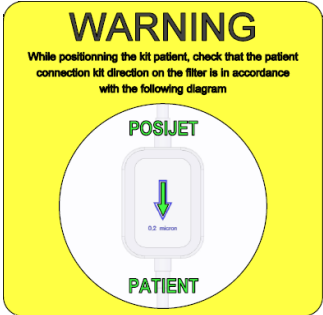
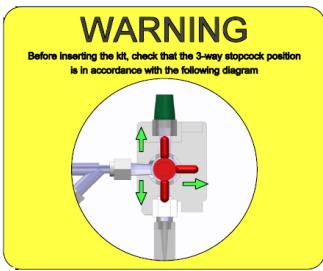

I.4. Data plates and safety labels

I.4.a. Posijet® data plates

	Pictogramme	Définition des symboles
		Consult the user manual
		The product is a medical device
		Electrical and electronic equipment must be disposed of properly.
		Lemer Pax is the manufacturer.
		Month and year of production
		The device features the CE mark by notified body 0459.
		Device in contact with the patient. The circuits in contact with the patient are Floating type circuits
		It is mandatory to check the instruction manual for all information in regards with safety (warning and precautions to be taken)
		Product brochure reference
		Serial Number
		Product compliant with european directive RoHS (2002/95/CE)










Posijet® V3

1.5. Posijet® specific labels

	<p>Risk of contamination and risk of external exposure due to the introduction of radioactive products used by the operator in order to measure radioactivity</p>
	<p>Risk of crushing: this label signals the danger of pinching due to the lowering of actuators.</p>
	<p>Label reminding the user to check the orientation of the patient kit</p>
	<p>Label reminding the user to check the position of the 3-way valve</p>
	<p>Label reminding the user to check that the venting kit has been installed</p>

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I.6. Sterile kit specific labels

	Sterilised with ethylene oxide
	CE marking approved by a notified body. The number corresponds to the notified body
	Use-by date (expiry date)
	Do not use if the package is damaged
 or 	Does not contain latex
	Does not contain phthalates
	Disposable kit
	Kit batch serial number

II. Overview of the product

II.1. Claimed use

POSIJET® is intended for the intravenous injection of radiopharmaceuticals for imaging or therapy.


POSIJET® can be used for patients older than 1 year or weighing more than 9.720 kg indicated for treatment or diagnosis by radiopharmaceutical injection.

POSIJET® must be used exclusively by medical or paramedical personnel trained and authorised to use it for

- The preparation and injection of radiopharmaceuticals for imaging or therapy,
- Work under ionising radiation,
- The use of Posijet®.

The POSIJET® as such is not in direct interaction with the patient. The part in contact is an infusion needle supplied by the hospital structure. The healthcare professional chooses to prick the most appropriate part of the body depending on the patient; age, pathology, etc. This part is manual and independent of the use of the injector. The connection between the patient tubing and the POSIJET® is made using 2 kits supplied by LEMER PAX: Posikit 1B and Posikit2. The POSIJET® is used in nuclear medicine departments, in a hospital medical environment. These centers perform an average of 25 injections per day with the POSIJET®.

The Posijet® first came onto the market in 2007.

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II.2. Clinical benefits

The POSIJET® increases the radiation protection of nuclear medicine personnel, but the device does not claim to improve therapy or imaging performance. The use of POSIJET does not provide any clinical benefit to patients.

II.3. Technical characteristics

Weight: 380 kg.

External dimensions:

- Height: 1,261 mm;
- Width: 620 mm;
- Depth: 929 mm.

Operating conditions:

- Temperature: between 15 and 30°C
- Relative hygrometry : 5% < rh < 95% non-condensing
- Atmospheric pressure: 79.5 to 101.3 kPa (between 0 and 2000 m above sea level)

Electrical characteristics:

- Maximum current consumed by the device: 1 A;
- Power supply voltage: 110 V / 240 V – 50/60 Hz.
- Operating mode: Continuous
- Electrical class:
 - o Internal sources of electrical power;
 - o Patient contact: BF Type (degree of protection from electrical shock according to standard EN 60601-1).

Protection rating: The Posijet is not protected against liquid ingress. It is intended for indoor use only.

Shielding:


Posijet® is designed to receive a maximum activity in the stock solution vial located in the door of 37GBq (1Ci) and a maximum activity of 500 MBq in the injection syringe (conditions of use with F18 and a Lemer Pax PosiSafe pot). With these activities, Posijet® respects the emerging doses of 25 µSv/h, 5 cm from the walls

1	Operator side	mm of lead	12
2	Patient side	mm of lead	16
3	Lateral sides	mm of lead	12
4	Around the dose calibrator	mm of lead	25

Other features:

- Accuracy of the prepared dose: +/- 2%.
- Battery life: 8 hours

Service life: The Posijet® is designed for an estimated service life of 6 years.

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II.4. Performance

The POSIJET® allows the injection of radiopharmaceuticals at a controlled rate.

The POSIJET® guarantees the precision of the dose preparation to be faithful to the medical prescription of the radiopharmaceutical.

POSIJET: AMMONIA VARIANT:

For the use of the Posijet with radioisotopes with a relatively short half-life (for example N13 with a half-life of 10 minutes), Lemer Pax has developed a dedicated software version to optimise the accuracy of the measurement and to meet the constraints imposed by the half-life of the radioelement in question. In this case, Lemer Pax prohibits the concomitant use of the Posijet for radioisotopes with longer half-lives such as F18 (half-life: 108min).

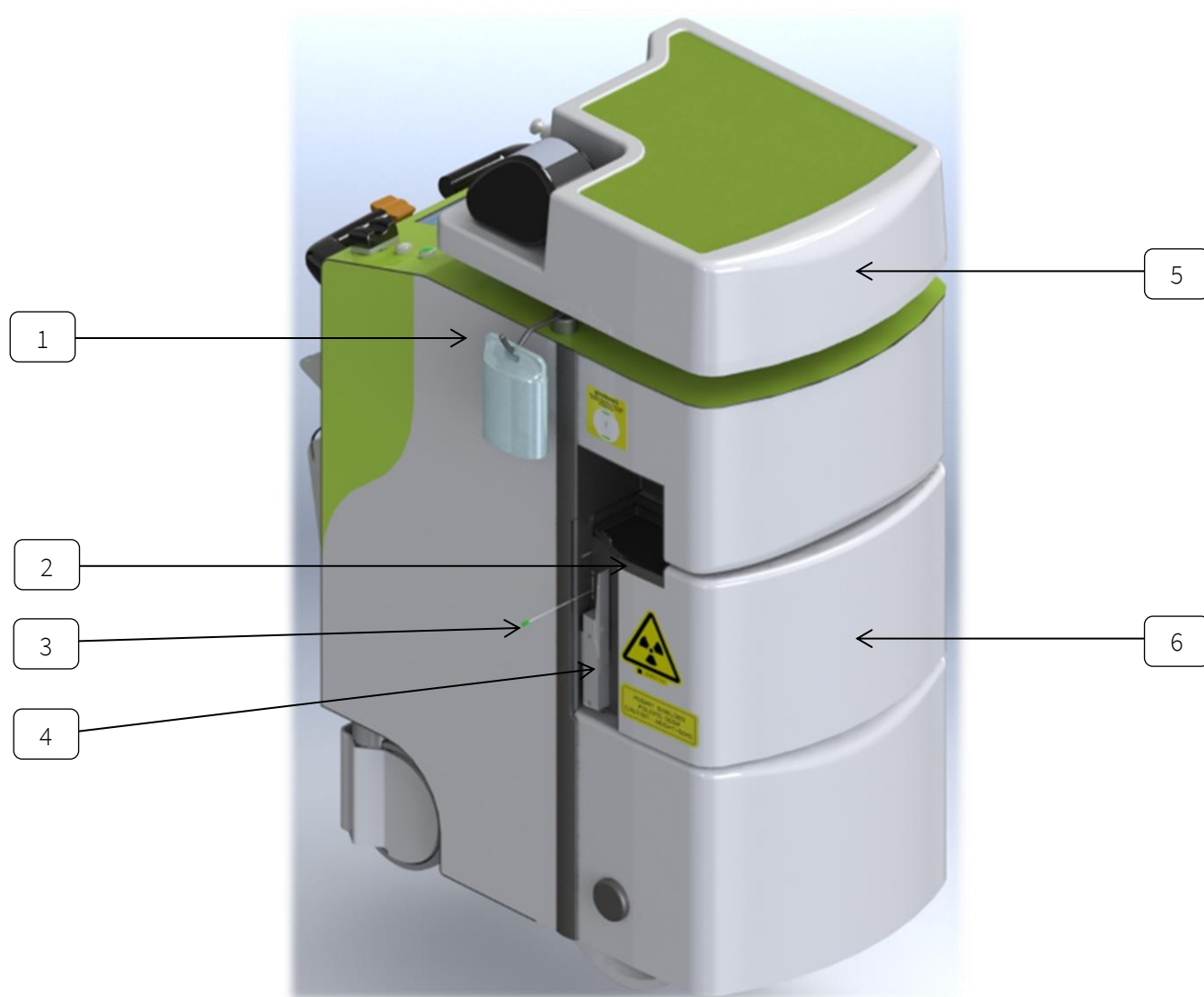
II.5. Contraindications

It is contraindicated to use the device intra-arterially and for children under 1 year or weighing less than 9,720 kg.

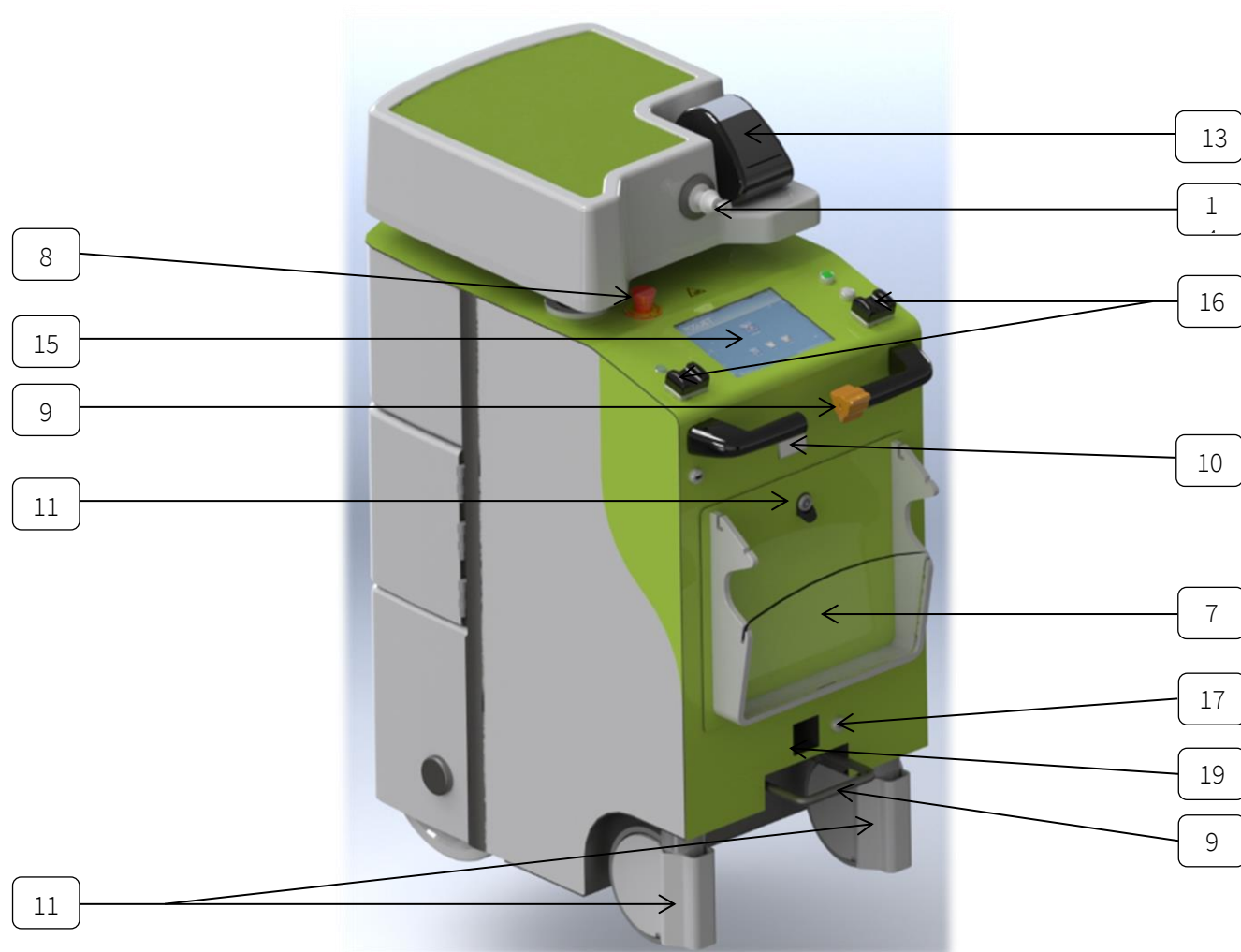
II.6. Side effects

To date, no adverse side effects have been identified with the use of the Posijet device. The possible side effects are those directly related to the injection of the radiopharmaceutical, as indicated in the instructions for use of the radiopharmaceutical.

II.7. Component parts

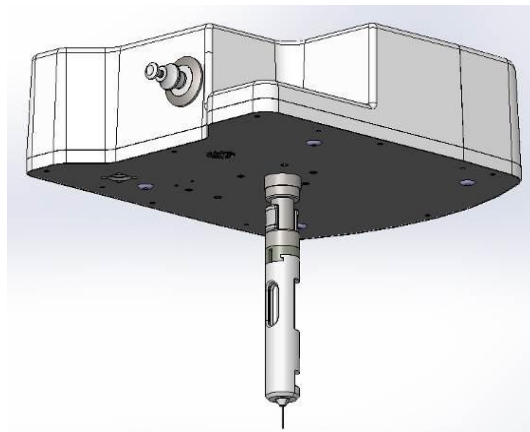


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1	Retractable NaCl bag hook	11	Anti-crush cover for swivel wheels
2	Tray for bionector	12	Label printer
3	Mother solution kit outlet (POSIKIT 1B)	13	Automatic or manual injection syringe plunger
4	Lockable handle for opening the shielded access door to the mother solution	14	Sensitive two-hand controls (to lower the sampling head)
5	Motorised sampling head	15	Barcode reader for sterile kits
6	Shielded access door to the mother solution	16	Storage tray
7	Emergency stop button	17	Ethernet port (RIS connectivity port)
8	Touch screen	18	Electrical plug with automatic retraction (5 m)
9	Rotating control of the motorised assistance	19	Wheel-locking pedal
10	Access door for maintenance		

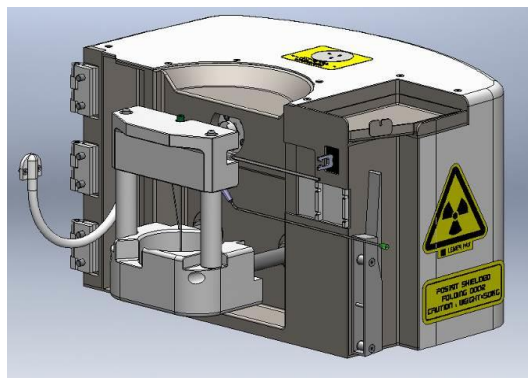
II.7.a. Sampling head



The sampling head consists of:

- A "syringe plunger" type motorised sampling system, to dose a preparation and inject it automatically;
- A shielded moving part receiving the sampling and injection syringe;
- A piston remote control protected by a clutch to perform the injections manually;
- A removable system to hold the sampling syringe, which slides vertically in the dose calibrator chamber in order to place the syringe more easily in the centre of the chamber to measure the sampled activity. The system can be removed to simplify installation of the syringe, disinfection and to allow the use of a dipper for the quality controls;
- A system to measure the force applied to the system in order to regulate the injection;
- A system to move the sampling head, controlled by the operator via a two-handed control device that requires maintained action.
- A label printer (2 formats available: large and small);
- A sound system to inform the user.

II.7.b. Mother solution container loading door



The container loading door consists of:

- A shielded chamber with a shielded front door, secured with a locking system. This chamber receives the container containing the multi-dose vial;
- A puncturing system to install the mother solution kit and the vial venting kit;
- A set of shims to position the container and vial correctly in order to extract the maximum amount of activity; the user may also use the container from the FDG supplier (which avoids transferring the vial into the LEMER PAX container).
- Radiation protective guide cones to guide the vial kit needle;
- A three-way shielded motorised secure valve to sample the activity or NaCl;
- A system to hold the kit at the door passage (kit attached ready between two patients);
- A system to detect air bubbles.

II.7.c. External structure and user interface

II.7.c.i. External structure

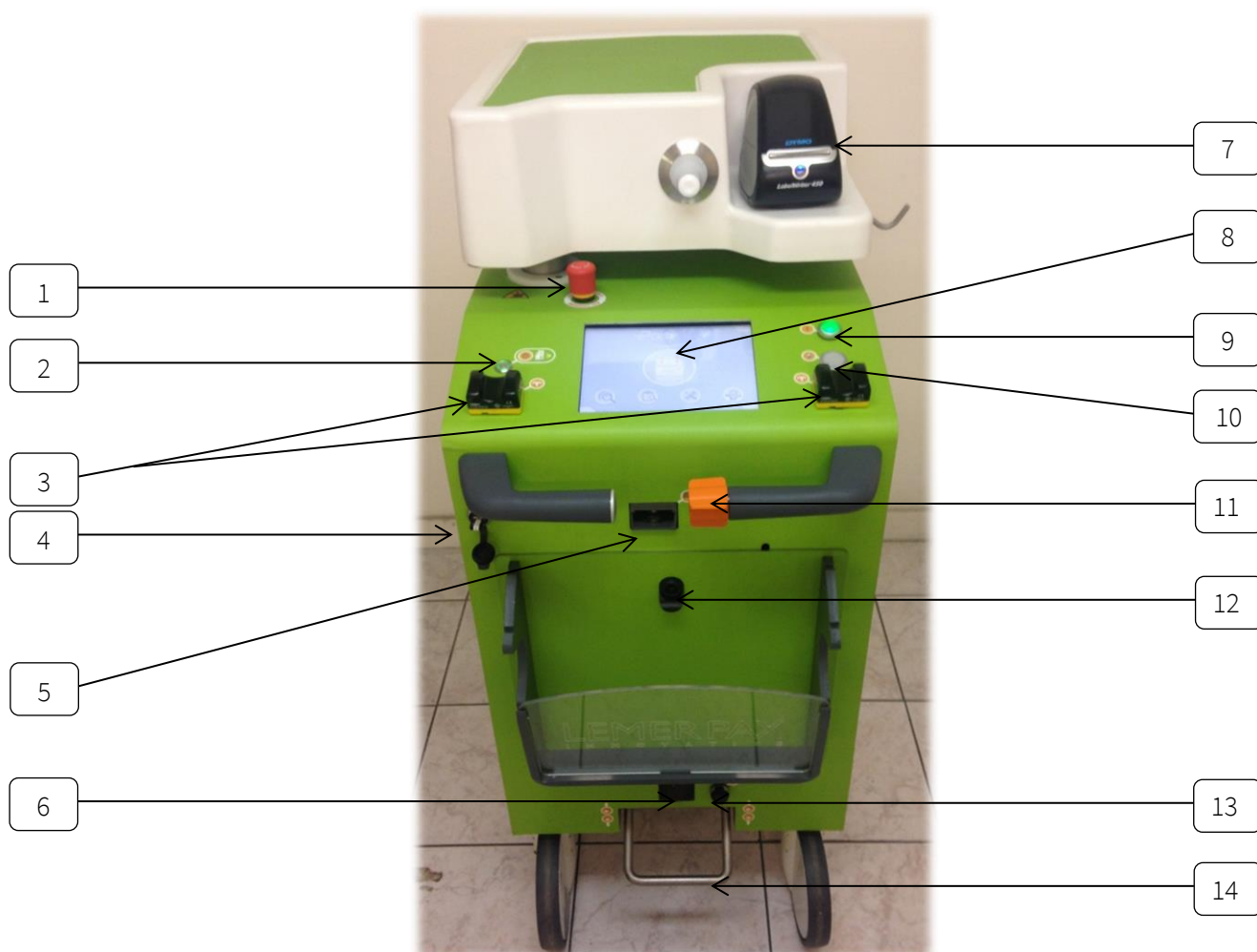
The external structure consists of:

- An NaCl bag or flexible bottle hook;
- Fixed, moving and motorised wheels to move the Posijet®;
- Handles including a rotating handle to move the product with or without assistance;
- A mechanical system to block the swivel wheels;
- Access doors for product maintenance;
- A kit storage container.

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II.7.c.ii. Control panel and user interface


On the front of the Posijet®, facing the operator, there is a control panel featuring several buttons and controls.






















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2.7

1		Avarinio stabdymo mygtukas: šis mygtukas sustabdo visus judesius (dozės paruošimas, injekavimas, apsauginės galvos judėjimas, motorizuotas asistentas ir kt.) Emergency Stop Button: This button stops all the movements in progress (dose preparation, injection, head movement, motorised assistance, etc.)
2		This button activates the use of the motorised wheel and provides information on the activation or deactivation of the wheel. <div>  Green The wheel is activated. </div> <div>  Switched off The wheel is deactivated </div>
3		Two-handed control for lowering the sampling head: to lower the head when the software allows. The operator must engage both controls simultaneously (operator safety).
4		USB Port: To insert a USB storage device for data backup.
5		Barcode reader: To scan the various kits used (mother solution kits and patient kits).
6		Location of the 5-meter retractable cord to plug in to an electrical outlet.
7		Label printer for printing patient data traceability labels (2 label formats available).
8		10.4 inch touch screen which can be used wearing gloves within the nuclear medicine department.

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9		<p>On/off button.</p> <table><tr><td></td><td>Off</td><td>The Posijet® is off.</td></tr><tr><td></td><td>Flashing green</td><td>The Posijet® is shutting down: button switched to OFF and the machine is shutting down.</td></tr></table>		Off	The Posijet® is off.		Flashing green	The Posijet® is shutting down: button switched to OFF and the machine is shutting down.						
	Off	The Posijet® is off.												
	Flashing green	The Posijet® is shutting down: button switched to OFF and the machine is shutting down.												
10		<p>Posijet® battery charge indicator</p> <table><tr><td></td><td>Off</td><td>The battery is not charging or is discharged.</td></tr><tr><td></td><td>Green</td><td>The battery is 100% charged.</td></tr><tr><td></td><td>Orange</td><td>The battery is charging.</td></tr><tr><td></td><td>Red</td><td>The battery is low or malfunctioning.</td></tr></table>		Off	The battery is not charging or is discharged.		Green	The battery is 100% charged.		Orange	The battery is charging.		Red	The battery is low or malfunctioning.
	Off	The battery is not charging or is discharged.												
	Green	The battery is 100% charged.												
	Orange	The battery is charging.												
	Red	The battery is low or malfunctioning.												
11		Motorised wheel rotary control (positive or negative control).												
12		Touchpad keyboard inside the maintenance compartment.												
13		Ethernet port to back-up the Wi-Fi connection.												
14		Pedal to lock / unlock the wheel brake: in the up position, the brake is released (the machine can move) and in the down position, the brake is locked (the machine cannot move).												

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II.7.d. Dose calibrator

The Posijet® is equipped with a shielded dose calibrator allowing the dose to be calibrated, by direct real-time measurement of the activity. It consists in an ionisation chamber connected to an electronic measurement system that transfers the measured activity values to the PC.

It is possible to select the type of isotope used and the packaging (vial, syringe or capsule) in the quality menu.

Measurement range:

- Detection threshold: 185 kBq
- Maximum activity: 74 GBq
- Accuracy of measurement: 5 % (including accuracy of the standard source)
- Repeatability (relative standard deviation/mean): $\leq \pm 0,2\%$
- Reproduciveness (relative standard deviation/mean): $\leq \pm 0,5\%$
- Counting time: 2 to 5 seconds

The Posijet® applies a voltage to the dose calibrator's electronics at all times. There is therefore no waiting time when switching on the Posijet® before being able to use the dose calibrator.

II.7.e. Biological protection

The device shielding consists of the biological protection.. This protection consists of a shielded chamber with front door and a shielded compartment with a drawer for the sterile kit.

1	Operator side	mm of lead	12
2	Patient side	mm of lead	16
3	Lateral sides	mm of lead	12
4	Around the dose calibrator	mm of lead	25

II.7.f. Power supply sources

The Posijet® has several power supply sources:

- The power supply (battery) for the POSIJET® associated with the dose calibrator and the touch screen;
- The Posijet® is powered via a 24 V stabilised power supply connected to the mains.

Characteristics of the rechargeable batteries:

- PANASONIC battery- 12V38Ah Lead (AGM) – LC-P1238APG (code: 0001 9743) - or
- NEC battery ALM 12V35s – Lithium-Ion – 13,2 V/462 Wh





Battery replacement must be realized by LEMERPAX technician or authorized technician to avoid any risk of burns, fire or explosion.

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II.8. Mobile parts

Designation	Picture
Calibration dipper: for conducting quality control testing of the dose calibrator.	
Top cone guides: for guiding the needle (L = 120 mm) of the syringe into the three-way stopcock spike (mother solution kit). It is therefore in contact with the sterile kit. In order to guarantee the patient's biological safety, this guide must be decontaminated and disinfected each time before use (according to the service practices).	
Mother solution kit holder: To set up part of the mother solution kit as well as the entire vial venting kit.	
Lower cone guides in tungsten: To guide needles (L = 100mm) and vent the mother solution vial. It is therefore in contact with the sterile kit. In order to guarantee the patient's biological safety, this guide must be decontaminated and disinfected each time before use (according to the service practices).	
Tray for bionector: To accommodate the bionector of the mother solution kit that will be connected to the patient kit.	

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Designation	Picture
Syringe holder: To set up the sampling syringe of the mother solution kit (10 mL dose preparation syringe).	
Syringe shield: To receive a dose prepared in the Posijet® which should not be injected (discard dose).	

II.9. Consumable sterile kits

The performance and safety of Posijet® has been tested with the specific kits described in this manual. The POSIKIT 1B and POSIKIT 2 sterile kits have been specifically designed to fit Posijet® and for the injection of radioactive products. No other sterile kit should be used in Posijet® without prior validation to demonstrate safe use with Posijet®. Lemer Pax is not responsible for the use of other kits that have not been previously checked for their suitability for use with Posijet®.

Furthermore, the kits described in this manual : POSIKIT 1B and POSIKIT 2 are 100% tested to guarantee their performance and in particular avoiding any leakage. The use of other non-validated kits could lead to further contamination and irradiation due to radiopharmaceutical leakage.

II.9.a. Mother solution kit: POSIKIT 1B

POSIKIT 1B is a sterile kit called "FDG MOTHER SOLUTION CONNECTION" for preparing the FDG dose to be injected into the patient. This kit is common to several patients. It must be replaced after each unloading cycle of the Posijet®.

This kit is composed of a cartridge (set of elements common to several patients) in turn composed of:

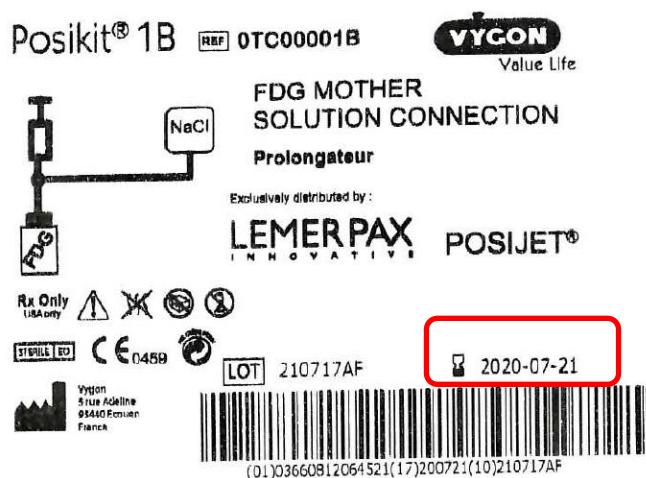
- A 3-way stopcock;
- A membrane seal;
- An unsleeved needle (L = 100 mm);
- A Y circuit;
- An anti-siphon valve;
- A catheter with a NaCl bag spike;
- A non-return valve;
- A drip-stop connector;
- A BD 10 ml syringe with sleeved needle (L = 120mm);
- An extension tube;



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The Posijet® Common Sterile Kit: POSIKIT 1B is a supply of Lemer Pax. It has been specially designed to adapt to the Posijet and for the injection of radioactive products. No other sterile kit should be used in the Posijet® without prior validation to demonstrate safety of use with Posijet®. Lemer Pax declines all responsibility when using non-recommended kit.

Service life: Comply with the expiry date indicated on the label.



II.9.b. Vial venting kit

To dilute the mother solution vial, a vial venting kit is required.

The venting kit is not supplied by Lemer Pax. However, Lemer Pax has tested and approved the following references for use in Posijet®:

- Millex-GV Syringe Filter Unit, 0.22 µ - ref. SLGV013SL;
- B BRAUN hypodermic needle - ref. 0.90x70mm BL-LB.



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II.9.c. Patient kit: POSIKIT 2

POSIKIT 2 is a sterile kit called the "POSIJET/PATIENT CONNECTION" for connecting the Posijet® to the patient kit. This kit is specific to each patient. It must be changed after each patient injection.

This kit comprises:

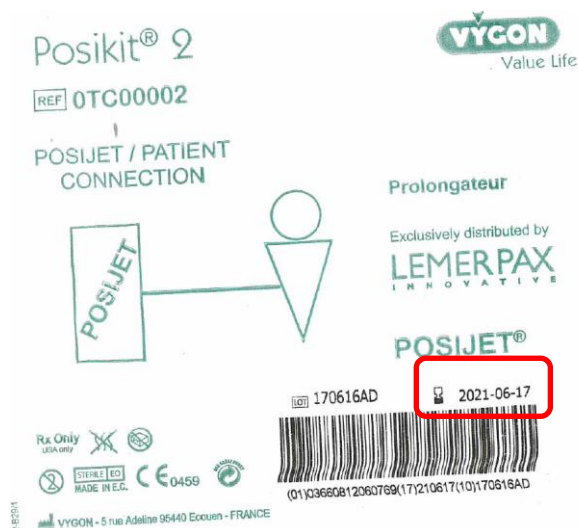
- An extension tube;
- A 0.22 µ filter;
- A bubble trap;
- A non-return valve;
- A flush liquid collection syringe.



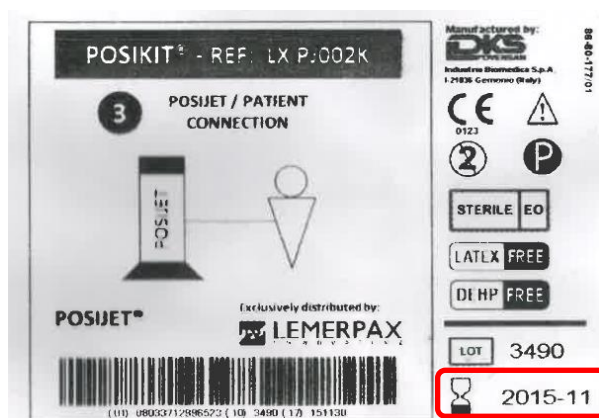
The Posijet® POSIKIT 2 kit called "POSIJET/PATIENT CONNECTION". No other sterile kit is to be used in the Posijet®.

The POSIKIT 2 (patient) is a supply of Lemer Pax. It has been specially designed to adapt to Posijet® and for the injection of radioactive products. No other sterile kit should be used in the Posijet® without prior validation to demonstrate safety of use with Posijet®. Lemer Pax declines any responsibility when using non-recommended kit.

Service life: Comply with the expiry date indicated on the label.



or



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III. Safety

The POSIJET® has the following safety features:

- Stopping of sampling if activity measurement malfunction is detected
- Stopping the injection in case of overpressure
- Stopping the injection in case of air bubble detection

IV. Packaging / Transport / Storage

The equipment is packaged by Lemer Pax in containers that are suitable for all types of transport. The Posijet is individually packaged in a 1500*850*1580 mm wooden crate, the device is securely blocked in the transportation space to avoid any risk of shock.

The following indications will be shown on the crate:

- Exact dimensions of the crate
- Weight of the empty crate
- Weight of the full crate
- "FRAGILE" reference
- "DO NOT TIP OVER" reference
- "DO NOT STACK" reference
- Location of the centre of gravity

It must be transported sheltered from dust and weather conditions (rain, snow, etc.) and in the following environmental conditions: 0 °C<T<+60 °C and 5 %<H<95 %.

The following symbols will be printed on the crate:



This symbol indicates that the crate must be stored in a dry area, since it may be damaged by water.



This symbol indicates the top side of the crate.



This symbol indicates that the content of the crate is fragile.

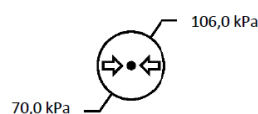
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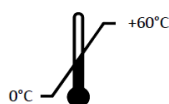
Indicates that the crate must not be handled with a forklift from the side on which this symbol is printed.



Indicates humidity limits during transport



Indicates pressure limits during transport



Indicates temperature limits during transport


If the Posijet® has to be stored before being placed in service, it must be stored in a clean room with an atmosphere which is not contaminated by other activities (waste, food, construction products, etc.) and in the following environmental conditions: $0^{\circ}\text{C} < T < +60^{\circ}\text{C}$ and $5\% < \text{Rh} < 95\%$.

V. Handling

The equipment must be handled using appropriate handling means if it cannot be moved by rolling. The Posijet® must not be moved other than:

- On the ground, using its wheels and only on flat surfaces;
- Elevated, for long distances or uneven surfaces (such as stairs), in its crate and only by using appropriate means (pallet truck, fork-lift truck).

In all other circumstances: by someone from LEMER PAX or appointed by LEMER PAX

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VI. Assembly / Disassembly

For a complete installation and training service, the equipment is delivered by LEMER PAX or a designated carrier. LEMER PAX unpacks the equipment, assembles the components and sets the equipment to work.

Training is provided to participants by the LEMER PAX technician(s).

Following this training session, the LEMER PAX technician(s) issue(s) a certificate to each person attending with the date of the training session; the certificate must be signed and dated by both parties.

In addition, the user must supply the manufacturer with fluid installations conforming to current regulations and, if necessary, they must be periodically checked. In addition, the user must make available one power socket with an earth connection, appropriately protected in accordance with current electrical safety regulations and with NFC 15-100, and located in a secure room such as a hot laboratory.


VII. Prerequisites for using the Posijet®

VII.1. Connecting Posijet® to the electrical network

Posijet® is equipped with a socket for connection to the electrical network, allowing Posijet® to be operated by means of an on-board power supply and to recharge the battery pack.

Posijet® has an integrated 24V power supply. This power supply allows Posijet® to be used without consuming battery power when the on/off button is turned on and the power cable is connected. In this case, the batteries are recharged while Posijet® is in use.

The Posijet® mains plug can be connected and disconnected at any time allowing Posijet® to switch to battery mode if the cable is disconnected or to switch to power mode with charging if the cable is connected.

 It is recommended to charge Posijet® every night so that it is operational every morning. To allow the batteries to be charged in good conditions, the Posijet® on/off button must be turned off.


 To avoid any risk of electric shock, Posijet® must only be connected to a mains supply equipped with a protective earth.

 The Posijet® power socket must remain accessible to allow easy disconnection of the appliance from the power supply.

VII.2. Connecting the Posijet® to IT networks

The Posijet® can be connected to a Ethernet and/or Wi-fi network operating using the TCP/IP standard.

The connection of Posijet® to IT networks including others equipment could lead to unidentified risks to the patients, operators or third parties.

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The user should identify, analyse, evaluate and monitor any risks generated by connections to the hospital department network.

If modifications are made to the network/data coupling, the user must conduct a supplementary analysis of these risks.

Modifications to the computer network include:

- Changes to the computer network configuration;
- Connection of additional units to the computer network;
- Disconnection of units from the computer network.


Software updates and upgrades of the Posijet® are prohibited without agreement of LEMERPAX.

Posijet® embeds a computer which includes a dedicated and validated operating system adapted to industrial and medical constraints.

 To avoid any risk linked to cybersecurity, the IT service stays responsible of integrating and managing Posijet® in the hospital network. Unhandled requirement or incompatible requirement from IT hospital service shall be validated and approved by LEMER PAX before being applied on the Posijet®.


 To avoid any unknown risk of malfunction of the Posijet®, the installation or connection of the Posijet® to third-party software not validated by LEMER PAX is strictly prohibited.

 To avoid any risk of malfunction of the Posijet®, the IT service shall keep the IT configuration validated by LEMER PAX.

 To avoid any risk of malfunction of the Posijet®, the IT service shall keep the version of the operating system validated by LEMER PAX. Any change on the system without LEMER PAX agreement could lead the Posijet® to dysfunction.

VII.2.a. Operating system / BIOS

- BIOS password protection;
- Customization of the Windows Embedded Standard Seven and Windows 10 image including the following elements:
 - Configuration of the software firewall ;
 - Activation of the "Windows defender" antivirus ensuring the protection of malicious codes;
 - Save traces on disk D;
 - Creation of 2 user accounts:
 - A "user" account for restricted use:
 - Activation of the "keyboardFilter" to avoid certain key combinations;
 - Restriction for modifying OS parameters, for installing software;

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- A local administrator account "ManagerLP" allowing to modify the configuration of the application, the parameters of the operating system and to deactivate the write protection on the system disk.

The Posijet® also allows the transfer from the office station of the Nuclear Medicine department, and allows the storage of the injection data of the Posijet®.

 *The Posijet® computer must under no circumstances be used for any application other than the application provided for in this instruction manual.*

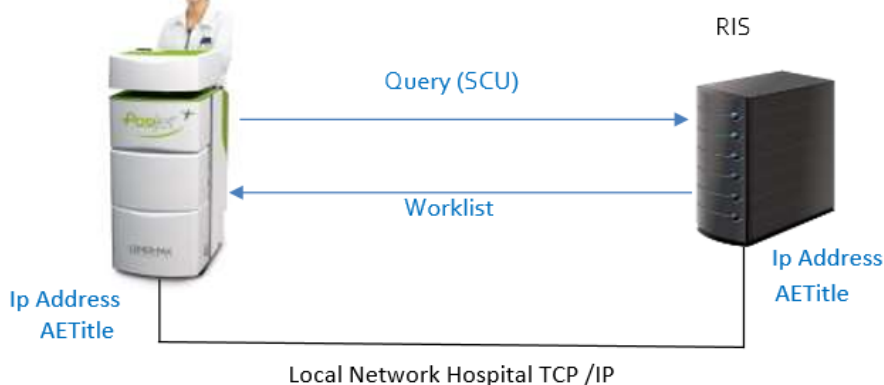
VII.2.b. Software application level

- Protection of access to the database engine by password;
- Management and administration of 2 user profiles within the application:
 - "Operator": See the manual for more details;
 - « Administrator » : See the manual for more details;
- Protection of calibration/calibration by an administrator password;
- Protection of software settings by password;
- Authentication and traceability of preparations and measurements.

3 VII.2.c. Connection to patient treatment software


When connecting to a DICOM server, the POSIJET® only makes a SCU request on the RIS to retrieve the Worklist of patients to be injected (patient name, weight, etc.). The Posijet® does not send any information back to the RIS or the PACS (no image manipulation). The Posijet® does not need any connection with the TEP.

Prijungus prie DICOM serverio, POSIJET® pateikia tik SCU užklausą į RIS, kad gautų darbo sąrašą pacientams, kuriuos reikia injakuoti



VII.3. Touch screen

The Posijet® screen is a touch screen. The keys are activated by pressing a finger on the screen.

 *Never use sharp objects on the screen. This could cause irreversible damage.*

The screen acts as the interface between the operator and the equipment operating mechanism. Special software guides the operator during all stages of operating the equipment.

The Posijet® computer must never be used for an application other than the one described in this instruction manual.

VII.4. Workstation

When using the machine, the operator positions himself close to and behind the Posijet® when injecting the patient, to protect himself and stand away from the radiation emitted by the tubing.

The dedicated accessories and sterile kits described above are available to the operator. The operator can access the control panel and the container compartment.

VIII. Using the Posijet® in normal injection cycle

VIII.1. Home screen



1	The central icon is contextual. It can represent the loading, dose preparation – injection and unloading phases.
2	The “ Qualité ” (Quality) icon opens various test screens on the dose calibrator (drift, self-test, linearity, etc.).
3	Indication of the onboard energy indicating the current mode (battery or mains) and the current charge


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	level.
4	The “Traçabilité” (Traceability) icon provides access to the summary screens of patients and mother solutions (used and upcoming).
5	The “30adioactive” (radioactive) icon notifies the operator that the Posijet® contains an active mother solution.
6	Name of the current software version.
7	The “attention” (warning) icon indicates the presence of a fault.
8	Zone describing the current state of the mother solution loaded in the Posijet.
9	The “Utilitaires” (Utilities) icon provides access to the tools used for dose calibrator monitoring, calibration and management of the maintenance mode of the machine internal logic controller.
10	The “Paramètres” (Settings) icon is used to configure the device. The following items can be configured: language, unit, interoperability management and print settings.
11	Current date and time.

VIII.2. Presentation of the Cycle management screen



1	Icon displaying the current cycle (loading, dose preparation-injection or unloading).
2	The “Opérateur” (Operator) icon displays the current operator and can be used to change operators during the cycle.
3	“Activimètre” (Dose calibrator) zone showing the status of the preparation syringe (volume, activity)
4	“Solution mère” (Mother solution) zone showing the status of the mother solution selected. Actions are available by selecting the zone.
5	The “30adioactive” (radioactive) icon notifies the operator that the Posijet® contains an active mother

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<p>Posijet® V3</p>		

	solution.
6	The “attention” (warning) icon indicates the presence of a fault.
7	The “Aide contextuelle” (Context help) zone provides the necessary information based on the current status of the machine.
8	The “NaCl” zone shows the current volume in the NaCl bag. This area is clickable to edit or reset the volume.
9	The “Patient” icon displays the patient information. This zone is clickable to edit the patient information or access operations.
10	The “Planning” icon allows to visualize the use of the radiopharmaceuticals vial according to the patient program
11	The “Accueil” (Home) icon takes the operator back to the home screen of the application.

VIII.3. Using the Posijet® in a full injection cycle

VIII.3.a. Description of Posijet® phases

The Posijet® normal patient injection cycle includes three phases:

Phase 1: Loading phase: during this phase, the user loads the items relating to the mother solution vial (Posikit 1B, vial shield containing the mother solution) and locks the machine. This is usually done in the hot laboratory of the Nuclear Medicine department. The loading phase is symbolized on the screen by the logo opposite.



Phase 2: Patient dose preparation and injection phase: this phase is usually carried out outside of the hot laboratory, near the patient. This phase will be repeated as many times as there are patients injected per vial. The dose preparation and injection phase is symbolized on the screen by the logo opposite.



Phase 3: Unloading phase: during this phase, the user unlocks the machine and disposes of the items used. This is usually done in the hot laboratory of the Nuclear Medicine department. The unloading phase is symbolized on the screen by the logo opposite.



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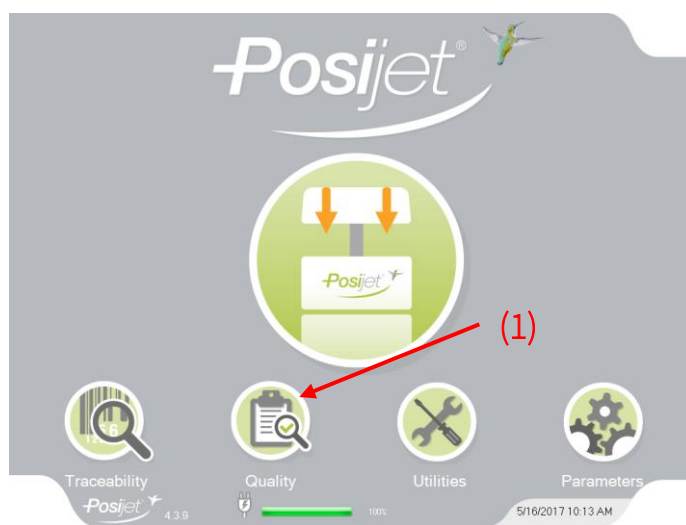
VIII.3.b. Power on and quality controls

Step 1: Power on the Posijet®



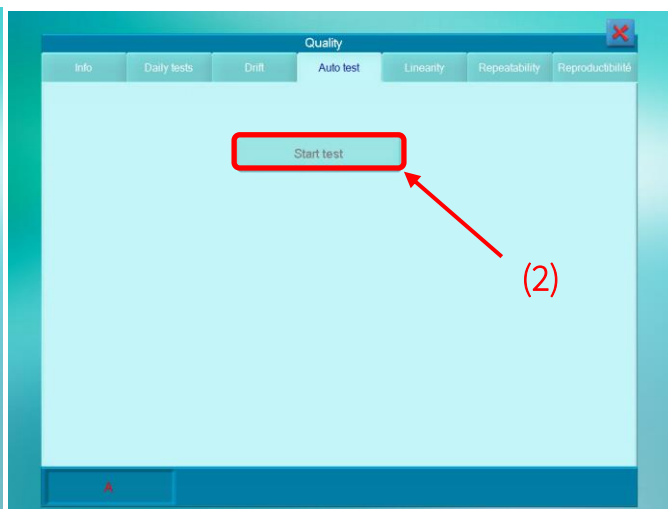
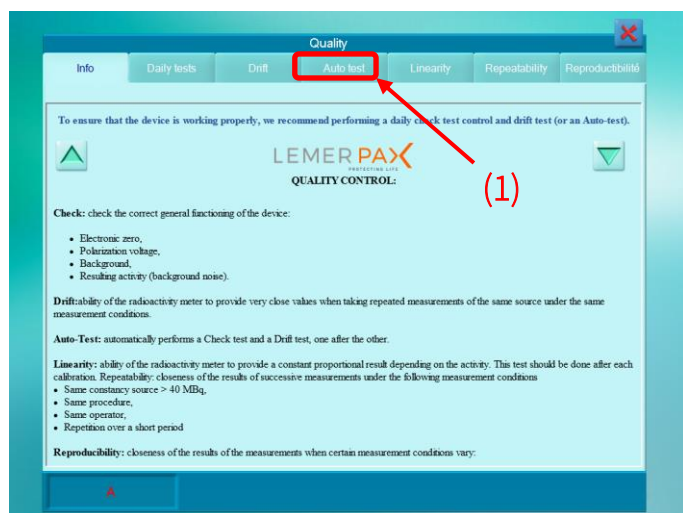
- Press the On/Off button (1): the green indicator light turns on.
- The PC will start automatically, the program opens on the home screen, the door unlocks and the sampling head clutch is activated.

Step 2: Daily checks;

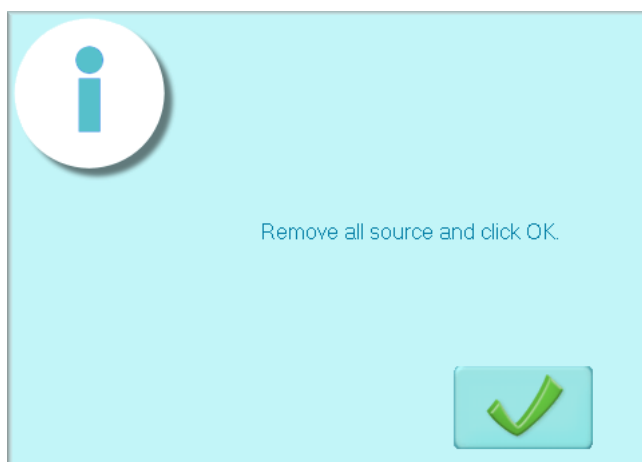


- Click the Qualité (Quality) icon (1) to access the dose calibrator quality controls (for details, please consult the dose calibrator instruction manual or the corresponding quick start guide).

At this stage, you can run a self-test. The self-test successively performs a Control test then a Drift test and prints all the results (if a label printer is configured and connected).

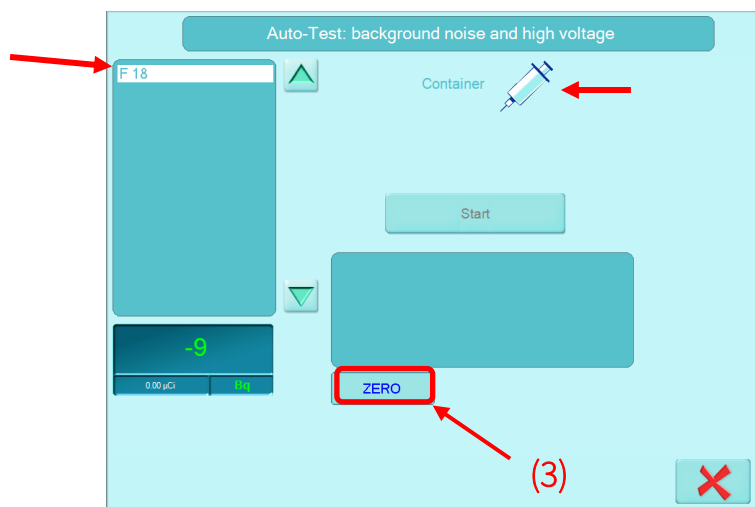


- Go to self-test tab (1).
- Click “Lancer le test” (Start the test) (2).



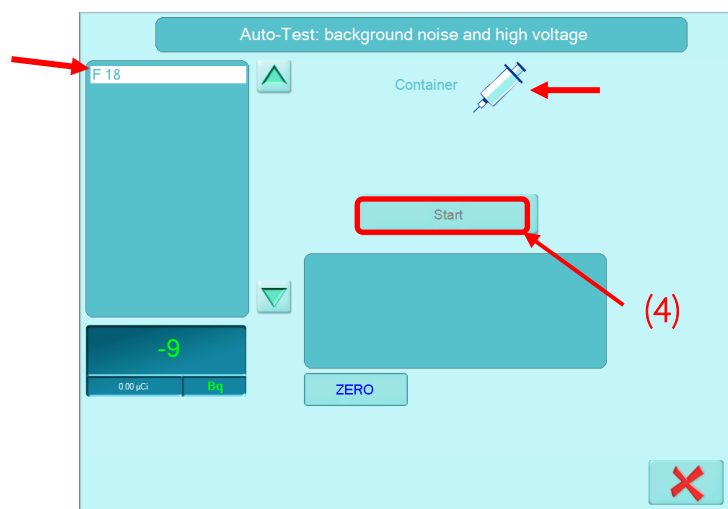
- The software displays the above message.
- Check that there is no source in the dose calibrator chamber and click OK.

Posijet® V3



To zero the dose calibrator:

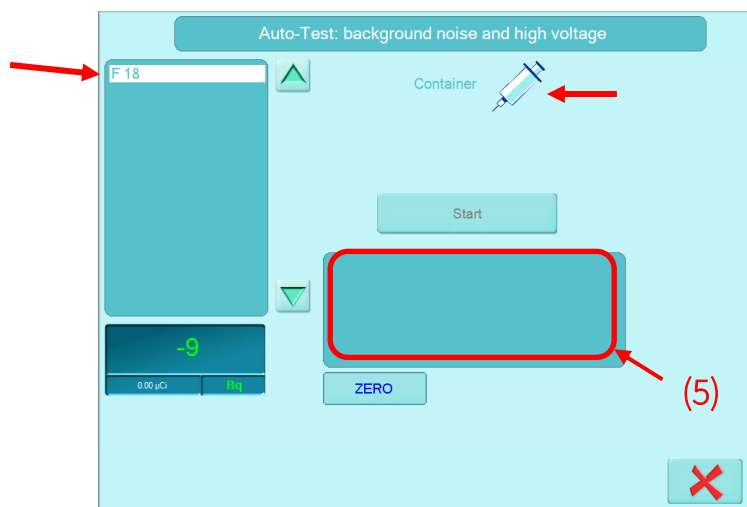
- Choose packaging syringe and the isotope F18.
- Click “Zéro” (3).



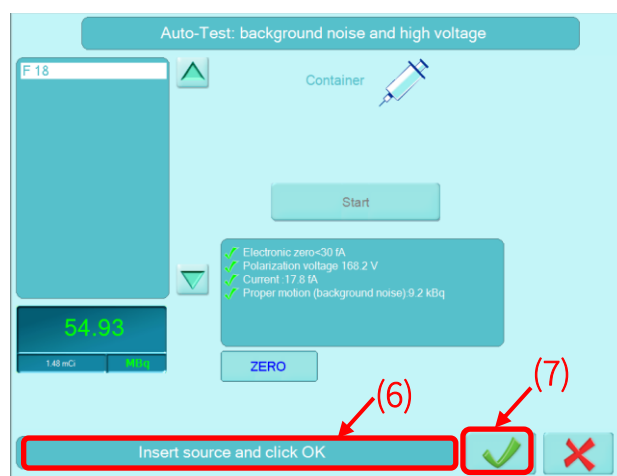
To start the self-test:

- Select the radionuclide and the packaging.
- Click “Démarrer” (Start) (4).

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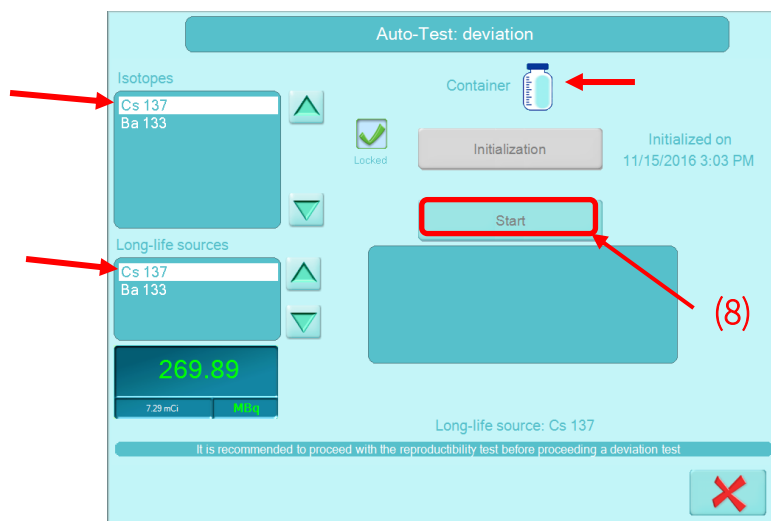


The programme will measure the high voltage, the no-load current value and the activity value corresponding to the radionuclide selected (F18). The deviation percentages appear in the blue box (5).



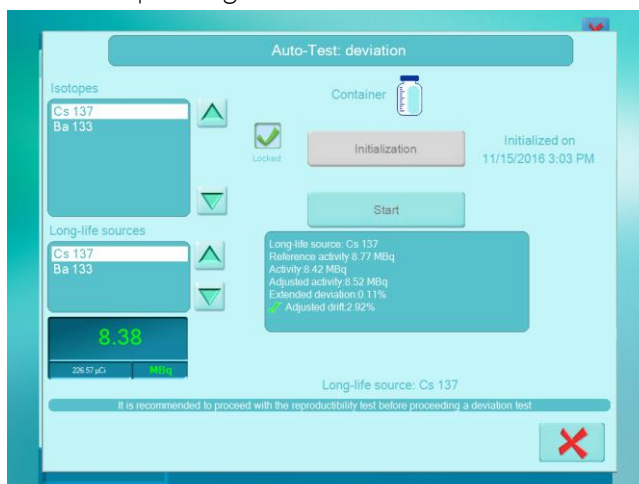
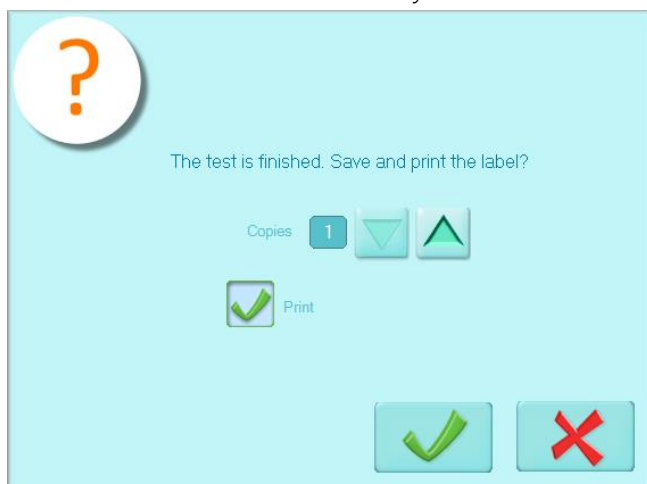
- Insert the constancy source in the dose calibrator chamber (6).
- Click OK (7).

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- Select the radionuclide and the corresponding channel (generally the drift test is performed using the isotope on the corresponding constancy source).
- Click “Démarrer” (Start) (8).

The software measures the constancy source and calculates the corresponding drift.



Once the drift is calculated, the software displays the message above:

- Select the number of print copies and if you want to preview the results before printing.
- Once the preview is closed, the results of the drift test are shown in the blue box.

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Quality Controls

4/25/2019
4:05 PM

TRAINER LEMER PAX

Serial N°:
SN ACT/072/2015

SW version:
453

Daily tests - F 18

Electronic zero (30 fA):
30 fA

High voltage [144 V - 176 V] :
163.6 V

Bgnd resp. (<100 kBq / 2.7 µCi):
23.0 kBq

Drift

Long life source:
Cs 137

Ref. date:
4/25/2019 4:04 PM

Ref. activity:
20.07 MBq

Isotope:
Cs 137

Measured act.:
20.00 MBq

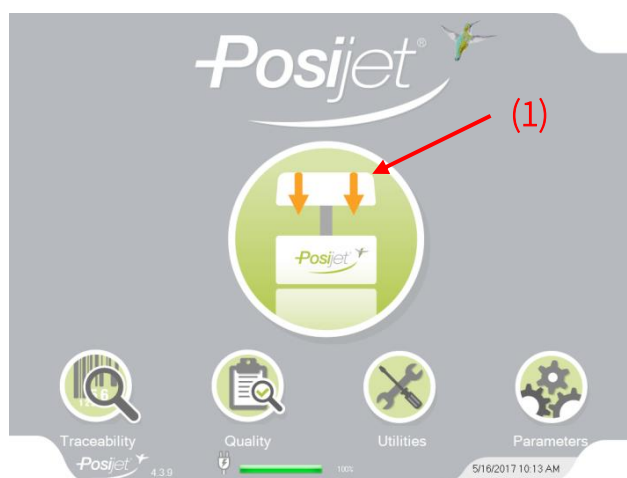
Corrected act.:
20.00 MBq

Drift (< 5 %):
0.35%

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VIII.3.c. Phase 1 – Posijet® loading phase

Step 3: Launch the loading cycle



- Click the Posijet® loading icon (1) to start the application.

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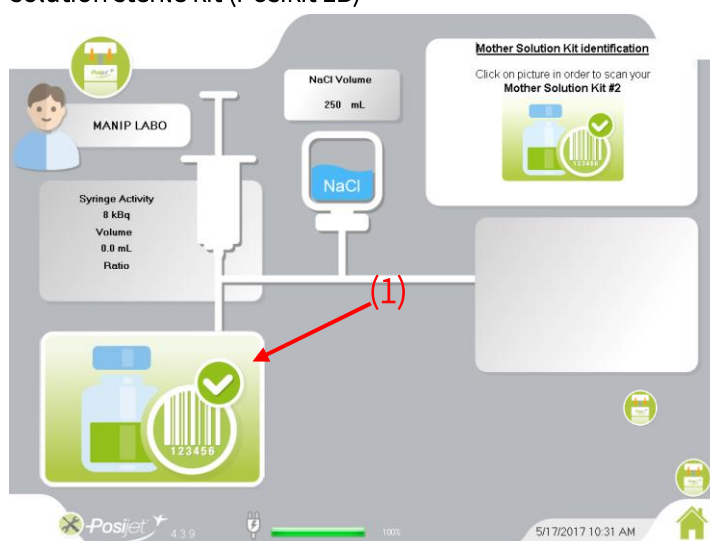
Step 4: Identify the operator

Note: Depending on the required configuration, the Posijet® can be configured with either identification mode (login) or authentication mode (login + password).



- Select the user name;
- Confirm

Step 5: Identify the mother solution sterile kit (Posikit 1B)



- Click the mother solution kit identification icon (1).

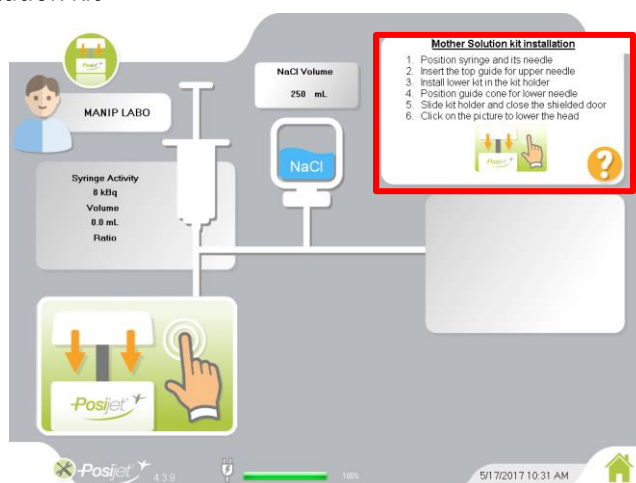
Posijet® V3



- Scan the barcode of the mother solution kit using the barcode reader.
- Confirm.


You can also identify the kit by filling in the fields using the keyboard. To do this, click the batch number field of the “N°Lot kit commun” (Common kit batch N°) window. Then click the touch screen keyboard icon. The keyboard appears and you can fill in the fields.

Step 6: Install the mother solution kit

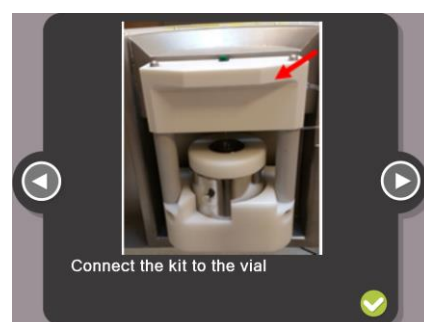
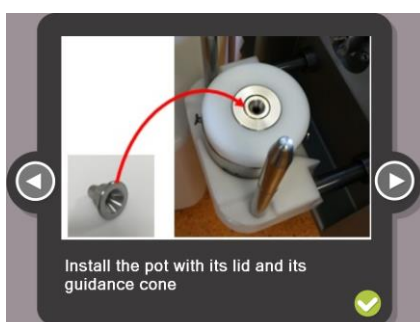
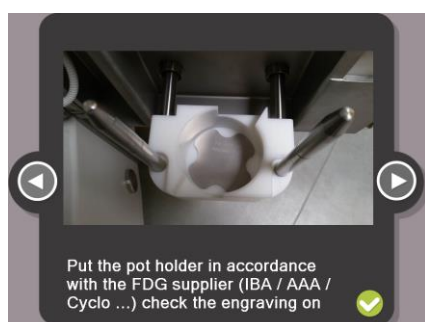
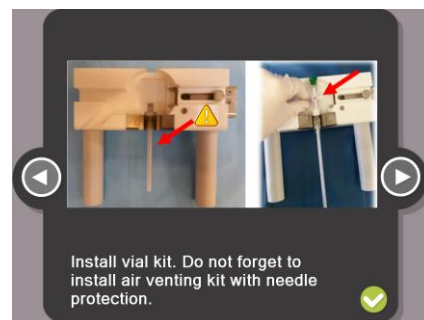


Follow the instructions in the Context Help window to install the kit.

- Position the syringe and needle in the sampling head.
- Insert the top guide
- Install the kit in the vial holder.
- Insert the lower guide
- Lock the kit holder and close the shielded door.
- Click the sampling head lowering icon.

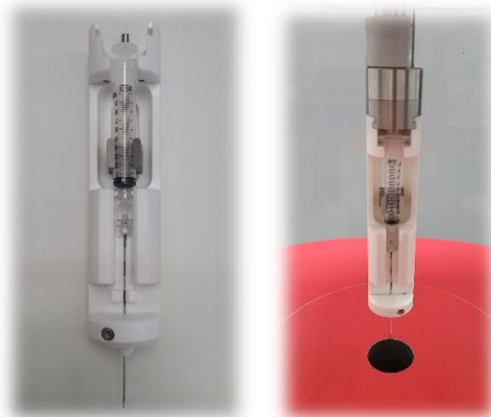
Click the  symbol to display visual help for each step:

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Posijet® V3

Step 6)a): Position the syringe and needle in the sampling head



- Insert the sampling syringe into the guide.
- Position the assembly on the sampling head.

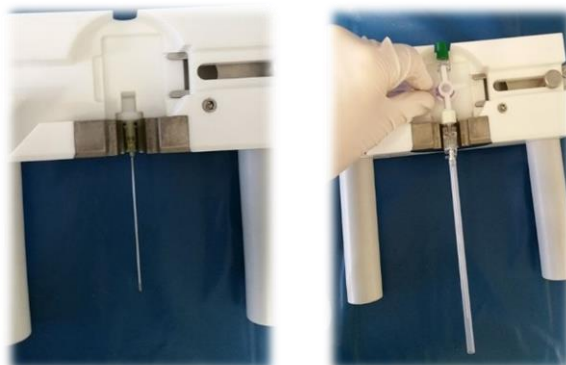
Note: Check that the syringe plunger is pushed all the way down.

Step 6)b): Insert the top guide cone



- Insert the top guide cone to guide the sampling needle.

Step 6)c): Install the kit in the vial holder

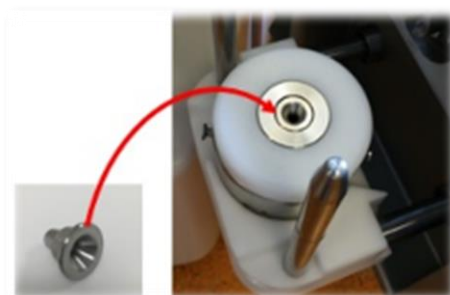


- Open the latch to open the kit housing;
- Install the vial venting kit (needle + 0.22 µ filter);

Posijet® V3

- Insert the mother solution kit into its housing;
- Close the latch of the kit;
- Check that the 3-way valve is correctly positioned: a label on the shielded door indicates the correct positioning.

Step 6)d): Insert the lower guide cone



- Position the vial shield with its adapter if necessary;
- Remove the flip-off top from the vial if necessary;
- Disinfect the vial septum with a compress and suitable tongs;
- Insert the disinfected lower guide cone

Step 6)e): Lock the kit holder and close the shielded door



- 1)a) Position and slide the kit holder on the two guide pins until it hits the lower stop;
- 1)b) Push the vial shield holder until it comes to a stop against the door;
- 2)a) Insert the NaCl tubing in the notches;
- 2)b) Set up the second tubing in the air bubble detector.
- 3) Place the bionector in the reserved area (tray)
- Close the shielded door.

Step 6)f): Click the sampling head lowering icon



- Click the sampling head lowering icon to start the animation showing the sampling head descending.



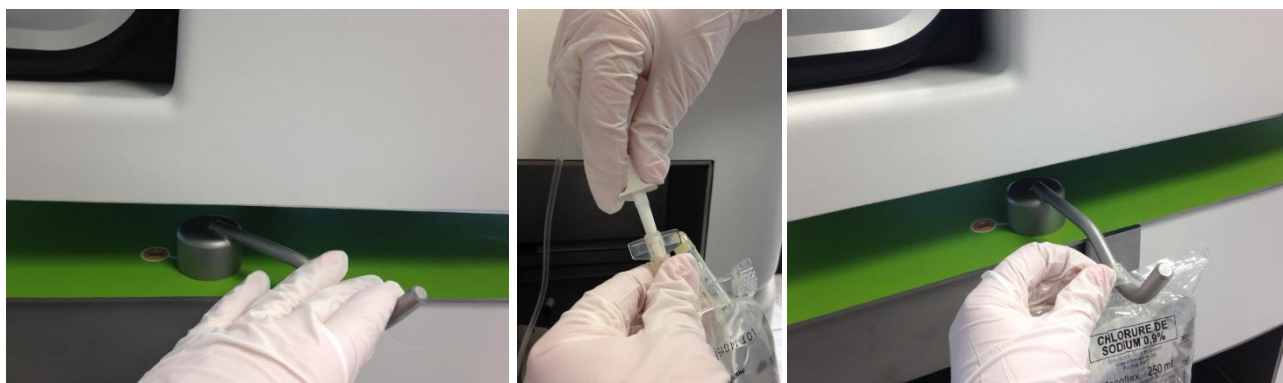
- Press the two-hand controls simultaneously in order to lower the sampling head (if the two-hand controls are released, the sampling head stops descending immediately).

Lowering the sampling head automatically locks the shielded access door to the mother solution.

Note: If necessary, you can raise the head (pictogram in the upper right corner of the head lowering animation).

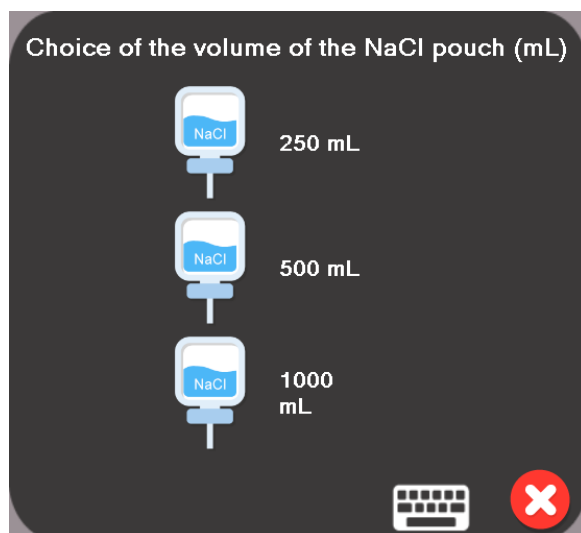


Step 6)g): Install and connect the NaCl bag



- Bring out the NaCl bag hook.
- Connect the NaCl bag to the mother solution kit.
- Position the NaCl bag on the retractable hook.

Step 6)h): Choose the volume of the NaCl bag

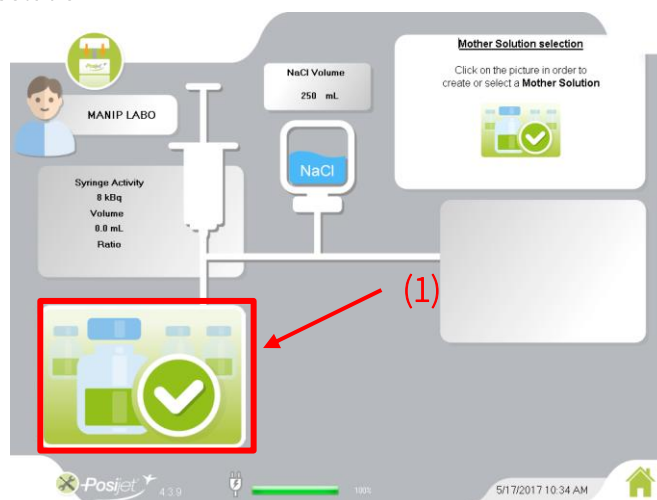


Click the volume corresponding to the NaCl bag installed.

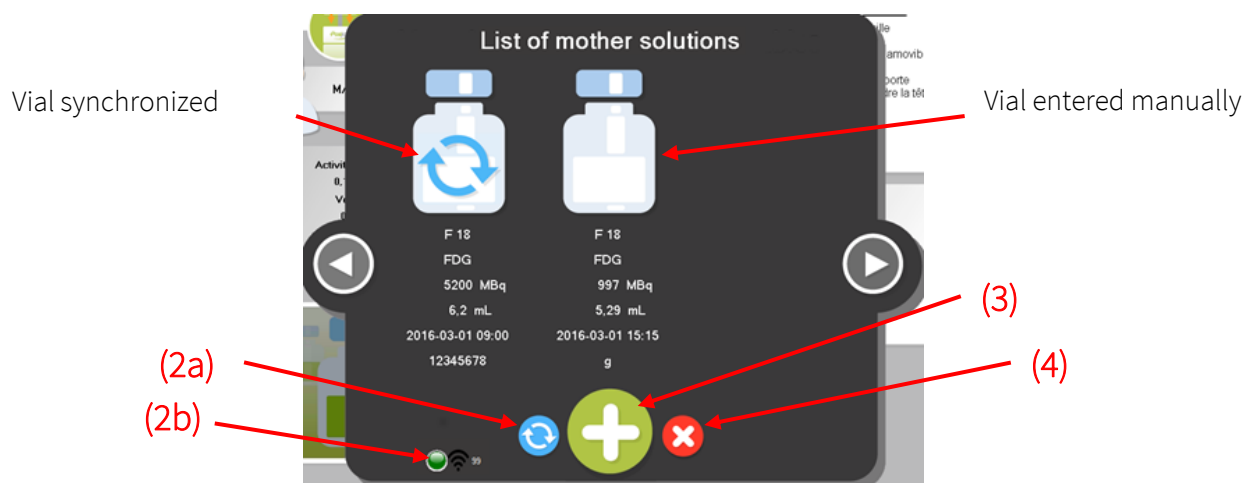
If the required volume is not proposed, click the  icon to enter the required value.

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Step 7: Identify the mother solution



- Click the vial zone (1) to create or select a mother solution.



When this screen opens, the application automatically synchronizes the data with the radiopharmaceutical software and retrieves any available information on the mother solution(s) that have been received and entered beforehand.

The mother solutions imported in this way are indicated with the following icon:

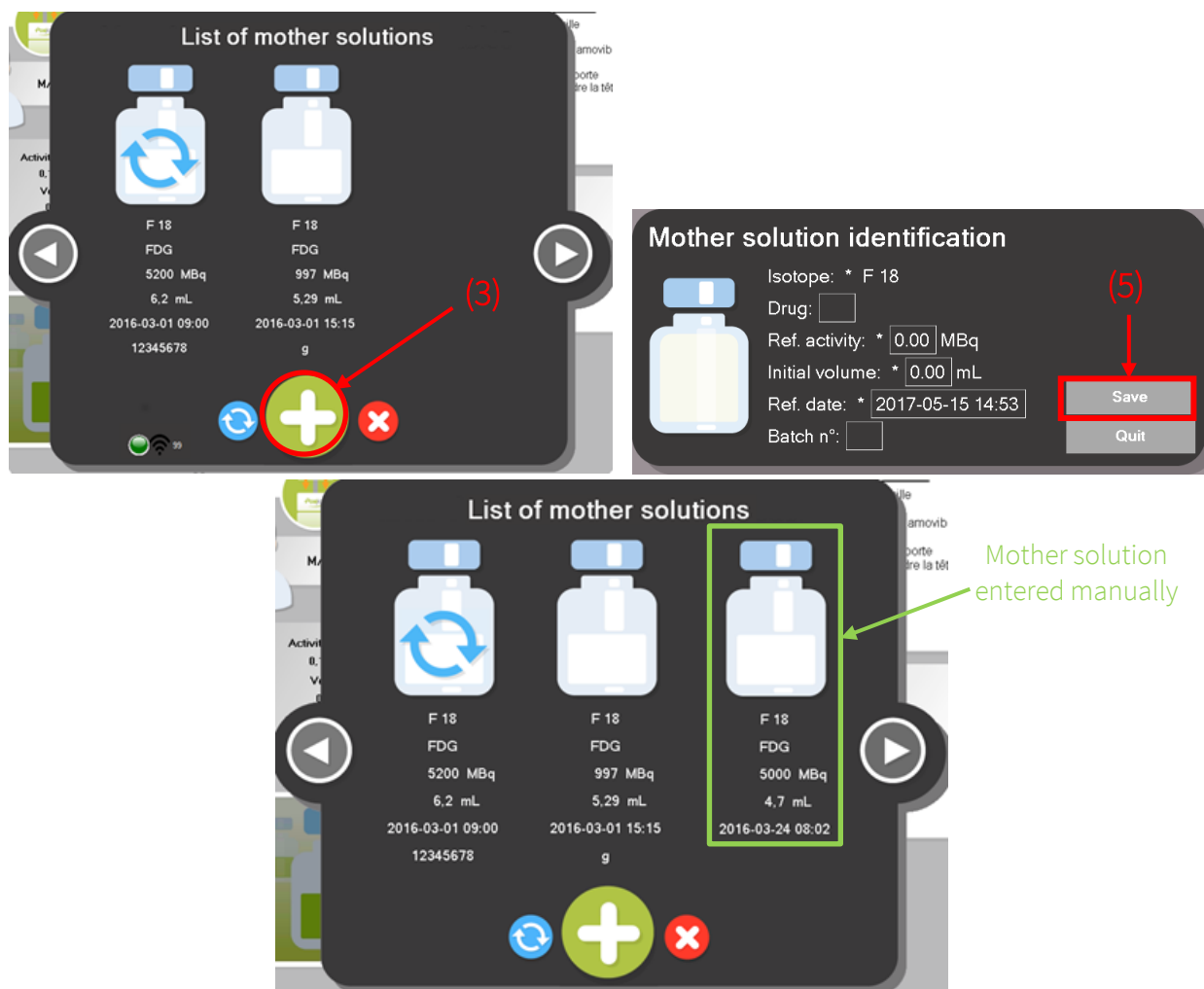



When this screen is open, it is possible at any time to select or create the mother solution to use:

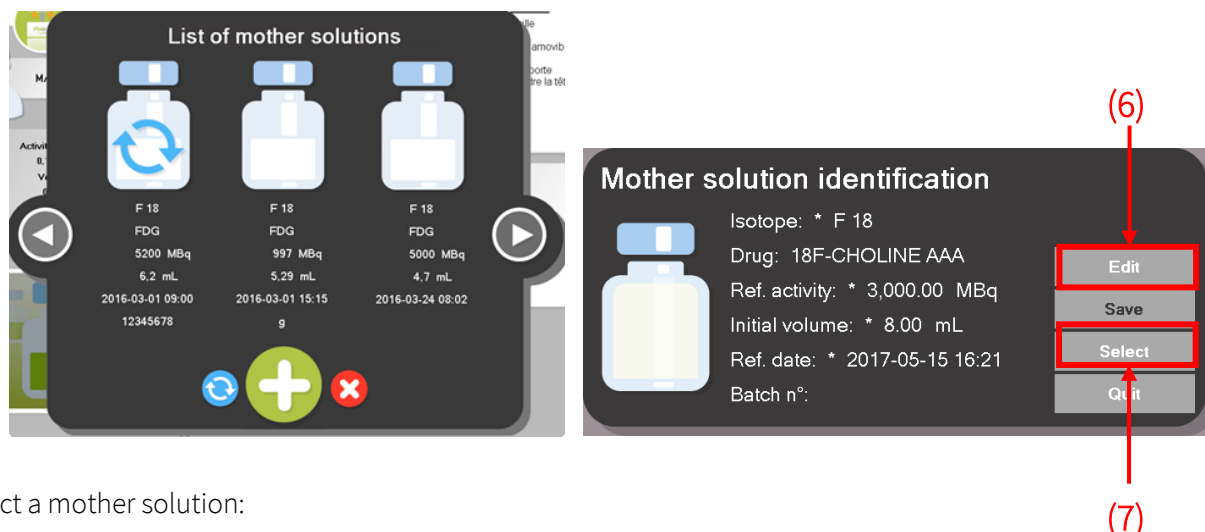
- The software has been synchronized with the radiopharmaceutical software and the available data on the mother solutions have been imported:
 - Select the mother solution installed in the Posijet®.
 - Verify and confirm the recorded data.

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- Note: If necessary, you can request synchronisation with the radiopharmacy software with the blue button (2a). An indicator (2b)) gives the state of the connection; click this zone to make a WIFI reconnection attempt in case of WIFI fault.



- b) The mother solution used is not known in the Posijet® software:
- Click the button  (3) to create a mother solution: a mother solution identification window opens.
 - Enter the information provided by the radiopharmaceutical supplier (isotope, drug, activity and volume at the date and time of calibration, batch number).
 - Save the data entered (5): the mother solution identification screen closes and the mother solution created is added to the list of mother solutions already saved in the program.



To select a mother solution:

- Click the desired mother solution: a window showing the mother solution characteristics opens. On this window you can edit the information, when the mother solution was entered manually. Click “Editer” (Edit) (6), to open the mother solution identification screen, and you can edit the data as described above. If you want to edit the information for a mother solution imported from the radiopharmaceutical software, you need to edit the information in the radiopharmaceutical software and resynchronize with the Posijet®.
- Click “Sélectionner” (Select) (7).

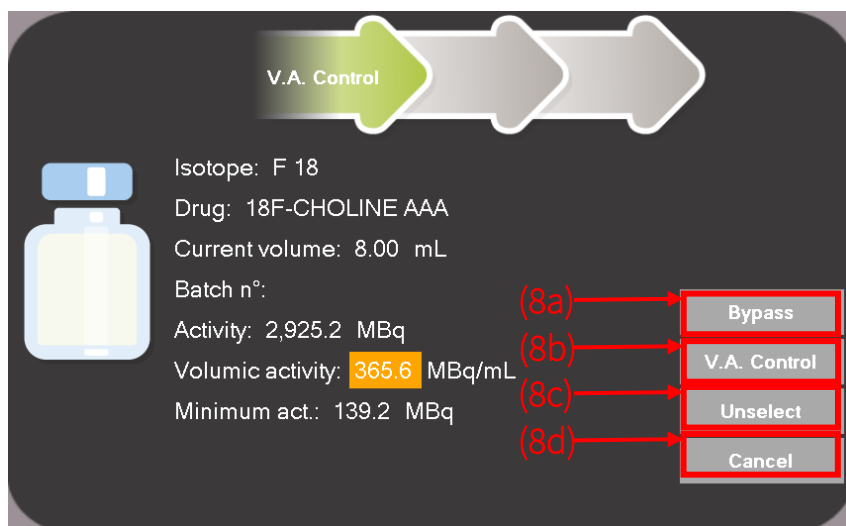
Step 8: Loading wizard

To simplify the loading steps, a wizard is displayed following the volumic activity check, flush and dilution steps.

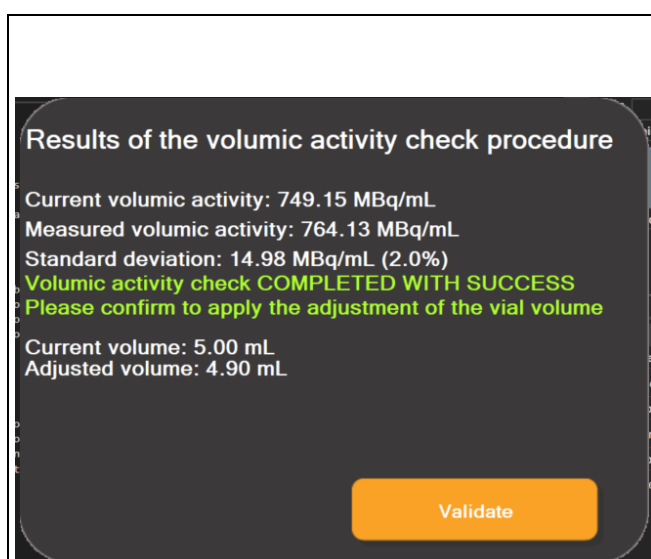


Posijet® V3

The first step consists in checking the volumic activity (VAC):



- After selecting the mother solution, the Posijet® prompts the user to check the volumic activity. This check verifies the data entered by the operator by sampling.
 - This check can be carried out by clicking the link (8b);
 - Otherwise, skip this check step by clicking the link (8a);
 - You can also deselect the current mother solution by clicking the link (8c);
 - Lastly, you can close the window by clicking the link (8d).
- At the end of the volumic activity check, the Posijet® displays the results:



- Successful volumic activity check: when the theoretical volumic activity and the measured volumic activity deviate by less than 20 % (Parameter), the check is considered successful. The program updates the volume and the theoretical reference activity is retained.

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Results of the volumic activity check procedure

Current volumic activity: 699.24 MBq/mL
Measured volumic activity: 804.13 MBq/mL
Standard deviation: 104.89 MBq/mL (15.0%)
Volumic activity check has FAILED. The standard deviation is TOO HIGH.

Check that the current volumic activity is consistent with the
Current volume: 5.00 mL
Adjusted volume: 4.25 mL

Apply measured data (2)

Keep provider data (1)

Failed volumic activity check: when the theoretical volumic activity and the measured volumic activity deviate by more than 20 % (Parameter), the check is considered a failure.

You have the choice between:

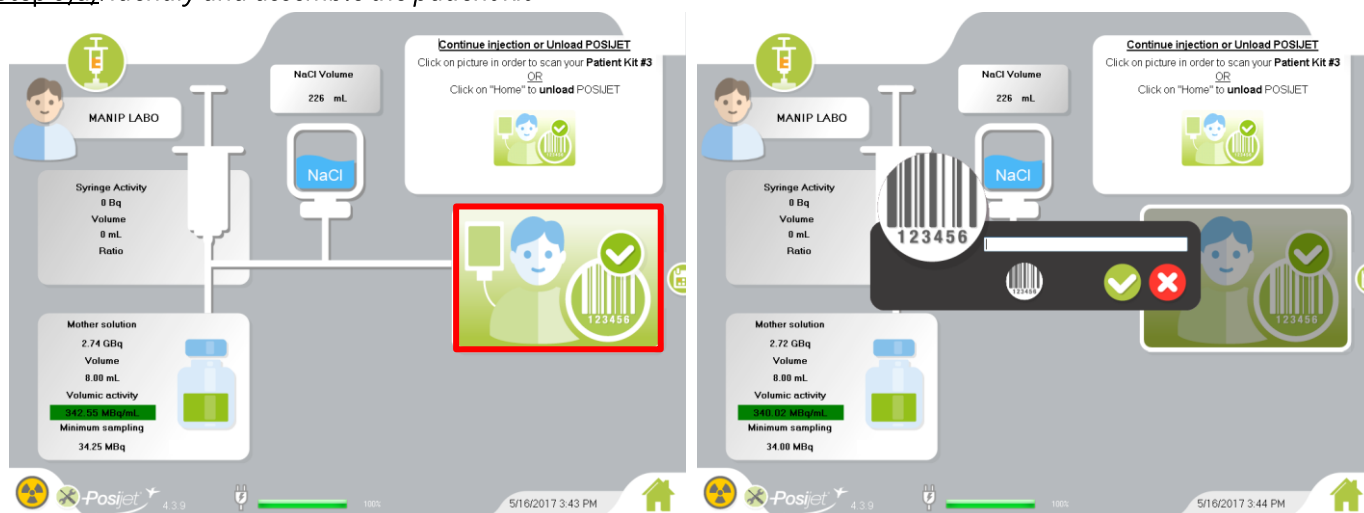
- Keep the theoretical data (1)
- Apply the data measured by the Posijet® (2), this function is subject to validation by an administrator password.

Before making your choice, please check the information entered for the vial beforehand.

It may be necessary in some rare cases, to unload to control the activity within the vial in a suitable hotcell .

Step 9: Flush the patient kit and dilute the mother solution (optional)

Step 9)a): Identify and assemble the patient kit



- Click the “Identification Kit Patient” (Patient kit identification) icon;
- Scan the barcode of the patient kit using the barcode reader;
- Confirm.

You can also identify the kit by filling in the fields using the keyboard. To do this, click the batch number field on the screen. Then click the touch screen keyboard icon. The keyboard appears and you can fill in the fields.

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No other sterile kit should be used in the Posijet® without prior validation to demonstrate safety of use with Posijet®. LEMER PAX declines all responsibility when using non-recommended kits.

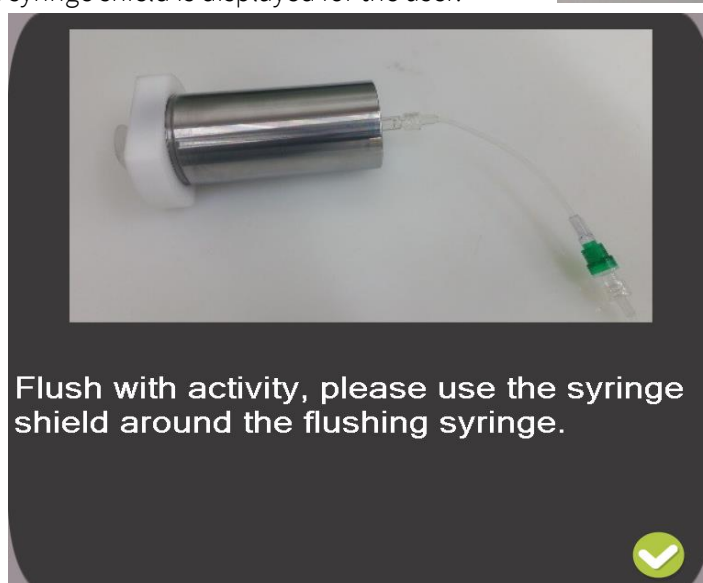


- Disinfect the bionector using a disinfectant compress.
- Connect the patient kit to the bionector of the mother solution kit
- Connect the 20 mL flush syringe to the patient kit tubing (caution: assemble according to the direction of the arrow on the filter indicating the fluid flow direction).

After conducting a volumic activity check, it is important to flush the patient kit in the syringe shield provided with the machine. To do this, insert the 20 mL flushing syringe in the syringe shield and then flush the kit (see step 9). Now dispose of this syringe in a suitable waste bin.

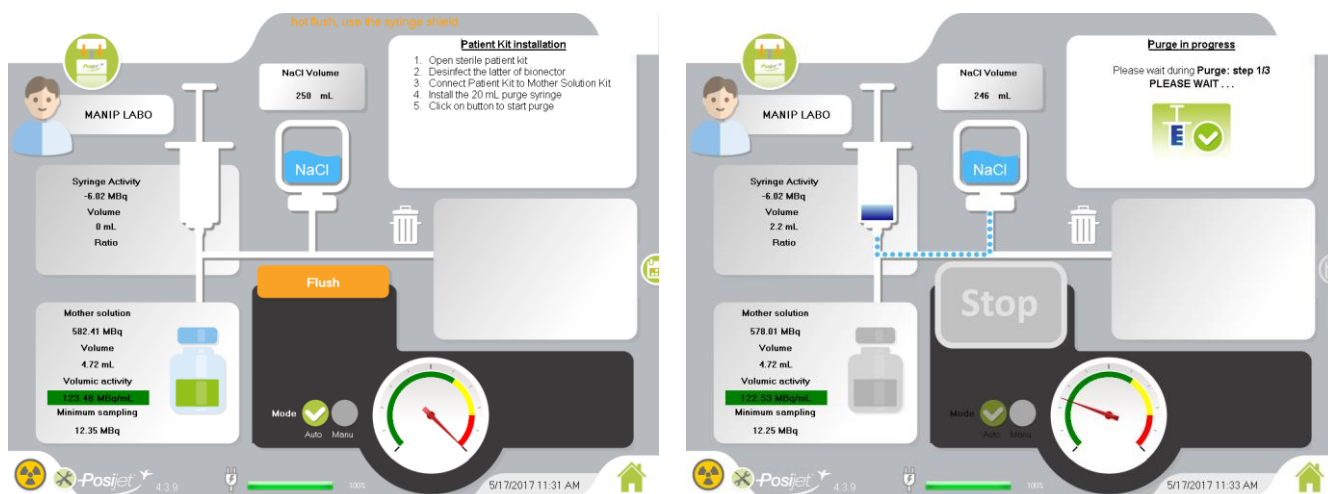


A reminder on how to use the syringe shield is displayed for the user:



Step 9)b): Perform the flush

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- Select automatic or manual flush mode (default flush mode is automatic).
- Click “Flush” to start the Flush.
- Wait for the flush to be completed (the 10 mL sampling syringe is filled 2 or 3 times)
 - o First flush: this 4.5 mL flush is done only at the first flush after installing the mother solution vial and its mother solution kit. It flushes the air from the kit.
 - o Second flush: 10 mL flush.
 - o Third flush: 10 mL flush.

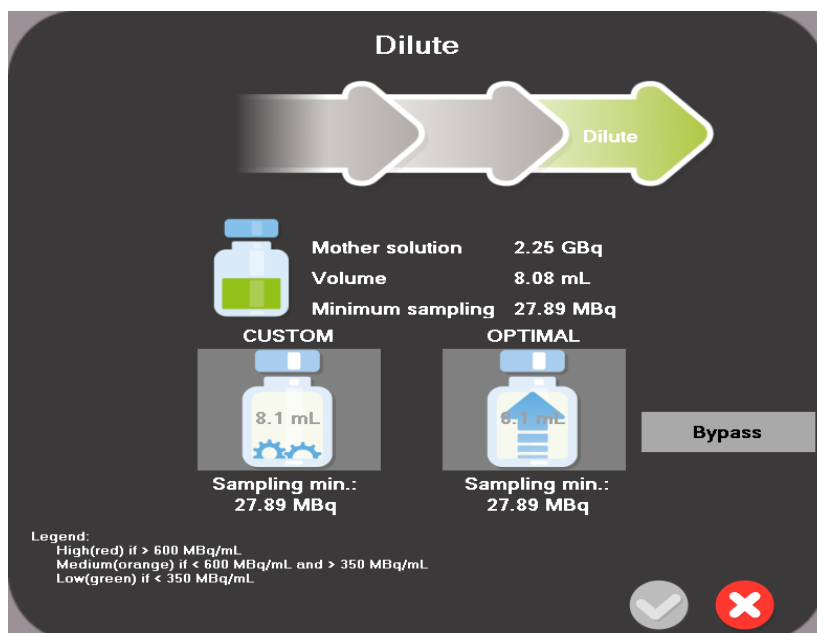
Before starting a flush cycle, verify that the saline solution bag contains at least 40 mL of fluid. A fault will be displayed to inform the operator if the volume of NaCl is less than 30 mL (parameters).

During the flush, the Posijet® automatically checks that there are no air bubbles in the patient kit. If there are air bubbles in the circuit, a **fault is generated and an indicator appears. In this case, you can remove the air bubbles and flush again.**

At any time during the flush, you can stop it by clicking the “Stop” button. You can resume the flush by pressing the “Flush” (Flush) button.



Step 9)c): Perform the dilution (optional)

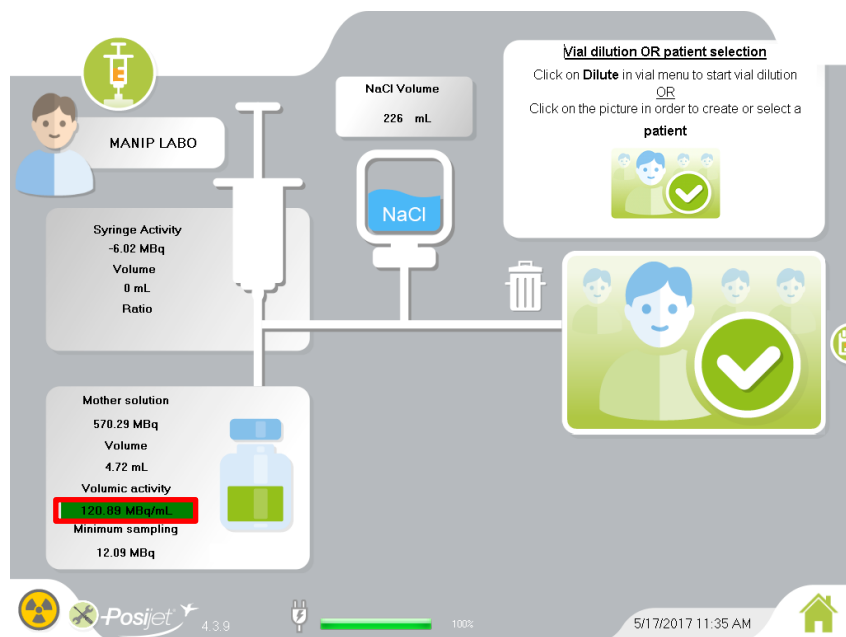


- The application offers 2 possible dilution levels taking into account the maximum volume of the vial.
- The first choice “CUSTOM” allows the user to enter the volume to be reached in the vial.
- The second choice “OPTIMAL” proposes to the user an optimum dilution calculated automatically by the Posijet®.

To assist the operator in selecting the dilution factor, the program displays the volumic activity (concentration) after dilution, the smallest possible dose given the selected target volumic activity and a colour code:

- **Red:** Volumic activity greater than 600 MBq;
 - **Orange:** Volumic activity between 350 MBq and 600 MBq;
 - **Green:** Volumic activity less than 350 MBq ;
 - **Grey:** Dilution is not possible because there is not sufficient empty volume in the mother solution vial. If the optimum volumic activity is already reached then the "Optimal Dilution" will not be proposed.
- Click the vial corresponding to the volumic activity required after dilution. The selection will flash.
 - Confirm to start the automatic dilution. An animation symbolises the dilution being performed.

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- When the dilution is complete, the mother solution data are updated automatically and the highlight colour of the volumic activity changes depending on the chosen level.

At any time during the dose preparation / injection cycle, further dilution is possible if necessary (and if the vial capacity so permits).

Note: Description of the dose preparation / injection environment of the Posijet® program.

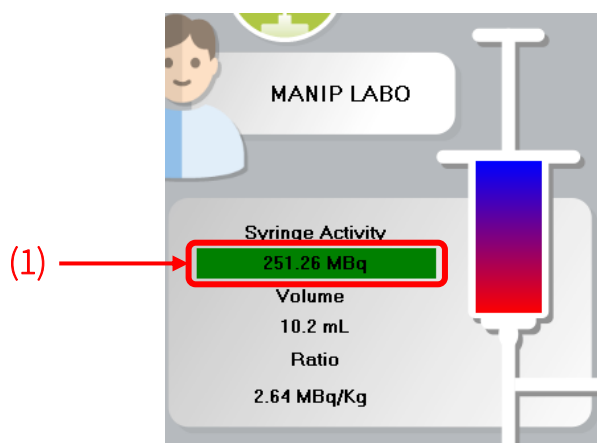


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- a) NaCl bag environment: This environment constantly displays the remaining volume of NaCl. When the available volume drops below 30 mL (parameters), the program informs the operator by displaying a

message. You can adjust the remaining volume or reset it by clicking .

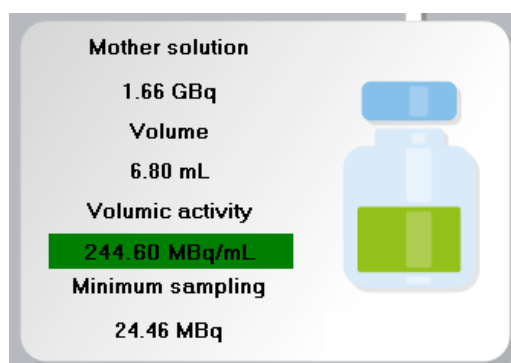
- b) Syringe environment:



The syringe environment always displays:

- The activity present in the syringe: a colour code (1) is assigned to the measured activity with respect to the prescribed activity:
 - Orange: the measured activity is less than 90% of the prescribed activity.
 - Red: the measured activity is greater than 110% of the prescribed activity.
 - Green: the measured activity is between 90% and 110% of the prescribed activity.
- The current volume in the syringe in mL.
- The current ratio (MBq/kg)

- c) Mother solution environment:

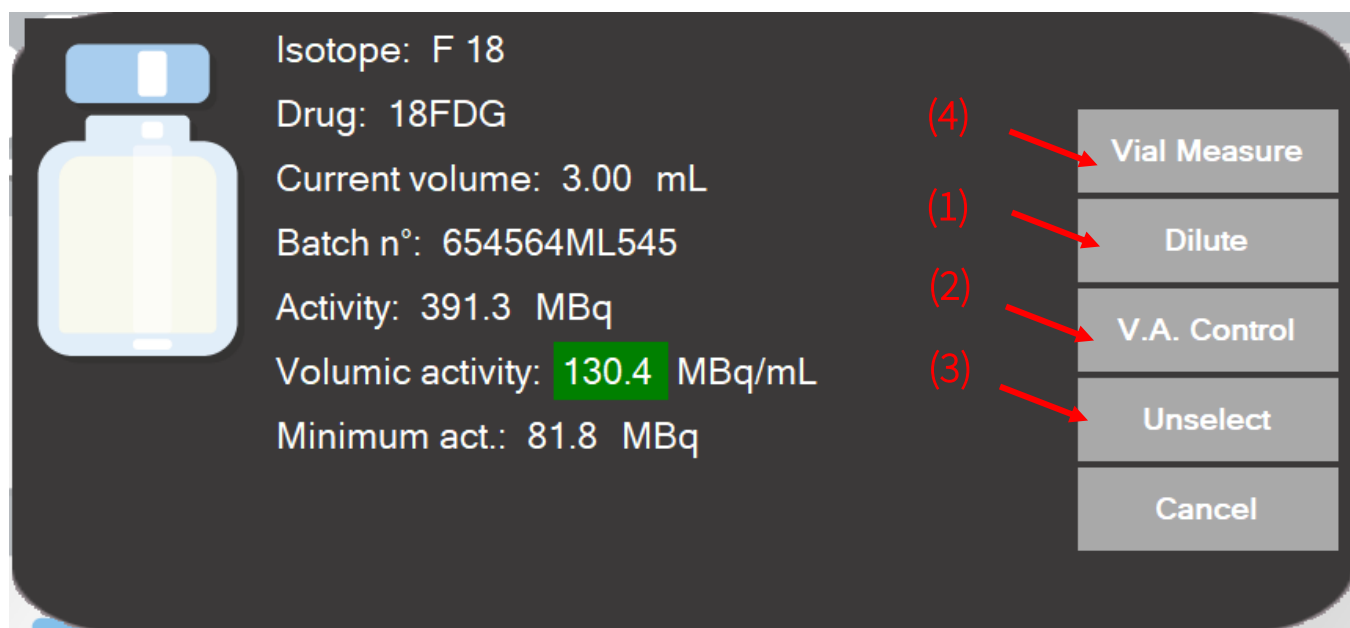


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The mother solution environment always displays:

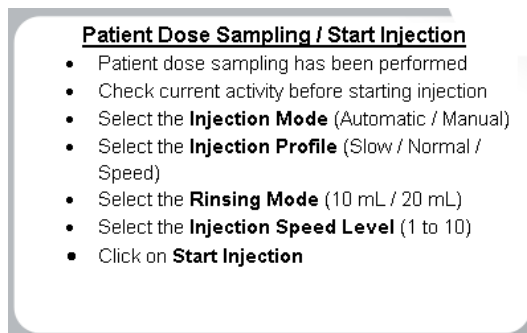
- The remaining activity contained in the mother solution vial loaded in the Posijet®.
- The remaining volume of mother solution.
- The volumic activity (concentration) contained in the mother solution vial: a colour code is assigned to the volumic activity based on its value:
 - o **Red**: volumic activity is **greater than 600 MBq**.
 - o **Orange**: volumic activity **is between 350 and 600 MBq**.
 - o **Green**: volumic activity is **less than 350 MBq**.
- The minimum activity that can be drawn up: this value describes the minimum activity that can be drawn up for the next patient. If this activity is too high, it is advisable to dilute, wait or choose a patient with a higher prescription.

By clicking the vial represented in this environment, an information screen opens. This screen allows you to:



- (1) Dilute the mother solution.
- (2) Check the volumic activity.
- (3) Deselect the mother solution vial (if no dose preparation or dilution has been performed).
- (4) “Vial measure” : At the end of use of the vial (Activity <500MBq parameters), it will be possible to carry out a complete measurement of the activity held in the stock solution vial.

d) Information environment (context help window):



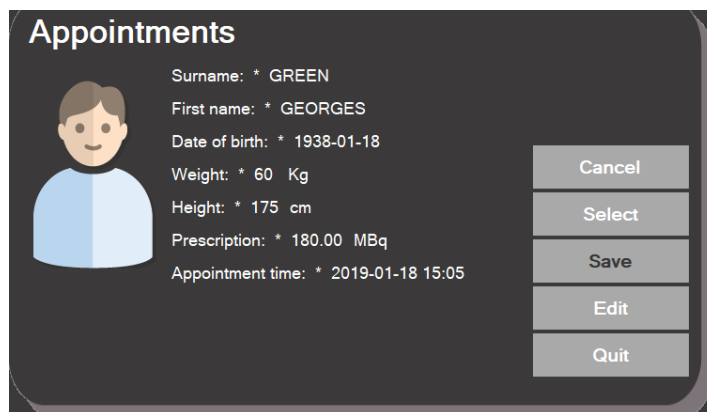
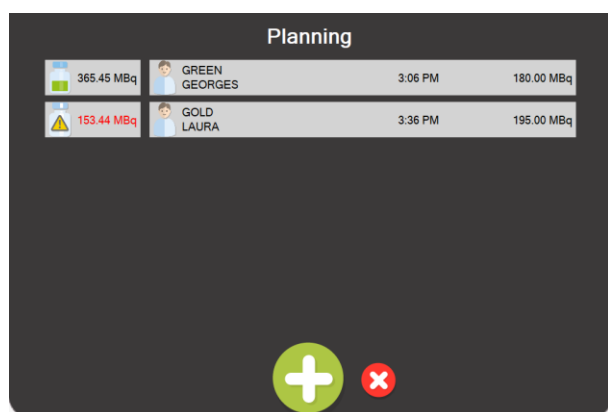
The information environment tells the operator what has been done and/or what to do next.

e) Patient environment:

Accessible by clicking on the box opposite:



Choice of the patient in the planning:



It is then possible to:

- Cancel the patient
- Select the patient's file being read on the screen
- Edit patient's file information
- Save, in case of previous modifications of the information of the patient's file
- Exit the menu

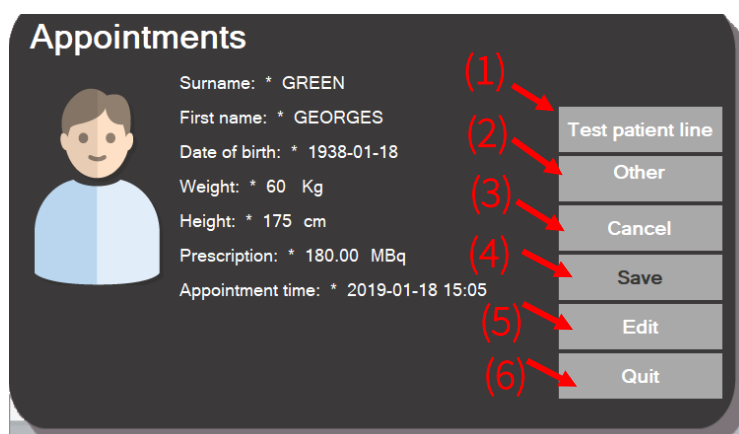
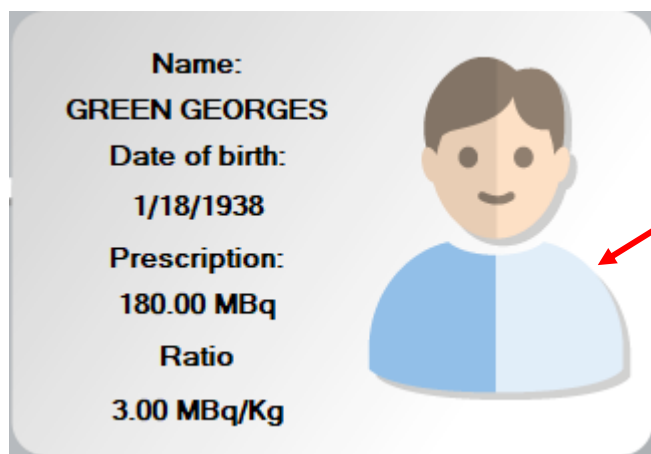
Posijet® V3

The patient environment always displays:

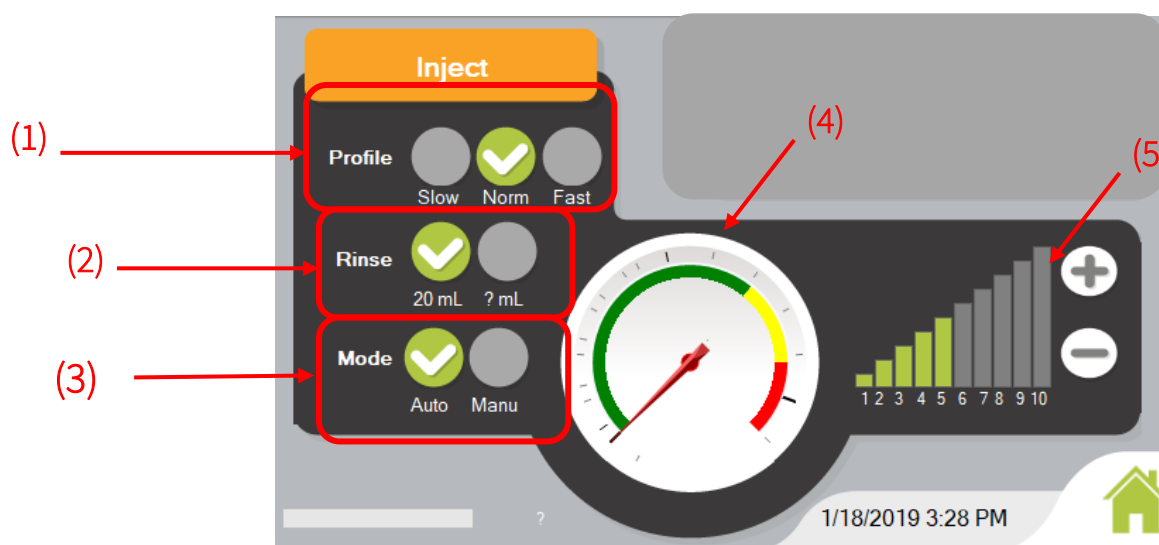
- The patient's first and last name.
- The patient's date of birth.
- The prescription.
- The prescription ratio (MBq/kg).

By clicking the patient symbol, you can:

- (1) Test patient's line
- (2) Choose another patient in the schedule
- (3) Cancel to deselect the patient record in use
- (4) Register in case of information modifications
- (5) Change if necessary the patient information
- (6) Leave the menu



f) Injection environment:



In the injection environment, you can control the settings and the injection rate:


- **Profile (1):** determines the speed of injection to select based on the injection site (arm, hand, foot, etc.) and the catheter used:

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- Slow Profile: 25 mL/min (example: yellow catheter) – Approximate injection duration: 24 seconds.
- Normal profile (default): 33.3 mL/min (example: blue catheter) – Approximate injection duration: 18 seconds.
- Fast profile: 50 mL/min (example: pink catheter) – Approximate injection duration: 12 seconds.
- **Rinse (2):**
 - 10 mL: the system performs a single 10 mL rinse (select only for reducing the volume to be injected, in paediatrics, for example). (Pay attention to the length of the connector used due to the risk of incomplete injection to the patient and therefore non-negligible residual activity in the tubing).
 - 20 mL (default): the system performs two successive 10 mL rinses.
- **Mode (3):**
 - Auto (default): the system performs the injection and rinses in automatic mode.
 - Manu: the operator performs the injection and rinse in manual mode using the remote injection plunger.
- **Injection gauge (4):**
 - Displays the injection speed, when in automatic mode. If the injection speed is too slow, an error message is displayed. The injection is then stopped automatically. You must check the injection site before resuming the injection in manual or automatic mode.
 - Displays the force applied on the syringe plunger, when in manual mode. If too much force is applied, an error message is displayed. You must check the injection site before resuming the injection in manual mode.
- **Speedcontroller (5):** you can change the speed for a selected injection profile. For example, you can start the injection at the slowest speed for the profile (speed 1 or 2) and then gradually increase it.
-
- g) Planning / schedule environment

The planning environment allows the user to display the planned use of the vial selected at any time during the cycle, provided that a mother solution has been selected.





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Column (1) shows for each one the estimated activity in the vial before injecting the dose to the patient. When sufficient activity remains in the vial, the value is written in black normal font with an icon representing the activity in the vial. When the Posijet® considers that there is not enough activity in the vial, the activity is written in red normal font with a warning vial icon.

Column (2) lists the planned patients, i.e. synchronised with the RIS software or created manually.

Note: If necessary, you can request a synchronisation with the radiopharmaceutical software using the blue button

 (2a). An indicator ( (2b)) gives the state of the connection; click this zone to make a WIFI reconnection attempt in case of WIFI fault.

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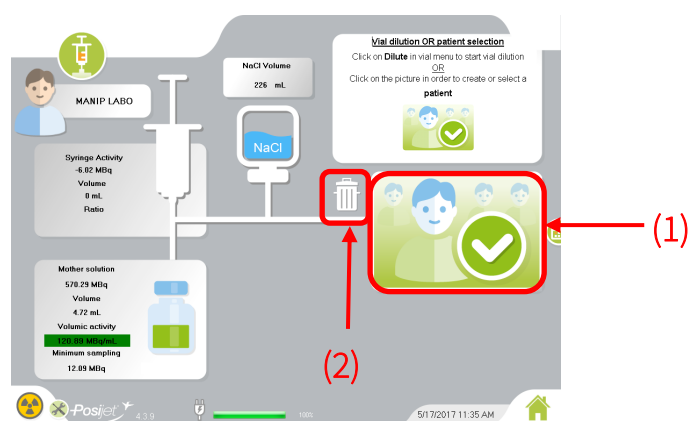
VIII.3.d. Phase 2 – Patient injection phase

Step 10: Confirm the patient record



Characteristics of the mother solution loaded

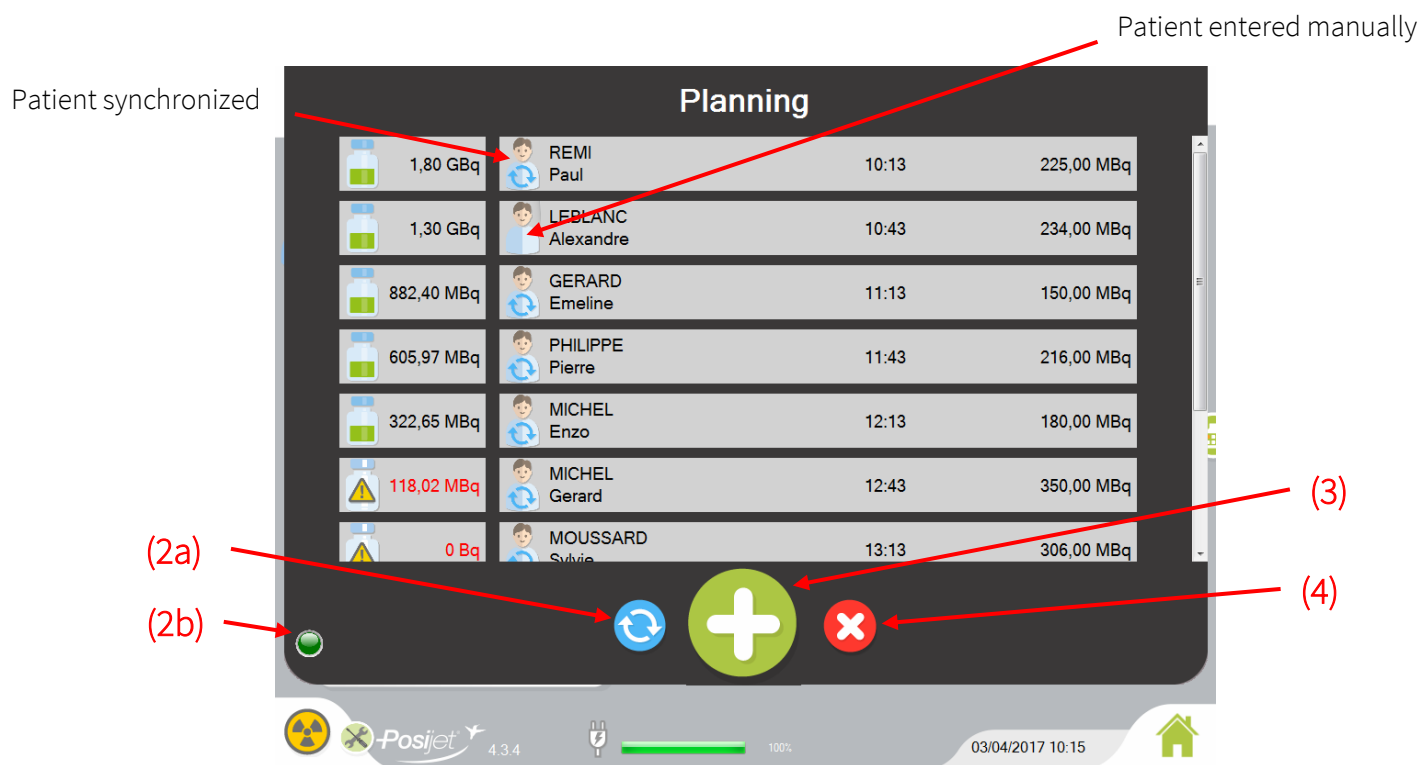
- Click the central icon to enter the injection environment. The mother solution is activated and displayed on the home screen.
- Log in and confirm.



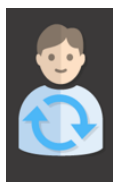
- Click the patient box to select or create a new record (1).

Note: if you have not performed a dilution of the mother solution vial, you must identify and install a new patient kit and then perform a flush (steps 9)a) and 9)b)).

Note: if necessary, you can also delete and replace the patient kit installed (if there is a change after dilution or a fault on the kit for example) by clicking the waste bin icon next to the patient zone (2).



When this screen opens, the application automatically synchronizes the data with the radiopharmaceutical software and retrieves any available information on the patients that have been entered beforehand. The patients imported in this way are indicated with the following icon:



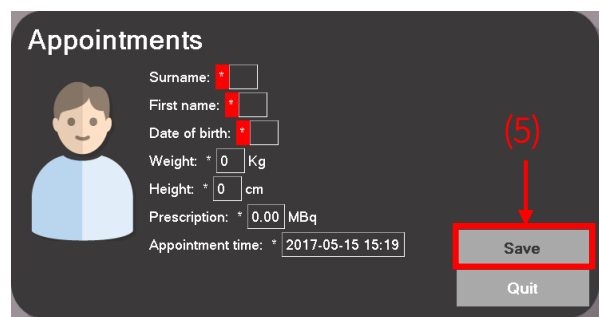
When this window is open, it is possible at any time to select or create a patient to use:

- The software has been synchronized with the radiopharmaceutical software and the available data on the patients have been imported:
 - Select the patient in the Posijet®.
 - Confirm the data recorded.


Note: If necessary, you can request a synchronisation with the radiopharmaceutical software using the blue button (2a). An indicator (2b) gives the state of the connection; click this zone to make a WIFI reconnection attempt in case of WIFI fault.

Note: If the data have been synchronized with the radiopharmaceutical software, you will not be able to edit all the fields.

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b) The patient is not present in the Posijet® software:

- Click the button  (3) to create a patient: a patient identification window opens.
- Enter the patient information (last name, first name, date of birth, weight, height – optional, prescription, appointment time).
- Save the data entered (5): the patient identification window closes and the patient created is added to the list of patients already saved in the program.

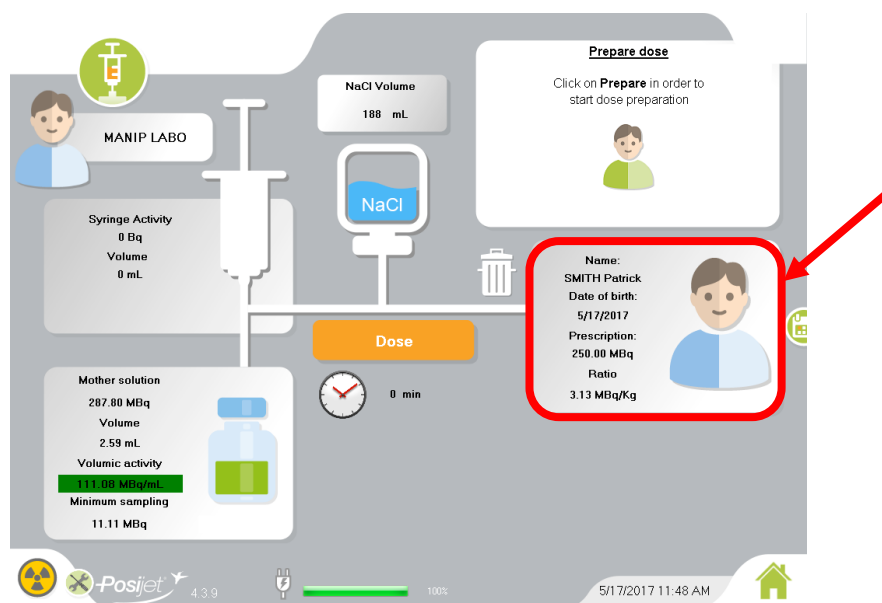


To select a patient:

- Click the desired patient: a patient information window opens. On this window you can edit the information, if the patient was entered manually. Click “Edit” (6), to open the mother solution identification screen, and you can edit the data as described above.
- Click “Sélect” (7).

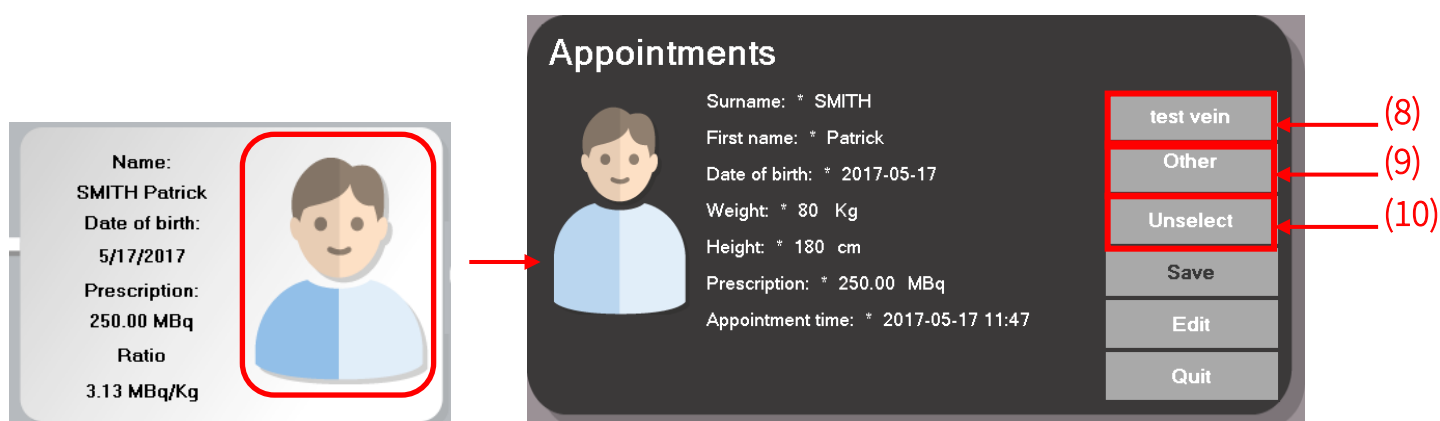
Note: You can configure the application to automatically update the patient prescription based on the patient’s weight (configure the prescription in MBq/kg or MBq/cm²). In this case, the setting is configured using a ratio, and a low and high dose limit.

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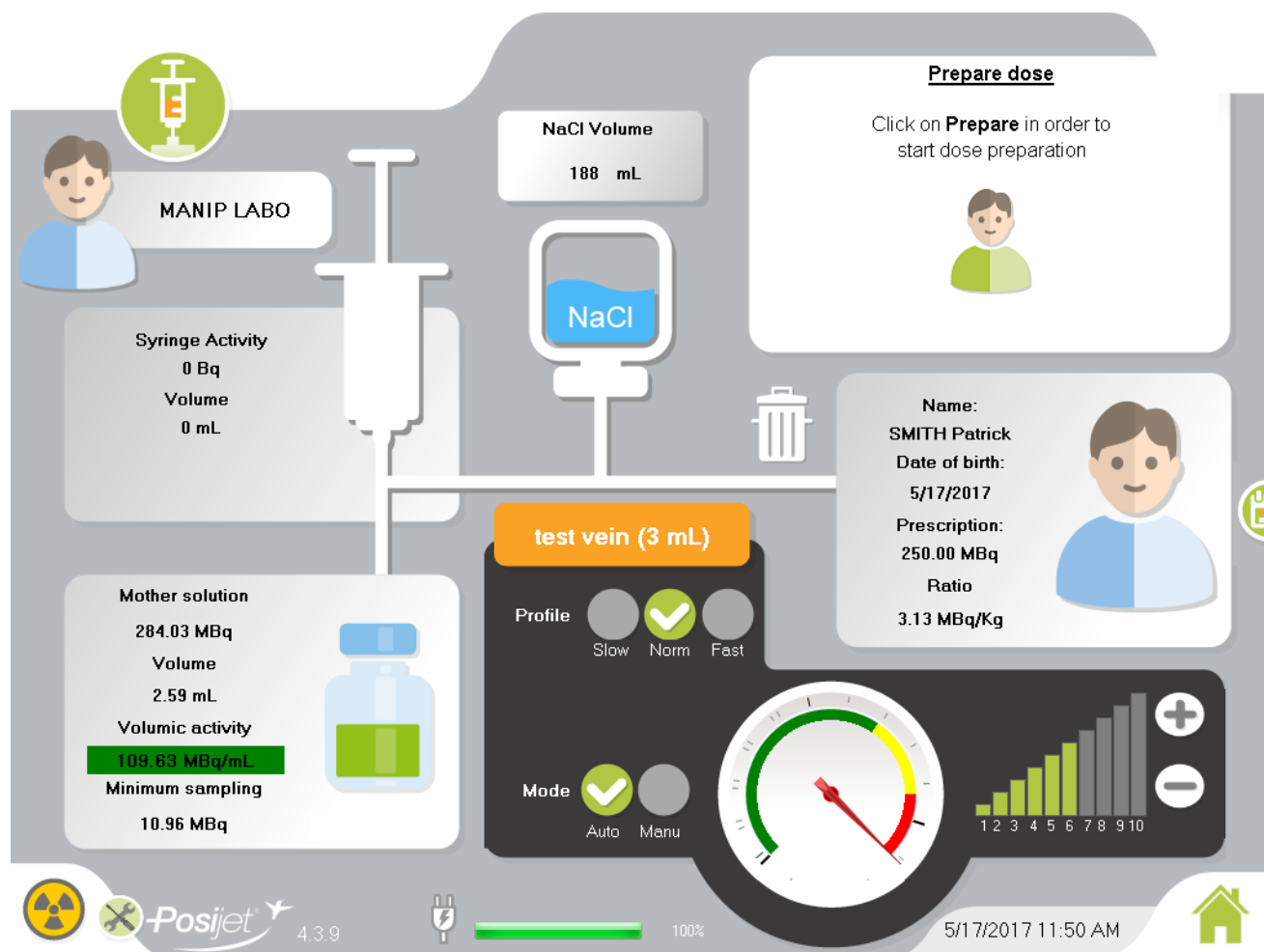
The information appears in the patient box during the cycle.

Once selected, the following operations can be carried out by clicking the patient:



Click the button (8) "Test Vein" to test the patient's vein.

To do this, the Posijet® proposes the following interface:



By choosing the injection profile associated with the type of catheter used on the patient and the injection mode, the Posijet® will inject 3 mL (configurable value) of NaCl in the patient's injection site.

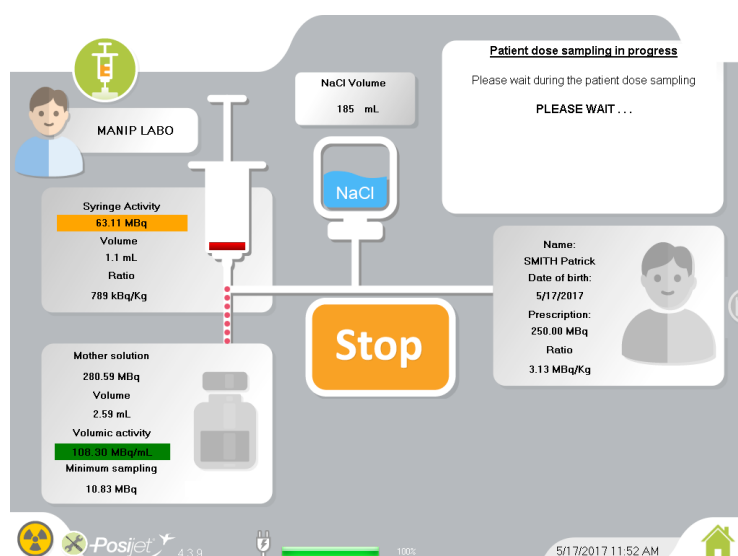
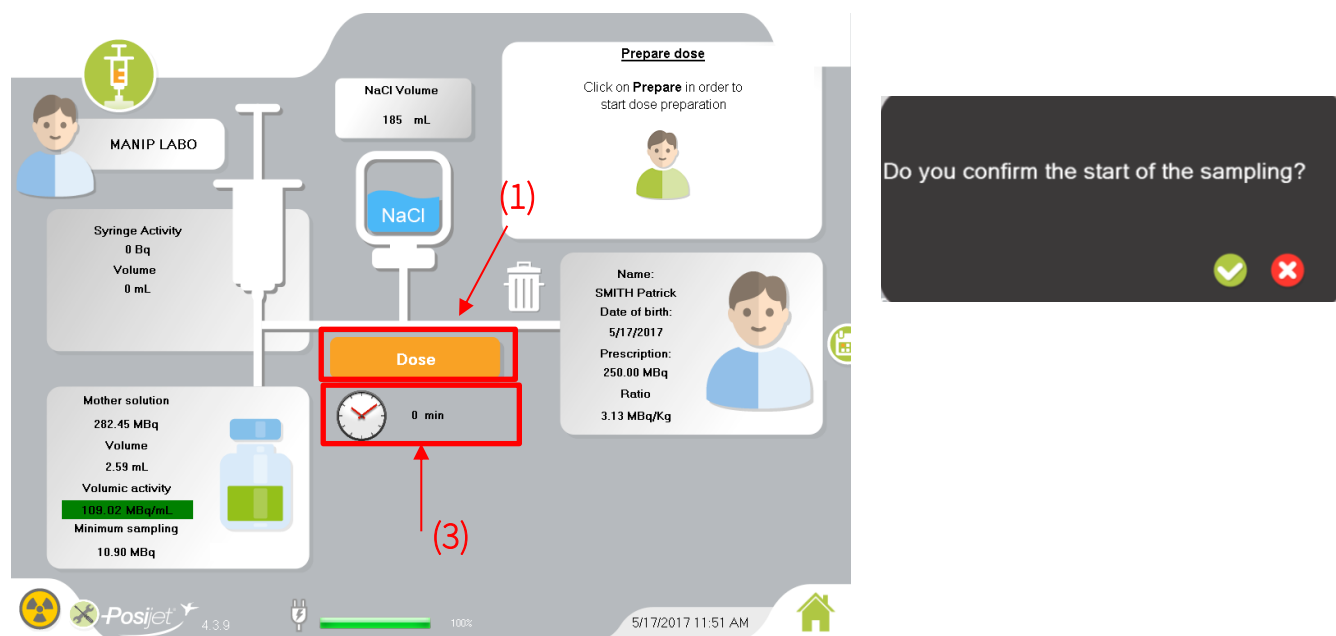
During the injection, the Posijet® activates all the safety mechanisms related to the injection. If a problem is detected, the user will be informed.

Note: For further details on the injection profiles, see step 12.

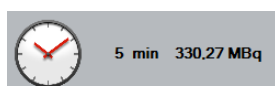
Click button (9) "Other" to select another patient in the list of patients.

Click button (10) "Unselect" to deselect the current patient.

Step 11: Prepare the patient dose

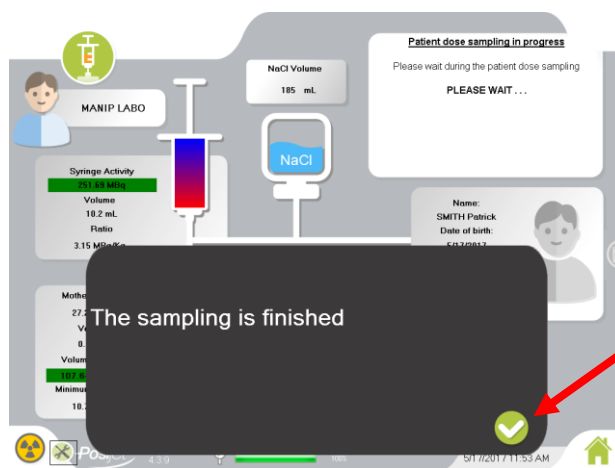


- To start the preparation, click “Doser” (Prepare) (1), then confirm: the dose is prepared automatically to the requested activity. The logic controller automatically completes to 10 mL with saline solution.
- Until the solution is diluted, you can click “Stopper” (2) (Stop) to stop the preparation. The product is pushed into the vial.
- Click the clock button to prepare a dose maximum 10 minutes in advance (parameter). Example:



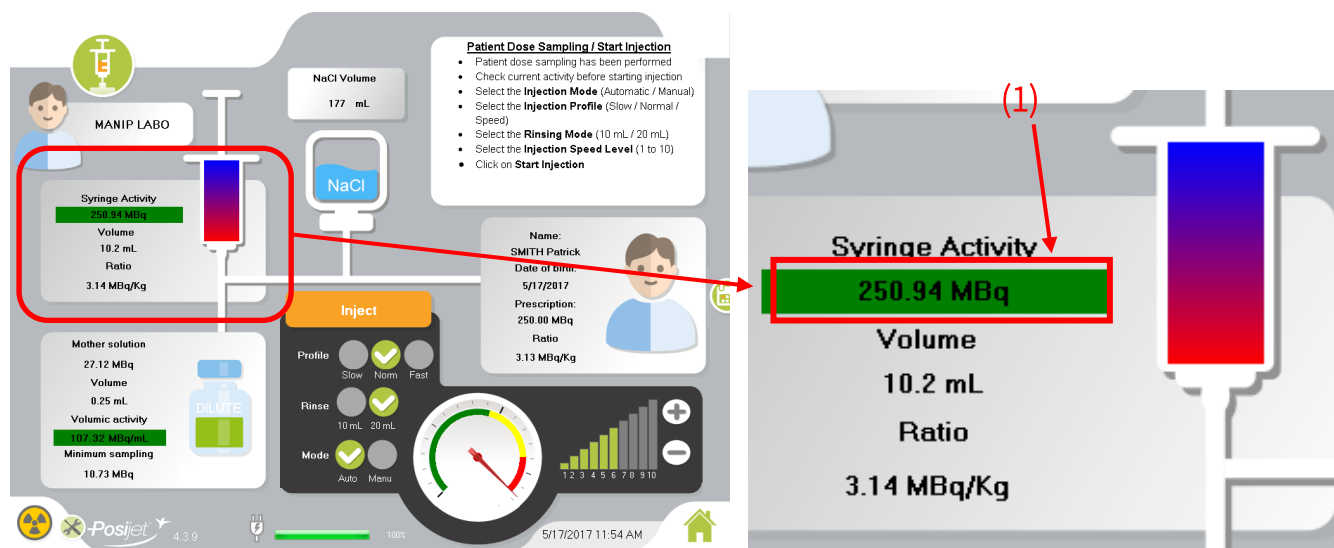
Note: Before preparing the dose, the application checks that there is sufficient activity in the vial and that the volumic activity is not too high.

- When the dose preparation is finished, the system displays an information message. Confirm to move on to the patient injection step.



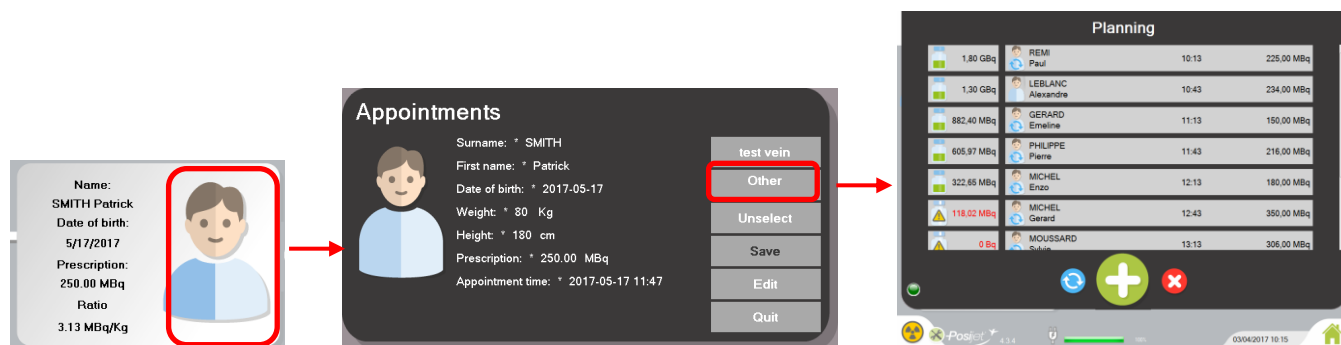
Note: A colour code (1) is assigned to the activity measured in the syringe:

- Orange: the measured activity is less than 90 % of the prescribed activity.
- Red: the measured activity is greater than 110% of the prescribed activity.
- Green: the measured activity is between 90% and 110% of the prescribed activity.



When the measured activity is greater than 110% of the prescribed activity or greater than the maximum limit, you can override and proceed with the injection by entering an administrator password.

Note: When the dose is ready, it can be reassigned to another patient by clicking the Patient icon. The colour code will change automatically according to the prescription of the new patient.



Step 12: Inject the dose into the patient



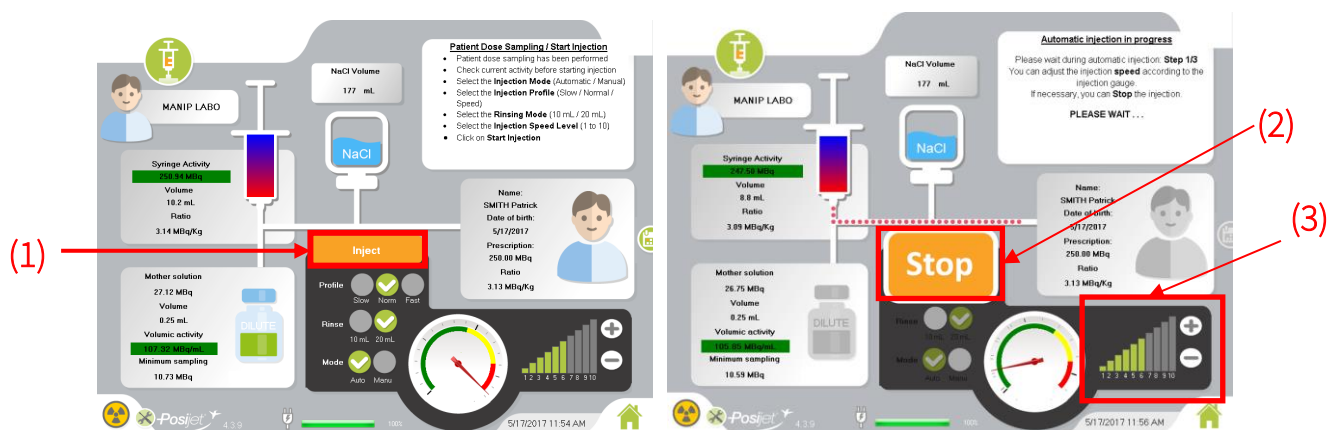
When the patient's dose is ready, the above screen appears.

- Prior to injecting, select:
 - o **The profile:** determines the speed of injection to select based on the injection site (arm, hand, foot ...) and the catheter used:
 - Slow Profile: 25 mL/min (example: yellow catheter) – Approximate injection duration: 24 seconds.
 - Normal profile (default): 33.3 mL/min (example: blue catheter) – Approximate injection duration: 18 seconds.
 - Fast profile: 50 mL/min (example: pink catheter) – Approximate injection duration: 12 seconds.
 - o **Rinse:**
 - ?mL: the user has the choice between 30mL (3 rinses of 10mL) and 10mL (1 rinsing of 10mL). For 10mL rinsing, the system performs a single rinse of 10mL (to be selected only for the reduction of the volume to be injected, in pediatric for example).

Note: Pay attention to the length of the connector used due to the risk of incomplete injection to the patient and therefore non-negligible residual activity in the tubing.

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- 20 mL (default): the system performs two successive 10 mL rinses.
- Mode:
 - Auto (default): the system performs the injection and rinses in automatic mode.
 - Manu: the operator performs the injection and rinse in manual mode using the remote injection plunger.

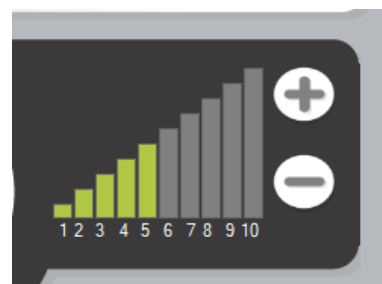


- Connect the patient to the Posijet® using the disposable patient kit (POSIKIT 2).
- 2.7 - Click “Inject” (1) to start the injection. During injection, you can suspend the cycle by clicking the “Stop” button (2) or change the speed with the speed controller (3).
- At the end of injection, the Posijet® performs 1 or 2 successive rinses (depending on the rinse volume configured). **Injekcijos metu galite sustabdyti ciklą paspausdami „Stop“ mygtuką (2) arba pakeiskite greitį greičio reguliatoriumi (3).**

Note: An injection gauge:

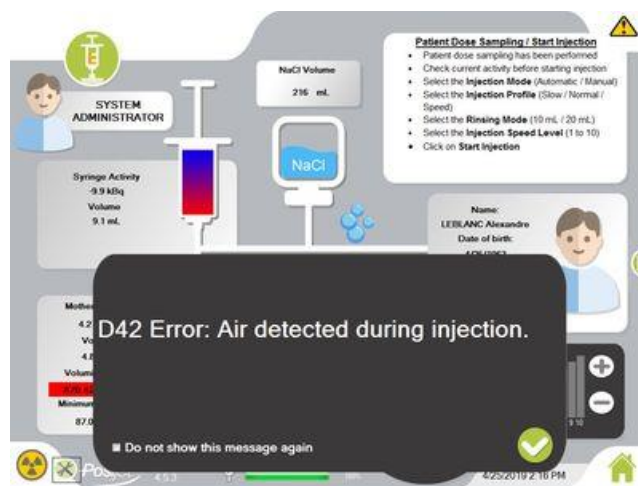
- Displays the injection speed, when in automatic mode. If the injection speed is too slow compared to the profile selected, an error message is displayed. The injection is then stopped automatically. You must check the injection site and all patient tubing, before resuming the injection in manual or automatic mode.
- Displays the force applied on the syringe plunger, when in manual mode. If too much force is applied, an error message is displayed. You must check the injection site and all patient tubing before resuming the injection in manual mode.

Note: Once the cycle is initiated with a certain profile, you cannot modify either the profile or the type of rinse. However, you can modify the injection speed within a profile via the speed controller. For example, you can start the injection at the slowest speed for the profile (speed 1 or 2) and then gradually increase it.

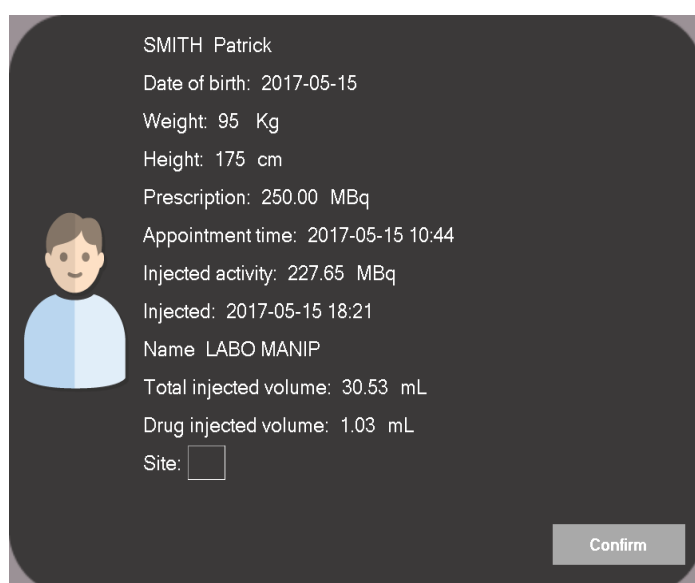
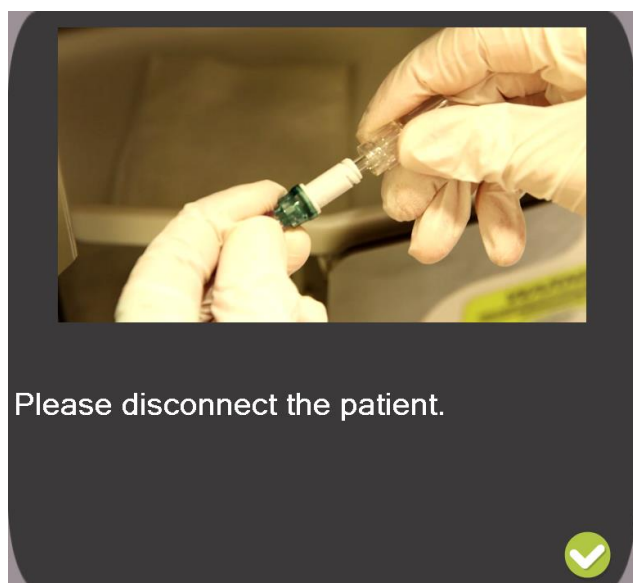


Note: During the injection, if an air bubble is detected, the air bubble indicator is displayed and an alert message appears on the screen. The operator must verify that the NaCl bag is not empty and is well connected and that the

tubing is well positioned in the air bubble sensor



- Disconnect the patient , at the end of the injection, a report is displayed and a label is printed automatically (configurable).



Note: You can define the injection site where the patient was injected.

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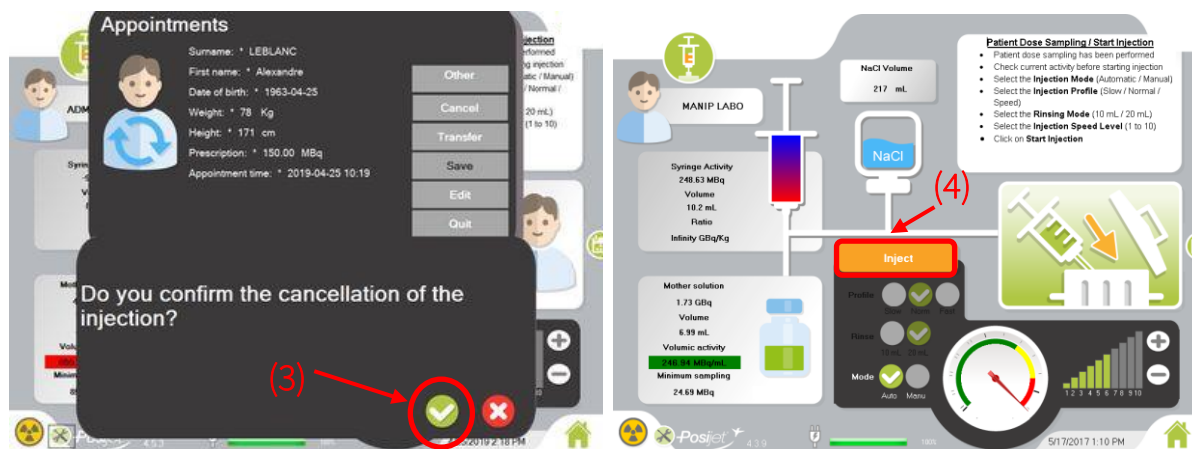


Note: If you are unable to inject the prepared dose into the patient, you can discard the prepared patient dose in a 20 mL flush syringe placed in a syringe shield supplied by Lemer Pax.



- Click the patient zone (1). A patient information window opens.
- Click on “Cancel” button (2), then confirm the confirmation message (3)
- Click on “Inject” (4), the Posijet® then injects the prepared dose followed by a 10mL rinse into the syringe shield.

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At the end of the injection / rinse cycle, a report is displayed. This report can be printed, as well as a patient injection label (with the name “Flush syringe” (Syringe Flush)).



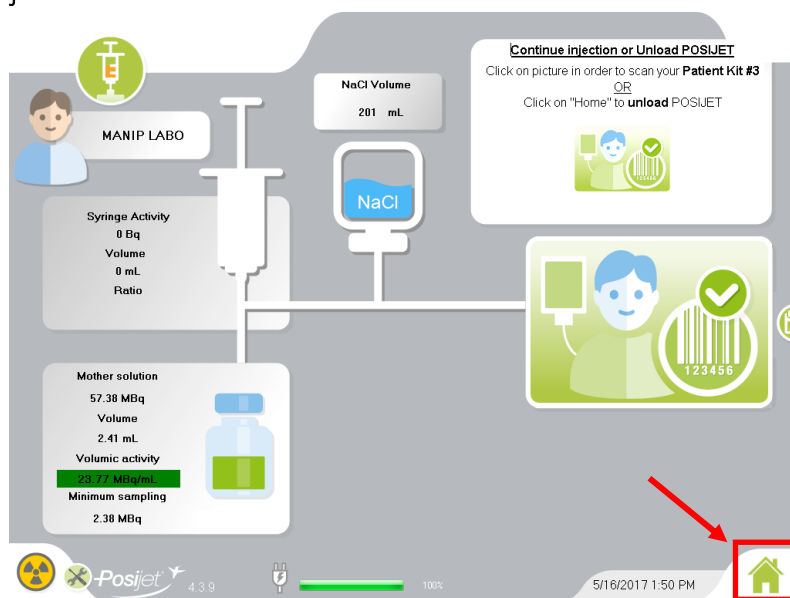
At this point, two options are available:

- Inject a new patient: In this case you must change the patient kit (go back to steps 9)a) and 9)b) and then go directly to step 10 and repeat the entire dose preparation / injection protocol).
- Unload the Posijet® (go to step 13): in this case, if possible, at the end of the day, we recommend allowing the residual activity in the mother solution vial to decrease overnight and unloading Posijet® the next morning, when it is time to load a new mother solution vial.

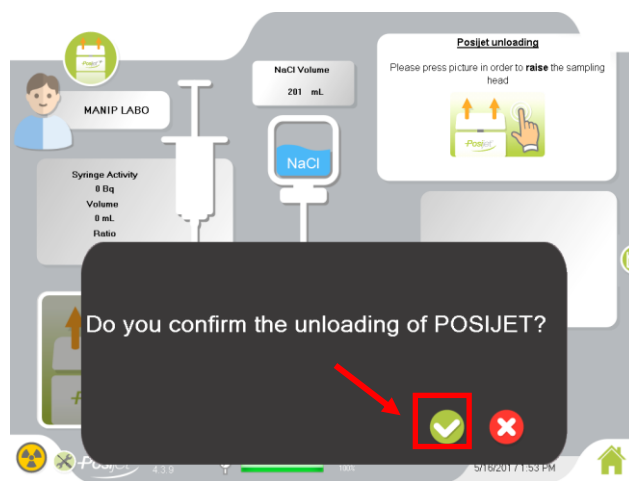
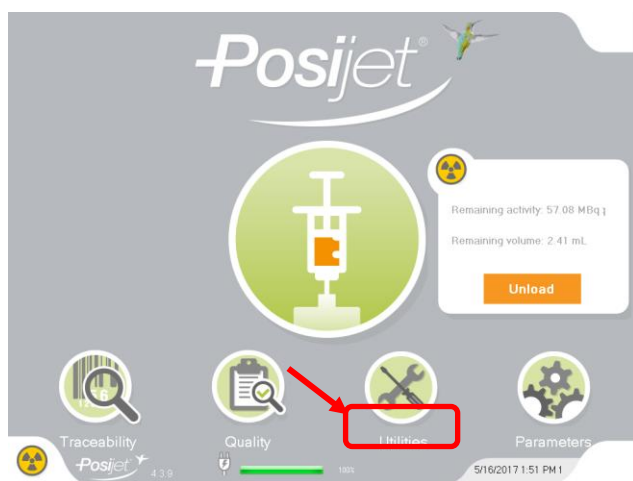
Posijet® V3

VIII.3.e. Phase 3 – Posijet® unloading phase

Step 13: Unload the Posijet®



- Click “Home” to return to the home screen.

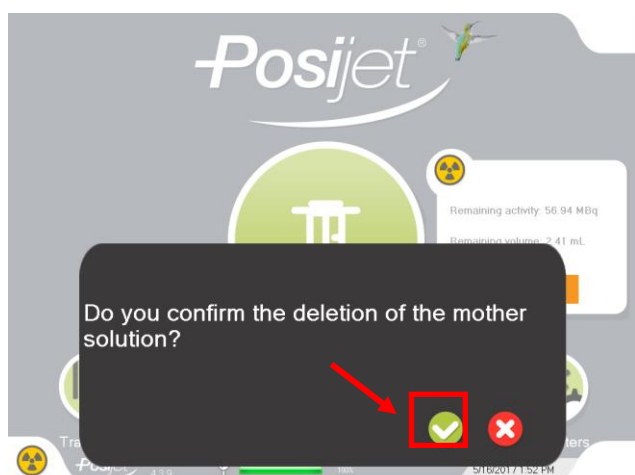
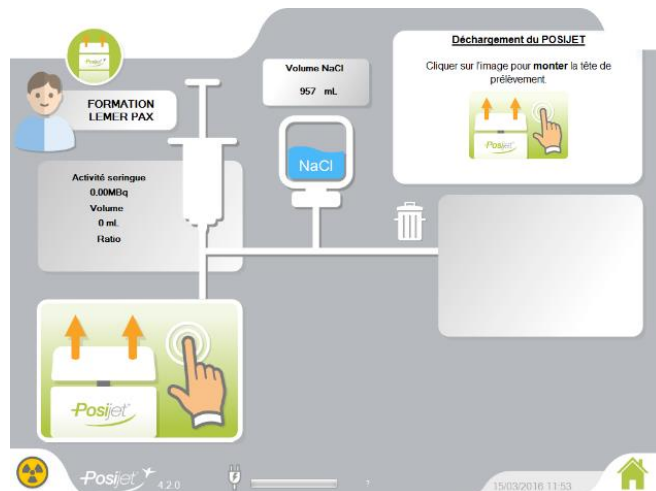


- Click the “Unload” icon.
- Confirm the deletion of the mother solution.

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- Log in and confirm.
- Click the Unload icon.



- Confirm unloading.



The system asks if you want to perform an automatic kit rinse. If you click OK, the system draws up 1 mL of NaCl and pushes it into the mother solution vial before automatically raising the head and unlocking the door. If you click NO, the system raises the head and unlocks the door straight away. The automatic rinse of the mother solution kit pushes the residual activity in the kit into the vial.

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After the automatic rinse of the mother solution kit, the Posijet® automatically raises the head and unlocks the door.

Step 14: Deinstall the kits and the mother solution vial

Once the head is raised and the door is unlocked:

- Unload the mother solution kit from the Posijet® (remove the syringe and needles in the sampling head, the 3-way valve and the venting kit from the vial kit holder).
- Also remove the tungsten vial shield containing the mother solution vial (remove the guide cone, put on the cap, then lift out the vial shield).
- Discard the items in a suitable waste bin, taking all necessary precautions.
- Remove the NaCl bag.
- Decontaminate the two cone guides (top and bottom).

Warning: there may be some non-negligible activity in the vial. It is absolutely imperative to take all necessary radiation protection precautions when handling this item.

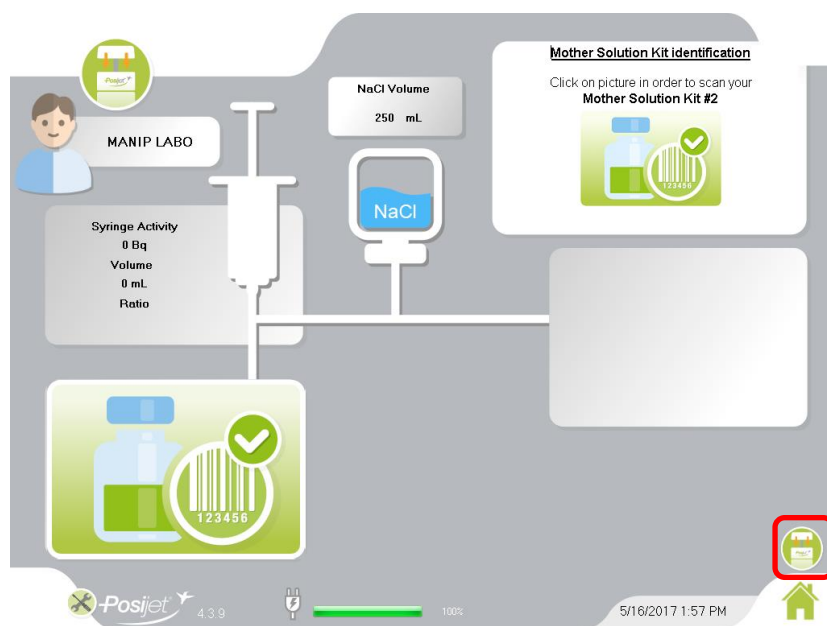
At this point, you can turn off the Posijet® or load a new vial.

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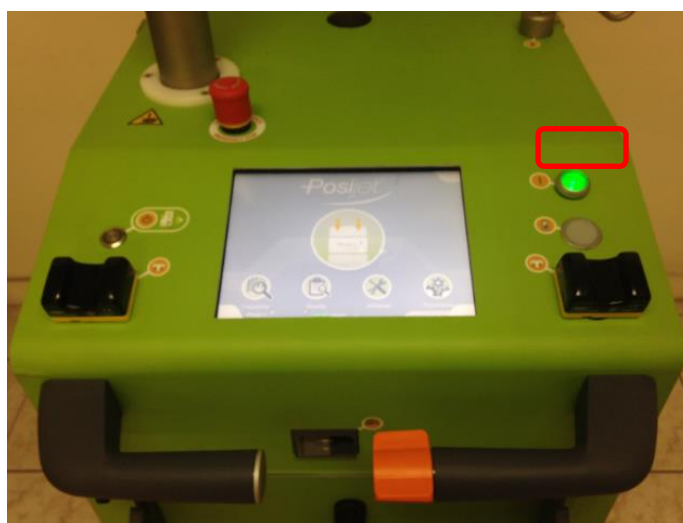
Step 15: Switch to standby mode

Once the head is raised and the door closed, the Posijet® can be set to standby mode. This mode allows you to close the access to the dose calibrator.

To switch to standby mode, simply open the cycle page and click the corresponding button:



Step 16: Power off the Posijet®

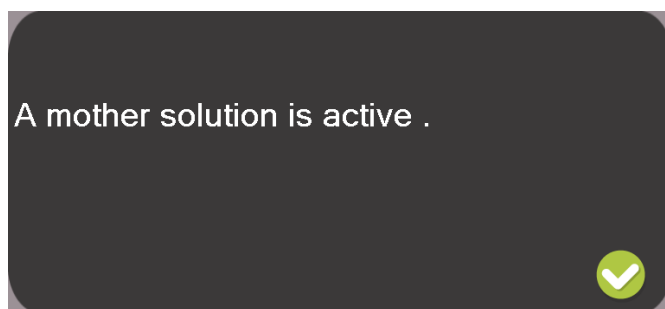


- Press the green power on/off button. The light will flash. There is a 90 second delay before the system powers off.
- Connect the Posijet® to an electrical outlet to recharge the battery.

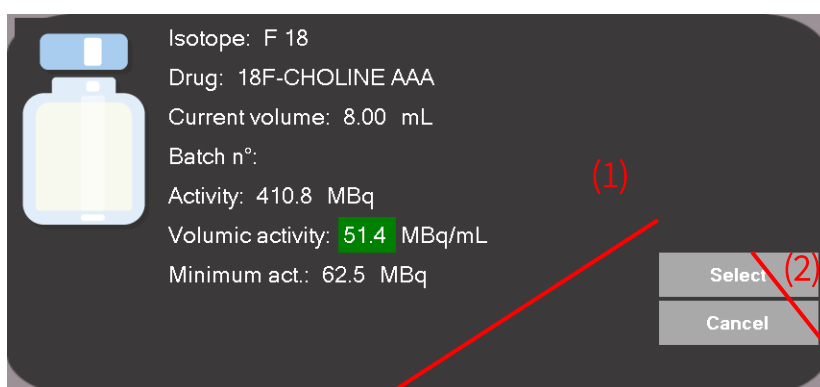
LEMER PAX <small>PROTECTING LIFE</small>	Instructions manual	English version V16-1 June 2024
Posijet® V3		

VIII.3.f. Phase 4 – Restarting with a mother solution loaded

- A message is displayed, indicating that a mother solution is present (no unloading).



- Details of the mother solution are displayed.
- You can continue (Select) (1) or start “empty” (Cancel) (2).



Reuse mother solution information saved



Start empty



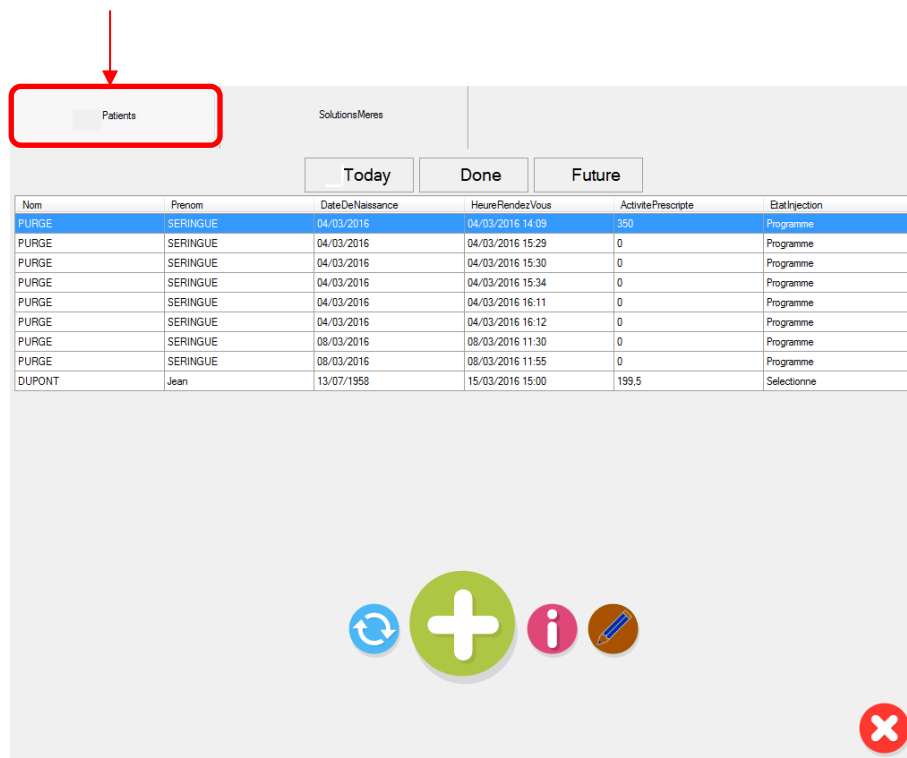
VIII.4. Presentation of the traceability tools

From the “Traçabilité” (Traceability) tab of the home screen, you can check a number of items.



- Click the “Traceability” icon (1).
- Log in and confirm: the following window opens with two menus: a mother solution menu and a patient menu.

Patient menu:






From this window, you can view:


- Default : the list of all patients saved in the Posijet® software (already injected or not).
- “Today”: the list of patients for the current day (already injected or not).

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- “Done”: the list of patients synchronized or entered in the Posijet® software who have already been injected (since the first time the Posijet® was used).
- “Future”: the list of patients synchronized or entered in the Posijet® software who have not yet been injected.

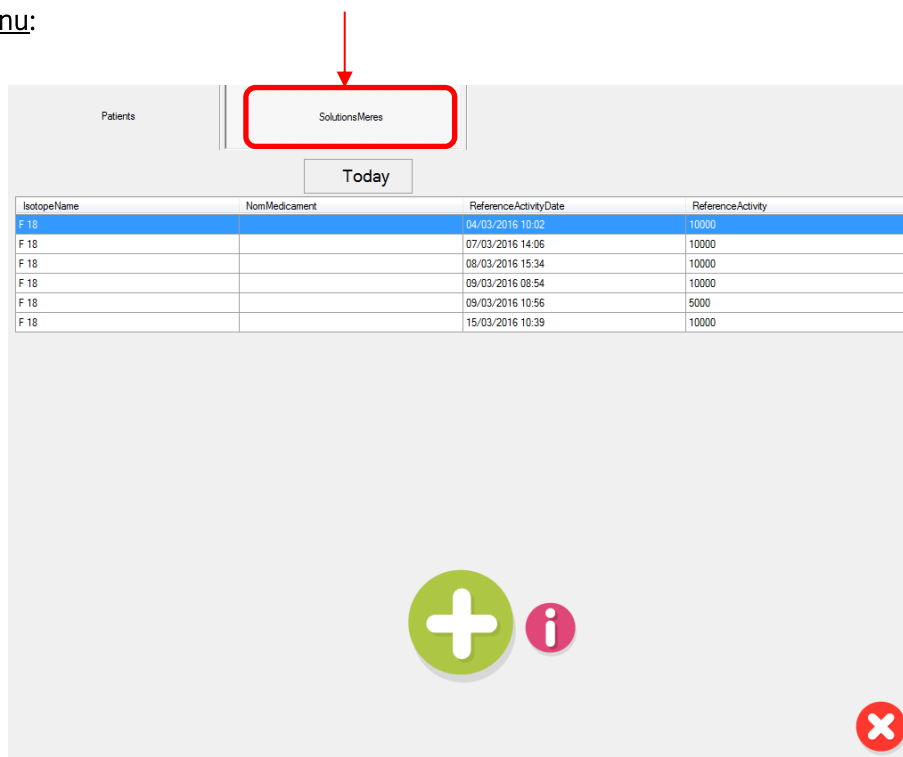
You can create a new patient record by clicking the button . A patient identification window opens. Enter the patient information and save the entered data: the patient identification window closes and the patient created is added to the list of patients already saved in the Posijet® program (see step 10).

When a patient has been entered manually in the Posijet® software and has not yet been injected (listed in the “Future” section), you can modify the information by clicking the button . To edit the information of a patient synchronized from the radiopharmaceutical software you need to edit the patient record in the radiopharmaceutical software and then re-synchronize by clicking the button .

Click the button  to view all the available data on a selected patient. If the patient has not yet been injected, you can also edit the patient information from this screen.

If the patient has already been injected, it will be possible to reprint injection report labels.


Mother solution menu:




From this window, you can view:

- By default : the list of all mother solutions saved in the Posijet® software.
- “Today”: the list of mother solutions for the current day.

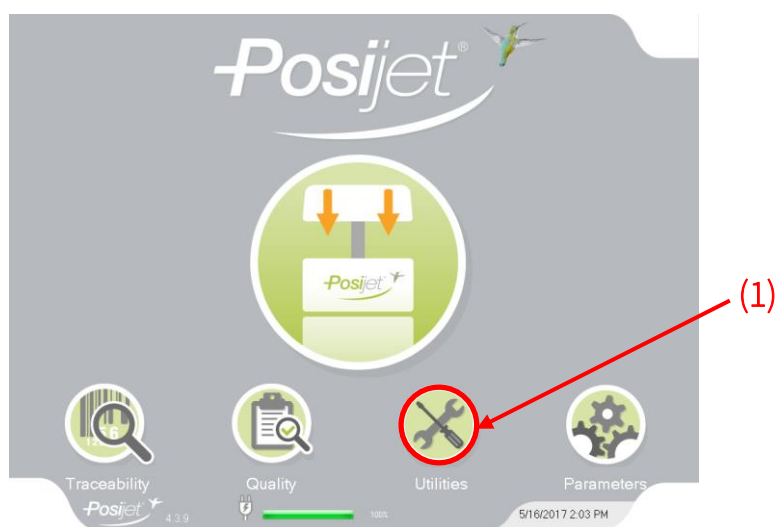
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You can create a new mother solution record by clicking the button . A mother solution identification window opens. Enter the mother solution information and save the entered data: the mother solution identification window closes and the mother solution created is added to the list of mother solutions already saved in the Posijet® program (see step 7).

Click the button  to view all the available data on a selected mother solution. You can also edit the mother solution information from this window.

VIII.5. Presentation of the Utilities

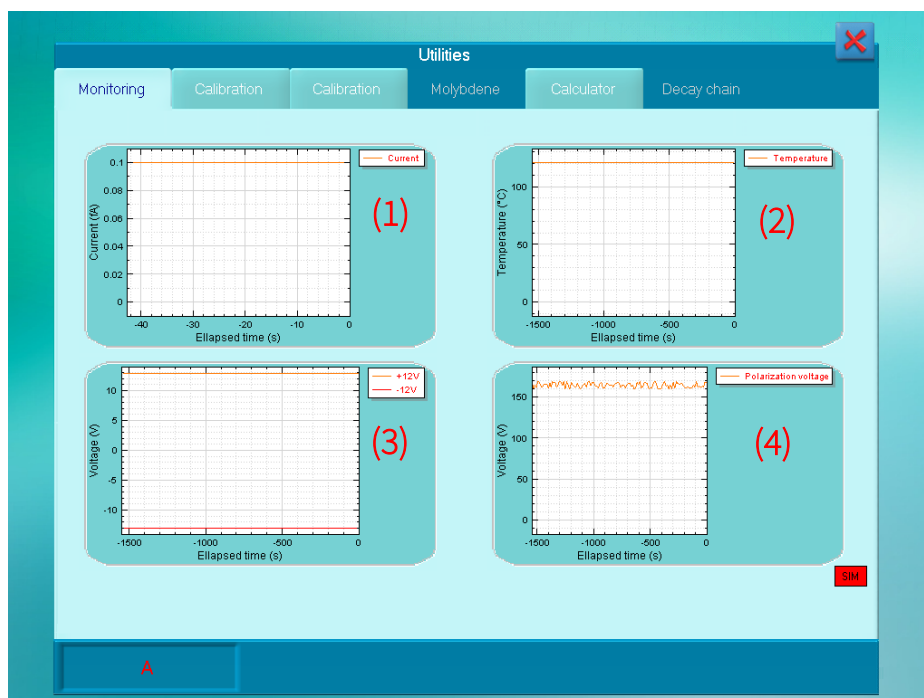
The “Utilities” menu provides access to calibration, monitoring and logic controller (PLC) tools.



- From the Home screen, click the “Utilities” button (1).
- Log in and confirm.

“Monitoring” tab

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This tab presents graphics allowing you to check that the ionization chamber is operating correctly (for each measurement system).

It is possible to monitor the following over a period of time:

- (1) Any changes in the ionization current (upper left);
- (2) The temperature of the electronics (upper right);
- (3) The +/- 12 V of the electronics (the curves at the bottom left should be stable)
- (4) The polarization voltage (the voltage on the lower right should be 160 +/- 16 V);

“Calibration” tab

For more information on calibration, please refer to the manual of the activimeter.

REMINDER :

By default, the Posijet is configured to inject FDG (F18) fluorinated radiopharmaceuticals. To inject other radiopharmaceuticals, check the dose calibrator configuration.

POSIJET : AMMONIA VARIANT

For the use of the Posijet with radioisotopes with a relatively short half-life (for example N13 with a half-life of 10 min), LEMER PAX has developed a dedicated software version, in order to optimize the accuracy of the measurement and to match the constraints imposed by the half-life of the radio-element in question. In this case, LEMER PAX prohibits the concomitant use of the Posijet for radioisotopes with longer half-lives such as F18 (half-life: 108 min)

The Posijet is configured to measure a single package: a 10 ml syringe containing 10 ml. Calibrations should therefore

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be carried out with a 10 ml syringe (that of the Posikit 1B) containing 10 ml of solution.

1. Preparation of the dose.

To perform a calibration you will need a 10 mL syringe containing 10 mL of the radioisotope you wish to calibrate. We recommend that you prepare a dose of approximately 200 to 300 MBq by withdrawing the activity from a 10 mL syringe (from the syringe of a Posikit 1B) and make up to 10 mL with saline. Use a small needle with a cap or stopper. The dose value of this syringe must be measured accurately: dose, date, time in another already calibrated dose calibrator, called reference dose calibrator.

CAUTION :

- For correct calibration accuracy, it is necessary that the time is synchronised on the reference dose calibrator and on the Posijet. Alternatively, the time of the Posijet can be chosen as the reference time.
- Since the Posijet only displays minutes, it is necessary to perform the measurement at minute changes to be sure to reduce the time error to a few seconds.

Before performing a calibration, you must have previously :

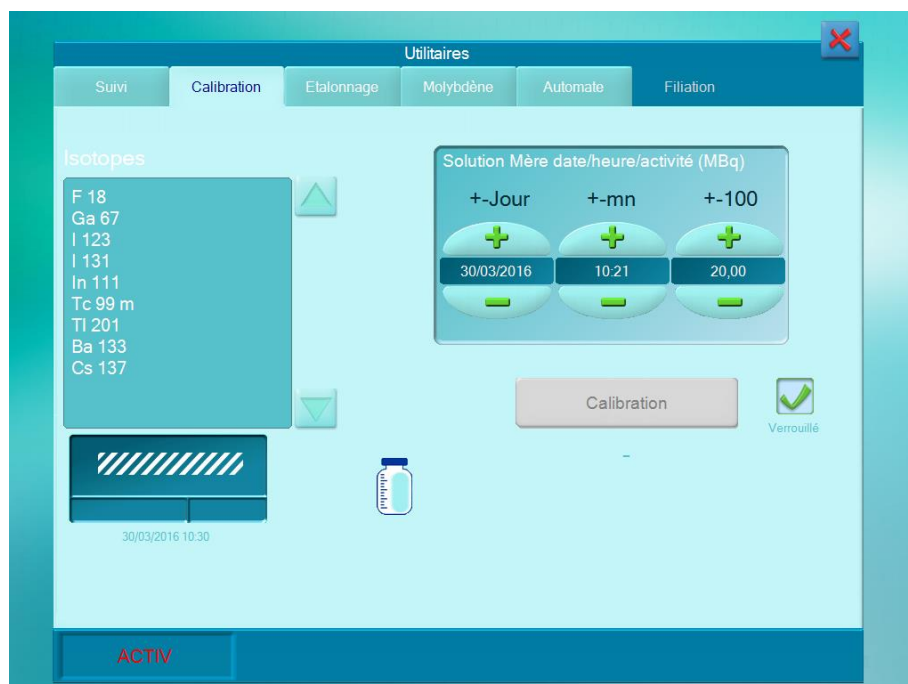
- Checked the zero point of the instrument.

Position the source (10 mL syringe measured above) in the Posijet syringe holder and insert it into the well of the Posijet ionisation chamber using the calibration holder (ref: 00024660)



2. Calibration

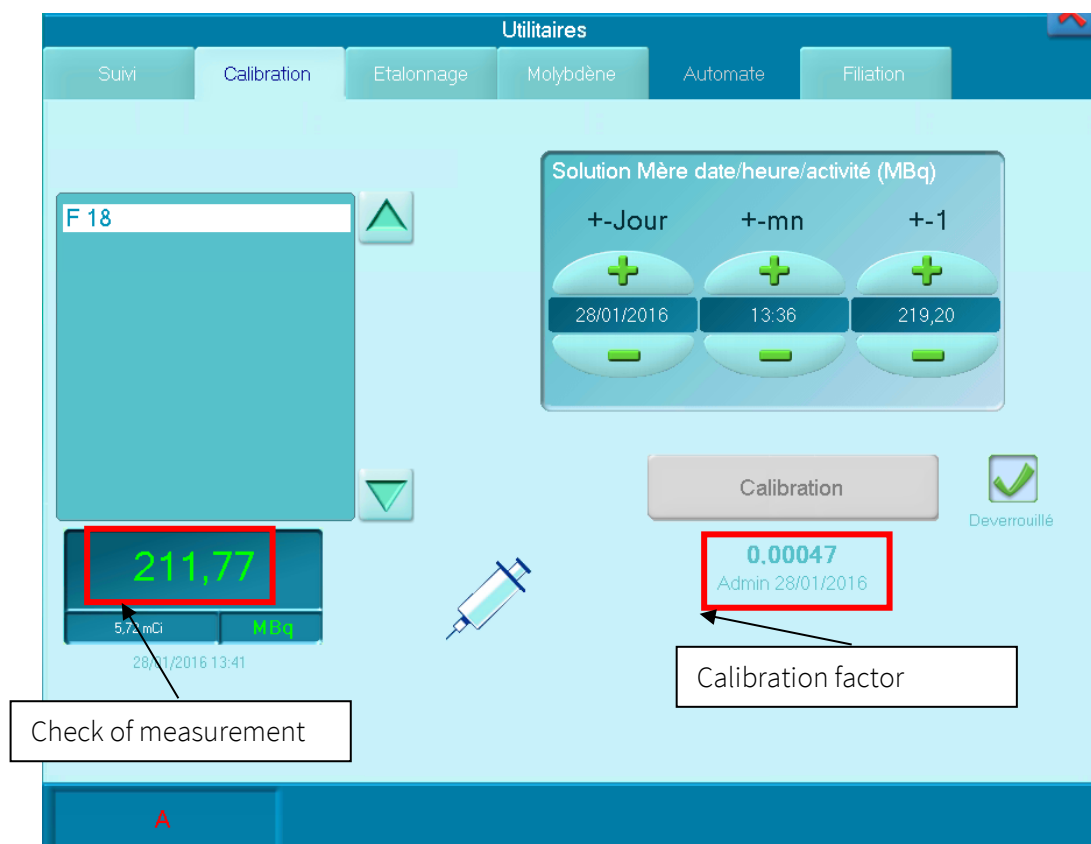
- - Open the "Utilities" menu,
- - Select the "Calibration" tab,
- Select the isotope in the list on the left*, Select the syringe packaging by clicking on the corresponding icon*.
- Indicate the date, time and activity in MBq of the prepared syringe as read in the reference activimeter (Posijet time),



**When the measurement window displays nothing, it means that the selected isotope in the selected conditioning has not been calibrated. On the contrary, if the measurement window is active, it means that it has been calibrated and the information of this calibration is displayed under the Calibration button.*

- Click on "Unlocked" to allow calibration and enter your password,
- Wait until the measurement is stable,
- Click on the "Calibration" button to determine and save the calibration factor automatically. The measurement window is activated and the calibration information is displayed under the "Calibration" button

Posijet® V3



3. Check of the calibration

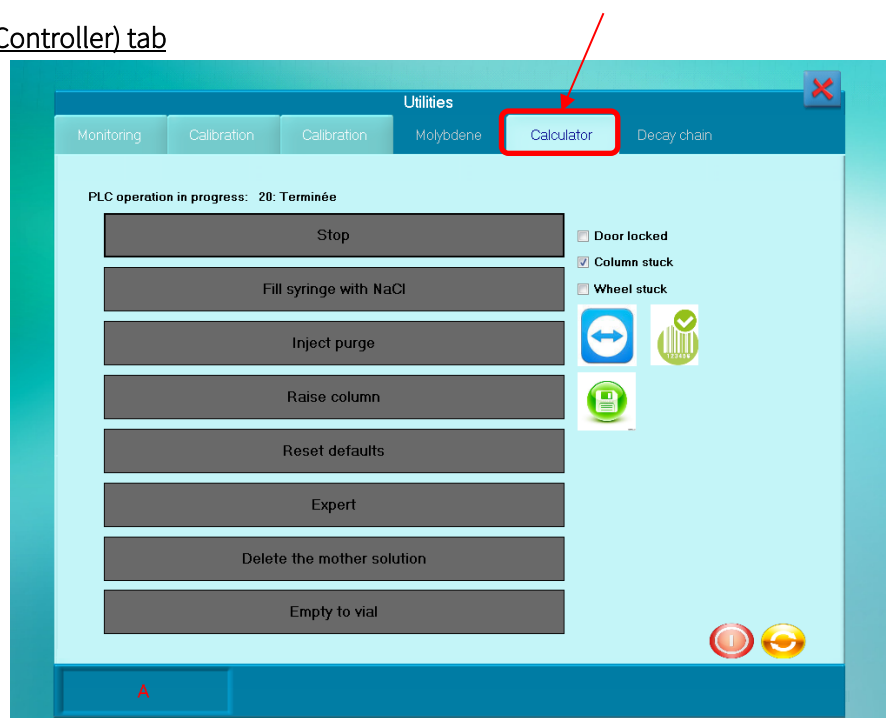
- 3.1. The syringe dose value is measured by the Posijet dose calibrator and displayed in the calibration tab (see above). Note this value and check that it does not differ by more than 5% from the decay-corrected value measured on the reference dose calibrator. Remove the syringe and reposition it in the well to check the measurement again. This is to ensure that the syringe was in the correct position during calibration. If a difference is noted, repeat the calibration and recheck using the same method.
- 3.2. Calibration verification can also be done by measuring a long life source on the channel of the radionuclide you have just calibrated. To do this, measure a long life source on the channel of the calibrated radionuclide in the reference dose calibrator and record the value. Then measure the same source on the Posijet dose calibrator on the channel of the same radionuclide. Introduce the source into the Posijet using the calibration dipper. Read the value on the calibration tab that has been left open. The values between the two instruments must not vary by more than 5%.
- 3.3. A check can also be made by preparing a syringe with the Posijet and injecting it into a vial or syringe.

CAUTION: Not only the syringe but also the rinse volumes must be injected. It is therefore necessary to provide a container sufficient to contain 30 mL. Several containers can be chosen but it will then be necessary to correct the measurements according to the decrease and the precision of the measurement will be less.

Posijet® V3

- Connect the Posikit 2 (patient kit) to a syringe or vial. A lead shield should be provided to reduce radiation to the handler.
- Use the Posijet to prepare a syringe in the usual way.
- Record the value measured by the Posijet and the time of the measurement.
- Use the usual Posijet functions to inject into the syringe or vial.
- Depending on the volume of the container, change the container if necessary before rinsing. Two rinses are required to remove the entire dose from the containers.
- Measure the entire dose in the reference dose calibrator : injection + 2 rinses. If you have several containers and you have to make several measurements, do not forget to correct the decay to have a value of injected dose at the same time.
- Compare this injected dose value with the dose value corrected for decay measured on the Posijet. The values should not differ by more than 5%.

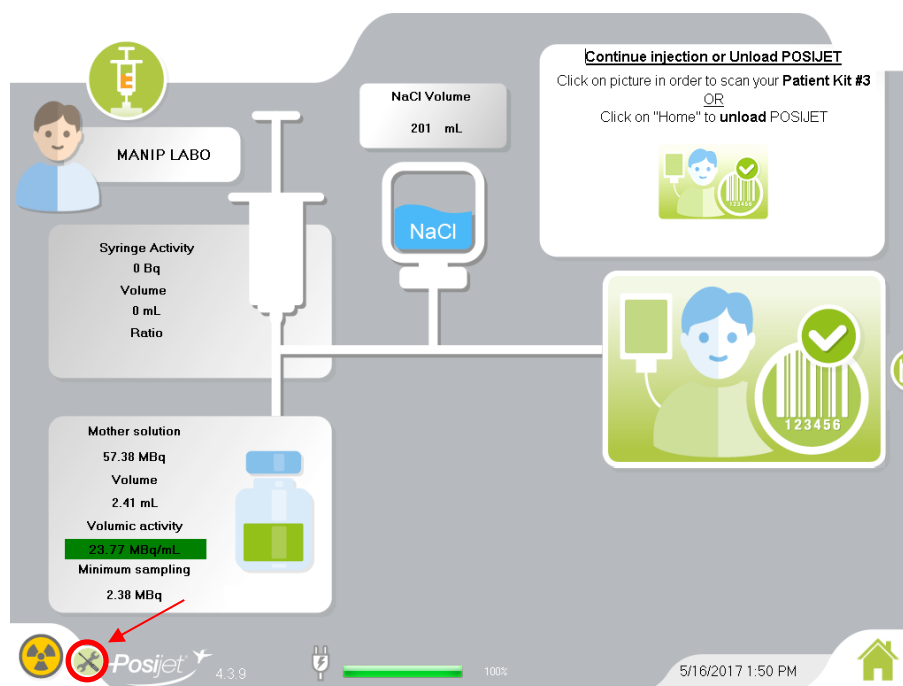
“Calculator” (Logic Controller) tab



The “Calculator” tab allows the operator to check the sensors and control the electrical components. In this way a diagnosis can be carried out in the event of a breakdown.

Note: At any time during the dose preparation / injection cycle, you can display this page to unblock a situation in degraded mode.

Posijet® V3



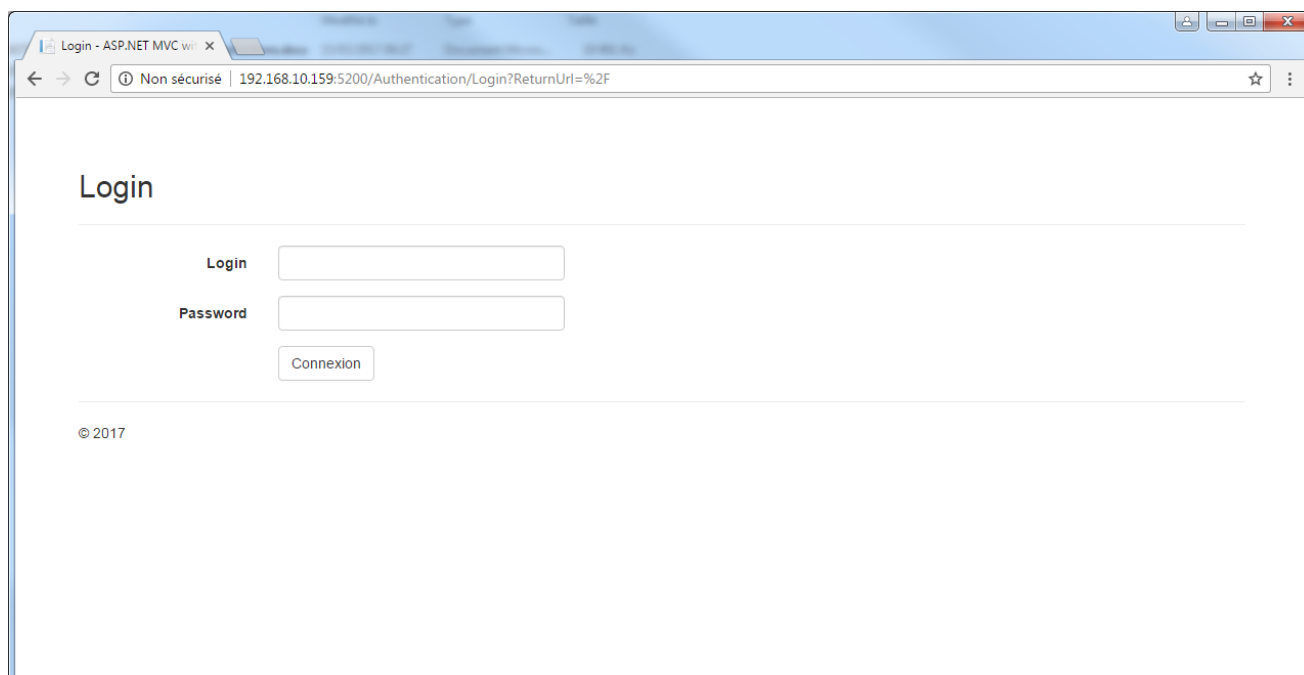
- Click the “Utilities” button on the bottom left of the screen.
- Log in and confirm: the logic controller management window opens.

VIII.6. Presentation of the Administration Website

All data saved via the Posijet® software (users, isotopes, test results, etc.) are stored in a database. The database is accessible via Internet Explorer at the address supplied when the equipment was installed (<http://localhost:5000/default> by default). It can be viewed from any computer connected to the hospital computer network (provided the Posijet® is also connected to the network and powered on).

Note: You do not need to have an internet connection to access this information.

Note: The best configuration to navigate on the site is to use Google Chrome.



- From Google Chrome, enter the address: <http://localhost:5000/default> (by default)
- Access to the administration website is protected: enter your username and password and click the button

Connexion

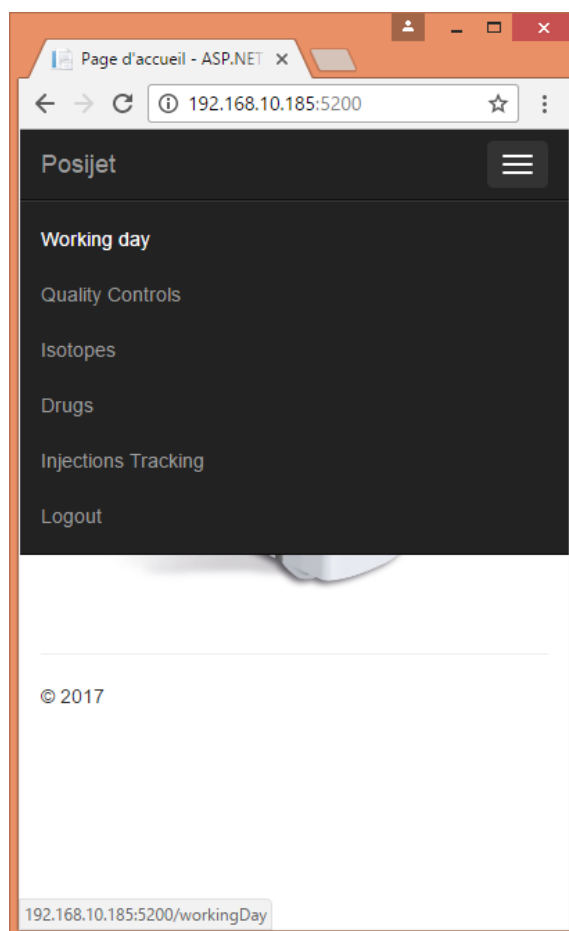
Note: Each user logs in with his username and password. The usernames and passwords are the same as those recorded in the Posijet®.

The various data are accessible according to the user rights of the person logged in.

VIII.6.a. Home page and menus

Posijet® V3

Home Working day Quality Controls Isotopes Drugs Injections Tracking Cav Tracking User Logout

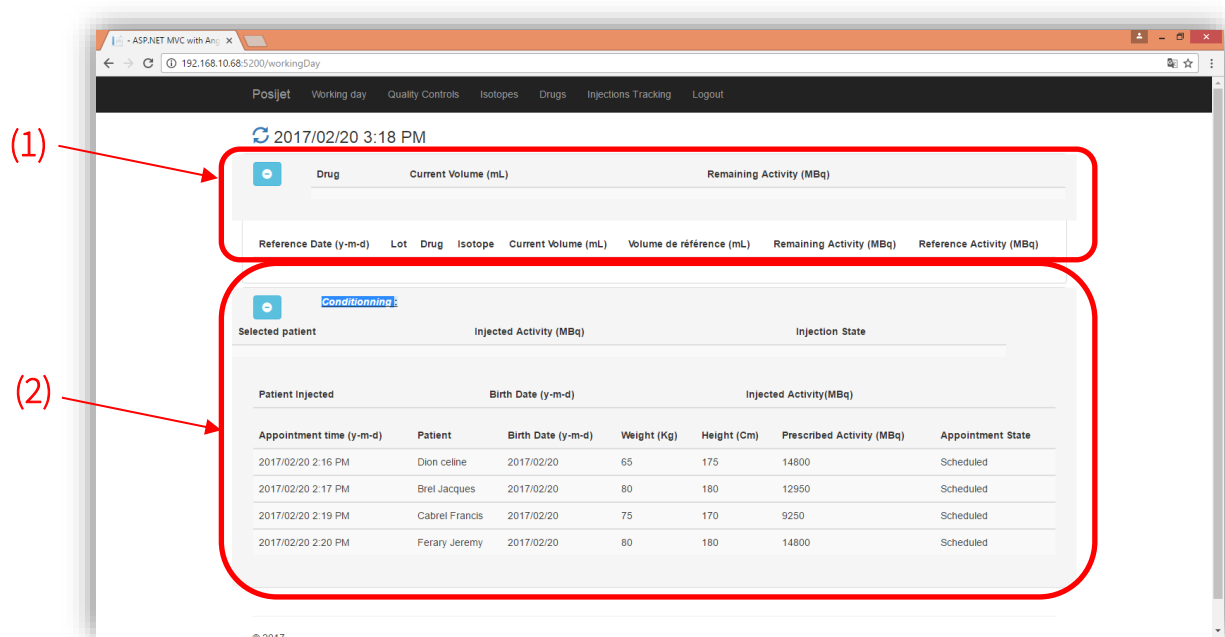


The following menus are available on the administration site:

- **Working Day:** Indicates the general condition of the Posijet (Mother solution and Patients);
- **Quality Controls:** Provides access to the history of all quality controls;
- **Isotopes:** Lists the Posijet isotopes;

- **Drugs:** Lists the drugs managed by the Posijet;
- **Injections Tracking:** Contains all injections made on the Posijet.

VIII.6.b. Working Day

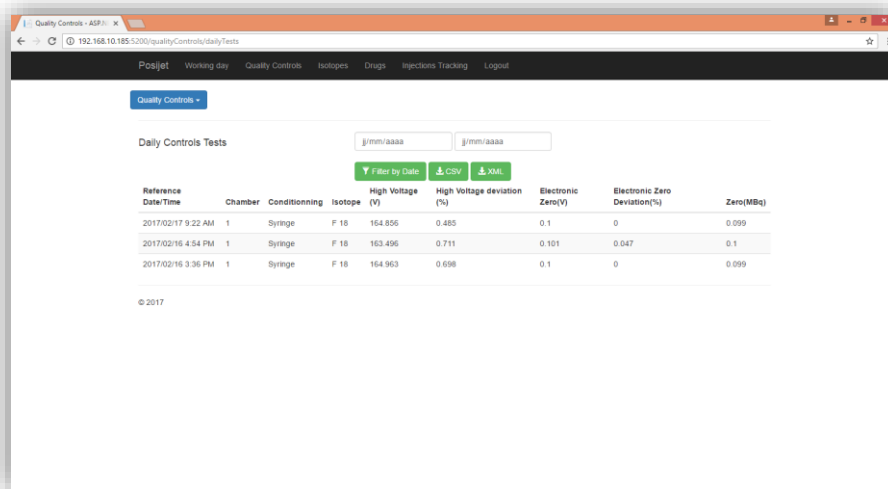


- Zone (1) displays all information concerning the mother solutions of the current day:
 - o The mother solution selected;
 - o The full list of mother solutions for the current day..
- Zone (2) displays all information concerning the patients of the current day:
 - o The content in real time of the sampling syringe;
 - o The patient selected;
 - o The list of patients programmed for the current day;
 - o The list of patients injected for the current day.

VIII.6.c. Quality Controls

Daily tests

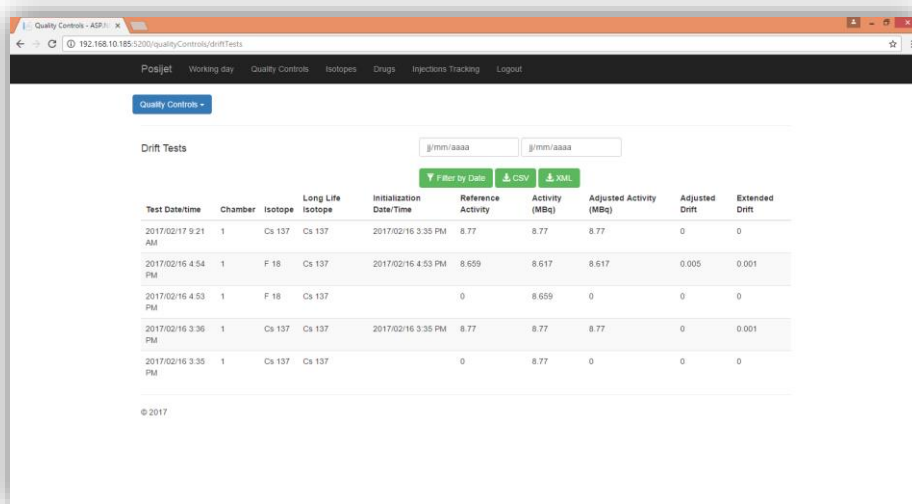
Posijet® V3



This menu is used to:

- Read all the test results;
- Filter the results by date;
- Export the results in CSV or XML format.

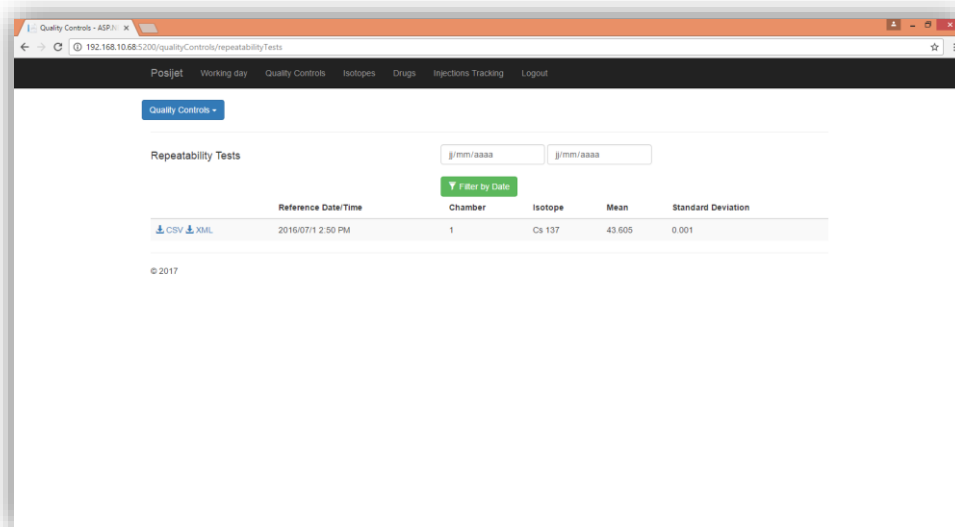
Drift tests:



This menu is used to:

- Read all the test results;
- Filter the results by date;
- Export the results in CSV or XML format.

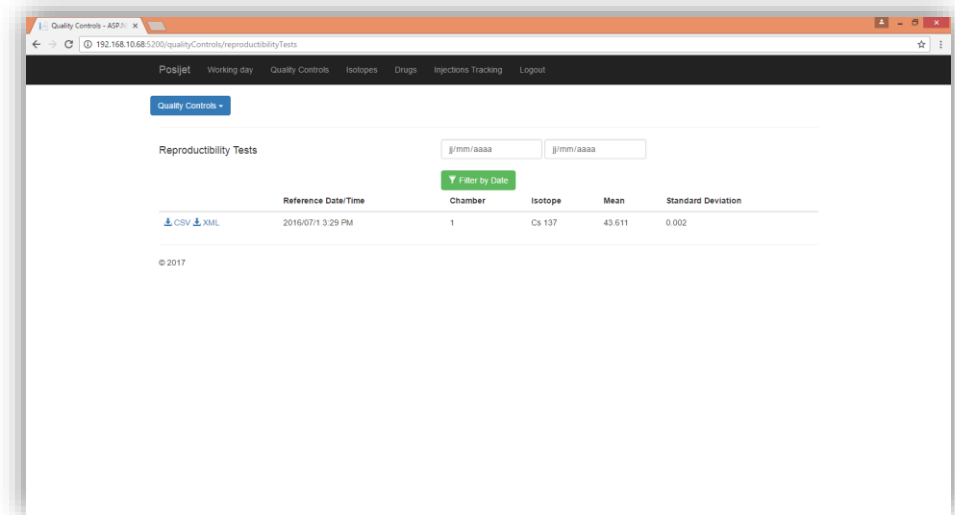
Repeatability tests:



This menu is used to:

- Read all the test results;
- Filter the results by date;
- Export the results in CSV or XML format.

Reproducibility tests:

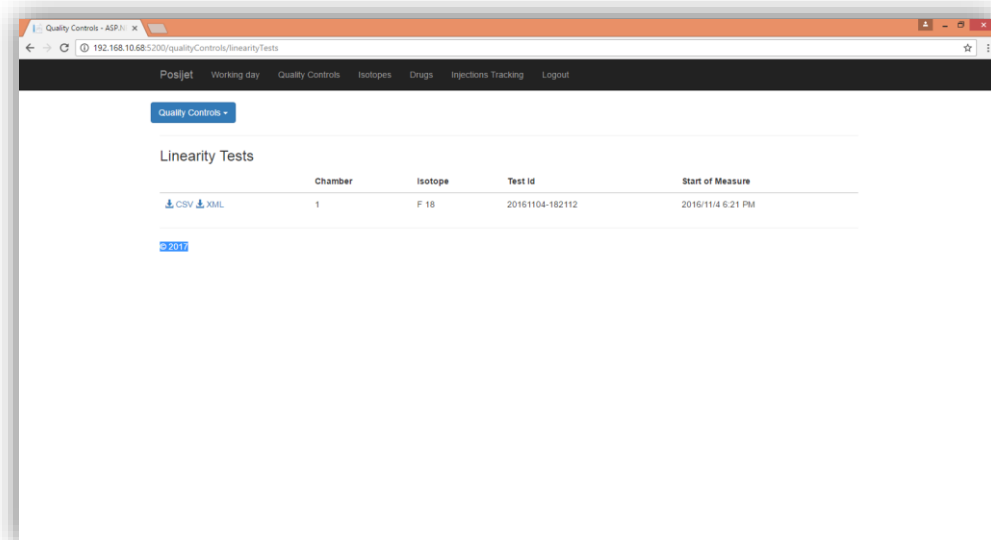


This menu is used to:

- Read all the test results;
- Filter the results by date;
- Export the results in CSV or XML format.

Linearity tests:

Posijet® V3



This menu is used to:

- Read all the test results;
- Filter the results by date;
- Export the results in CSV or XML format.

VIII.6.d. “Isotopes” menu

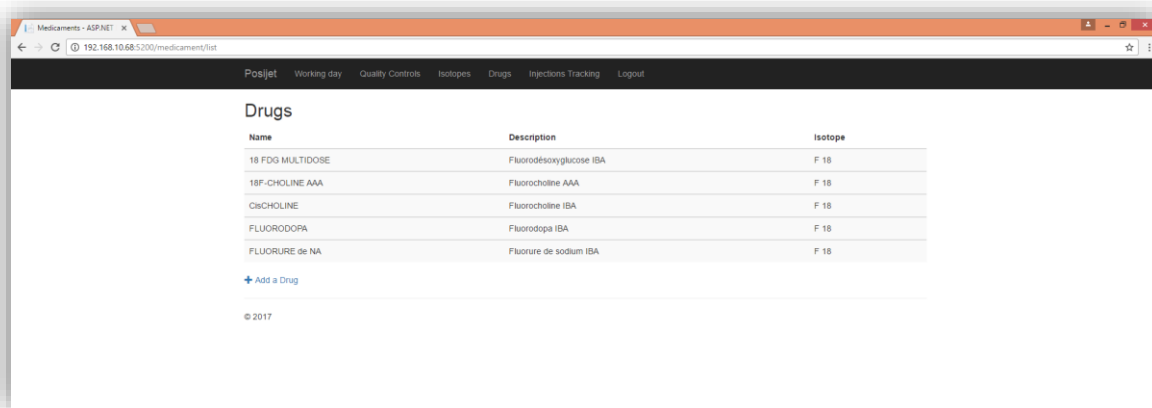
Symbol	Half Life Time
Ac 228	369
Ag 108 m	230370480
Ag 110	0.409
Ag 110 m	359683.2
Ag 111	10726
Al 28	2.241
Am 241	227530296
Am 243	3876325200
Ar 41	109.34
As 76	1552.032
At 218	0.023
Au 197 m	0.129
Au 198	3879.936
Au 199	4520.16
Ba 131	16560
Ba 133	5543466.6
Ba 135 m	1722

This page is used to display the list of isotopes managed by the Posijet.

Note: For more information, refer to the Scintidose® manual.

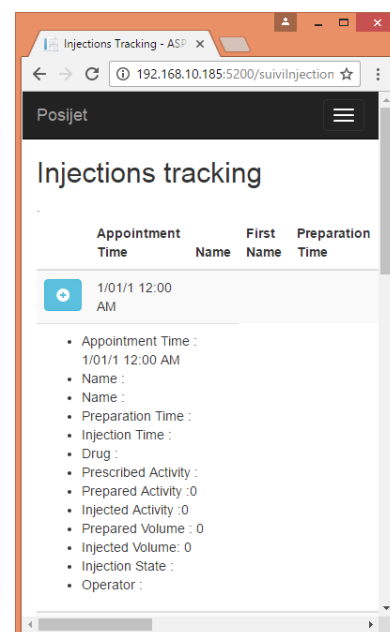
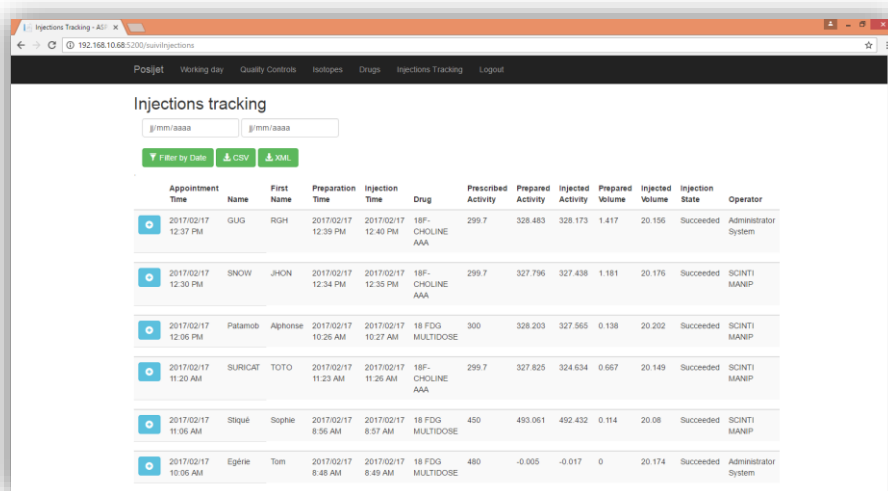
VIII.6.e. “Drugs” menu

Posijet® V3



This page is used to display the list of drugs managed by the Posijet.

VIII.6.f. “Injections Tracking” menu



This menu is used to:

- Read all the injections;
- Read the details of an injection;
- Filter the results by date;
- Export the results in CSV or XML format.

VIII.6.g. Menu « CAV tracking »

Home
Working day
Quality Controls
Isotopes
Drugs
Injections Tracking
Cav Tracking
User
Logout

Cav tracking

By default the injections of the day are displayed

Filter by Date

CSV

XML

Lot	Drugs	Isotope	Date	Time	Theoretical Act(MBq)	Theoretical VA (MBq/mL)	Theoretical Vol. (mL)	Adjusted VA (MBq/mL)	Adjusted Vol. (mL)	Deviation	Operator	Apply

© 2019

- This menu allows:
- Read all the results of the Volumetric Activity Control;
 - Read the details of the CAV;
 - Filter the results by date;
 - Export the results in CSV or XML.

VIII.6.h. Menu « User »

Home
Working day
Quality Controls
Isotopes
Drugs
Injections Tracking
Cav Tracking
User
Logout

User

+Add User

	Login	Name	First name	Administrator	Display order
Edit	Admin	Administrator	System	Yes	0
Edit	Denis PESQUER	PESQUER	Denis	Yes	0
Edit	FLP	LEMER PAX	FORMATION	Yes	0
Edit	LEA	LEA	CERCA	Yes	0
Edit	LNHB	Saclay	CEA	Yes	0
Edit	ESP	Esprimed	Esprimed	Yes	55

© 2019

- This menu allows:
- View all the users set in the machine ;
 - Check administrator rights ;
 - Change passwords ;
 - Create new users ;

Posijet® V3

VIII.7. Spécificities for short period radionuclide (Ammonia Variant)

In order to correspond to the uses and practices of use of short-lived radionuclides, LEMER PAX, in a version dedicated to these radioelements, renders inactive the following functionalities of the daily mimic of use of the machine:

- the volume activity control or C.A.V
- dilution.


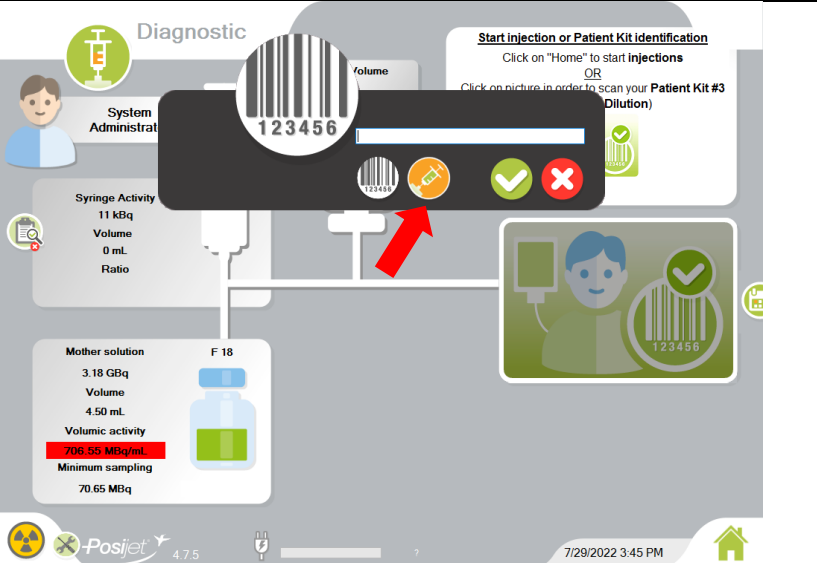
In addition, a specific parameter setting for flushing and rinsing times is also set up to suit the use of short-lived radionuclides.

Therefore, a Posijet® configured to use short-period radioisotopes can not be used simultaneously with radioisotopes of longer periods.

If you want to change the setting of the device for another configuration (other types of radioisotope), you must necessarily contact LEMER PAX.

VIII.8. Posijet® use in preparation mode only

When using the Posijet® in preparation mode only, the operation is relatively similar to the operation developed in chapter VIII with the following specificities at the user interface level:

<p>When the patient kit' scan screen appears, clic on the icon of the Remote Injection</p>  <p>System</p>	
<p>Connect a 20mL with its shielded protection directly to the green bionector and launch the flush operation.</p>	
<p>Perform an optimal vial dilution if needed</p>	
<p>Create or select a patient</p>	

Posijet® V3

On the dose preparation screen, it's possible to modify the number of minutes before injecting the patient with the **Remote Injection System** by clicking on the button



When all the parameters are set, click on

Dose

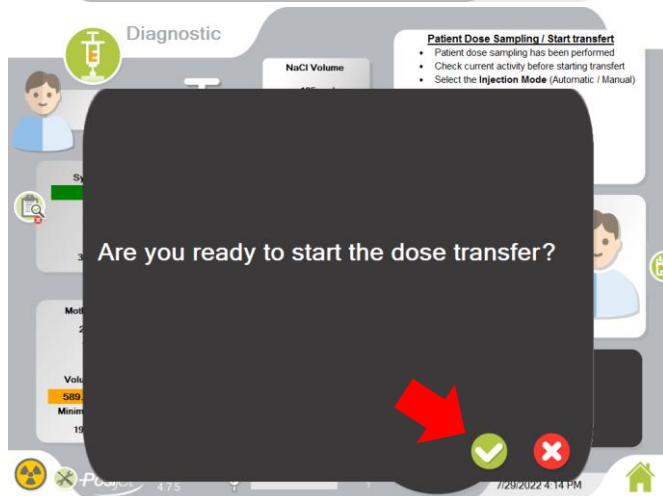
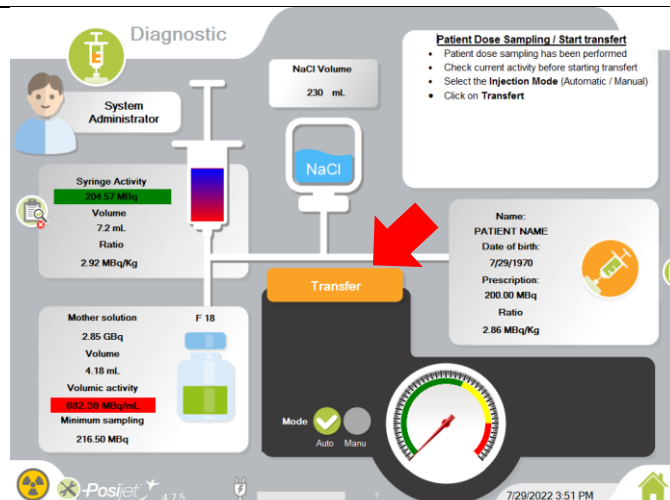
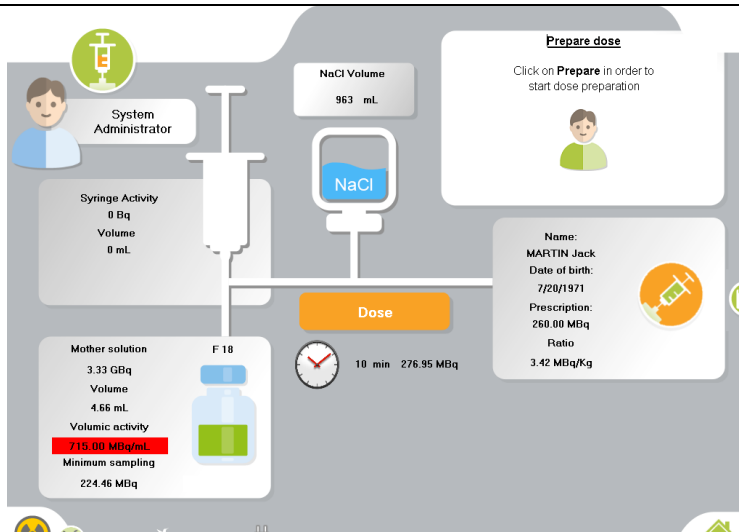
It is possible to anticipate the sampling in accordance with the injection scheduled, the sampling done by the Posijet will be surestimated in the limite of **10 minutes** maximum.

The sampling will be in a volume of **10mL**

When the dose is ready, connect the **Remote Injection System** to the bionector of the mother solution kit and launch the transfer.

The injection will be done in three stages:

1. Injection of the syringe containing the medicine
2. Flushing with **5mL** of saline solution
3. A second flush with **5mL** of saline solution

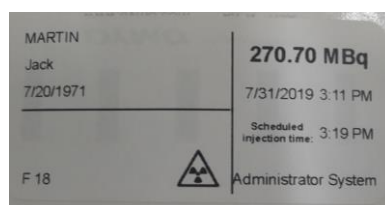


Posijet® V3

Once the transfer done, disconnect the bionnector of the mother solution kit from the Remote Injection System.



After validating the injection, a label is printed including the activity present in the system and the time of the measurement, as well as the forecast injection time.



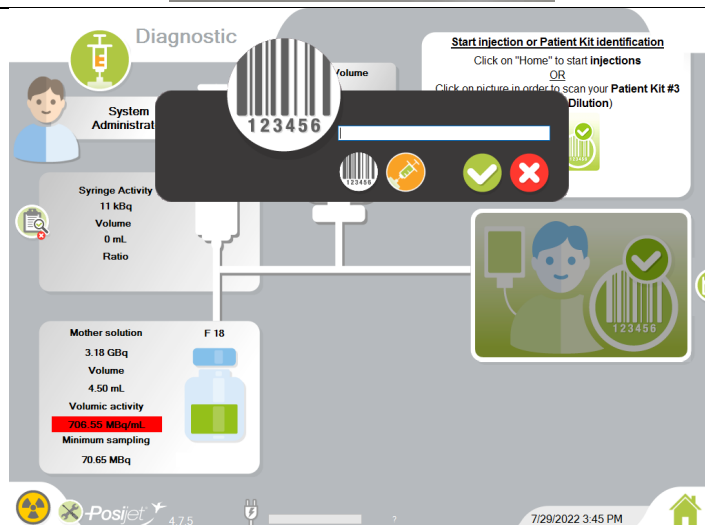
For the next patient, on patient kit scan screen, 2 options :



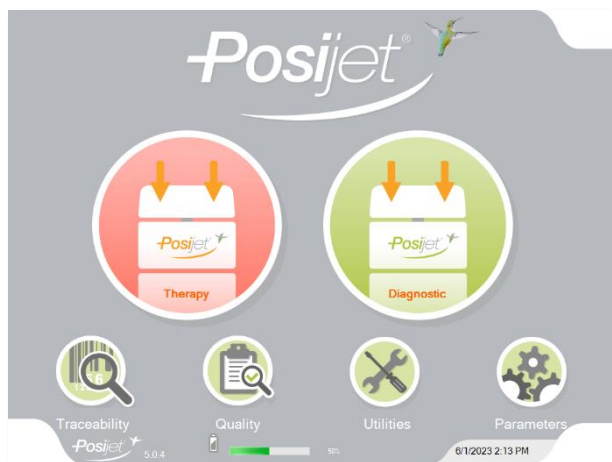
→ Use the Remote Injection System



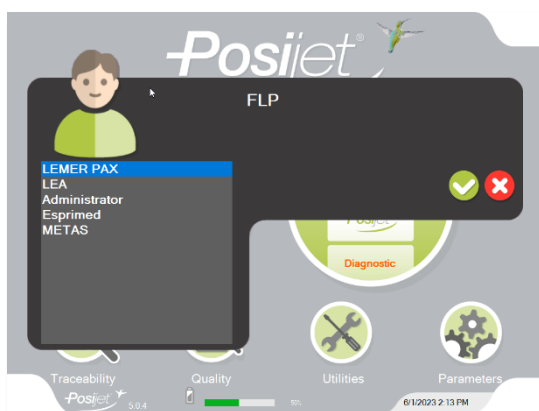
→ Scan a patient kit for a direct injection with the Posijet.



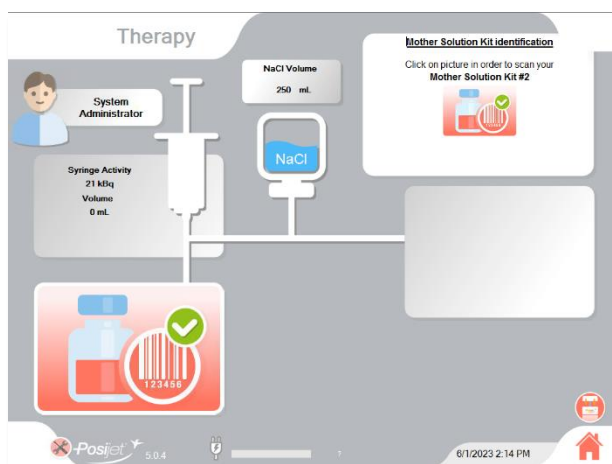
VIII.9. Use of Posijet® over a therapeutic injection cycle



When Therapy option is enabled, the Therapy menu appears on the home screen

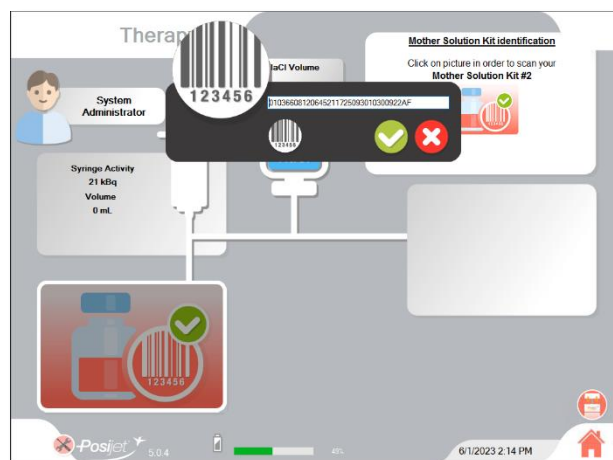


To open the Therapy menu, press the corresponding icon and choose the identifier. In the case of authentication, a password is requested.

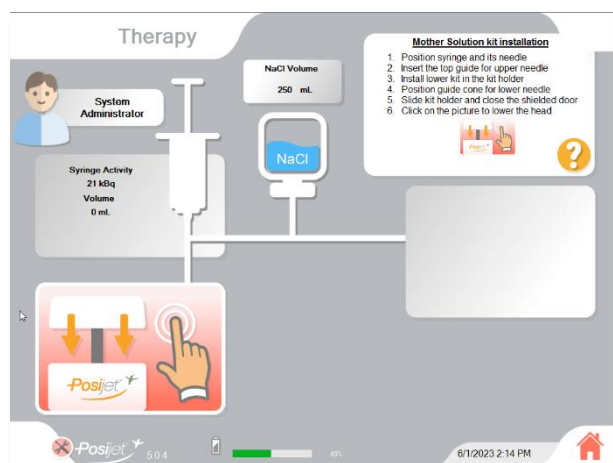


The Therapy menu is open and its structure is identical to that of the Diagnostic menu.

Posijet® V3



Click on the image to scan the Mother Solution kit and scan the kit barcode.

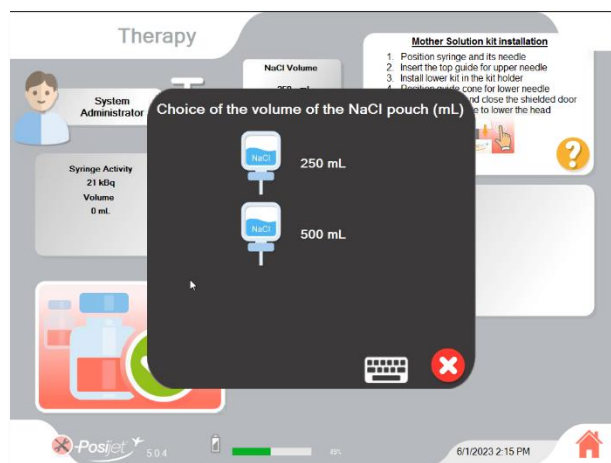


Proceed to load the Posijet following exactly the same steps as those in the Diagnostic menu.
During this step, be sure to insert the pot and vial suitable for therapeutic use.

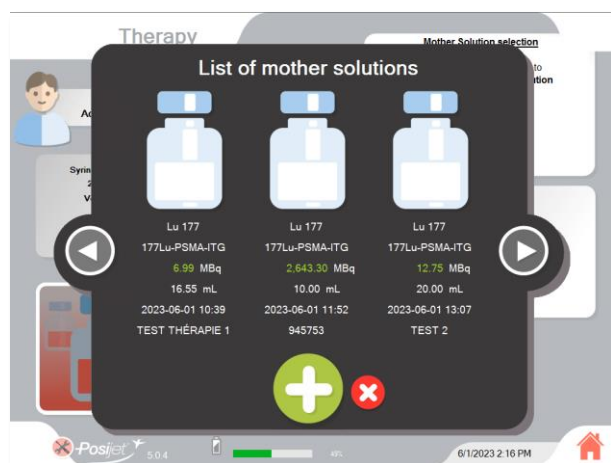


Lowering the head of the Posijet V3

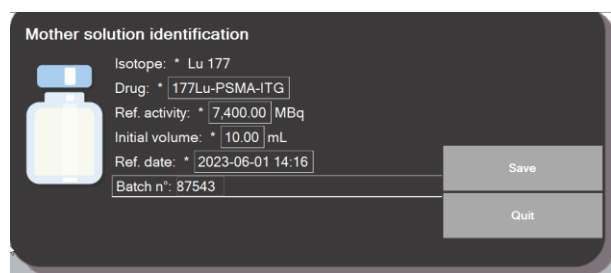
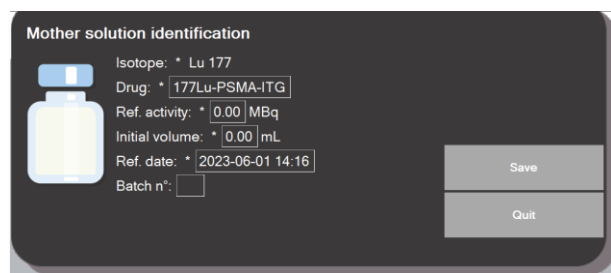
Posijet® V3



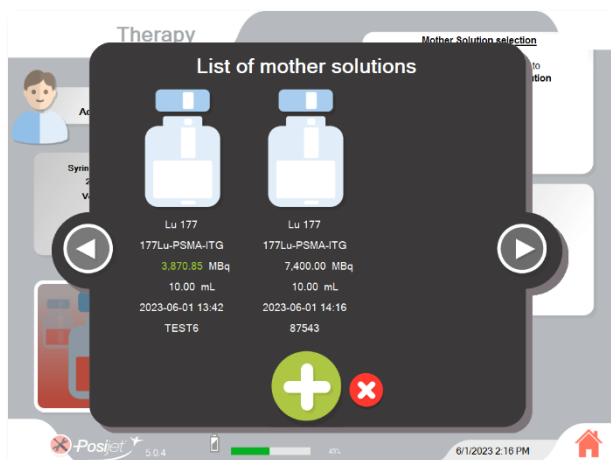
Choose the volume of the NaCl pouch installed during loading



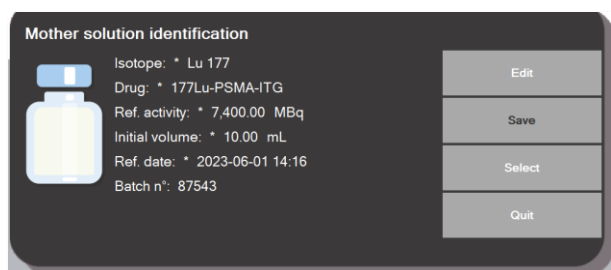
By clicking on the solution image, the creation page opens. In the same way as for Diagnostic mode, synchronization of vials is possible as well as manual creation.



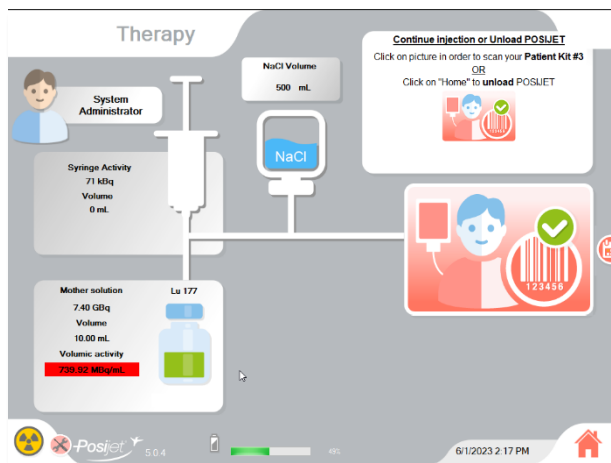
During manual creation, the user can enter the data of the received vial



When the entry is completed, the vial is displayed in the list of solutions



By clicking on the vial in the list, its file appears and the user can select it to continue

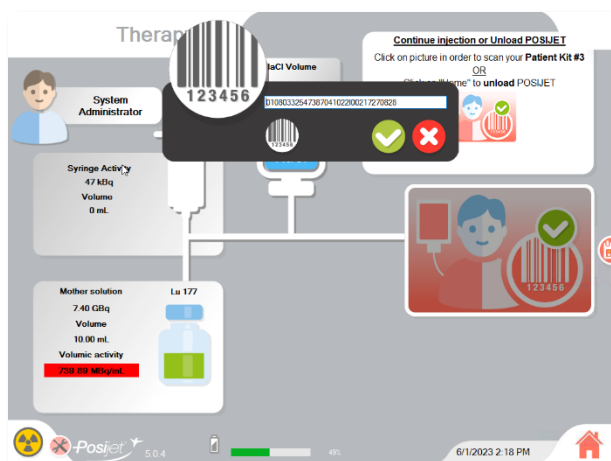


When the vial is selected, the vial information appears in the location provided.
Click on the patient icon to scan a patient kit

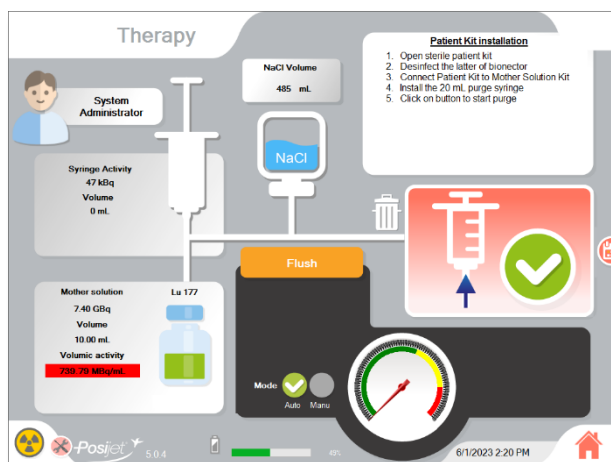
Posijet® V3



Validate the confirmation request

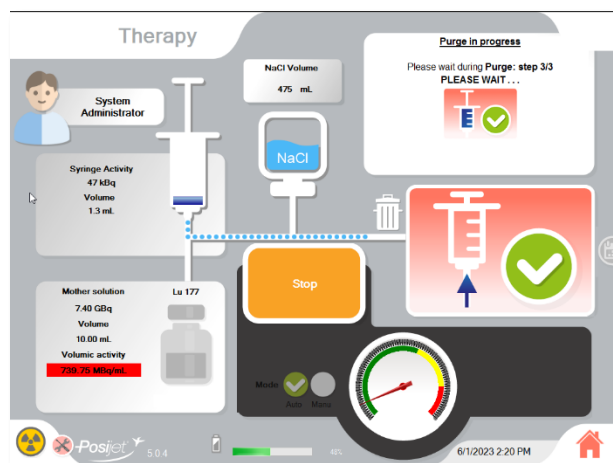


Scan the barcode of the patient kit and validate



Click on "FLUSH" to start rinsing the kits

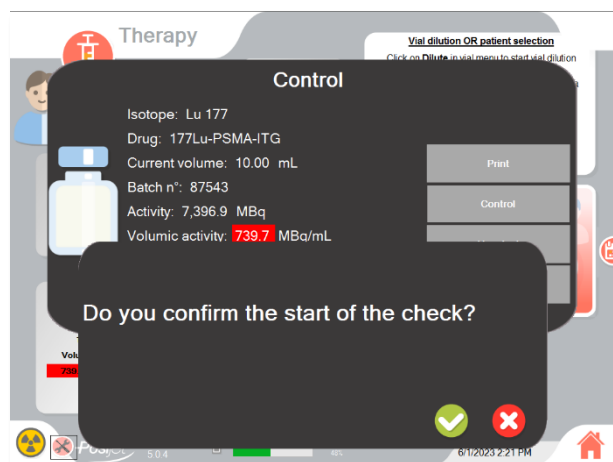
Posijet® V3



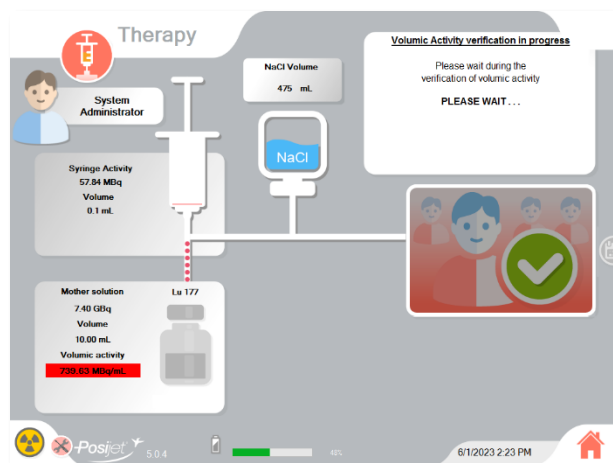
Rinsing of the kits is in progress



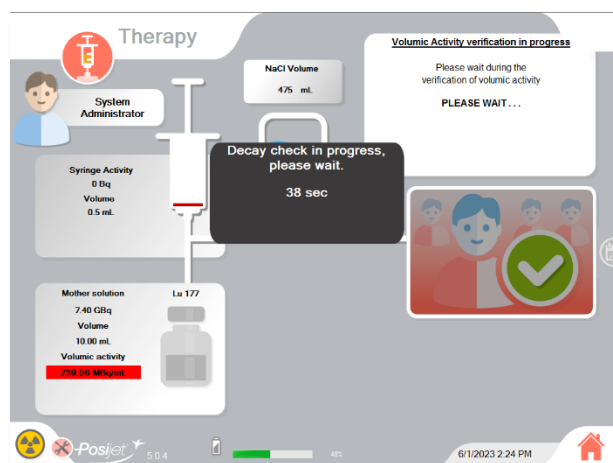
Click on “Control” to run the automatic vial control



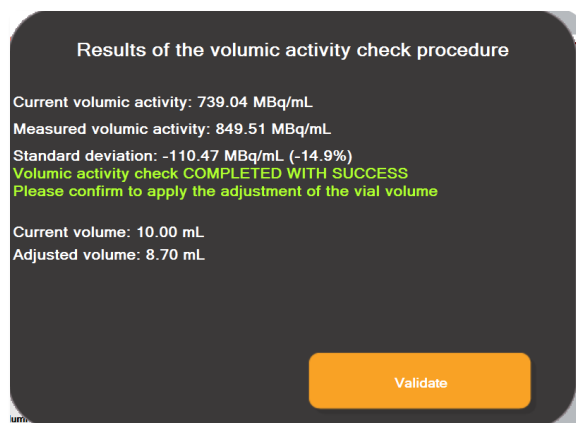
Validate the confirmation popup



Vial concentration control runs automatically



The control ends with a check of the decay of the sample.



When the control result is OK, the application displays the adjusted vial information

Results of the volumic activity check procedure

Current volumic activity: 739.68 MBq/mL
Measured volumic activity: 1,063.29 MBq/mL
Standard deviation: -323.61 MBq/mL (-43.8%)
Volumic activity check has FAILED. The standard deviation is TOO HIGH.
Check that the current volumic activity is consistent with the data from the
Current volume: 10.00 mL
Adjusted volume: 6.96 mL

Apply measured data

Keep provider data

When the concentration in the vial exceeds a threshold, the application displays the deviations and the user must choose between:

1. Apply the data measured by the Posijet
2. Retain supplier data

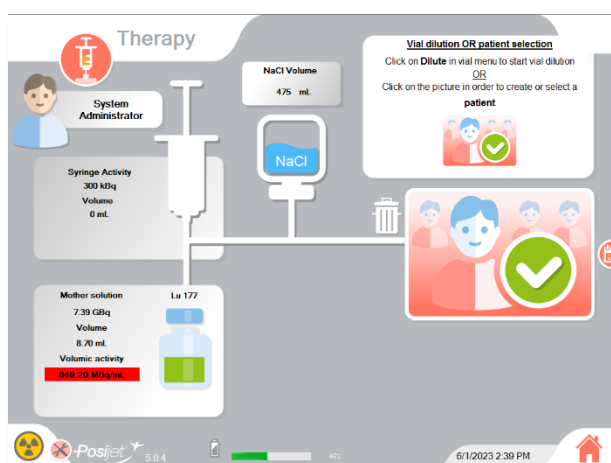
Decay control

ECHEC


The isotope present in the POSIJET has a half-life less than 20h. This period is similar to a diagnostic drug.

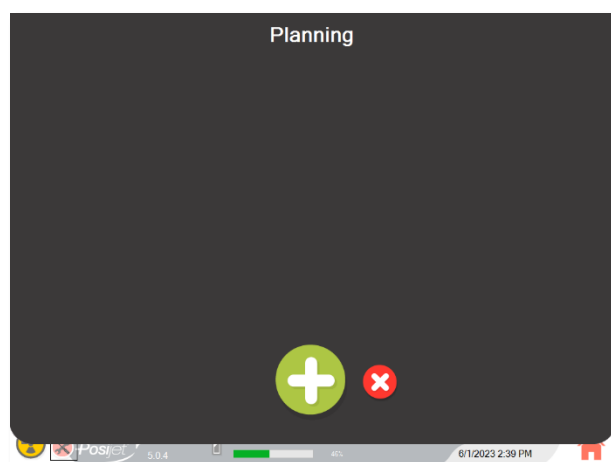
UNLOAD

When the decay control fails, this corresponds to too rapid a decay of the sample, which suggests that the vial does not contain the desired product and it is preferable in this case to unload.

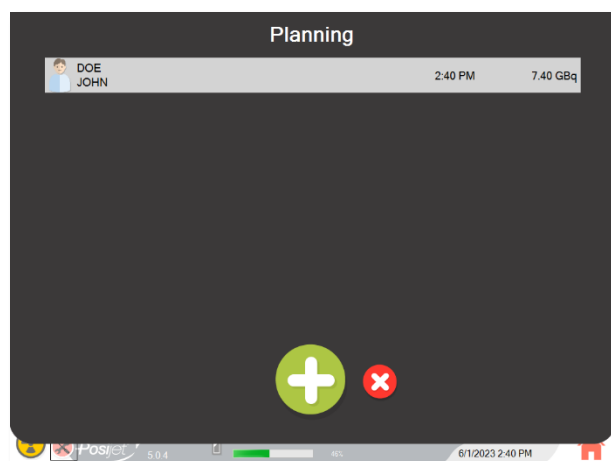


Click on the patient icon to open the patient creation/selection page

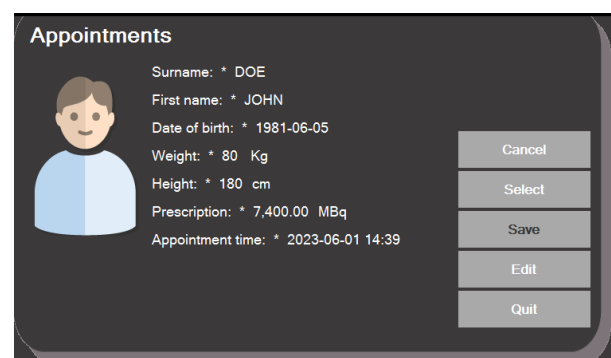
	<p>Instructions manual</p>	<p>English version V16-1 June 2024</p>
<p>Posijet® V3</p>		



Click on green button to create a new patient
Click on the blue button to synchronize the patient list
with the radiopharmacy software
Click on the red button to close the window



Click on the desired patient



Check patient information and click “select”

Choose the administration
protocol for this patient

Whole vial

Partial vial
Max prescription = 4.84 GBq



Choose the administration
protocol for this patient

Whole vial

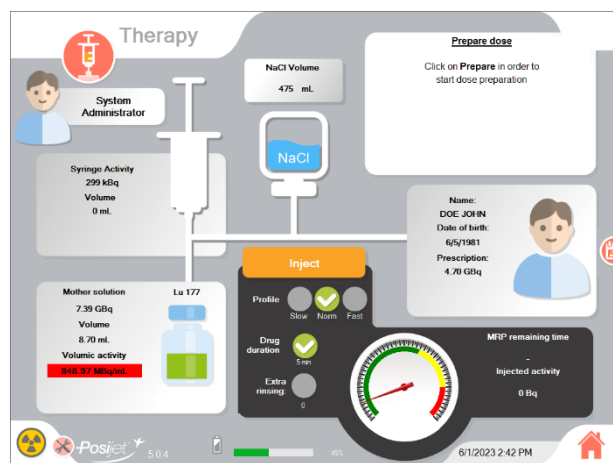
Partial vial
Max prescription = 4.84 GBq



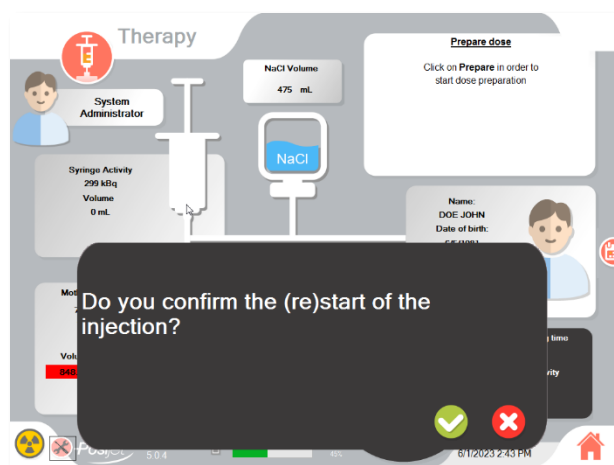
Choose the injection protocol:

Whole vial corresponds to the complete administration
of the vial

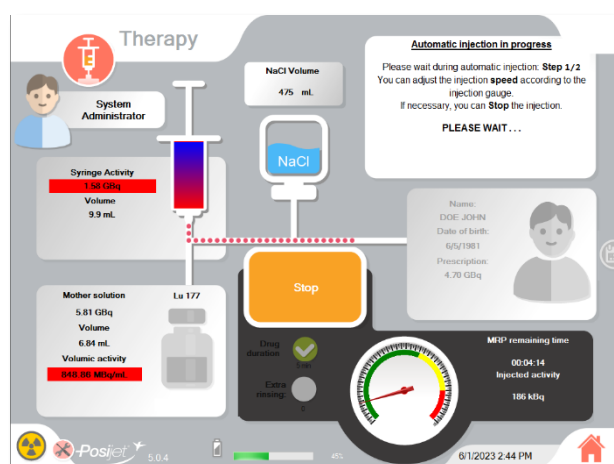
Partial vial corresponds to the preparation and
injection of part of the vial



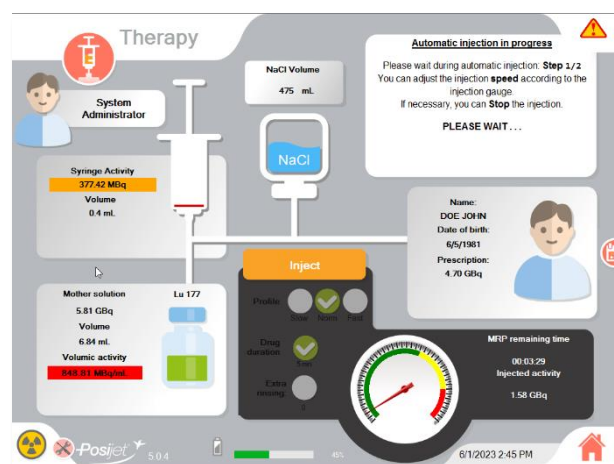
Choose injection options and click Inject



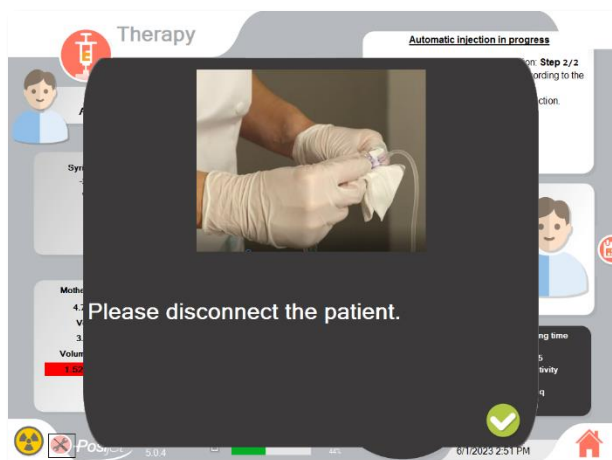
Validate the injection start confirmation page



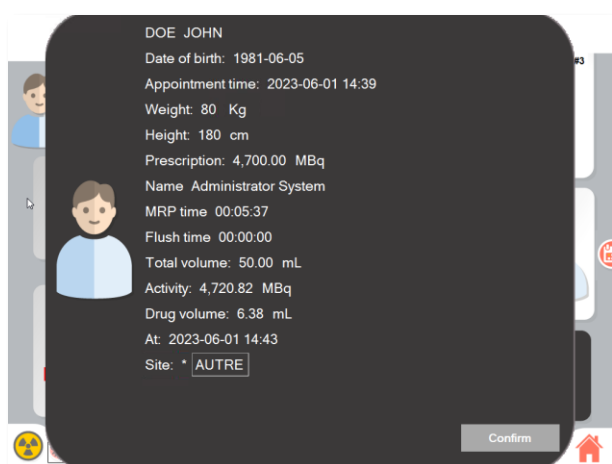
The application displays all injection tracking data. It is possible to stop and resume the injection at any time



If a fault is detected by the Posijet, the injection stops. After solving the problem, it is possible to resume the injection



Disconnect the patient kit and validate the confirmation



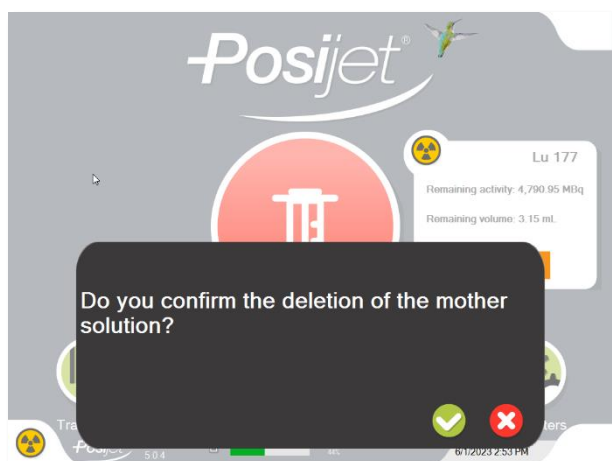
Check patient injection data
By validating this page, a label corresponding to the injection is printed



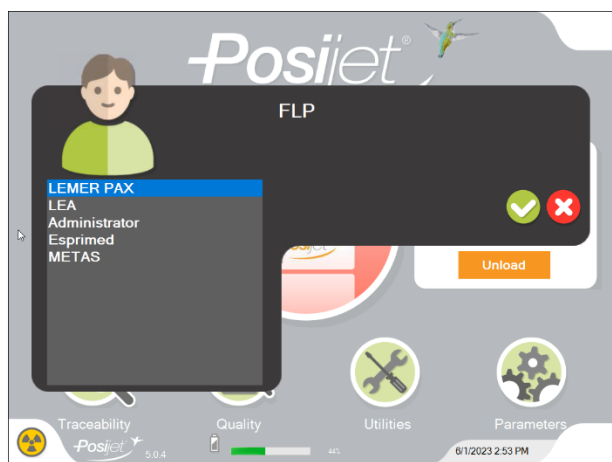
Validate the unloading confirmation and click on the return to main menu button



Click on the unload button

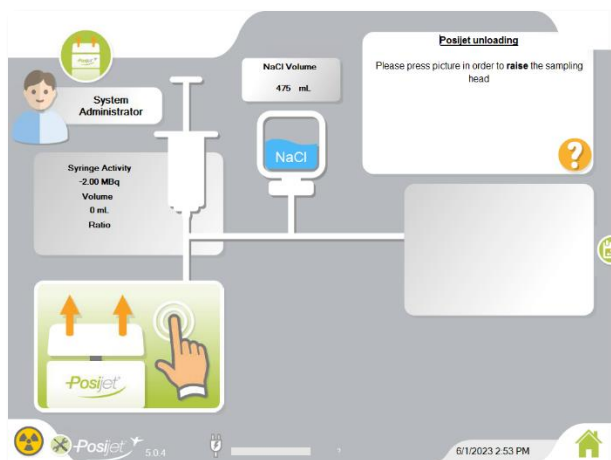


Validate the unloading confirmation request

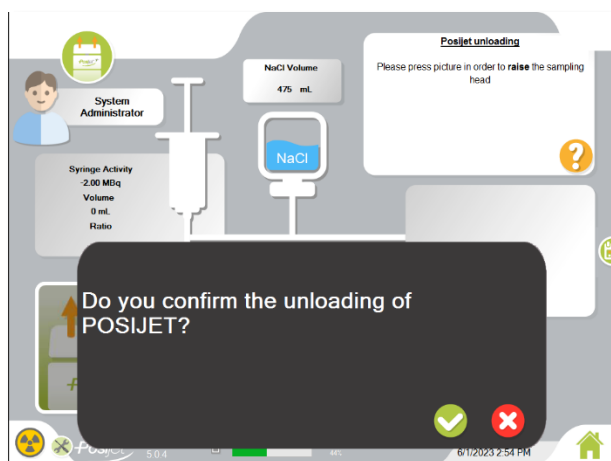


Select your login

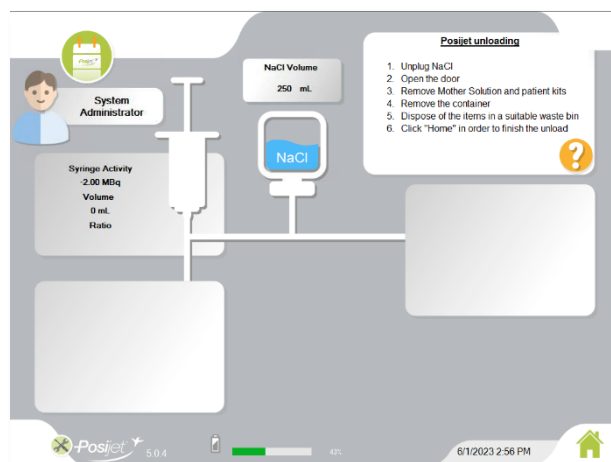
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Click on the unload button

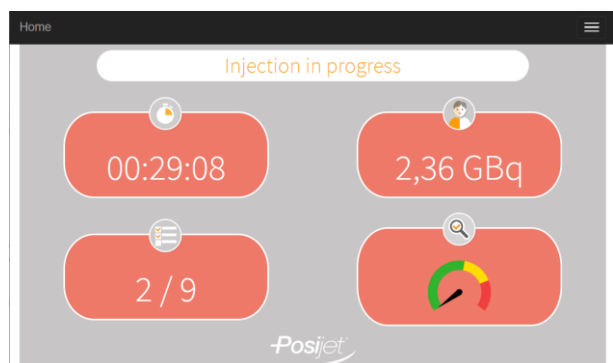


Automatic rinsing of the kit is then requested.
Rinsing corresponds to maximum dilution of the vial

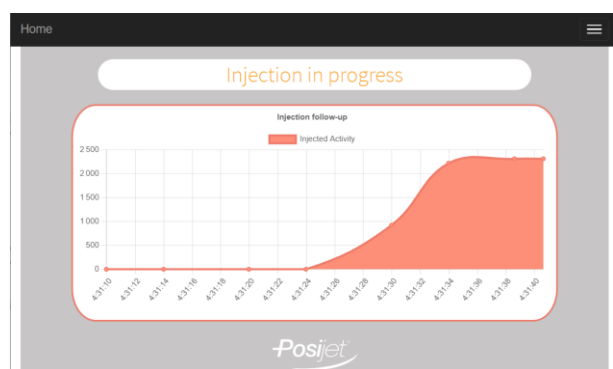



Click on the return to main menu button to perform a next loading.

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Note: During the injection, it is possible to monitor the data remotely with the tablet provided with the injector.



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IX. Using the Posijet® in extended mode


IX.1. Emergency stop

If there is a problem with the machine (leak, failure, danger to patient or third party, anomaly detected by operators, etc.) or operator error, press the Emergency Stop button to stop the current operation.

 **THE EQUIPMENT MUST NEVER BE OPENED AND EMPTIED OF ITS CONTENTS UNLESS IT IS IN A HOT LABORATORY.**


IX.2. Error messages and solutions to be implemented

Fault ID	Fault description	Actions required
1	Slot A expansion board config error	Contact the Lemer Pax SUPPORT service
2	Slot B expansion board config error	Contact the Lemer Pax SUPPORT service
3	Slot C expansion board config error	Contact the Lemer Pax SUPPORT service
4	Emergency stop	Emergency stop pressed Release the emergency stop to resume
5	Mother board UC1 error	Contact the Lemer Pax SUPPORT service
6	EB A board UB error	Contact the Lemer Pax SUPPORT service
7	EC A board UB error	Contact the Lemer Pax SUPPORT service
8	EB B board UB error	Contact the Lemer Pax SUPPORT service
9	EB B board GND error	Contact the Lemer Pax SUPPORT service
10	Ethernet communication error	The logic controller detected a timeout on the communication Contact the Lemer Pax SUPPORT service
11	Error: cannot find ECU configuration file	Contact the Lemer Pax SUPPORT service
12	Error: cannot open ECU configuration file	Contact the Lemer Pax SUPPORT service
13	Error: configuration file too; long	Contact the Lemer Pax SUPPORT service
14	Error: incorrect configuration file type	Contact the Lemer Pax SUPPORT service
15	Error: syringe travel limit sensors	Check the behaviour of the sampling system in the Utilities menu /Logic controller If necessary, contact the Lemer Pax SUPPORT service.
16	Error: syringe position full	Check the behaviour of the sampling system in the Utilities menu /Logic controller If necessary, contact the Lemer Pax SUPPORT service.
17	Error: syringe position empty	Check the behaviour of the sampling system in the Utilities menu /Logic controller If necessary, contact the Lemer Pax SUPPORT service.
18	Error: syringe encoder redundancy	Check the behaviour of the sampling system in the Utilities menu /Logic controller If necessary, contact the Lemer Pax SUPPORT service.

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19	Error: syringe initialisation	The fault is raised if the syringe is not empty when powering up
20	Error: bi-manual command contacts	Bi-manual commands not activated synchronously. Wait for 2 seconds and repeat the procedure.
21	Error: force sensor signal	Validate the fault and resume the cycle. If the fault persists, contact the Lemer Pax SUPPORT service.
22	Error: syringe not empty	The command is refused since the syringe is detected as being not empty. Open the Utilities menu/Logic controller and empty the syringe (caution if activity present)
23	Error: valve travel limit	The 2 sensors of the 3-way valve have been activated simultaneously. Check that nothing is blocking this area in the door , otherwise contact the Lemer Pax SUPPORT service.
24	Error: column travel limit	Contact the Lemer Pax SUPPORT service
25	Error: door open	The operation was refused since the door was detected as being open. Close the door and repeat the request.
26	Error: door unlocking	Unlock the door manually in the "Utilities" menu and then "Calculator". If manual unlocking is not possible please contact the Lemer Pax SUPPORT service
27	Error: activity measurement	Contact the Lemer Pax SUPPORT service
28	Error: initial activity	Operation refused due to the presence of activity in the dose calibrator.
29	Dosage timeout	Dosage time exceeded.
30	Column upper stop timeout	Contact the Lemer Pax SUPPORT service
31	Column lower stop timeout	Contact the Lemer Pax SUPPORT service
32	FDG pos valve movement timeout	Contact the Lemer Pax SUPPORT service
33	NACL pos valve movement timeout	Contact the Lemer Pax SUPPORT service
34	Incorrect config file	Contact the Lemer Pax SUPPORT service
35	Unknown parameter in config file	Contact the Lemer Pax SUPPORT service
36	Valve motor: current too high	Contact the Lemer Pax SUPPORT service The current measurement of the valve motor is too high. Check that nothing is blocking the rotation of the 3-way valve.
37	Column actuator current too high	Contact the Lemer Pax SUPPORT service The current measurement of the column actuator is too high. Check that nothing is stopping the sampling head from moving up or down.
38	Syringe motor current too high	Contact Lemer Pax SUPPORT service The current measurement on the syringe motor is too high. Check that nothing is blocking the sampling system (in dosage and injection).

39	Injection auto-speed too low	Detection of back pressure during an injection. Check the injection site before resuming.
40	Manual injection – Suction prohibited	Detection of liquid suction during a manual injection. Resume the manual injection without pulling the piston.
41	Injection time too long	The injection time is exceeded. Repeat the procedure.
42	Detection of air bubble during injection	The air presence sensor became active during injection
43	Emergency stop mode	The emergency stop is pressed. If the emergency stop was pressed deliberately, contact the Lemer Pax after-sales service to explain the reason why. If the emergency stop was pressed accidentally, release it.
44	Column descent not authorised	Descent operation prohibited by the PC
45	Error: force sensor calibration	Check carried out during the syringe filling operation
46	Injection speed too high.	The speed measured during injection is too high. Resume the manual injection with a lower speed.
47	Column ascent prohibited – Initial activity not zero	You are trying to raise the column (in Auto mode) while the syringe still contains activity
48	Column ascent/descent prohibited – Syringe not empty	You are trying to raise or lower the column (in Auto mode) while the syringe is not empty
49	The syringe cannot be filled if it is not empty at the start	Check the behaviour of the sampling system in the menu Utilitaire/Automate (Utilities/Logic controller) If necessary, contact the Lemer Pax SUPPORT service.
50	Column ascent not authorised	Column ascent is refused since this movement is not authorised.
51	Injection operation prohibited without force sensor	If the force sensor is deactivated, the automatic injection operation is refused. Make a manual injection.
52	Maintenance mode required	You must be in maintenance mode to perform the requested operation. Contact the Lemer Pax SUPPORT service.
53	Auto mode required	You must be in automatic mode to perform the requested operation

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X. Risks

X.1. Special precautions

X.1.a. Dose calibrator

The activimeter is not designed to operate in an environment above 30°C and below 0°C. Above this limit, the activity values shown on the display may be distorted. The temperature limits specified in this manual must be observed.

It is recommended that Posijet® be charged every night so that it is operational every morning. To allow the batteries to be charged in good conditions, the Posijet® on/off button must be turned off.

Radiopharmaceuticals are very specific products whose use must be perfectly controlled and which cannot be delivered to anyone without a medical prescription.

The Posijet has been specially configured for your application: radiopharmaceutical, administration protocol.

X.1.b. Radiopharmaceutical

Radiopharmaceuticals are very specific products whose use must be perfectly controlled and which cannot be delivered to anyone without a medical prescription.

The Posijet has been specially configured for your application: radiopharmaceutical, administration protocol.

It is necessary to check the compatibility of the mode of administration with the recommended protocol for the patient and/or the radiopharmaceutical. For any modification of the radiopharmaceutical or protocol, ask your manufacturer LEMER PAX.

Posijet® must not be used in any other setting or for any other application than those defined in this manual.


The data entered by the users on the patient charts and the data of the mother solution must be filled in accurately. It is the user's responsibility to check this data.

X.1.c. Radiation protection

The Posijet® was not designed for activities other than those mentioned in this manual for F18 (paragraph II.2). For other radionuclides, you must check the maximum admissible activity or request confirmation from the manufacturer Lemer Pax.

Posijet® must never be opened when it contains a radioactive solution, outside the hot laboratory (or equivalent secure room).

The Posijet®, as configured for your centre according to the information providing when placing the order ("DOC 114":

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Questionnaire before installing the Posijet), cannot be used with vials other than those indicated in this document. To use any other type of vial, please consult the manufacturer Lemer Pax to confirm compatibility.

X.1.d. Other precautions

Posijet® must not be used outdoors: it is not protected against splashing liquids. Any splashing can cause irreversible damage to the device. However, in the event of leakage, spillage or splashing of liquids, the voltage must be switched off immediately and any accessible liquids mopped up.

Posijet® must not be disassembled by anyone who is not authorised or recognised by Lemer Pax.

X.1.e. Precautions during flushing or injection

When using the Posijet® in a patient injection cycle, you must check that during each flush liquid flows from the sterile kit to the flush syringe, and that during each patient injection the patient receives the dose.

If no liquid flows out during flushing or injection, stop the injection immediately with the stop button.

The equipment must imperatively be returned to the hot laboratory before opening.

Similarly, if the operator detects a leak of solution (FDG or saline solution), s/he must stop the injection immediately and return the equipment to the hot laboratory (refer to paragraph XII.3 if radioactive contamination has occurred).

X.1.f. Precautions during the activity measurement

When sampling to make up a dose for a patient, you should check that the activity shown on the screen increases. Before the injection, the operator must make sure that the activity displayed on the screen corresponds to the activity to be injected to the patient. In case of anomaly, return to the hot laboratory then evacuate the dose into a protected syringe using the syringe shield then unload the Posijet®.

Similarly, check that the residual activity in the dose calibrator is close to zero after an injection and two rinses of the tubes going out to the patient.


The preparation technician must check the accuracy of the data for the vial of stock solution before validating the stock solution file. The system uses these data in order to calculate the theoretical volumetric activity in the flask. If the initial data are wrong, this can have serious consequences for the injection cycle.

The operator must check the accuracy of the “Patient” data on the patient file.

In addition, the dose calibrator is not designed to operate in an environment at a temperature above 30 °C and below 0 °C. It is possible that beyond these temperatures the activity levels displayed on the screen may be false. The temperature limits shown in the present manual must be respected.

X.1.g. Precaution when moving or during using

Posijet® is designed for use on level ground and for crossing thresholds. It is not intended for use over steps or expansion joints. It is imperative to respect this precaution in order to guarantee optimal operation of the

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machine

X.1.h. Precaution against shock

The Posijet® weighs 380 kg. It is a heavy and mobile device. Collisions could cause injury. When moving the Posijet® therefore, move slowly, make sure there is nobody in its path and never lose control of the equipment.

Operate the shielded door (> 50 kg) with great care and make sure that no one has his/her fingers on the sharp edges when closing it.

The Posijet should only be used by one user at a time: risk of entrapment when lowering the sampling head. The user should initiate an emergency stop of the device for any unusual movement or display.

When fitting the common sterile kit, make sure that nobody has fingers in the path of the needle. If accidental pricking from a needle does occur the needle concerned must be discarded and replaced by a sterile needle.

X.1.i. Biohazards precautions

Posijet® must be used in accordance with the hospital's procedures for patient biosafety. The guide cones must be decontaminated and disinfected (according to the department practice) for each mother solution used.

The kits are individually packaged in sterile bags. Take all the usual precautions to avoid contaminating the product (wear a laboratory coat, gloves, etc.), ensure the biological safety of the patient by checking the expiration date of the products and ensure that the pouch is not damaged before opening it.

X.2. Residual risk


The residual risk to the measurement is almost zero if the periodic checks recommended by the manufacturer are systematically carried out (paragraph XIV).

Taking into account all the safety measures and warnings provided by the LPDose software, the risks related to overdosing of radiopharmaceuticals are extremely low and not considered as residual risks.

There is only one residual risk of leakage of radioactive product in the event of incorrect use or use of a defective kit. In the event of radioactive projection, priority must be given to the rules and procedures for radiological protection in force in the establishment after powering off the electrical circuit.

X.3. Notification of serious incidents

Any incident or risk of a serious incident that has resulted or may result in the death or serious deterioration of the state of health of a user or a third party involving the Posijet must be reported without delay to the competent national authority and to Lemer Pax.

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XI. Electromagnetic Compatibility (EMC)

The device conforms to standard 60 601-1-2. It does not create interferences with other devices, if they also comply with the same standard:

- The Posijet® requires precautions with respect to EMC. It must be installed and put into service according to the following EMC recommendations;
- The Posijet® can be affected by portable and mobile RF communication devices;
- The Posijet® should not be used near or stacked with other devices. If it is not possible to do otherwise, the Posijet® must be monitored to verify normal operation in the configuration in which it will be used.
- The POSIJET V3 needs special precaution (s) according to the environment. The POSIJET V3 is installed and commissioned in hospitals, with the exception of facilities close to electrosurgical equipment and remote from HF source magnetic resonance imaging;
- **WARNING:** RF portable communication devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the POSIJET V3, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired;
- **NOTE:** The emission characteristics of this device allow it to be used in industrial and hospital areas (Class A defined in CISPR 11). When used in a residential environment (for which class B defined in CISPR 11 is normally required), this device may not provide adequate protection for radio frequency communications services. The user may need to take corrective measures, such as relocating or reorienting the device.
- The field strengths of fixed transmitters, such as base stations for radiotelephones (cellular / wireless) and land mobile radios, amateur radio, AM and FM broadcasting, and TV broadcasting, can not be theoretically predicted accurately. To evaluate the electromagnetic environment due to fixed RF transmitters, an on-site electromagnetic investigation should be considered. If the field strength, measured at the location where POSITJET V3 is used, exceeds the applicable RF compliance level above, POSITJET V3 should be observed to verify that operation is normal. If abnormal performance is observed, additional measures may be necessary to reorient or reposition POSITJET V3.



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Table 1 – Guidance and manufacturer's declaration – electromagnetic emissions – for all EM equipment and systems.

Guidance and manufacturer's declaration – electromagnetic emissions		
The POSITJET V3 is intended for use in the electromagnetic environment specified below. The customer or the user of the POSITJET V3 should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The POSITJET V3 uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The POSITJET V3 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliant	

Table 2 – Guidance and manufacturer's declaration – electromagnetic emissions – for all POSITJET V3 devices.

Guidance and manufacturer's declaration – electromagnetic immunity			
The POSITJET V3 is intended for use in the electromagnetic environment specified below. The customer or the user of the POSITJET V3 should ensure that it is used in such an environment.			
Immunity Test	Test level IEC 60601	Compliance level	Environment Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	For 230 Vac / 50Hz ± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	For 230 Vac / 50Hz 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	For 230 Vac / 50Hz ± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

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<p>Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11</p>	<p><5 % <i>UT</i> (dip >95 % in <i>UT</i>) for 0.5 cycle 40 % <i>UT</i> (dip =60 % in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (dip =30 % in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (dip >95 % in <i>UT</i>) for 5 s</p>	<p>For 230 Vac / 50 Hz 0 Vac for 10 ms 92 Vac for 100 ms 161 Vac for 1 s 0 Vac for 5 s</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user of the POSITJET V3 requires continued operation during power mains interruptions, it is recommended that the POSITJET V3 be powered from an uninterruptible power supply or a battery.</p>
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m at 50Hz</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>NOTE: <i>UT</i> is the a.c. mains voltage prior to application of the test level.</p>			



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Table 4 – Guidance and manufacturer’s declaration – electromagnetic immunity – for EM equipment and systems that are not life-supporting

Guidance and manufacturer’s declaration – electromagnetic immunity			
<p>The POSITJET V3 is intended for use in the electromagnetic environment specified below. The customer or the user of the POSITJET V3 should ensure that it is used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V</p> <p>3 V/m</p>	<p>Portable and mobile RF communications should be used no closer to any part of the POSITJET V3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = [1.16] \sqrt[3]{P}$ $d = [1.16] \sqrt[3]{P} \text{ 80 MHz to 800 MHz}$ $d = [2.33] \sqrt[3]{P} \text{ 800 MHz to 2.5 GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (1), should be less than the compliance level in each frequency range (2). Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>(23) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site should be considered. If the measured field strength in the location where the POSITJET V3 is used exceeds the applicable RF compliance level above, the POSITJET V3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the POSITJET V3.</p> <p>(2) Over the frequency range 150 kHz to 80 MHz, field strength should be less than [V1] V/m.</p>			

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Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the EM equipment or system for all EM equipment and systems that are not life supporting

Recommended separation distances between portable and mobile RF communications equipment and the POSITJET V3			
The POSITJET V3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the POSITJET V3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the POSITJET V3 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [1.16] \sqrt{P}$	80 MHz to 800 MHz $d = [1.16] \sqrt{P}$	800 MHz to 2.5 GHz $d = [2.33] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.37
100	11.6	11.6	23.3
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

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The product is tested and validated according to the following test plan:

Phenomena	Environment of an establishment professional care
RF conducted and radiated emissions	CISPR 11 Class A/B * Group 1/2 *
Electrostatic discharge	IEC / EN 61000-4-2 contact ± 8 kV air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV
Radiated EM Fields and Proximity Fields issued by Com devices . wireless RF	IEC / EN 61000-4-3 Discrete frequencies of §8.10 of the 60601-1-2 standard
Magnetic fields to the industrial frequency ASSIGNED	IEC / EN 61000-4-8 30 A/m // 50 Hz
Electrical transients fast / bursts	IEC / EN 61000-4-4 On AC power input -> level ± 2 kV/100 kHz
Conducted disturbances, induced by RF fields	IEC / EN 61000-4-6 6V at discrete frequencies in Table 5 of the 60601-1-2 standard
Hollow of voltage and interruptions of voltage	IEC / EN 61000-4-11 0 % UT; 0,5 cycle 0 % UT; 1 cycle et 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles

XII. Cleaning / Disinfection / Decontamination

XII.1. Daily cleaning (refer to the following procedure proposal)

Parts that are accessible to the user must be cleaned every day using a compress soaked in isopropyl alcohol. The various accessories and guide cones must also be disinfected by soaking in disinfectant baths, in compliance with the applicable procedure in the establishment and cleaned with alcohol before positioned at the start of daily use.

XII.2. Disinfection (refer to the following procedure proposal)

The Posijet® must be disinfected according to the hygiene procedure used in the establishment except for the use of the following products: biguanides; iodised alcohol; strong oxidising agents (such as bleach). It is recommended to use products containing quaternary ammonium and aliphatic amine.

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XII.3. Decontamination

The Posijet® is designed for the injection of Fluorine 18 to a patient. It is a radioactive molecule of energy 511 keV and half-life 1.83 h.

It is a radiopharmaceutical product for very special use, and must be fully under control; it must not be given to anyone without a medical prescription. Even if the quantities used in the the Posijet® are small, there are certain safety rules that must be abided by.

The Posijet® is to be handled exclusively by authorised hospital personnel. The Posijet® must never be open with a radioactive solution inside, when it is outside a hot laboratory (or equivalent secure room).

The operator must put on sterile garments (operating room type) in order not to be a source of contamination and must plan a table covered with sterile drapes nearby.

- Raise the sampling head, open the Posijet® door;
- Take out the removable elements (tungsten container, tungsten needle guide, drip recovery container, etc.);
- Dispose of the kits in a suitable waste bin and lay all of the removed parts on the table;
- Clean with TFD 4 at 10 % (or with TFD foam) then rinse all the inside faces of the Posijet®, including the doors, with demineralised water;
- Clean all of the objects on the table using the same protocol.

FDG has a very short half-life, thus it is possible to let the solution decay for 36 hours before cleaning normally with isopropyl alcohol, provided that the exposure to the leakage is under control.







It is strictly prohibited to spray any disinfectant or decontaminating products whatsoever into the dose calibrator chamber. This could seriously damage the device and correct operation would no longer be guaranteed.

XII.4. Daily hygiene procedure proposal

The hygiene recommendations to be applied when using the Posijet.

- When starting the machine:
 - Clean the machine using a compress and alcohol as follows:
 - Work surface on the head;
 - Worktable (dose calibrator);
 - Screen;
 - Bi-manual command;
 - Wheel control handles;
 - Container support and motorised valve;
 - Then the various components as proposed in the following table:
 -

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<u>Steps</u>	<u>Images</u>
<p>Prepare the accessories near the Posijet, before placing them successively in their final positions, clean them using a compress soaked in alcohol</p>	
<p>If necessary, position the container wedge</p>	
<p>Wearing gloves, place the container in the door after first cleaning the container base.</p>	
<p>Pour alcohol in the top guide cone. Recover the liquid using a compress. Then position the cone in its location, lock it, without touching the central hole through which the needle passes.</p>	

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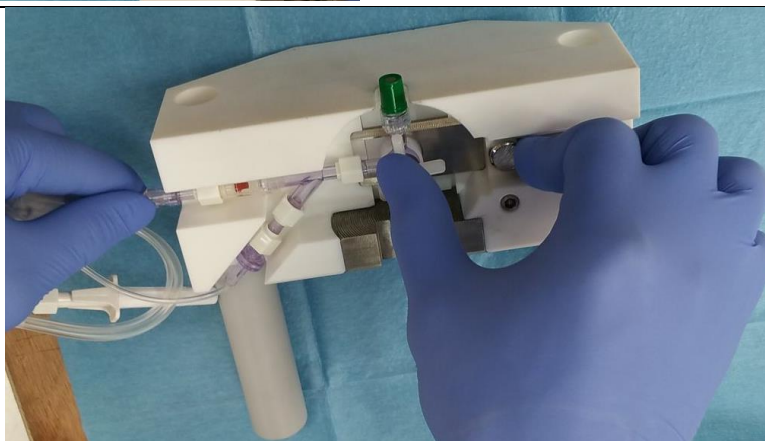
Clean the location of the mother solution kit with alcohol



Connect the needle and the 0.22 µm filter under sterile conditions. Then install the venting kit without removing the needle protection.



Install the MS kit, holding it by the 3-way valve (do not touch the green connector)



Disinfect quickly the guide cone support then the cone by pouring alcohol directly on. Now position the cone in its support without touching the central hole.



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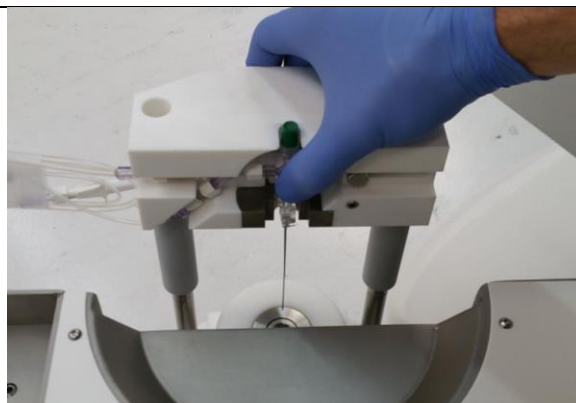
Disinfect the vial septum using a compress soaked in alcohol. A clamp MUST be used to reduce the irradiation at the ends and avoid any contamination. (fast action)
Install the cone support + cone



Remove the 2 needle protections simultaneously without letting anything touch the needles



Connect the MS kit to the vial.
Install the kit holding the 3-way valve when connecting to the vial

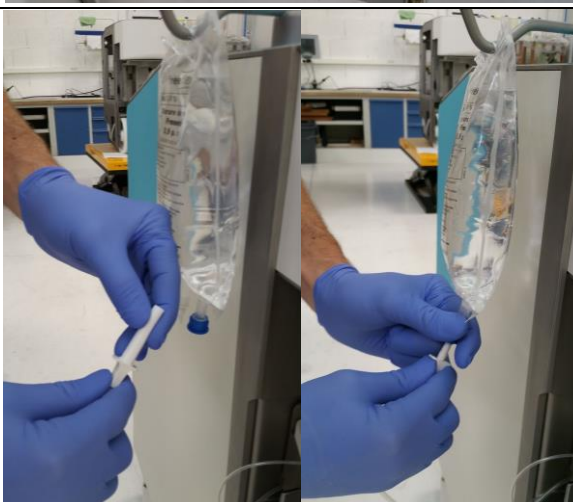


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Install the tubes and position the bionector ready inside the tray.



Remove the protection for the connection with the NaCl bag.
Connect the kit to the NaCl bag straight away

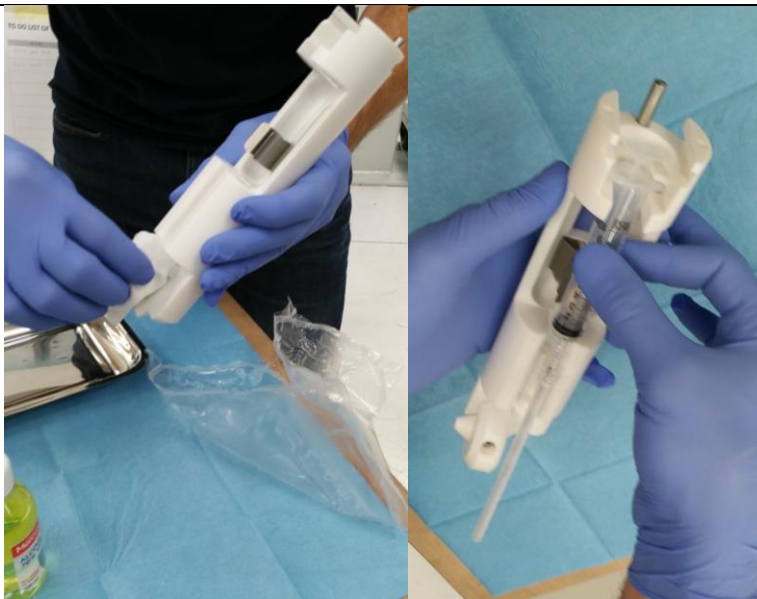


Position the bionector ready for the kit if possible on a piece of drape or compress in the tray to catch any drips after disconnecting the patient kit



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Disinfect the syringe support
lightly before use with a compress
and alcohol.
Position the syringe



Remove the needle protection
Lock the needle without touching
the end.



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Position the syringe support without letting the needle touch the worktable.

Once the head of the device is lowered, position a plate on the sampling head to position the syringes being flushed.



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FLUSH AFTER THE VOLUMIC ACTIVITY CHECK

(Recommended – not mandatory)
Put a cap on the end of the flush syringe



Put the 20 mL syringe in the liquid waste bin (special syringe shield)



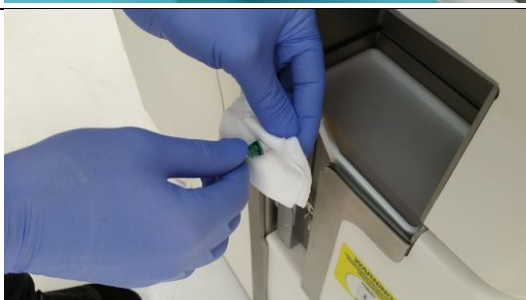
Lock the syringe by screwing the white part holding the piston.








Place the assembly in the plate



Between each connection, it is
MANDATORY to disinfect using a
compress + disinfectant for at
least 20 seconds

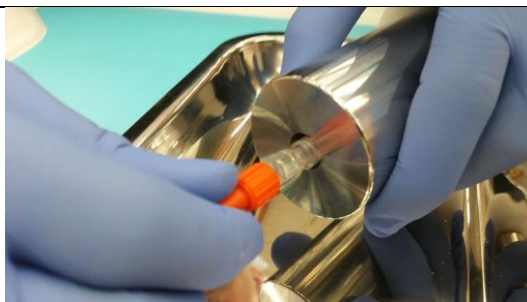


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Connect the patient kit to the mother kit (remove the cap just before making the connection)	
Place the kit ready in the tray on the drape or compress to view and/or catch any leaks	
Connect the kit to the syringe shield	
Put back the assembly in the plate.	
After purging, disconnect the kit from the flush syringe	

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Put back the cap to confine the flush syringe which still contains some activity



Connect as soon as possible to the patient line.



After injecting the patient, disconnect from the patient line (if necessary, use a compress to catch any drips)



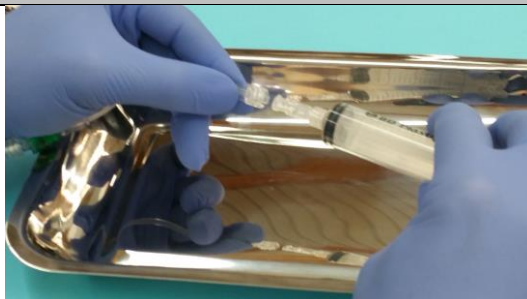
Disconnect the patient kit from the mother solution kit



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FLUSH WITHOUT THE VOLUMIC ACTIVITY CHECK

Connect the syringe directly



Position the flush syringe in the stainless steel plate



UNLOADING

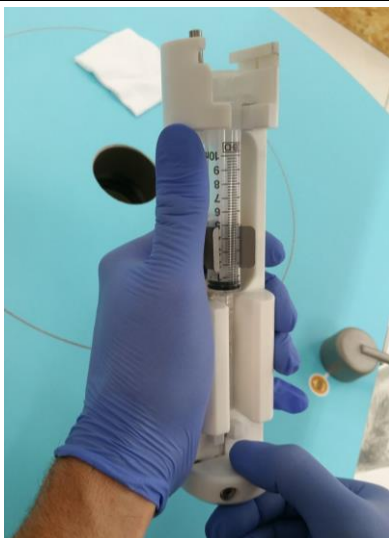
Remove the removable syringe holder, holding the syringe body so that the piston does not get stuck inside the metal support.
 If possible, put a compress or absorbent paper under the dose calibrator to catch any drips.



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Open the needle blocking system.

Remove the syringe body by pressing on the needle to avoid splashing liquid when the needle is removed from the metal clamp.



Remove the removable kit holder and remove the kit and the needles with a clamp.
If possible, put a compress or absorbent paper to catch any drips.



XIII. Personnel training


On receipt of the Posijet®, a Supervisor (= an Administrator) appointed from within the receiving Nuclear Medicine department will be trained by a competent person from the issuing company.

This person will receive the codes for access to the different equipment menus, and will be responsible for their use and distribution. The administrator must be a doctor from the Nuclear Medicine department of the establishment.

The training will familiarise the supervisor with the risks and safety precautions and will constitute qualification to train the users of the Posijet®.

The administrator is also responsible for periodically changing the passwords (in order to prevent any illegitimate or dangerous use of the equipment).

This manual contains the instructions for using the equipment.

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XIV. Checks / Servicing / Maintenance

The Posijet® requires daily and quarterly checks as well as annual preventive maintenance. LEMER PAX cannot be held liable if the annual preventive maintenance described below is not completed.

XIV.1. Maintenance under the responsibility of the user

XIV.1.a. Dose calibrator checks

The “Zero” test measures the background noise of the electronics in the dose calibrator chamber in order to adjust the activity measurements during the measurement process.. This test should be performed every day at the beginning of service before starting an activity measurement.

The high voltage test checks the bias voltage of the dose calibrator chamber. This test should be performed every day at the beginning of service before starting an activity measurement. Any deviation must be within a range of $\pm 10\%$.

The drift of the dose calibrator is measured by comparing the activity displayed to the activity of a radioactive reference source..

The laboratory must have a reference source sealed in a penicillin type vial containing approximately 100 μCi (4 MBq) of Cs 137 or 5.4 mCi (200 MBq) of Co 57.

The activities recorded every day must be within a range of values of $\pm 5\%$ (correcting for the decay of the reference sources which is 0.2% per month for Cs 137 and 7.5% per month for Co 57).

If a slight drift in the dose calibrator’s accuracy is noticed over a period of time, it may be cancelled out by re-calibration of the radionuclide factors. If the drift is significant ($\geq 5\%$), contact your Distributor.

For more information on the dose calibrator, refer to the Scintidose® user manual.

XIV.1.b. Inspection of the equipment

All equipment, accessories and machines must be checked daily. A visual check is sufficient. If you detect the slightest fault or have the slightest doubt regarding one of the accessories, contact Lemer Pax as soon as possible.


XIV.2. Preventive maintenance

Preventive maintenance is annual and must be performed to maintain the performance of Posijet®

The maintenances are described as follows:

- Verification of electrical connections
- Verification of the sampling head
- Check the loading door
- Change of 3-way valve sensors
- Checking the batteries

The following operations are added:

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- Even year: Replacement of air bubble detectors
- Odd year: Verification of the telescopic column

Any preventive maintenance action is performed exclusively by the manufacturer. The user must not under any circumstances carry out a maintenance operation. Maintenance will be the subject of a specific manual accessible only by authorized maintenance personnel.

Note : Maintenance personnel must be qualified and authorized for maintenance operations (electrical authorization, radiation protection authorization, etc.). Constituent components leaving the restricted area for external maintenance shall be subject to a radiation protection check with a certificate of non-radioactive contamination.

XIV.3. Corrective maintenance

All corrective maintenance must be carried out exclusively by the manufacturer. The user must never undertake maintenance. Maintenance will be described in a specific manual that is accessible only to authorised maintenance personnel.

Note

Maintenance personnel must be qualified and accredited to carry out maintenance operations (electrical accreditation, radiation protection accreditation, etc.);

Components removed from the restricted zone for external maintenance must undergo a radiation protection inspection and be issued a certificate stating that they are free from radioactive contamination.

XIV.4. Spare parts


Batteries: 2 technologies:

- Technology 1 : Lead batteries
 - References: PANASONIC battery 12V/38Ah Lead (AGM) MV-P1238APG
 - Replacement frequency: every one year
 - Replacement by Lemer Pax or technician approved by Lemer Pax.
- Technology 2 : Lithium-ion batteries
 - References: NEC ALM 12V35s battery – Lithium-Ion – 13,2 V/462 Wh
 - Replacement frequency: every four years
 - Replacement by Lemer Pax or technician approved by Lemer Pax.


Fuses:

- References:
 - Fuses F1, F2 and F3: T5AL 250V (timer)
 - Fuses F4 and F5: F3.15AL 250V (rapid)
- Replacement by a qualified technician

Power supply cable:

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- Must be replaced if the cable is damaged
- The cable cannot be replaced by the establishment maintenance department. It must only be replaced by Lemer Pax or a technician approved by Lemer Pax
- Maintenance procedures in preventive maintenance ensures the effectiveness of shields and masses;

 **WARNING:** Use of accessories, transducers, and cables other than those specified or supplied by the manufacturer of this equipment may cause increased electromagnetic emissions or decreased immunity of this equipment and cause improper operation.

LEMER PAX cannot guarantee the supply of spare parts beyond 7 years after delivery of the device.

LEMER PAX makes available, upon request, circuit diagrams, component lists, descriptions, calibration instructions or any other useful information to MAINTENANCE PERSONNEL to repair the parts of the Posijet® that LEMER PAX has designated as repairable by MAINTENANCE PERSONNEL.

XV. In case of breakdown

In case of breakdown, contact the Lemer Pax maintenance department for troubleshooting support:

- Email: support@lemerpax.com
- Support: +33 820 205 098

XVI. Disposal

XVI.1. Replacing electric batteries

When the electric accumulators are changed, spent batteries must not be disposed of with the public waste but must be disposed of in accordance with the instructions in force on the site where the product is used. Whatever the case, the accumulators must be returned to the supplier or sent to a specialist company.

XVI.2. Other electric components

Directive 2002/96 dated 27 January 2003 relating to waste from electrical and electronic equipment must be complied with (OJEU dated 13 February 2003).

XVI.3. Contamination of the device

Before discarding all or part of the device, a non-radioactive contamination certificate must be issued by an ASN type inspection organisation or an equivalent. Once the device is decontaminated, contact LEMER PAX.

XVI.4. Used kits (Posikit)

After having been used once, each Posikit becomes an item of hospital waste for disposal by an external company or by local incineration. It must be disposed of in a waste bin that is suitable for radioactive waste.

XVII. Posijet® Breackdown Cases Procedure

XVII.1. Wifi

When the Wifi connection is lost, you can restart it from the mothers solutions selection page.

By clicking on the green or red button



Another way :


1.Go through the Tracability icon from the main menu

2. Identification

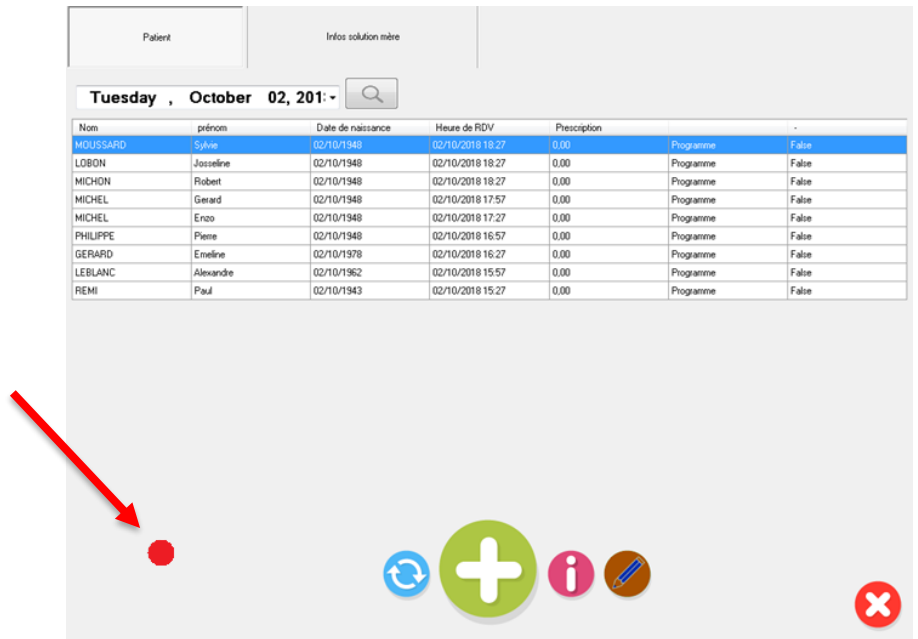


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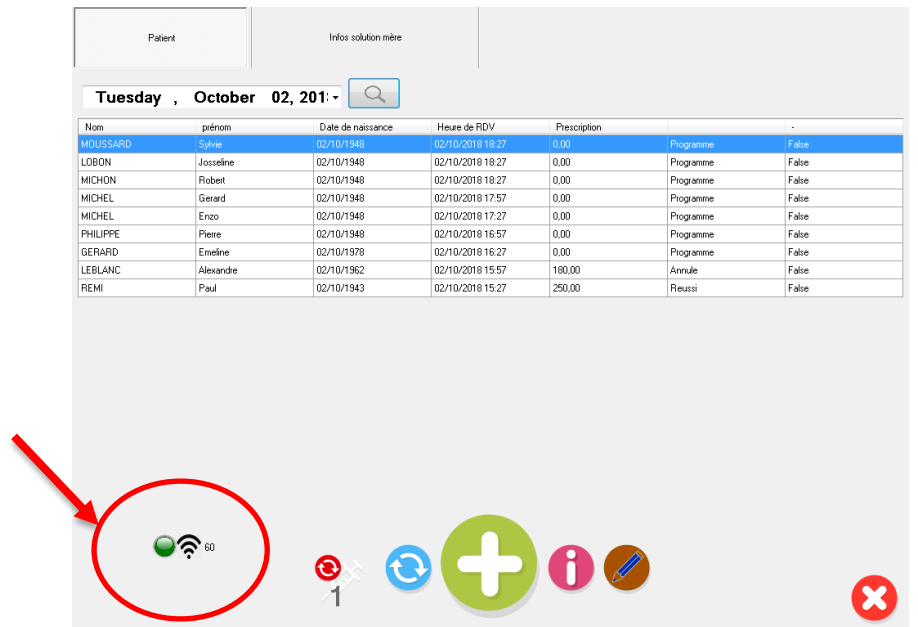
3. Check the wifi light state. (Red connection: off; or Green connection: on)

If it's red  the connection is lost.

To restart the connection, click on the red button (left down corner on the screen).



When the connection is on, the button is green with a percent of network recovering.



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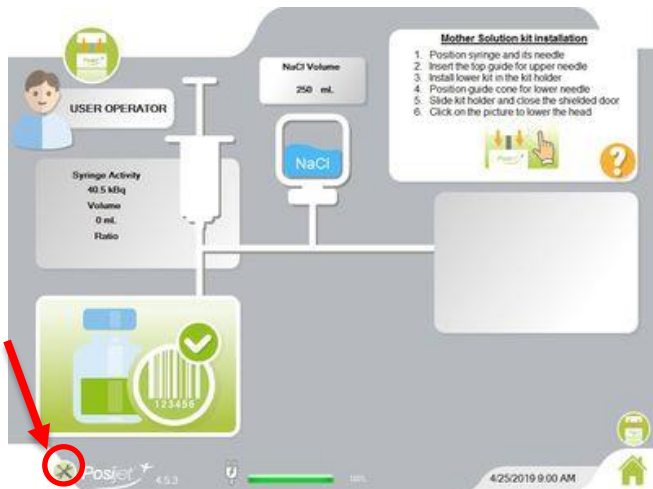
XVII.2. Barcode reader

If the barcode reader is not working during the scanning

1. Click on the red cross



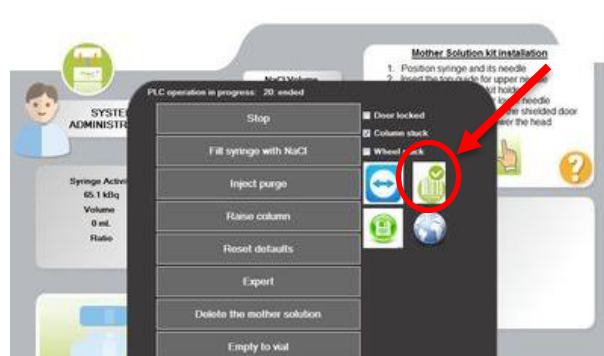
2. Click on the **Utilities** menu shortcut



3. Identification



4. Click on the managing barcode reader button in order to reset it



XVII.3. Volumic Activity Control (VAC)

Note : A minimum activity of 500MBq of the vial is necessary to perform a VAC, please make sure that this activity is **> or equal than 500MBq**. A VAC is taking an average time of 2min, the real time measured activity can be viewed in the follow-up box of the filling of the sampling syringe around **0.7mL**.



It is important to check those points to be sure the activity start indeed to be measured and increased from this 0.7mL volume, it gives an indication of the good connection between all the different elements of the machine.

So from this way operator will be able to interpret easier a failed VAC result.

A normal using VAC result shall be like the picture below.

That means **measured datas by the Posijet®** are with **theoretical informations of the provider**.

In those conditions, operator can click on “Confirm” and continue the normal cycle of use.



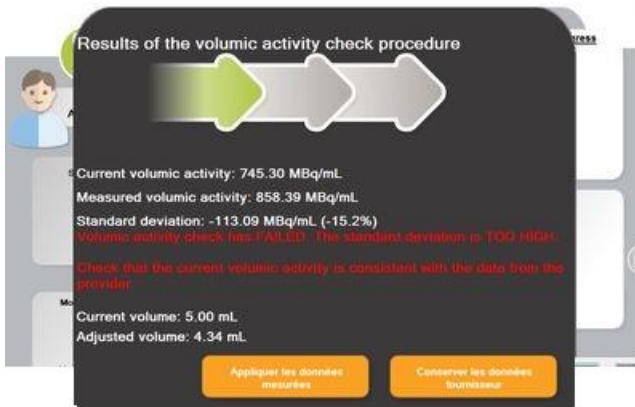
XVII.3.a. Failed VAC case with over threshold value

Means there is inconsistency between provider theoretical values and Posijet® measured datas.

The following actions should be performed in this order:

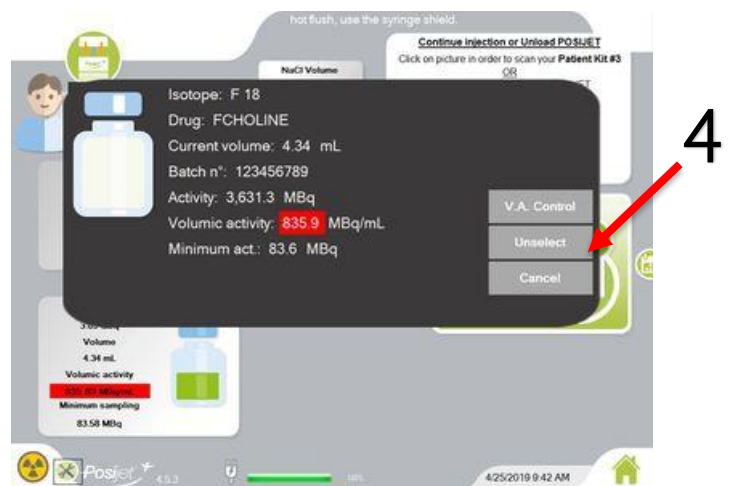
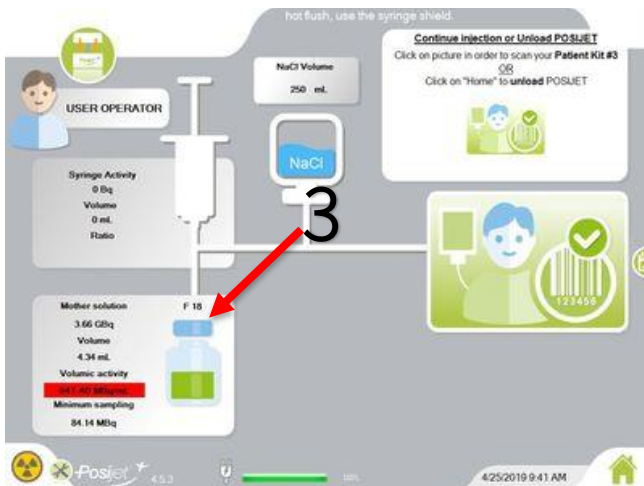
1. Click on "Keep provider data"

2. Click on the red cross to leave the normal cycle of use



3. Click on the vial in the mother solution box in order to verify the information entered

4. In case of error on the information, click on "unselect"



Confirm the unselectioning

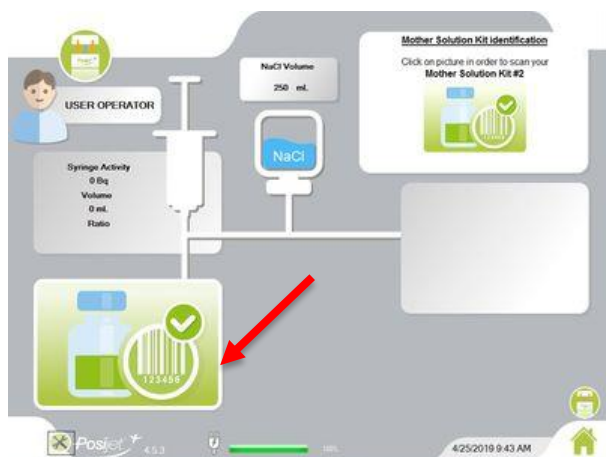
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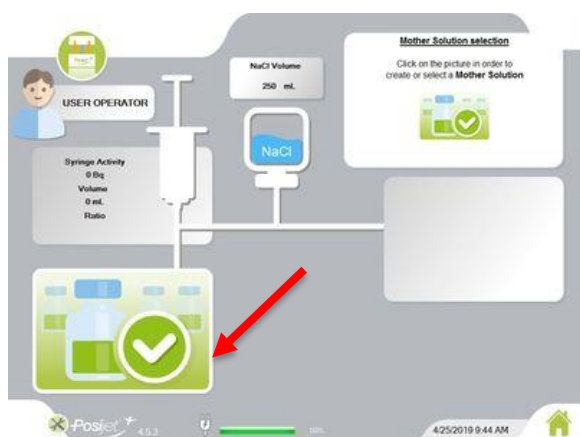
Modify the informations

(Be carefull to errors and confusions between the activity of the vial to the time of calibration of the delivery)

7. Click on the vial

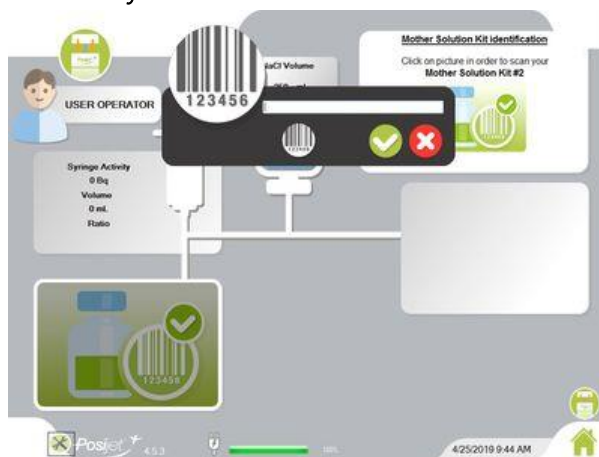


9. Click on the vial



11. Check the informations then « Select » and

8. Identify the mother solution kit one more time



10. Click on synchronize to import the modified Mother solution



12. Restart a VAC by clicking "VA Control"

« Edit » if you need to modify



XVII.3.b. Failed VAC result with threshold near to the value

Subject in advance, to have been able to notice during the CAV procedure that there was indeed a measurement of the activity taken from 0.7mL and then progressively up to about 450MBq (this allows to guarantee to the operator that the connections between all the elements of the machine are functional)

1. It must first be checked that the data entered are correct.
-
2. If everything is correct, it is recommended to proceed a new VAC.
3. If the new VAC result is always over but close to the 20% threshold you will have to choose to select:
 1. Click on « Apply measured data » under responsibility of a referent user then continue a normal using.
 2. Or click on « Keep provider data »

Implies that without the Posijet adjustment, it probably will a difference between the first sampling and the corresponding prescription in case of an activity dosage, the reason is because of a bad estimation of the dead volume.

XVII.3.c. Failed VAC without numeric result:

When the message « Failed VAC » appears, that means the Posijet failed to complete de VAC procesus probably due to

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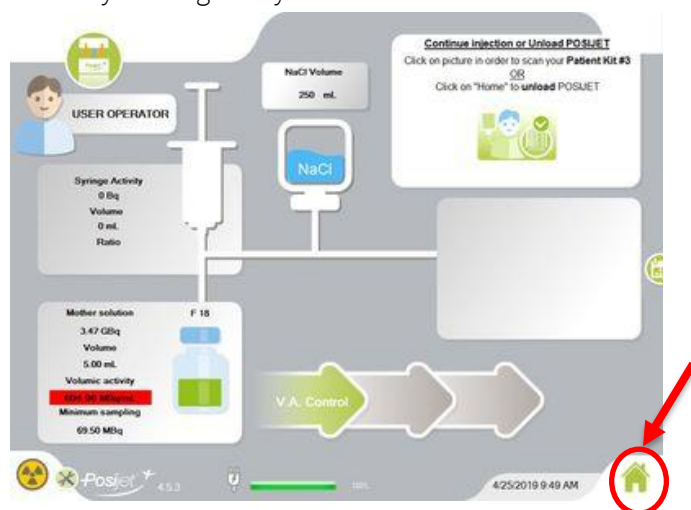
a wrong connection to :

1. Vial connection issue
2. Venting connection issue
3. High cone missing...

An unloading is necessary in order to check mainly the needles and the points mentionned above.



Leave by clicking the cycle « home »



Click on "Unload"



Delete mother solution

Identification

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Click on raising sampling head

Confirm Unload

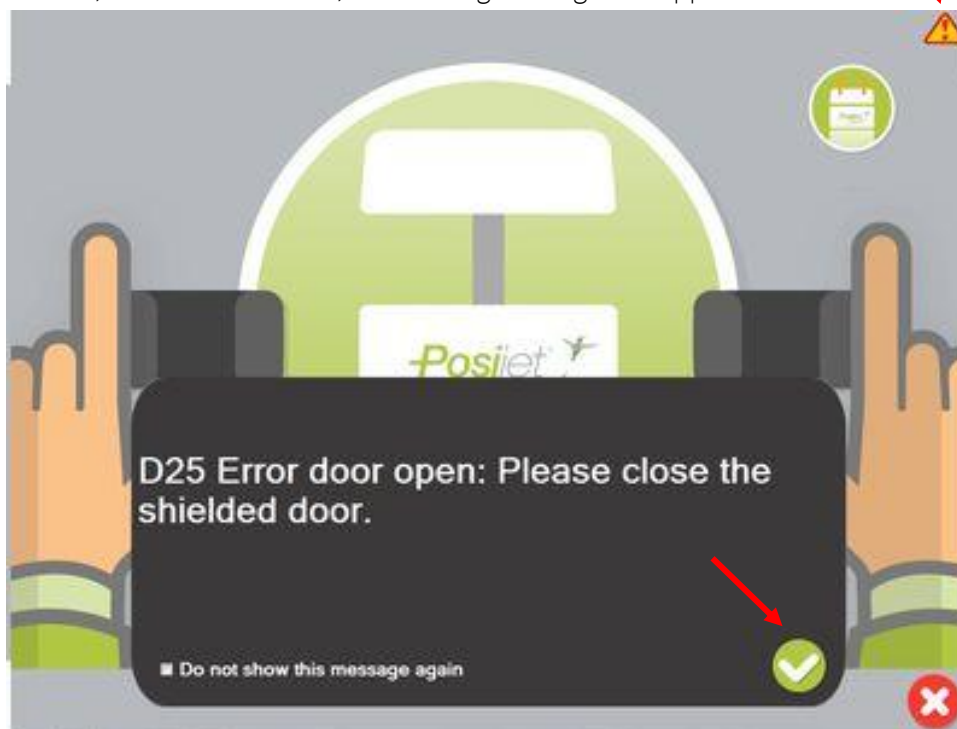


Do not proceed the flush in order to avoid to modify the vial volume used forward.



XVII.4. Failed door closing

When the head is lowered, if the door is closed, the warning message D25 appears.




Just close the door and resume the cycle. (if need, reset the fault at the top right)

XVII.5. Emergency stop

XVII.5.a. General informations

When the emergency stop button is pressed, this implies an instant stop of any movement / action in progress. (In no case this action closes the application).



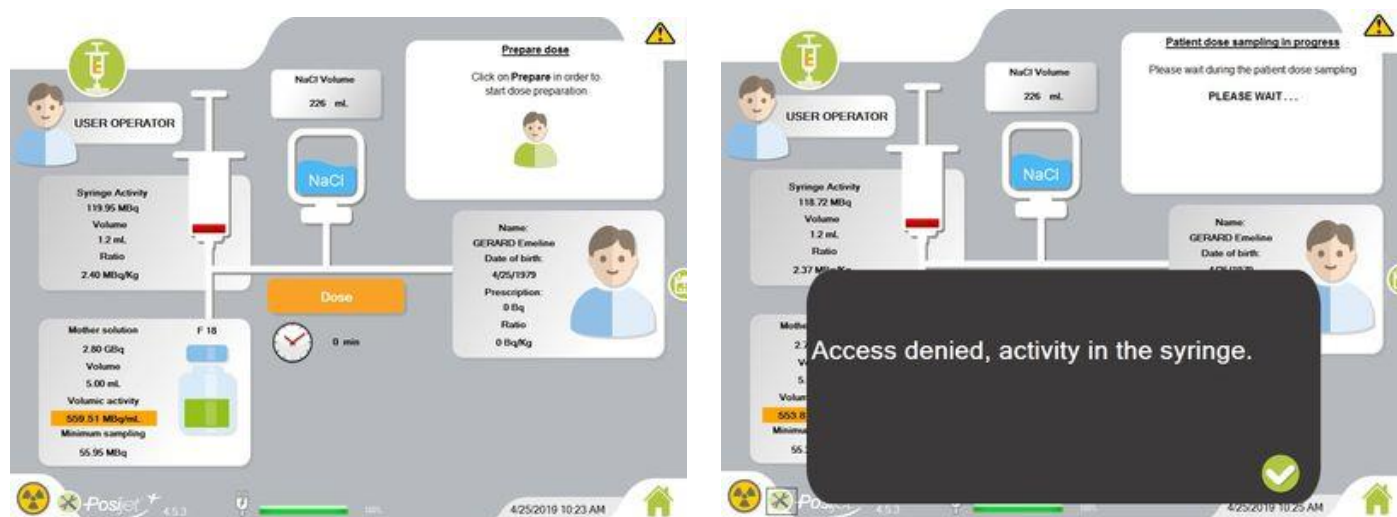
It is advisable to validate the message  then appearing on the screen and to unlock the emergency stop button on the console before resuming the cycle.

(Reset the default if necessary  )

XVII.5.b. Emergency stop during a preparation of a patient dose

If an emergency stop is triggered during patient dosing. The dosage can not be restarted, it will be necessary to transfer the dose.

After having made the recommendations of the paragraph above, and that the user clicks on "Prepare"; proceed as follows.



1. Click on « Utilities » shortcut
2. Connect a flushing syringe positioned in the specific syringe shield.
3. Click on « Inject flush/purge »
4. Manually press the injection piston.



XVII.6. D39 / Injection speed message too low

When this message appears it means that the machine detects a back pressure during an injection. It is important to

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check the injection site of the patient, the tubing Examples: patient moving arm during injection - no patient kit connected - patient's 3-way valve not rotated - pinched tubing - Piston rubber of sampling syringe stuck - venous extravasation (if injection underway) ...

It is common to check the message, identify the cause and solve it then take back the cycle automatically or manually if you prefer.



WARNING : If this message appears during flushing, the Posijet® will automatically switch to manual mode so you will need:

1. Click on the "Flush" button
2. Press directly on the injection piston to finish flushing as soon as the piston is released.
(indication: a sound clack will sound as soon as the piston is free)

If you want to go back to automatic mode you have to click on "Auto" before restarting "Flush"

XVII.7. Air detection case in the tubing

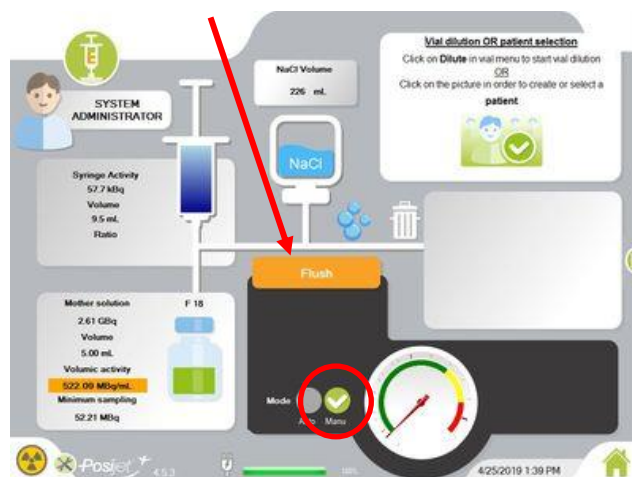
XVII.7.a. During Flush

If an air volume > 300µl is detected during flushing then the message below accompanied by its

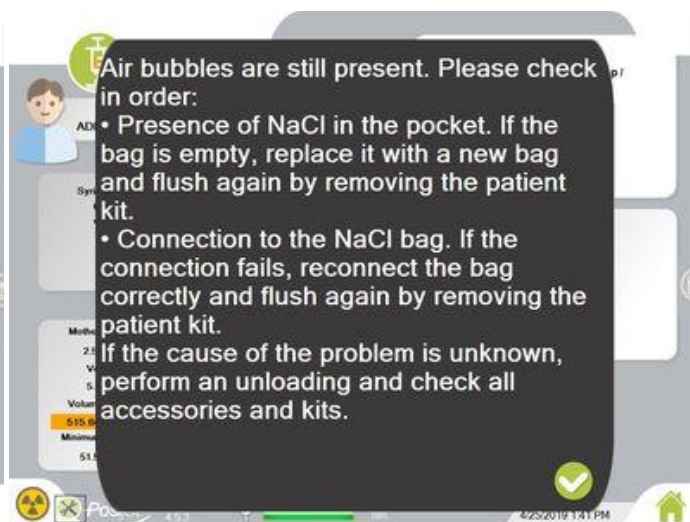


indicator appears in the application. That means it's necessary to follow the indications of the message. (you must also visually check for bubbles in the tubing)

CAUTION: The flush is automatically switches to manual mode. (press on «Flush» then on the injection piston as soon as it is unlocked)



If the air bubble indicator remains displayed it means that the problem is still present. Follow the recommendations of the message in order.



If no bubbles are visible, the connection to the bag of non-empty NaCl is effective and operational, and visually the operator ensures that there is no stress on the tubing, it is imperative unloading to check the correct position of the tubing in the air bubble detector as shown in the photo below:

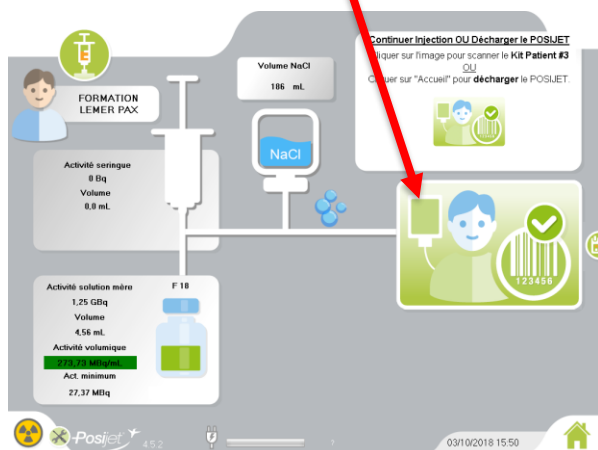


In the case of the need to discard the patient kit:

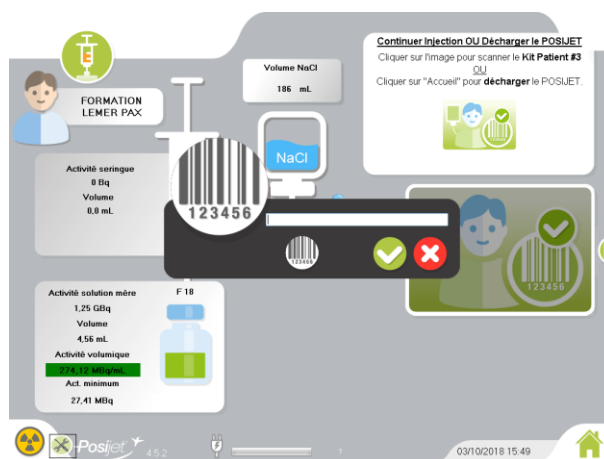
Click on the trash



Click on the patient file

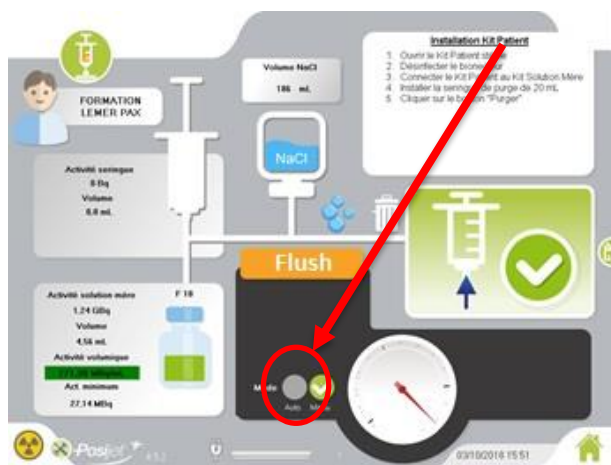


Scan a new kit



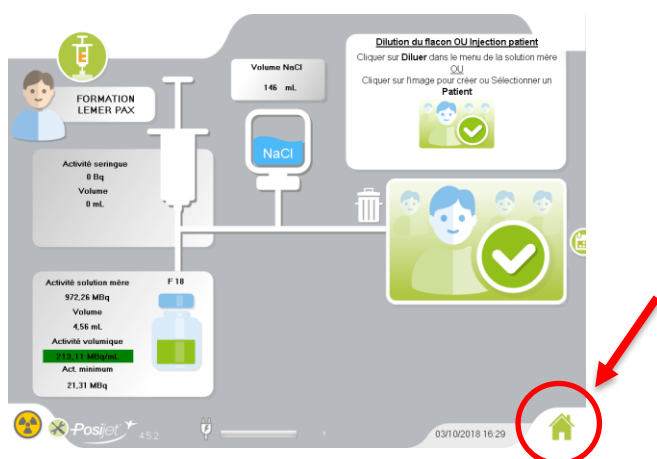
Be careful to switch back to Automatic mode before restarting a new flush or to proceed manually.

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In the case of the need for unloading to verify that the tubing is well positioned in the air bubble sensor.

Click on Home «button»



Click on unloading and proceed as usually



XVII.7.b. During injection

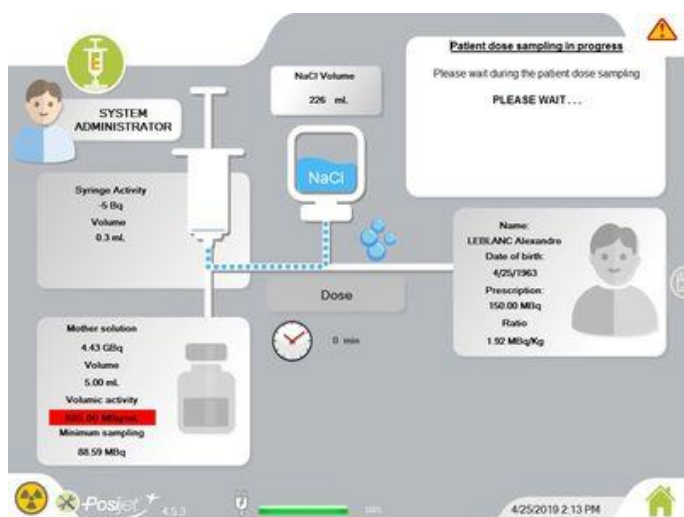
In the case where the operator does not follow the recommendations, there is a high risk of obtaining a dosage inconsistent with the prescription and / or not being able to inject the prepared dose.

Lemer Pax strongly recommends not to continue and proceed with the unloading and verification of the presence of the tubing in the air bubble detector as indicated above.

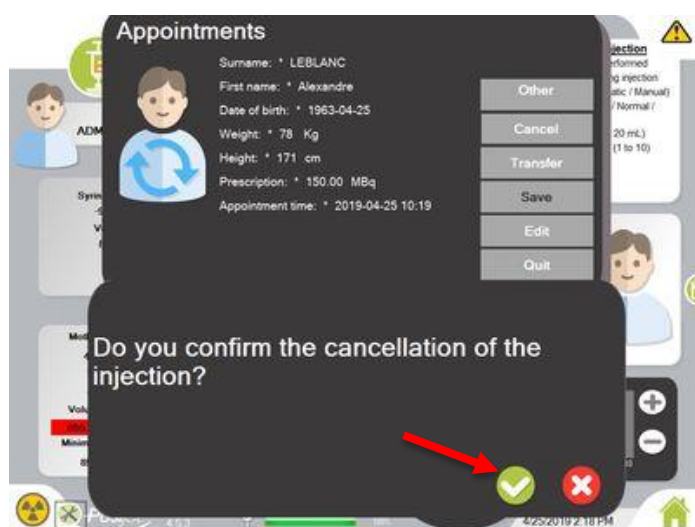
The Posijet will make a new alert that only an administrator password can pass.



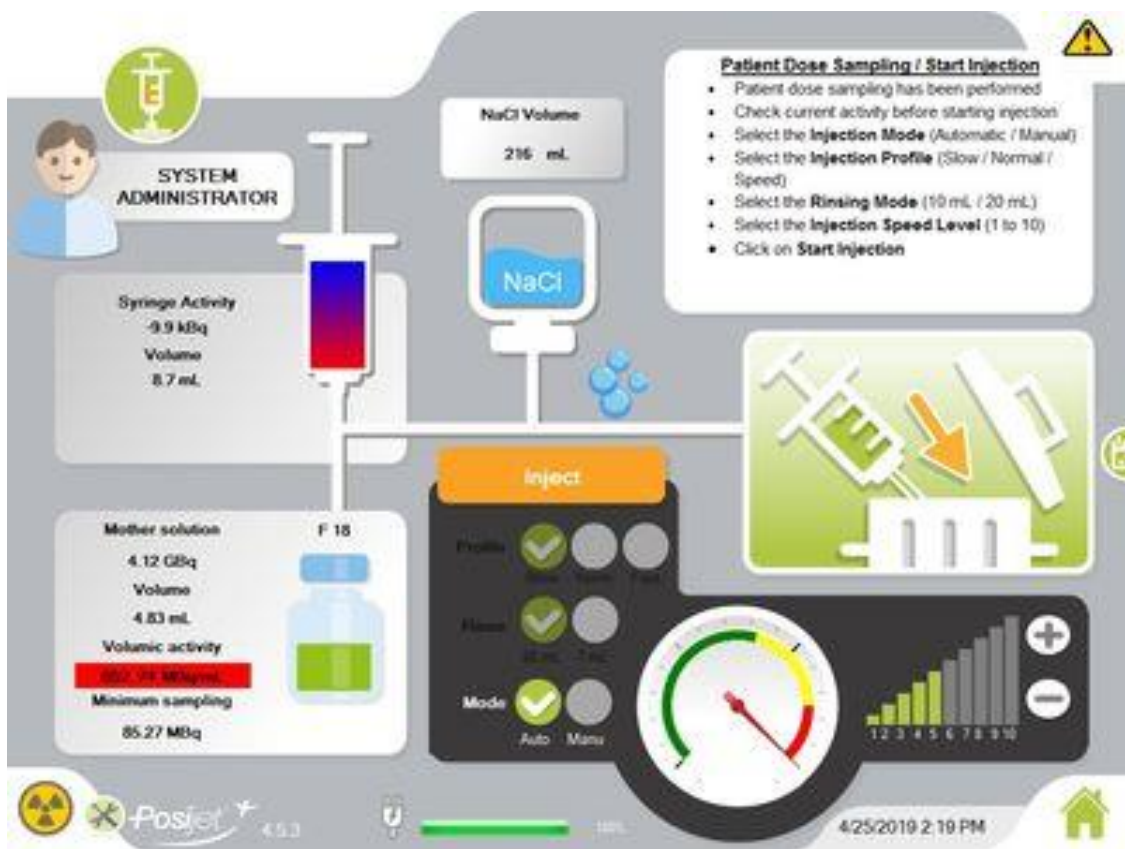
New alerts will follow each other, preventing the injection



Click on the patient and select « Cancel » then confirm



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Unfasten the patient kit and connect it to the specific syringe protector to transfer the dose before clicking on "Inject"



Validate and disassemble the syringe protector of the patient kit and set the syringe + syringe

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protector decreasing.

A label with the informations of the syringe is printed

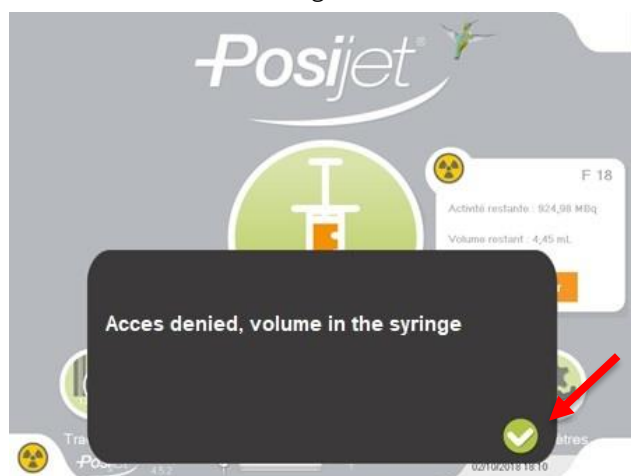


XVII.8. Non empty syringe

During an unloading request, it is possible to have the "non-empty syringe" warning message, if the previous injection was not completed completely; or if there is activity left in the collection syringe.

It is then necessary to derive the liquid present in a purge syringe previously inserted into the specific syringe protector.

1. Confirm the message



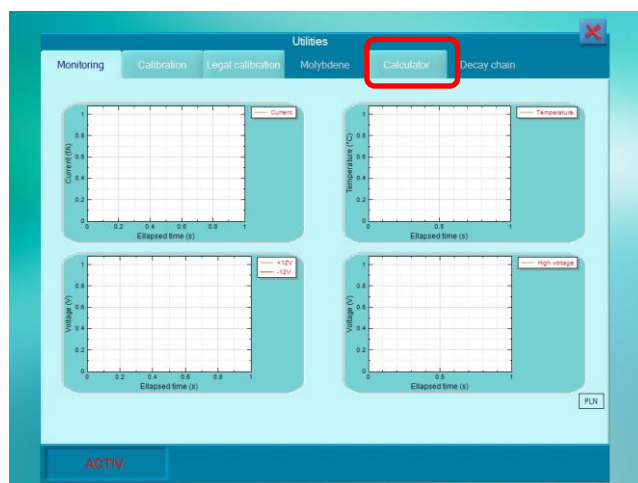
2. Click on « Utilities»



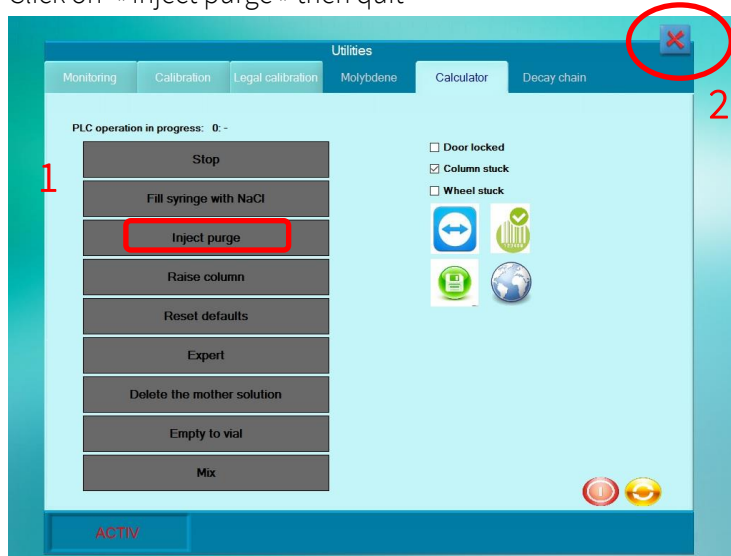
3. Login

4. Click on « Calculator »

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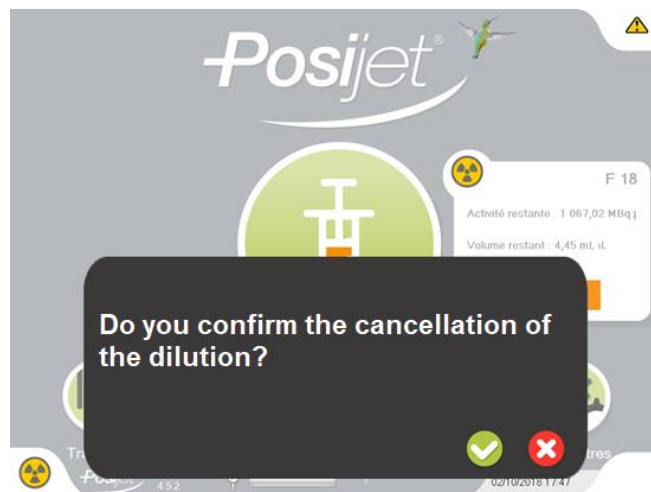


5. Click on « Inject purge » then quit



If a non-negligible residual activity remains on the screen, it is preferable to carry out the actions "Fill syringe with NaCl" and then "Inject purge" again in the PLC menu.

XVII.9. Delete a mother solution



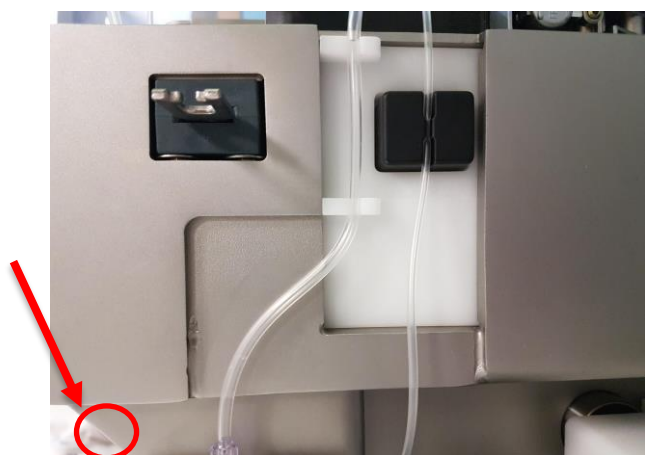
When we validate the message of suppression of the mother solution it will no longer be active in the application but information about it (volume, activity) will be saved so that we can reselect it in the list of mother solution where appropriate. The information will be kept up to date.

XVII.10. « Utilities » & « Calculator » menu

There is functionality differences between the shortcut available into the injection menu and the main menu icon

XVII.10.a. During a cycle

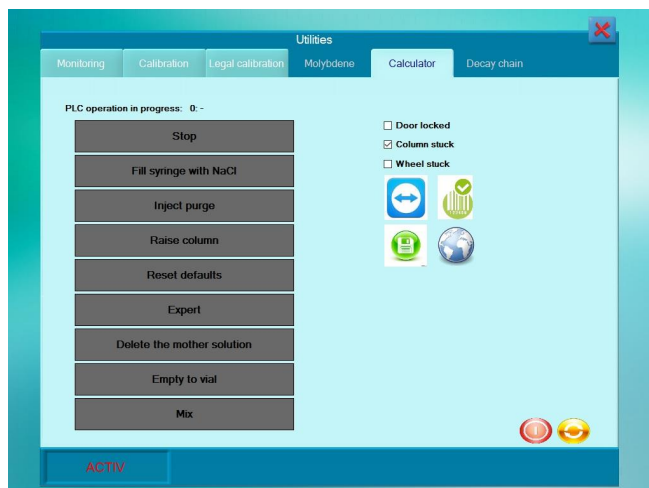
Clicking on the shortcut displays the "Calculator" menu.



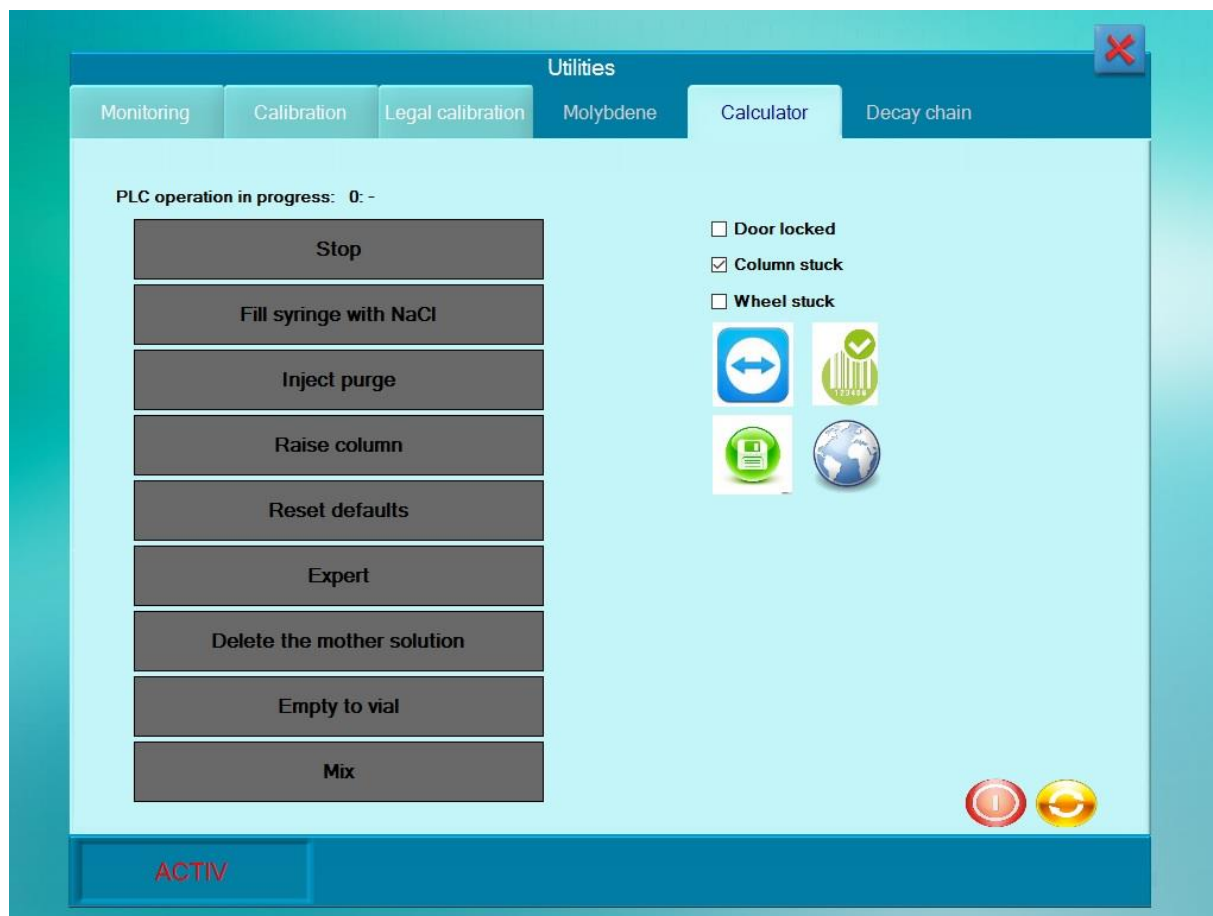
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XVII.10.b. Main menu

Clicking the "Utilities" icon from the main menu allows full access to the features of the "Calculator" tab



XVII.11. Calculator features



XVII.11.a. « Stop »

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Click stop allows to stop all underway actions

XVII.11.b. « Fill syringe with saline »

Clicking on this command automatically allows to fill the saline syringe, this can be indicated for example:

- When the operator wants to rinse the syringe when he has the message "Syringe not empty"

XVII.11.c. « Inject purge »

Clicking on this command allows you to derive the content of the sampling syringe and thus be able to empty it into a purge syringe when the operator is locked in the cycle.

This command can be useful for example:

- When the syringe is not empty
- When there is still activity in the sampling syringe

Attention this action will be carried out manually (= by pressing directly on the piston)

XVII.11.d. « Raise column »

This command may be required when the Posijet® refuses to raise the sampling head during unloading, for example. It is first necessary to check that there is no activity in the sampling syringe.

(If "activity" or "syringe not empty" perform the procedure above at first)

<input type="checkbox"/>	Door locked
<input checked="" type="checkbox"/>	Column stuck
<input type="checkbox"/>	Wheel stuck

Then you must uncheck "blocked column" on the right of the screen to allow movement

Then click on « Raise column »


XVII.11.e. Column lowering


To go back down the column in degraded mode, you have to uncheck "blocked column" then activate the two-hand controls by positioning the 2 simultaneous fingers on them in order to trigger the movement.

XVII.11.f. « Reset defaults »

This command is used to erase faults that persist in the application and can not be erased with the normal fault

acknowledgment procedure:  .

Simply click directly on the "Reset defects" command and the attention sign  must disappear at the top right of the application screen.

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XVII.11.g. « Expert »

This command opens the maintenance menu of the machine, only Lemer Pax technicians are allowed to use this menu. **The only possible exception, if the technician Lemer Pax accompanies the operator in this menu during a remote intervention.**

XVII.11.h. Delete vial»

This command is requested and required if the machine is degraded due to malfunction:

- During a Posijet® remote acces.
- When vendor information from the solution is inaccurate and caused a CAV with an out-of-threshold / standard value.
- This means that the mother solution selected will no longer be active.
It will then be necessary to identify the mother silution kit again and choose a stock solution.

XVII.11.i. « Empty Vial »

CAUTION this action can have serious consequences since it means that the contents of the sample syringe will be pushed all the way to the mother solution vial (**without** automatic updating of the mother solution data).

It is best to have Lemer pax support before initiating this action.

To perform this movement, press the Posijet® injection piston manually.

XVII.11.j. « MIX »

This feature allows you to homogenize the liquid from the mother solution vial, it is recommended and useful only after dilution.

The Posijet performs automatically and successively samples and reintroductions of liquid from the vial in order to mix the NaCl and radiopharmaceutical well after dilution.

XVII.11.k. Remote maintenance

If the feature is not active for you because it is not allowed by your computer network service. In your case, for a remote start please contact the support by phone at 0 820 205 098 and hold the posijet lit.

XVII.11.l. Logs and back up

When a functioning analysis is required you have to do a back up or recording of the Logs files, for that it is advisable to:

1. Click on  .

2. Then confirm by clicking on « yes »
3. Place a USB disk or save on the disk (D :)
4. Click on OK
5. Wait “back up ended” or “back up terminé” messages
6. Send the Zip file by mail at support@lemerpax.com

XVII.11.m. Web app



Click on this icon allows to connect to the Web application directly.
Then just enter his Login and password to connect.

XVII.11.n. Bar code reader



Icon resets the bar code reader if it does not turn on when scanning the mother solution kit or patient kit.

XVII.11.o. Unlocking access door solution mother

To unlock the access door to the mother solution in the event of an unloading blockage, for example, simply uncheck "Door locked" to be able to open the door.

☐ **Door locked**

☒ **Column stuck**


☐ **Wheel stuck**

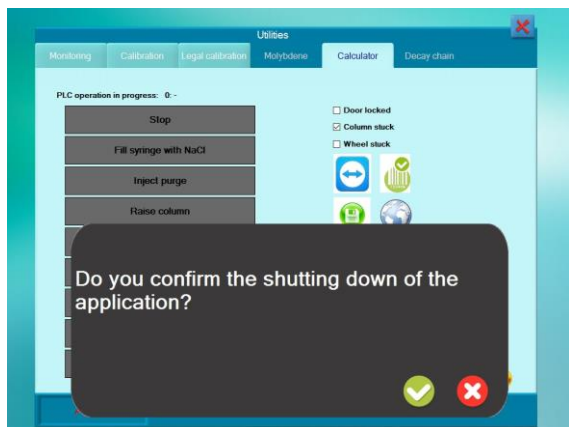
XVII.11.p. « Column stuck bloquée »

When you want to force the descent or lifting movement of the Posijet® pick-up head, you must first uncheck "Colonne bloquée" in order to allow degraded movements.

XVII.11.q. Application shut down




Click on this Icon  then confirm the order. The application will shut down.



XVII.11.r. Application restart



After an extinction of the application just restart the LpDose program 

If a restart  was requested, the application will restart automatically.

XVII.12. Application Restart

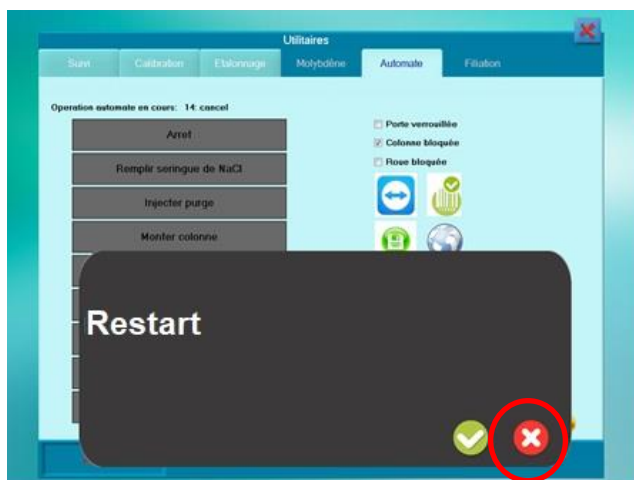
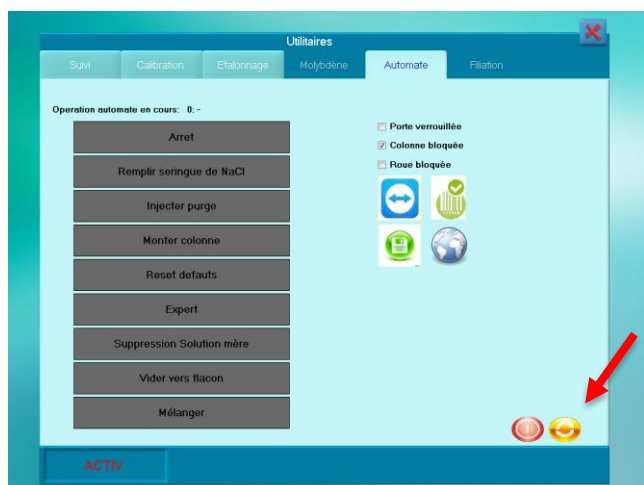
Upon the occurrence of a problem requiring Lemer Pax telephone intervention, it is possible that the technician Lemer Pax asks the operator to restart the application under his supervision.

It is then recommended to proceed as follows:

Click « home »  if during the cycle. Then click on the "Utilities" menu .
Then click on « Calculator » tab

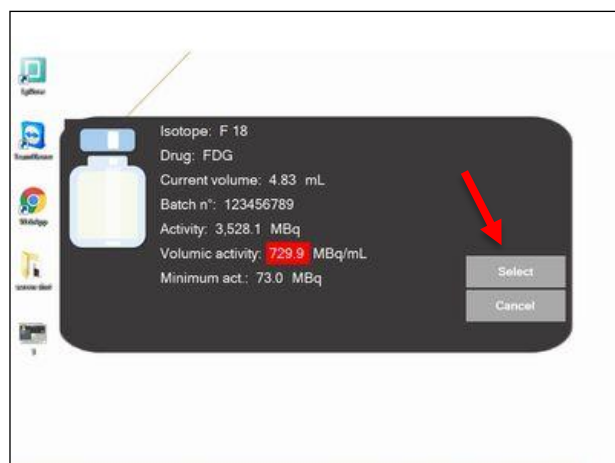
Click on the restart icon at the bottom right of the screen. 

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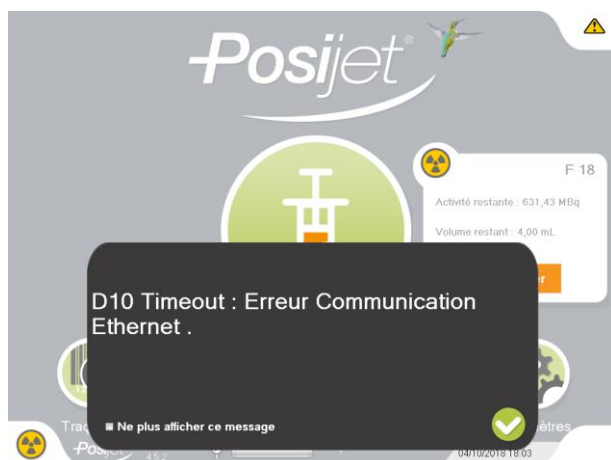
Posijet® automatically restarts the application.

If a stock solution is loaded the message below will be displayed. To continue using this solution, simply click on "Select". Thus the information will be automatically reloaded in the application.



It will be necessary to acknowledge the message D10 which informs the operator of the loss of communication

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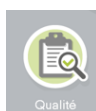


between the PLC and the machine normally occurring when the application was shut down or restarted.

XVII.13. Problem of Zero

It can happen that the Posijet® alerts on problems of zero. Potentially due to a zero shift following, for example the realization of several CAV in successive failures.

Then you have to go to home menu  . Then Quality.



- Click on « Control »
- Click on « Zero »
- Return to the cycle

XVII.14. Patient file and features



When a dose has been prepared for a patient and injection is not possible, several actions are possible:

XVII.15. Reassignment of a dose already prepared "Other RDV"

Clicking on "Other appointment" allows the operator to access the planning and:

- Reassign the already prepared dose if the injection to the initial patient is canceled and the same dose corresponds (in activity and weight) to another patient.
- Select another patient in the planning if the patient initially selected is not the right one

XVII.16. Cancelling an injection with the "canceled" tab



When you click on "Canceled", the Posijet® goes into "throw syringe" mode

This means that the prepared dose of radiopharmaceutical will be derived in a purged syringe and no longer injected into a patient.

This function is required when a prepared dose can not be assigned to any patient in the schedule.

It is then necessary to connect a purge syringe inserted in the specific syringe protector before clicking on "inject".

A single rinse will be automatically performed after the injection of the dose, to take into account the capacity of 20mL of the purging syringe.

At the end of the injection, a label with the wording "purge" will be printed including the indications of activity, volume, and radiopharmaceutical.

XVII.17. Editing patient record data

Any modification of the patient card (identity, date of birth) must be made in the radiopharmacy software and then imported on the Posijet® by synchronization.

Nevertheless it is possible to modify locally (= directly in the application of the Posijet®) information of weight, size and prescription. However, it is preferable, in order to ensure perfect traceability of the data to make these changes in the radiopharmacy software also beforehand and then synchronize the patient record before selecting a patient.

However, any modification made locally, if necessary, must be recorded before clicking on the "select" tab for the changes to be effective.

XVII.18. Vial measurement or end of vial test

When the user arrives at the end of the vial (vial activity $\leq 500\text{MBq}$) it is possible to ask the Posijet® to measure the total activity of the vial and thus to be able to support which dose can be taken.

For that it is necessary :


- Click on the vial in the mother solution box at the bottom left of the application screen.
- Choose "Vial Measurement" from the menu that appears
Then Confirm the message

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Posijet® will perform a sampling and an instantaneous measurement of the total volume of the vial then it will modify the mother solution data accordingly.

IMPORTANT: When the dose is taken afterwards, it is imperative that the prescription be \leq to the activity measured during the end-of-vial measurement operation, otherwise the operator will be exposed to a failure of sampling, in particular because during a sampling "in activity" the setting of the Posijet® is to reach: the prescription + 5MBq. It is therefore necessary to take this point into account when requesting the last dosage of a vial.

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XVIII. Version history

Version	Date	History
(1) May 2016	27/05/2016	<ul style="list-style-type: none"> First issue (from software version LPDose V420)
(2) July 2016	02/07/2016	<ul style="list-style-type: none"> Update related to changes to the LPDose V427 software (see release note)
(3) September 2016	20/09/2016	<ul style="list-style-type: none"> Update related to changes to the LPDose V430 software (see release note) Addition of recommendations concerning daily cleaning
(4) April 2017	06/04/2017	<ul style="list-style-type: none"> Update related to changes to the LPDose V435 software (see release note)
(5) September 2017	07/09/2017	<ul style="list-style-type: none"> Changing the battery characteristics Minor changes to the document layout Modification of the aseptic conditions for the guide cones
(6) June 2018	05/06/2018	<ul style="list-style-type: none"> Update related to changes to the LPDose V450 software (see release note)
(7) September 2018	01/09/2018	<ul style="list-style-type: none"> Update related to changes to the LPDose V452 software
(8) January 2019	01/2019	<ul style="list-style-type: none"> Addition of degraded cases
(9) March 2019	03/2019	<ul style="list-style-type: none"> Update related to changes to the LPDose V456 software (dedicated version isotopes of short periods : Ammonia Variant) EMC Compliance
(10) June 2021	06/2021	<ul style="list-style-type: none"> Details of the calibration method
(11) April 2022	04/2022	<ul style="list-style-type: none"> Compliance with MDR 2017/745
(12) May 2022	27/05/2022	<ul style="list-style-type: none"> Compliance with 60601-1
(13) May 2022	31/05/2022	<ul style="list-style-type: none"> Add IT Networks risk
(14) June 2022	01/06/2022	<ul style="list-style-type: none"> Update claimed use
(15) Janvier 2023	11/01/2023	<ul style="list-style-type: none"> Population limitation, addition of side effects, alignment of characteristics with data sheet Description of Posijet in preparation mode only (chap. VIII)
(16) July 2023	04/07/2023	<ul style="list-style-type: none"> Description of Posijet for therapeutic mode
(16-1) June 2024	19/06/2024	<ul style="list-style-type: none"> Update external dimensions

NOTES :

[illegible]