



OUR VISION FOR DESIGN

The **Scintidose dose calibrator** was designed to provide **reliability** and **safety** for both patients and users. The choice of materials, the **precision of the electrometer** and the **guarantee of a long-lasting leak-free seal**, have made it possible to achieve this high-performance objective.

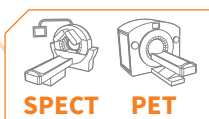
The **user-friendly and intuitive LPDose application** provides users with safe and comfortable daily working conditions.



SCINTIDOSE DOSE CALIBRATOR

MEASURING DEVICE FOR LOW, MEDIUM AND HIGH ACTIVITIES

ALL ENERGIES





The **Scintidose dose calibrator** is a **measuring device** designed for the measurement of radioisotope activities of **all energies**. It can be integrated into manual and automatic preparation equipment such as shielded hot cells, benchtops or L-Block with an adaptable sample dipper and removable lining. Its **very broad energy range from 25 KeV to 3 MeV**, as well as its **theoretical measurement range from 4 kBq to 4 TBq (for ¹⁸F)**, allow for **extensive use** in **SPECT** and **PET** activities. **The 3 mm lead shield built into** the ionisation chamber for the standard model ensures that background noise is kept to a minimum.

The **LPDose software** supplied with the dose calibrator, features all the necessary functionalities and is **easy to use for precise and accurate applications**. It mainly allows for **regulatory quality control, calibration of multiple radioisotopes, dose measurement** according to their packaging and **synchronisation with radiopharmacy software for improved traceability**.

FOCUS

[1] The very high sensitivity ($I \geq 15fA$) **shielded ionisation chamber** incorporates an electrometer which allows the measurement and digitisation of the amount of current received. It is also equipped with a removable protective liner placed inside the detector to prevent accidental contamination.

The **isosensitivity zone** is 7 cm for the Standard version. The Scintidose dose calibrator is also available in a 2/3 chamber version [5] when embedded in equipment such as the Posijet® preparation and injection unit and the Easypet shielded hot cell. In this case, a volume calibration algorithm also ensures measurement accuracy beyond the 3.5 cm isosensitivity zone.



[2] The **sample dipper** made of natural POM can hold syringes and vials. It is compatible with the optional "Posilift" foot-operated pneumatic raising and lowering system, for a significant reduction in exposure to users' hands and fingers.



[3] The integrated **Posibox computer** allows to run the LPDose user interface. It is equipped with the necessary safety features for integration into a hospital network.

[4] The **LPDose application** is configurable according to isotope requirements. The **diversity of the menus** and the display have been designed to provide the user with a **simple and functional** device.

In order to guarantee **full and secure traceability** of information concerning the radiopharmaceuticals, Lemer Pax proposes **a configurable interface between the LPDose application and the radiopharmacy software** used by the service. This connection enables the exchange of radiopharmaceutical stock solutions, patient appointments or worklists, **real-time measurements** and prepared doses between the two systems. Software compatible with this **two-way communication interface** includes: Venus (Nicesoft), PharmaManager (Softway Medical), Gera (Thélème) and Xplore (EDL).

[6] The **Dymo 550 printer** is fully compatible with the LPDose application and the label content can be configured to the users' needs.

REGULATORY FRAMEWORK

The Scintidose dose calibrator meets the requirements of **EU regulation 2017/745** as a **Class I medical device** for the measurement function. Electromedical device, compliant with **EN 60601-1:2006 (+ A1/2013)** for general safety requirements, **EN 60601-1-2:2015** for electromagnetic compatibility, **EN 60601-1-6:2010 (+ A1/2015)** and **EN 62366: 2015 (+ A1/2020)** for application of usability engineering to medical devices. The control software for the LPDose dose calibrator meets the requirements of **EN 62304:2006 (+ A1/2018)** for the software life cycle process.

This software features inspection functions regulated by the **French decree of 25 November 2008** and **international standard IEC 61948-4**.

Calibration and Presetting:

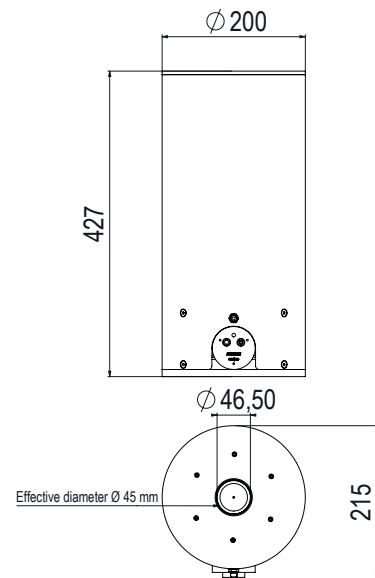
A factory calibration of ^{99m}Tc , ^{201}Tl , ^{67}Ga , ^{111}In , ^{123}I , ^{18}F radioisotopes for BD plastipak 2 mL syringe packs and for CIS bio vials is built into the software by default. The Scintidose dose calibrator can also be calibrated on site by the Medical Physics Department of the hospital. Calibration by a certified body can be carried out in accordance with the requirements of the **COFRAC ISO 17025 accreditation standard** as an option.

CHARACTERISTICS

| General |
|--|
| External dimensions: Ø 200 x H 427 mm |
| Inner Ø: 46,5 mm |
| Possible Ø of the sample: 40 mm |
| Weight: 20,5 kg |
| Standard equipment: Standard ionisation chamber Posibox Standard LCD screen Wireless keyboard + mouse Dymo label printer |
| Measurable energy range: 25 KeV to 3 MeV |
| Measurement stability: ≥ 99% |
| Measurement accuracy: ≥ 95% |
| Filling gas: argon (99%) |
| Operating temperature: 10°C to 45°C |
| Linearity: < 5 % (over the operating range of the dose calibrator) |
| Overall accuracy: +/- 2% |
| Response time: 1 to 7 s |
| Isosensitivity zone at 2 %: Total height 70 mm |
| Theoretical measurement range 4 kBq - 4 000 GBq (^{99m}Tc) 2 kBq - 2 000 GBq (^{18}F) |
| Repeatability (relative standard deviation/mean): ≤ ± 0,2% |
| Reproducibility (relative standard deviation/mean): ≤ ± 1% |
| Shielding: 3 mm of lead |

| Computer platform |
|--|
| Posibox computer: Intel® Celeron® J1900 Quad Core 2.0 GHz RAM 4GB 100 V ~ 240 V / 50 ~ 60 Hz Medical power supply 60601-1-2 |
| Connectivity: 4 COM ports / 5 USB 2.0 ports / 1 USB 3.0 port / 2 Ethernet 10-100 ports / VGA Out / HDMI Out / Audio Line-out, Mic-in, Line-in |
| Operating system: Windows 10 |
| Package |
| Package dimensions: L 780 x D 480 x H 680 mm |
| Package weight (product without options): 60 kg |

EFFECTIVE DIMENSIONS (mm)



Ref.:

| | |
|-----------------------|--|
| 00031601_CA_SA | SCINTIDOSE STD dose calibrator - Calibrated - Std screen -AZERTY |
| 00031601_CA_SQ | SCINTIDOSE STD dose calibrator - Calibrated - Std screen -QWERTY |
| 00031601_CA_SS | SCINTIDOSE STD dose calibrator - Calibrated - Std screen - SPANISH |
| 00031601_CA_TA | SCINTIDOSE STD dose calibrator - Calibrated - Touchscreen -AZERTY |
| 00031601_CA_TQ | SCINTIDOSE STD dose calibrator - Calibrated - Touchscreen -QWERTY |
| 00031601_CAL | SCINTIDOSE STD chamber dose calibrator - Calibrated - without screen or keyboard |
| 00031601_ET | SCINTIDOSE STD chamber dose calibrator - Adjusted - without screen or keyboard |
| 00031601_ET_SA | SCINTIDOSE STD dose calibrator - Adjusted - Std screen -AZERTY |
| 00031601_ET_SQ | SCINTIDOSE STD dose calibrator - Adjusted - Std screen -QWERTY |
| 00031601_ET_TA | SCINTIDOSE STD dose calibrator - Adjusted - Touchscreen-AZERTY |
| 00031601_ET_TQ | SCINTIDOSE STD dose calibrator - Adjusted - Touchscreen-QWERTY |

LPDOSE APPLICATION



[1] The Main Menu of the LPDose application gives access to the Measurement, Quality Control, Utilities and Settings features [2] The Quality Control Menu includes the automation of the daily regulatory checks of the dose calibrator through a dedicated programme. [3] The Measurement Menu is mainly used by the operator when preparing and measuring radiopharmaceuticals. This menu also includes features optimising the work of users including: integrated decay calculation, subtractive measurement, user identification. The reliability and accuracy of the radioisotope measurement is ensured by the “reset” function, also present in the software, performed by the user before each measurement. [4] The Utilities Menu allows monitoring of ionisation chamber information and operating curves in real time as well as performing calibrations of new radioisotopes and constancy sources. [5-6] The web application accessible to Department Managers, Radiopharmacists, and Radiophysicists allows archiving and analysis of the history of stock solutions used, patient doses prepared, and regulatory quality control results.

Characteristics

Functions:

- Communication with the radiopharmacy software (RIS)
- Automatic isotope calibration
- Over 300 pre-programmed isotopes
- Shortcut to 7 isotopes/packages
- Automatic adaptation of the unit of measurement
- Display configurable in Curie and Becquerel
- Integrated quality controls
- Molybdenum and Filiation rate built-in specific tests
- Real-time graphs of dose calibrator data
- Customisable printing labels
- Possibility to connect 4 chambers on the same software
- Customisable user list
- Reliable and secure data recording
- Built-in web application to view production history and quality control results
- Multi-language application
- Recording of traces to facilitate fault location
- Multi-package management
- Management of preparations by patient appointment
- Built-in decay calculation tool
- Built-in subtractive measurement tool

Certifications:

Complies with EU regulation UE 2017/745
 EN 60601-1:2006 (+ A1/2013)
 EN 60601-1-2:2015
 EN 60601-1-6:2010 (+ A1/2015)
 EN 62366: 2015 (+ A1/2020)
 EN 62304:2006 (+ A1/2018)
 Complies with the French decree of 25 November 2008
 Complies with international standard IEC 61948-4
 Complies with EU regulation 2016/679 (GDPR)

Options

Radiopharmacy software connection

COFRAC calibration service on request (ISO 17025)

Touchscreen 15 inches

Posilift automatic and pneumatic system for raising and lower the sample dipper by foot control

Voice control allows to control the measuring device by voice (selection of the stock solution, of the patient, of the isotope, of the conditioning, record a dose, print a label, etc.).