

DOSE CALIBRATOR FOR GMP PRODUCTION

Measurement of radiopharmaceuticals for pet and spect applications

- ✓ CENTRLIZED DATA
- **✓** REMOTE CONTROL
- ✓ FOR GMP USE
- ✓ Optimized for Quality Control



The i-DOSE is a software-controlled ionization chamber, designed for the fast and accurate determination of the activity, the volume activity or the half-life time of radiopharmaceuticals that are used in nuclear medicine for diagnostics and therapy.

The system has been designed and optimized for use in radio-pharmaceutical quality control and production laboratories. The dose calibrator can be used for the quality control of most radiotracers as it is calibrated for all common radionuclides, including the RSO nuclides (Y-90, Er-169, Re-186) and the PET nuclides (e.g. F-18, I-124). It is fully integrated into the GINA software and is a perfect combination to our other QC instruments.

The i-DOSE is a user-friendly device. The measuring chamber connects to the PC via a USB interface and is controlled with our GINA software. Use the i-Dose for the determination of half-life or the determination of impurity percentage of your radiopharmaceuticals. Calibration factors for different vials, are considered to reduce the error in total Activity measurement of nuclides used for PET and SPECT.

Compliancy



The system is not designed for use as a medical device. The hard and software have been adapted for using the system in production and QC of radiopharmaceuticals under GMP regulations. Audit trail, user access control and centralized data storage are only some features for compliance.

Shieldings

Depending on the isotope and the activities you use we can provide a 5 cm lead shielding for enhanced radiation safety and better measurement performance.

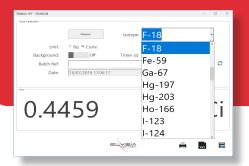


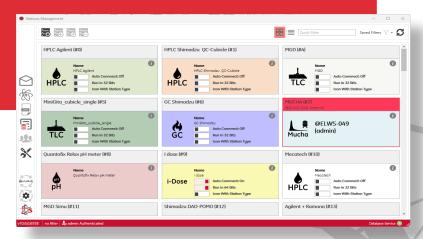


Software

The GINA interface can be used as the central software for your Quality Control laboratory. GINA an integrated isotope database for easy method an measurement setting's.

Direct control ensures digital signal transfer and a complete integrated solution according to GMP/GLP standards. GINA can not only control the i-DOSE, but all your relevant quality control instruments. A perfect solution for paperless work and increasing demands in digitalization.





Specifications

Technical

Measuring range

Gain

Bias Correction Zero adjustment

Calibration

Background substration
Energy range for γ-sources

HV test accuracy

Linearity error

Linearity error

Temperature coefficient

Stored isotope table

Three ranges with auto ranging function.

Digital adjustment

Digital adjustment

Digital adjustment Digital adjustment

Digital control

25 keV to 3 MeV

±5%

 \pm 1 % between 1 MBg and 200 GBg (Tc-99m)

0,1%/°C between 10°C and 40°C at 5 MBq and up Reproducibility

± 1% over 24 hours, stable conditions

Am-241, Au-195, Au-198, Ba-133, C-11, Cd-109, Co-57, Co-58, Co-60, Cr-51,

Cs-137, Cu-64, Er-169, F-18, Fe-59, Ga-67, Hg-197, Hg-203, Ho-166, I-123,

I-124, I-125, I-131, In-113, Kr-81, Lu-177, Mn-52, Mn-52, Mn-54, Mn-56, Mo-99,

N-13, Na-22, Na-24, O-15, P-32, Ra-223, Ra-226, Rb-81, Rb-82, Re-186,

Re-188, Sc-46, Se-75, Sm-153, Sr-85, Sr-87m, Sr-89, Tc-99m, Tl-201, Xe-127,

Xe-133, Y-88, Y-90, Yb-169

Physical

Contents (sample quantity) 0.1 ml - 99.9 ml

Measurement chamber Chamber 280, xl ø 69 mm

Well liner 270 x ø 57mm

Dimensions 150mm ø (bottom 160mm) x 451 mm height

Weight 15.5 kg (without extra shielding)

Lead Shielding
Additional Lead Shielding (optional)

3 mm basic Pb shielding
50 mm extra Pb shielding



1.00 ‡ mi