

NuMED x40 Dose Calibrator



The NuMED x40 is dedicated to determine the activity of radioactive isotopes in nuclear medicine. The simple and intuitive menu supports the users in their daily routine. This means that the NuMED x40 is ready for use at any time and the radiopharmaceuticals to be administered are quickly available. The system is the successor of the well-known ISOMED series using the proven NUVIA measuring chamber, and full compliance with the EU Medical Device Regulation (MDR).

Benefits

- MDR compliance
- User-friendly interface
- Windows-based Dose Calibrator
- Calculation of the activity to ensure the correct time of medication administration
- Integrated quality controls according to DIN 6855-11 (IEC 61948-4)
- Only 1 test source for daily quality control and calibration needed
- Secure, server-based database system
- Audit trail (optional) to record all events
- Measured value output via serial interface possible

Key figures

3 different types
↳ of measuring chambers are available

>30 nuclides*

up to 63 geometry
↳ factors per nuclide*

* factory pre-set, can be extended by the customer

Functionalities

The NuMED x40 enables the following activity determinations:

- Activity determination of a radioactive sample
- Activity determination at a desired application time
- Application time determination for the desired activity

The measurements can be started either manually or automatically. With the automatic operation, the interval between the measurements can be adjusted.

Other functionalities:

- Printout of the measured values on labels or protocols
- Extensive user administration
- Audit trail (optional)

Patient data management (optional):

- Allocation of the measured values to patient data / radiopharmaceuticals
- Documentation of the measured values stored within internal databases
- Possibility of accessing several NuMED x40 to ensure consistency of patient and measured value databases

Optimized Quality Control

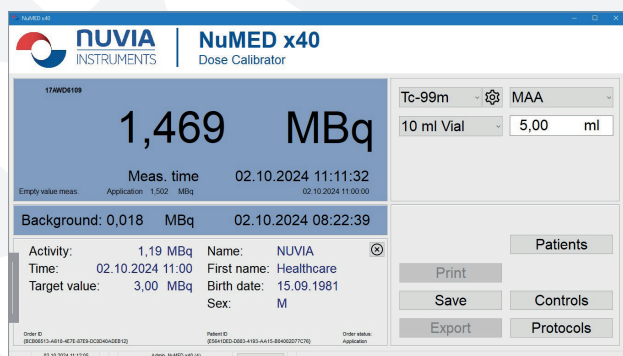
The integrated menu for quality control implements all requirements of DIN 6855-11 (IEC 61948-4) and the requirements of medical authorities. The user interface of the dose calibrator prompts quality control checks such as background or responsiveness to be carried out (in some cases daily) and provides documented evidence. For background measurements, one measurement with and one without the sample holder is carried out. The activated schedule control reminds users of checks to be performed. For example, a linearity check can be performed every 6 months. In this case a measurement of the sample is carried out automatically, with definable time intervals. The linearity curve can also be printed out as a graph. A menu for molybdenum breakthrough according to DIN 6854 is available.

Product Description

- The NuMED x40 consists of the NuMED x40 software and a measuring chamber (gas-filled ionization chamber with electrometer amplifier and analog-to-digital converter). Measured values and all data exchange between the measuring chamber and the PC software are transmitted via a USB interface. The software is also used to control the activity measurement. Only 1 Cs-137 source is needed for quality control.
- One of the main performance features of the NuMED x40 is the precise activity determination of radioactive isotopes, which are used in nuclear medicine for diagnostics and therapy.
- Radioactive isotopes can be measured as a radioactive substance either alone or as part of a radioactively labelled medicinal product (radiopharmaceutical). The NuMED x40 can measure all isotopes stored in the internal nuclide database (isotope list). This nuclide database is extendable.
- Radiopharmaceuticals are administered differently depending on the type of examination, e.g. by injection or orally. Therefore, the radioactive isotopes to be measured can be liquid or solid. Liquid radiopharmaceuticals are filled into injection syringes, vials or ampoules. Solid radiopharmaceuticals are available, for example, in the form of capsules. The NuMED x40 can be used to determine the activity of all these samples.

System Properties

- Pre-set for more than 30 nuclides, including some alpha and beta emitting radionuclides
- Calibration factors for different combinations of containers, container capacity and content (volume or weight) are taken into account
- Measurement of the nuclides used in radiosynoviorthesis (Y-90, Er-169, Re-186) and pain therapy (Sm 153, Re-188)
- Measurement of all radionuclides used in PET production and PET applications
- Calculation of the activity to assure the correct time of medication administration
- Measurement and compensation of background
- Windows-based application software
- Integrated quality control according to DIN 6855-11 (IEC 61948-4) with possibility of data storage, protocol printout and schedule review
- Integrated databases can be stored / uploaded to a server to meet cyber security requirements



NUVIA INSTRUMENTS | NuMED x40 Dose Calibrator

17AWD109

1,469 MBq

Meas. time: 02.10.2024 11:11:32
Empty value meas.: Application: 1,502 MBq

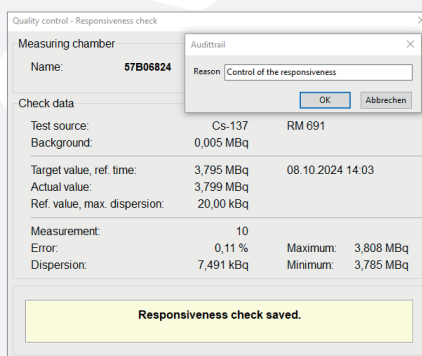
Background: 0,018 MBq 02.10.2024 08:22:39

Activity: 1,19 MBq Name: NUVIA
Time: 02.10.2024 11:00 First name: Healthcare
Target value: 3,00 MBq Birth date: 15.09.1981
Sex: M

Order ID: (B20415) 4418-4276-02040428 (2) Patient ID: (95641000-0003-4193-AA15-68400007C7C) Order value Application

Buttons: Patients, Print, Save, Controls, Export, Protocols

Main screen



Quality control - Responsiveness check

Measuring chamber: 57B06824

Audit trail: Reason: Control of the responsiveness

Check data:

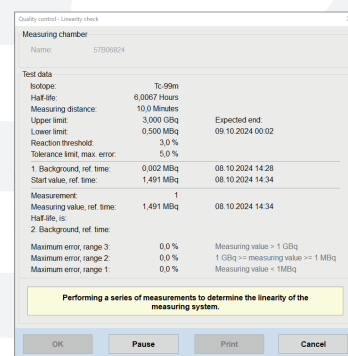
Test source: Cs-137 RM 691
Background: 0,005 MBq

Target value, ref. time: 3,795 MBq 08.10.2024 14:03
Actual value: 3,799 MBq
Ref. value, max. dispersion: 20,00 kBq

Measurement: 10
Error: 0,11 % Maximum: 3,808 MBq
Dispersion: 7,491 kBq Minimum: 3,785 MBq

Responsiveness check saved.

Responsiveness test with audit trail



Quality control - Linearity check

Measuring chamber: 57B06824

Test data:

Isotope: Tc-99m
Half-life: 6,0067 Hours
Measuring distance: 10,0 Meters
Upper limit: 3,000 GBq
Lower limit: 0,500 MBq
Reaction threshold: 3,0 %
Tolerance limit, max. error: 5,0 %

Expected end: 09.10.2024 00:02

1. Background, ref. time: 0,002 MBq 08.10.2024 14:28
Start value, ref. time: 1,491 MBq 08.10.2024 14:34

Measurement: 1
Measuring value, ref. time: 1,491 MBq 08.10.2024 14:34
Half-life, is: 6,0067 Hours

Maximum error, range 3: 0,0 %
Maximum error, range 2: 0,0 %
Maximum error, range 1: 0,0 %

Measuring value > 1 GBq: 1 GBq <= measuring value <= 1 MBq
Measuring value < 1 MBq

Performing a series of measurements to determine the linearity of the measuring system.

Buttons: OK, Pause, Print, Cancel

Linearity test

Technical data

Measuring chamber type	Special chamber. 680000 (Small)	Standard chamber. 640000 (Medium)	Special chamber. 660000 (Large)
Measuring range e.g. for Tc-99m / F-18:	50 kBq to 45 GBq / 55 kBq to 45 GBq	40 kBq to 45 GBq / 60 kBq to 60 GBq	50 kBq to 50 GBq / 70 kBq to 70 GBq
Measuring range settings	Automatically, alternatively fixed measuring range adjustable		
Energy range for Gamma sources	25 keV to 3 MeV		
Measurement time	With change of measuring range 2 s - 15 s. Without change of measuring range 1 s - 3 s		
Basic error	± 5 %		
Measured value display	4-digit with display of unit, isotope, chemical compound, container and content		
Stored isotope table	C-11, Cs-137, F-18, I-131, In-111, Lu-177, N-13, O-15, Re-188, Tc-99m	Ac-225, Ba-140, C-11, Co-57, Co-58, Co-60, Cr-51, Cs-137, Cu-64, Er-169, F-18, Fe-59, Ga-67, Ga-68, Hg-197, I-123, I-124, I-125, I-131, In-111, In-113m, Lu-177, Mn-54, Mo-99, N-13, O-15, Ra-223, Re-186, Re-188, Se-75, Sm-153, Sr-89, Tc-99m, Tl-201, Xe-133, Y-86, Y-90, Yb-169, Zr-89	C-11, Co-57, Cs-137, Cu-64, Ga-68, I-131, In-111, Lu-177, Mo-99, N-13, O-15, Tc-99m, Y-86
Containers	Injection syringes 1 ml, 2 ml, 3 ml, 5 ml, 10 ml, 20 ml. Bottles 2 ml, 5 ml, 10 ml (P6), 15 ml, 20 ml. Ampoules 5 ml Capsules for Co-57, Co-58, I-123, I-125, I-131. Tightly sealed for Am-241, Cs-137, Co-57, Co-60 Content (sample quantity) 0.01 - 99.99 volume (ml) or weight (g)		
Measurement chamber	Chamber Ø 115 mm, well Ø 35 mm	Chamber Ø 120 mm, well Ø 47 mm	Chamber Ø 140 mm, well Ø 64 mm
Dimensions	Total height 232 mm, well depth 120 mm	Total height 347 mm, well depth 218 mm	Total height 434 mm, well depth 272 mm
Lead shielding	0.5 mm Pb basic shielding, additional shielding 30 mm	4 mm Pb basic shielding, additional shielding 20 mm or 50 mm	1.5 mm Pb basic shielding, additional shielding 50 mm
PC system (selectable)	without PC, from Windows 10**	All-in-one PC with touchscreen or standard PC or without PC, from Windows 10**	Standard PC or without PC, from Windows 10**

The NuMED x40 is a MDR certified Medical Device in the EU.

Made in Germany

