

RADIONUCLIDE DOSE CALIBRATOR SERIES

DOSE CALIBRATORS FOR RADIOISOTOPES



FDA



TD_DOSE-CALIBRATORS-SERIES_R9_ENG - 12/07/24



PHARMA



RADIOPHARMA



ATMP

ENG



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1 GENERAL INFORMATION

1.1 OVERVIEW

Comecer is one of the leading manufacturers of radionuclide dose calibrators for nuclear medicine and radiopharmacology departments. The dose calibrators are also known as radioisotope calibrators, radionuclide calibrators, Curie measurement systems and activity meters.

Based on 30 years of experience, combined with the technological knowledge of Veenstra Instruments, today Comecer offers a vast range of models to satisfy any type of request.

Comecer is specialised in checking, measuring and safely managing radiation. In addition to this specific know-how, Comecer also takes care of design software, mechanics and electronics, obtaining a wide range of unique products for nuclear medicine, radiochemistry, radiopharmacy and calibration laboratories.

The radionuclide dose calibrators developed and manufactured by Comecer Netherlands B.V. have now been certified with full compliance to the new Medical Device Regulation 2017/745 on Medical devices, Annex IX Chapter I and III by the notified body DEKRA (0344).



1.2 MAIN EQUIPMENT

There are two main dose calibrators, the RDC-VIK-202 and RDC-VIK-203 both a combination of the ionisation chamber VIK-202 or VIK-203 working with the IBC-Lite software and called IBC Dose calibrator.

The VDC-606 Dose Calibrator is a configuration of the IBC Dose calibrator with a VDC-606 touch screen panel PC.

Main equipment		Models	VDC-606 Dose Calibrator	IBC Dose Calibrator
Measurement range	F-18	Up to 2 Ci (74 GBq) with VIK-202 Up to 20 Ci (740 GBq) with VIK-203	Up to 2 Ci (74 GBq) with VIK-202 Up to 20 Ci (740 GBq) with VIK-203	
	Tc-99m	Up to 6 Ci (222 GBq) with VIK-202 Up to 60 Ci (2220 GBq) with VIK-203	Up to 6 Ci (222 GBq) with VIK-202 Up to 60 Ci (2220 GBq) with VIK-203	
User interface			10.4” touch screen with IBC-LITE software	IBC-LITE software on Windows PC (PC not included)
No. of available isotopes			> 55 of which 15 presets in user interface	> 55 of which 15 presets in user interface
Instrument quality control checks				
Zero adjustment			YES	YES
BIAS adjustment			YES	YES
Background effect			YES	YES
Accuracy and constancy test			YES	YES
High voltage test			YES (weekly)	YES (weekly)
Linearity			YES	YES
Calibration check			YES	YES
Molybdenum breakthrough measurement			YES	YES
Radionuclidic Purity Test			YES	YES
Connections			PC Label printer	PC Label printer
Output			Possible integration with Comecer dispensers Automatic save of instrument quality control checks on the device	Possible integration with Comecer dispensers Automatic save of instrument quality control checks on the PC

2 CONSTRUCTIONAL FEATURES

2.1 VIK-202 AND VIK-203 IONISATION CHAMBERS

The heart of every Comecer radionuclide dose calibrator is the ionisation chamber: a completely digital detector that gives a fast, reliable reading. The 100% digital output allows the detector to be flexibly integrating into other instruments or structures with no need for a converter or a separate reading unit.

The VIK-202 ionisation chamber is pressurised at 14 bar (absolute) of Argon and its measurement range is up to 2 Ci (74 GBq) of F-18; the VIK-203 ionisation chamber is also available, pressurised at 1.4 bar (absolute) of Argon, for a measurement range of up to 20 Ci (740 GBq) of F-18.

As Comecer produces its own ionisation chambers in-house, we can evaluate dimensions or measurement features dedicated to individual needs.

	Ionisation chamber model VIK-202	Ionisation chamber model VIK-203 Extended Range
Ionisation chamber	Pressurised (14 bar abs. Argon)	Pressurised (1.4 bar abs. Argon)
Ionisation voltage	150 V lithium battery	
Well size	Ø 69 mm x 280 mm	
Well liner (inside)	Ø 57 mm x 270 mm	
Saturation	>200 GBq (Tc-99m), >70 GBq (F-18) >6 Ci (Tc-99m), >2 Ci (F-18)	>2000 GBq (Tc-99m), >700 GBq (F-18) >60 Ci (Tc-99m), >20 Ci (F-18)
Energy range	25 keV - 3 MeV	
Lead shielding	3 mm Pb	
Linearity	± 1 % between 1 MBq and 200 GBq (Tc-99m)	± 1 % between 50 MBq and 2000 GBq (Tc-99m)
Electrometer accuracy	± 1 %	
HV test accuracy	± 5 %	
Temperature coefficient	0,1%/°C between 10°C and 40°C at 5 MBq and up	
Reproducibility	± 1 % over 24 hours, stable conditions	
Overall accuracy	± 3 % dependant of specific calibration source and geometric variations	
Response time	Maximum 2 seconds for 95% of the end value	
Isotope factor	Digital adjustment	
Gain	Digital adjustment	
Bias correction	Digital adjustment	
Zero adjustment	Digital adjustment	
Calibration	Digital adjustment	
Background subtraction	Digital control	
High voltage test	Digital control	
Interface	Ionisation chamber interface	
Power supply	5 VDC, 250 mA	
Cable	2.5 meters	
Dimensions	Ø 150 mm (bottom Ø 160 mm) x 451 mm height	
Weight	15.5 kg	

2.2 CONFIGURATIONS

2.2.1 IBC DOSE CALIBRATOR



The IBC Dose Calibrator is a completely digital radionuclide dose calibrator managed by the IBC-LITE software. The ionisation chamber is connected directly to a PC with Windows (not supplied).

Like all Comecer dose calibrators, each model is used in combination with a completely digital ionisation chamber.

The IBC-LITE software offers a simple and user-friendly interface that supports all functions required for dose calibration when preparing radiopharmaceuticals.

The IBC Dose Calibrator is suitable for radio pharmacy use within a Nuclear Medicine department, as it can be easily integrated into any type of Microbiological Safety Cabinet.

Features IBC-LITE software

- Built-in isotope list
- Isotope preset list
- Suitable for measuring vials and syringes
- User-definable containers
- Quality control tests for the ionisation chamber:
- Molybdenum breakthrough measurement
- User-definable labels

With the IBC-LITE software, the IBC Dose Calibrator can perform the Radionuclidic Purity Test of the radiopharmaceutical: the system takes a series of automatic measurements in a defined range of time (user definable) and it is able to determine radiopharmaceutical half-life and impurity percentage. The results are stored and it is possible to produce a report.

IBC Dose Calibrator can work simultaneously with two ionization chambers connected in parallel. Both measures values are displayed next to each other.

The radionuclide dose calibrators RDC-VIK-202 and RDC-VIK-203 developed and manufactured by Comecer Netherlands have now been certified with full compliance to the new Medical Device Regulation 2017/745 on Medical Devices, Annex IX Chapter I and III by the notified body DEKRA (0344).

Minimum system specifications

- PC system with Windows 10 or Windows 11
- 1x RS-232 interface for each ionisation chamber
- 1x USB interface for label printer (not included)

2.2.1.1 *Standard supply*

- IBC-LITE Software (PC not included)
- Ionisation chamber (VIK-202 or VIK-203)
- Power supply for ionisation chamber
- Well liner
- Dipper

2.2.1.2 *Optional accessories*

- Extra lead shielding (20/50 mm Pb)
- Mo-99 breakthrough kit
- Copper dipper
- Extra well liner
- Extra dipper
- Dose calibrator reference sources

Label printer

The IBC Dose Calibrator supports all printers that use Windows drivers. The labels can be defined by the user via a dedicated tool in IBC-LITE that is easy to use.





Dose Calibrator inserts



Extra lead shielding

2.2.1.3 *Upgrade to IBC Nuclear Medicine and IBC GMP Radiopharmacy*

IBC-LITE can be integrated with the software versions to manage activity in nuclear medicine and radiopharmacy: IBC Nuclear Medicine and IBC GMP Radiopharmacy.

The IBC Nuclear Medicine is a client-server based software environment to manage the daily routines in a Nuclear Medicine department. The software guarantees full traceability from ordering stock to injection of the patient dose. The software also offers the functionality to implement user definable protocols for a guided and controlled workflow to standardise the preparation process from stock to patient dose.

The IBC GMP Radiopharmacy is a state-of-the-art solution based on client/server to manage the daily routine in radiopharmaceutical production centres that require "GMP" traceability. In these centres, the IBC GMP Radiopharmacy management system offers a high level of integrated automation to standardise processes. In radiopharmacies, the software supports order management, preparation and dispatch of ready-made multi-dose vials and/or syringes. The software guarantees full traceability from ordering stock to the end product.

Today's GMP guidelines dictate that all processes need to be reported, validated and justified. Thanks to IBC GMP Radiopharmacy, the highest level of GMP compliance can be integrated.

2.2.1.4 Technical Data of IBC Dose Calibrator

Reading		Curie / Becquerel (selectable)
Resolution	MBq μCi	0.001 0.01
Operating system		Windows 10 or Windows 11
Peripheral interface		1x RS-232 interface for each ionisation chamber 1x USB interface for the optional printer.
Defined Isotopes		Selectable isotopes RDC-VIK-202 > 55 RDC-VIK-203 > 15
User-definable isotopes		Limitless
Pre-set isotopes		15
Voltage	V	100 – 240
Frequency	Hz	50-60
Power	W	15

2.2.2 VDC-606 Dose Calibrator



The VDC-606 Dose Calibrator combines the best of both worlds: it has the versatile functionality of a software based dose calibrator and it is as robust as a stand-alone dose calibrator. Like all Comecer radionuclide calibrators, each model is used in combination with a completely digital VIK-202 or VIK-203 model ionisation chamber.

The device has an ergonomic and intuitive touch-based user interface and is optimised to support the work flow of the user.

Features IBC-LITE software

- Performing the quality controls is very easy and intuitive and the user is completely guided through the process
- Built-in isotope list
- Isotope preset list
- Suitable for measuring vials and syringes
- User-definable containers
- Quality control tests for the ionisation chamber
- Molybdenum breakthrough measurement
- User-definable labels
- Touch screen control

IBC-LITE can perform the Radionuclidic Purity Test of the radiopharmaceutical: the system takes a series of automatic measurements in a defined range of time (user definable) and it is able to determine radiopharmaceutical half-life and impurity percentage. The results are stored and it is possible to produce and print a report.

The VDC-606 can work simultaneously with two ionization chambers connected in parallel. Both measures values are displayed next to each other.

The radionuclide dose calibrators RDC-VIK-202 and RDC-VIK-203 developed and manufactured by Comecer Netherlands B.V. have now been certified as class Im medical device with full compliance to the new Medical Device Regulation 2017/745 on Medical Devices, Annex IX Chapter I and III by the notified body DEKRA (0344).

2.2.2.1 *Standard supply of the VDC-606 Dose Calibrator*

- RDC-VIK-202 or RDC-VIK-203
- VDC-606 read-out unit
- Power supply for read-out unit and ionisation chamber
- IBC-LITE Software
- Well liner
- Dipper

2.2.2.2 *Optional accessories to the RDC-VIK-20x*

- Extra lead shielding (20/50 mm Pb)
- Mo-99 breakthrough kit
- Copper dipper
- Extra well liner
- Extra dipper
- Dose calibrator reference sources

Label printer

The VDC-606 Dose calibrator supports the following label printer models:

- Seiko SLP-650
- Brother PT-9700 PC



Dose Calibrator inserts



Extra lead shielding

2.2.2.3 Technical data of the VDC-606 Dose Calibrator

Reading		Curie/Becquerel (touch screen selectable)
Resolution	MBq μCi	0.001 0.01
Display		10.4" display, 1024 x 768 pixel
Control		10.4" touch screen
Operating system		Microsoft® Windows
Peripheral interfaces		1 x Display port 2 x Ionisation chamber port (M8) 2 x USB 2 x Ethernet
Defined Isotopes		Touch screen selectable isotopes RDC-VIK-202 > 55 RDC-VIK-203 > 15
User-definable isotopes		Unlimited Properties (name, half-life, calibration factor)
Working temperature range:	°C °F	0 - 40 35 - 105
Humidity		Max. 90% relative humidity, non-condensing
Voltage	V	100 – 240
Frequency	Hz	50-60
Power	W	15
Dimensions	mm	256 x 45 x 193 (LxDxH)
Weight	kg	2

2.3 REFERENCE SOURCES

Reference sources are in vials contain a uniform distribution of activity in 10 ml of epoxy covered by 10 ml of inactive epoxy resin. This all is captured in a colour-coded polyethylene vial. The total vial volume is 27 ml with a height of 8.5 cm and a diameter of 3.1 cm.

Each source is NIST traceable and calibrated to less than $\pm 5\%$ uncertainty. The source will be delivered in a lead shield and a certificate of calibration and leak test report will be included.

Available sources:

- **Co-57 (5.0 mCi/185.0 MBq)**
- **Cs-137 (0.2 mCi/7.4 MBq)**
- **Co-60 (0.05 mCi/1.85 MBq)**
- **Ba-133 (0.25 mCi/9.25 MBq)**



INFORMATION

Dose calibrator reference sources cannot be delivered world wide. Please contact Comecer Netherlands for more information.

3 STANDARD ISOTOPE LIST

Name	Available for RDC-VIK-202	Available for RDC-VIK-203	NIST traceability	Comment
Am-241	X	X	YES	
Au-195	X		NO	
Au-198	X		NO	
Ba-133	X	X	YES	
C-11	X	X	YES	(Calculated to F-18)
Cd-109	X		NO	
Co-57	X	X	YES	
Co-58	X		NO	
Co-60	X	X	YES	
Cr-51	X		YES	
Cs-137	X	X	YES	
Cu-64	X		PENDING	
Er-169V	X		YES	
Er-169S	X		YES	
F-18	X	X	YES	
Fe-59	X		NO	
Ga-67	X		YES	
Ga-68	X	X	PENDING	
Hg-197	X		NO	
Hg-203	X		NO	
Ho-166	X		NO	
I-123	X	X	YES	
I-123CV	X	X	YES	
I-123CS	X	X	YES	
I-124	X		YES	
I-125	X		YES	
I-131	X		YES	
In-111V	X	X	YES	
In-111S	X	X	YES	
In-113m	X		NO	
Ir-192	X		NO	
Kr-81m	X		NO	
Kr-85m	X		NO	
Lu-177	X	X	YES	

Name	Available for RDC-VIK-202	Available for RDC-VIK-203	NIST traceability	Comment
Mn-52	X		NO	
Mn-54	X		NO	
Mn-56	X		NO	
Mo-99 (5mm Pb shielding)	X	X	YES	
N-13	X	X	YES	(Calculated to F-18)
Na-22	X		NO	
Na-24	X		NO	
O-15	X	X	YES	(Calculated to F-18)
P-32	X		NO	
Ra-224	X		YES	
Ra-226	X		NO	
Rb-81	X		NO	
Rb-82	X		NO	
Re-186V	X		YES	
Re-186S	X		YES	
Re-188	X		NO	
Sc-46	X		NO	
Se-75	X		NO	
Sm-153V	X		YES	
Sm-153S	X		YES	
Sr-85	X		NO	
Sr-87m	X		NO	
Sr-89V	X		YES	
Sr-89S	X		YES	
Tc-99m	X	X	YES	
Tl-201	X		YES	
Xe-127	X		NO	
Xe-133	X		NO	
Y-88	X		NO	
Y-90V	X	X	YES	
Y-90S	X		YES	
Yb-169	X		NO	
Zr-89	X		NO	

Suffix V: Vial

Suffix S: Syringe

4 QUALITY CONTROL CHECKS

Comecer radionuclide calibrators are designed to carry out routine quality control checks on the instrument. The checks can be daily or at longer intervals.

Quality control checks required for each calibrator:

Check		VDC-606 Dose Calibrator	IBC DOSE CALIBRATOR
DAILY CHECKS	Zero adjustment	YES	YES
	BIAS adjustment	YES	YES
	Background effect	YES	YES
	Accuracy and constancy test	YES	YES
	High voltage test	YES (weekly)	YES (weekly)
CHECKS AT LONGER INTERVALS	Linearity	YES	YES
	Calibration	YES	YES

4.1 DAILY CHECKS

Daily checks must be done at the beginning of every work session before making the measurements on the doses intended for patients. Daily checks foresee:

- Zero adjustment
- BIAS correction
- Background effects
- Accuracy and constancy test

4.1.1 Zero adjustment

This test allows to adjust for an amplifier offset automatically. For a correct adjustment of the amplifier offset, there must not be any activity inside the chamber. It is also advisable to remove the liners from the well.

After a short time, the result is displayed on the screen with two values: the preamplifier gain and the "i to ub" factor.

4.1.2 BIAS correction

BIAS correction is necessary to obtain an ionisation chamber reading close to zero. The amplifier connected to the chamber must amplify tiny currents. These currents are so weak that the leakage currents in any electronic circuit must be compensated.

4.1.3 Background effect

The background is measured to determine whether the chamber reading is stable when there is no activity inside of it. When the test is launched, the program carries out several measurements and calculates any deviations.

4.1.4 Accuracy and constancy test

The accuracy and constancy test is a reference test for source measurements. It allows you to verify instrument performance by measuring the same source repeatedly over a period of time.

4.2 HIGH VOLTAGE TEST

The VIK-202 and VIK-203 ionisation chambers have an incorporated high-voltage battery. This battery guarantees a nominal voltage of 150 V to the ionisation chamber. Without this voltage, the ionisation chamber will not be able to measure activity. Therefore, it is very important to check the battery to ensure reliable operation of the calibrator itself. The battery is expected to last at least 8 years. The battery has a very low self-discharge and the cells themselves are high-quality and stable over time.

Performing this test, the ionisation chamber amplifier measures the battery and communicates the result, which is shown on the display. For correct measurement, there must be no activity inside the chamber (a message will appear, asking you to make sure the ionisation chamber is empty).

The test takes up to 30 seconds and during the measurement, a message on the display updates the operator on the progress.

4.3 CHECKS AT LONGER INTERVALS

These checks can be done weekly, monthly or at longer intervals, depending on the instrument, on the protocols in practice in the specific department and the local regulations.

4.3.1 Linearity test

The linearity of the ionisation chamber is $\pm 1\%$ between 1 MBq and the highest specified activity value, a measurement range of over 6 decimals. The linearity test checks if this is actually true by repeatedly measuring, over a specific time span, the decay of a source. The most used isotopes to perform the linearity test are F-18 and Tc-99m.

4.3.2 Calibration check

The response of the chamber depends on the energy of the measured isotope. To check the response, it must be checked using isotopes whose energies cover most of the energy range of the ionisation chamber. Usually Co-57, Co-60 and Cs-137 are used.

5

MAINTENANCE

The system do not require maintenance by the final user, except for normal cleaning procedures.

However, some aspects require particular attention:

- Battery check: the high-voltage battery is expected to last 8 years. It must be checked regularly (every day). If the voltage goes under 140 Volt, the battery must be replaced. Only qualified personnel are authorised to replace the battery.
- The well liners and sample dipper must be cleaned regularly and they must be checked for potential contamination. Never use alcohol to clean the ionisation chamber accessories.
- Zero adjustment must be done daily.
- The BIAS must be checked and, if necessary, it must be adjusted every day.
- It is advisable to perform an accuracy and constancy check only with Cs-137.
- It is good practice to check the instrument calibration at least once a year. Calibration tests should be performed with Co-57, Cs-137 and Co-60 sources.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



ISO 9001 & ISO 13485
Certified Quality System

ISO 45001
Health and Safety Management System

ISO 140001
Environmental Management System

ISO 50001
Energy Management System

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