epidermal radioisotope therapy

OncoBeta® Measurement Station

Rhenium-SCT® procedure

User Manual
English

OncoBeta® GmbH

CE

Contents

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Last updated on: 2021-07-20 (YYYY-MM-DD)
Revision level: B

1 Introduction

This user manual is intended solely for qualified personnel. The product shall only be used by **qualified medical personnel who have been trained** by OncoBeta® GmbH or sister organizations of OncoBeta® GmbH or its certified sales partners.

1.1 Intended Use

The **OncoBeta® Measurement Station** (later referred to as **MST**) is intended to exclusively be used as part of the Rhenium Skin Cancer Therapy (Rhenium-SCT®) to measure the exact activity of the compound used for the treatment.

1.2 Indication

The MST is indicated to only be used as part of the Rhenium-SCT®.

1.3 Contraindication

The MST shall not be used for any other purposes than measuring the activity of Re-188 of the REC-Carpoule and performing quality controls.

1.4 Intended Users

Only health professionals that have been trained by OncoBeta® GmbH or one of its certified representatives are allowed to use this product.

Note: The device is designed for the use by healthcare professional with background in nuclear medicine or radiation therapy or a trained person under the supervision of such a professional.

1.5 Other products and devices

The following products are needed in addition to the **OncoBeta® Measurement Station** to perform a **Rhenium-SCT®** procedure:

- **OncoBeta® REC Carpoule** with Re-188-compound
- **OncoBeta® Application System**
- **Sterile Protective Foil**
- A waste container for radioactive substances (e.g. the **OncoBeta® Waste Station**)

1.6 Complaints / vigilance

Any complaints and vigilance related information shall be reported to OncoBeta GmbH. Vigilance related information shall also be reported to the competent authority of the member state where the user/ patient is established.
Information can be shared with OncoBeta by using the following email ID: **complaints@oncobeta.com**

1.7 Software updates

Software updates will be distributed by download or physical distribution and will be installed manually. In case of software updates, those will be communicated through OncoBeta GmbH to the customer.

2 Safety

2.1 General safety information MST

- The rooms in which the MST is administered must meet the requirements of providing treatment with sealed nuclides and be equipped with the appropriate infrastructure for practising nuclear medicine or brachytherapy.
- The treatment room must be designated as a controlled area in line with the national radiation protection regulations. Neighbouring rooms must be monitored for exposure to radiation and, if necessary, also designated as controlled areas.
- National requirements governing the medical use of sealed radioactive substanc-es as a form of treatment must be complied with. Radioactive material may only be handled by persons authorised to do so by the national radiation protection regulations.
- The operator must have gained approval from the competent authority to handle radioactive Rhenium-188.
- If possible, the treatment rooms should be chosen to prevent radioactive substances or components contaminated with radiation from having to be transported over long distances inside the treatment centre. Transporting these materials through public areas must be avoided whenever possible.
- Great care and attention are required when handling radioactive substances. Distractions must be avoided at all costs. It is recommended any foreseeable tasks to be trained in advance without radioactivity.
- The MST must be handled with care. Careless handling may result in serious injury.
- Radioactive material that is being handled should, as far as possible, always be shielded. Suitable shielding must therefore always be available for use during all tasks.
- The time spent near Rhenium-188 and components contaminated with Rhenium-188 must be minimised as far as possible. Maximum possible distance from Rheni-um-188 shall be maintained at all times.
- The measurement station may only be installed and maintained by qualified personnel working for OncoBeta® GmbH, sister organizations of OncoBeta® GmbH or its certified sales partners.
- After use, the device must be checked for contamination.
- When moving the MST to its' final position in the treatment room, it is advised to move it with the measurement chamber in its' low position. This assures more stability of the device if the ground is uneven.

- The device may only be moved over ramps with a maximum inclination / declination of 25%.
- Setting up the MST in the treatment room, the brakes of the wheels must be activated. This prevents unwanted movements of the device during the treatment.
- Use only for the MST approved disinfectant (for further information see section 6.2).
- The MST may only be used as part of the Rhenium-SCT.

2.2 General safety information VDC-606

- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- The connectors of the reading unit are dedicated for Comecer Netherlands ionization chambers. No other devices should be connected to these sockets.
- Extra care must be exercised when cleaning the display area. No pressure should be on the transparent part of the display.
- It is not permitted to connect any other equipment to the ionization chamber.

2.3 Safety precautions during treatment

- Inspections must be made before use, to check that the MST is in full working order.
- Before each treatment, a zero-measurement needs to be performed with the dose calibrator to be used to rule out any contamination of the device.
- The medical professional must wear suitable personal protective equipment during the treatment process. As a minimum, this should comprise the following:
  - Lead glasses or a face mask that shield against radiation
  - Lead apron
  - Impermeable disposable gloves
  - Disposable apron
- After treatment, the patient, personnel administering the treatment and the radiotherapy room, including the instruments and devices used, must be tested for contamination.
- In the event of contamination and/or incorporation, the appropriate contingency plan must be followed (see chapter 8)
- Contaminated instruments must be packed away in a liquid-tight manner and shielded appropriately by using lead bricks for example.
- In case of power failure, discontinue the treatment immediately

3 Description

The Measurement Station (short MST) is used to determine the activity of the radioactive substance being applied. The MST consists of a portable activity meter, so called dose calibrator, which is fitted into a trolley. With the connected reading unit, the necessary settings of the dose calibrator can be applied, and the activity being read off.

Figure 1.: OncoBeta® Measurement Station

1	Trolley
2	Ionization chamber (not visible)
3	Readout unit

3.1 Performance characteristics

3.1.1 Trolley

The performance characteristics specific to the trolley are:

- Adjustable height for readout unit
- Four wheels that can be locked
- Functionality of height adjustment of the calibration chamber

3.1.2 Dose Calibrator VDC-606

The dose calibrator used for the MST consists of the ionization chamber and its readout unit.

3.1.2.1 Ionization chamber VIK-202

The ionization chamber is an argon filled well type chamber which can measure the activity of radioactive sources. The ionization chamber can be connected directly to the dedicated readout unit running Comecer Netherlands dose calibrator software.

Ionization chamber type	Well type 5.0 Argon 14 bar absolute
Linearity	± 1% (1 MBQ – 200 GBq Tc-99m)
Resolution	0,001 MBq 0,01 µCi
Saturation	>200 GBq (Tc-99m) >6 Ci (Tc-99m)
Energy range	25 keV – 3 MeV
Electrometer accuracy	± 1%
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% dependent of specific calibration source and geometric variations
Response time	Maximum 2 seconds for 95% of the end value
Ranges	Auto ranging
Lead shielding	3mm Pb + additional lead rings
Storage, transport and operational conditions	
Temperature range	0° - 40°C / 35° - 105°F
Relative humidity	Max. 90% non-condensing
Interface	Comecer Netherlands (Veenstra Instruments) special
Power requirements	5 Vdc, 1,8 W
Dimensions	452 mm x 159 mm Ø
Well size	69 mm diam. x 280 mm
Weight	15,5 kg
Pressurized gas content	13 bar gauge pressure, 25,2 liters (stp), 45 grams

Table 1.: Specifications of the ionization chamber

3.1.2.2 Readout Unit

The readout unit runs with its own software called IBC-Lite.

Display	10.4” display, 1024 x 768 pixels
Control	10.4” touch screen
Operating System	Microsoft ® Windows Embedded Standard 7
Peripheral interfaces	Display Port : 1 Ionization chamber port (M8) : 2 USB : 2 Ethernet : 2
Input voltage	24 V d.c.
Input current	< 1 A
Input power	15 W
Dimensions (w x d x h)	256 mm x 45 mm x 193 mm
Weight	2 kg
Area of use	Indoor
Temperature range	0 °C – 40 °C 32 °F – 104 °F
Humidity	20 % - 90 % RH (none condensing)
Altitude	< 2000 m
Pollution Degree Rating	Pollution Degree 2
Overvoltage Category	Category I

Table 2.: Specifications of readout unit

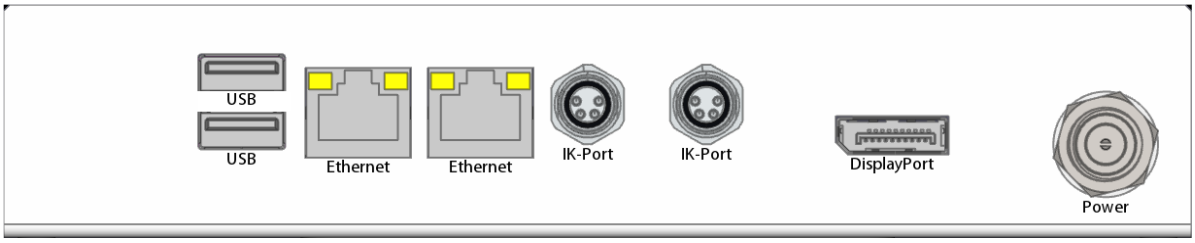


Figure 2.: Back panel connections of the readout unit

Port	Description	Number of Ports
IK-Port	‘Ionisatie Kamer’-port for connection of a compatible ionization chamber	2
Ethernet	Ethernet connection for connection to a Local Area Network (LAN) **WARNING: *Do not use without permission by OBG***	2
USB	Connection Universal Serial Bus according to version 2.0 of the USB standard **WARNING: *Do not use without permission by OBG***	1
	Connection Universal Serial Bus according to version 3.0 of the USB standard **WARNING: *Do not use without permission by OBG***	1
DisplayPort	DisplayPort for connection to an external monitor	1
Power	Power connection of the read-out unit	1

Table 3.: Port description

3.1.2.3 Cables

Port	Description	Cable termination	Cable type	Supplied length (m)	Maximum length (m)
Power inlet	Supplied with the power supply 100 - 240 V a.c. 50/60 Hz power supply inlet	IEC 60320-C13	H05VV-F 3G0.75 mm² 300/500V	2,5	3,0
IK-Port	Communication and power for a compatible ionisation chamber	M8-connector IEC 61076-2-104, 4 pole	4x0.25 mm2 PUR, UL AWM 20549	0,3 + 2,5	15,0

Table 4.: Cable description

3.2 Loss of performance during EMC events

3.2.1 Essential operation

During an electromagnetic (EMC) event the ionization chamber will meet the following performance as specified by Comecer Netherlands:
“The equipment shall continue to operate as intended without operator intervention. To comply with performance criteria A the following faults shall NOT occur:
- The displayed activity deviates more than 30% from the normal displayed activity.
- The readout unit freezes and does not update the displayed value every two seconds”

3.2.2 Exceptions

For the following events additional performance criteria have been specified:

- Electronically fast transients (EFT)
Immunity to EFT events will meet the following performance as specified by Comecer Netherlands:
“During the event, degradation of performance is allowed. After the event the device shall continue to operate as intended without operator intervention.
To comply with performance criteria B the following faults shall NOT occur:
- The degradation of performance persists after the test has finished”

- Voltage dips and variations
Immunity to voltage dips of more than 95% relative to the normal voltage level with a duration of more than 0.5 cycles will meet the following performance as specified by Comecer Netherlands:
“Loss of function is allowed, provided the loss of function is self-recoverable, can be restored by the operation of the controls or is restored after reconnecting the power supply.
To comply with performance the following faults shall NOT occur:

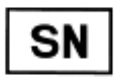
- Component failure
- Changes in programmable parameters

- Data corruption of any kind
- Reset to factory defaults”

- Electrostatic discharges (ESD)
Immunity to ESD events will meet performance criteria C as specified by Comecer Netherlands:
“Loss of function is allowed, provided the loss of function is self-recoverable, can be restored by the operation of the controls or is restored after reconnecting the power supply.
To comply with performance criteria C the following faults shall NOT occur:

- Component failure
- Changes in programmable parameters
- Data corruption of any kind
- Reset to factory defaults”

3.3 Symbols used

Order number		Keep in a dry place	
Date of manufacture		CE mark	
Serial number		Observe the instructions for use	
Manufacturer			

4 IBC-Lite Software

The software to use the dose calibrator is already pre-installed on the readout unit and is ready to be used at the customer’s site. It is a touch screen and can be interacted with fingers or a touch screen suitable pen.
This section will give you an overview how to use the software and interact with its interface.

4.1 Main screen

Starting the dose calibrator by plugging it in, the following screen will become visible:

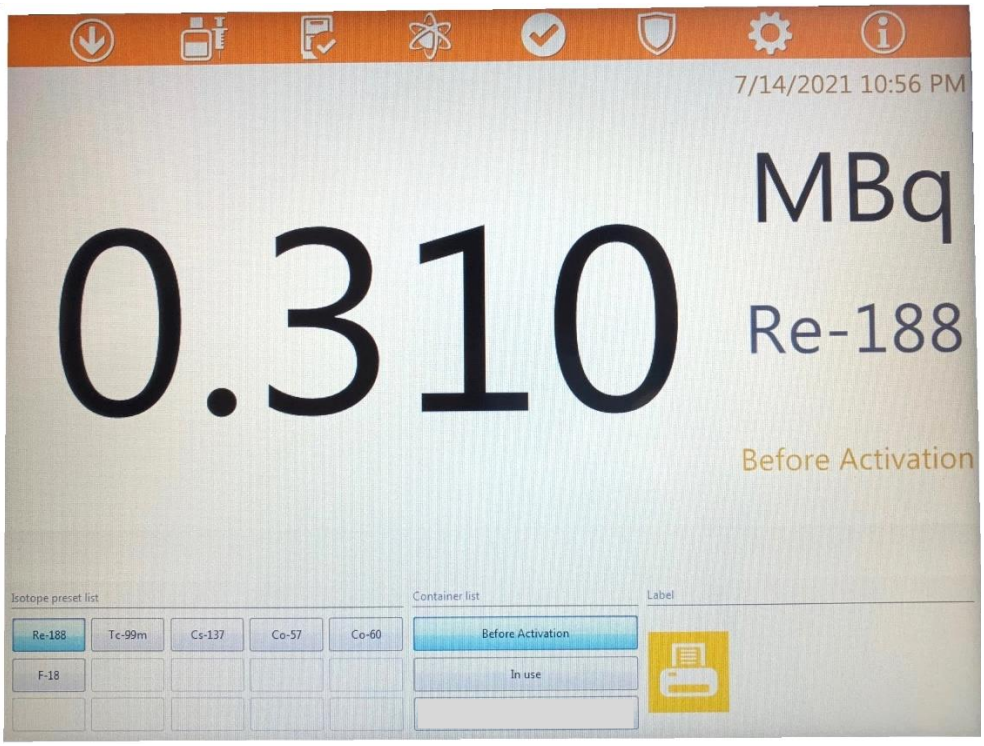


Figure 4.: Main IBC-Lite screen for Rhenium-SCT

4.1.1 Isotope preset list:

The **Isotope preset list** in the bottom left of the screen is preset with Re-188 for the Rhenium-SCT treatment. It might also be preloaded with Co-57, Cs-137, Co-60 and Tc-99m and/or F-18 for quality testing. These isotopes can therefore be accessed only by clicking on them.

4.1.2 Container List:

On the right of the Isotope preset list you will find the **Container list**. For Re-188, it is preloaded with three different containers. “Before Activation” and “In Use”. These different containers have different absorption correction factors due to different geometries of the measured source.

Before Activation	Before activation of the Carpoule
In Use	After activation of the Carpoule

Table 5.: The different containers for Re-188

During the Rhenium-SCT, the containers “Before Activation” and “In Use” are being used by clicking on one or the other. This will change the absorption correction factor to the respective geometry of the carpoule.

4.1.3 Read out values:

In the centre of the main window the values measured by the ionization chamber can be read off. To the right of the value, you can also see the unit of the value, the selected isotope as well as the selected container.

4.1.4 Background subtraction:

It may be advisable to remove the background radiation (contamination) before measuring the radioactive substance when measuring **low activities** with possibly a **slight contamination** in the ionization chamber. If this is not the case, the background subtraction shall not be used.

NOTE: The configuration of the background subtraction must, in this case, be performed before the radioactive source is exposed to or near the dose calibrator. If not, this may have an influence on the correction and may therefor display an activity that is too low when measuring.

The background subtraction button can be found in the top left corner of the main screen as downwards pointing arrow and be activated by clicking it. When activated, the arrow changes to point upwards instead. “Background subtraction ON” will be displayed on top of the measuring value.

Figure 5.: Background subtraction

4.1.5 Selecting a different Isotope:

If the isotope preference list does not contain the required isotope, the list with all isotopes can be opened. To do so, click the “Selecting an isotope” button.

Figure 6.: Button “Selecting an isotope”

After clicking the button, the list with all available isotopes will be displayed in alphabetically order. Select the isotope to be measured and close the window.

5 Quality Tests

5.1 Accessing quality tests

The quality tests to be performed can be accessed by the  button at the top in the button bar. Alternatively, it can be accessed through a message automatically displayed at the bottom right of the screen as soon as actions must be performed (Figure 6.). If you do not perform any actions, the message will disappear after approximately 30 seconds.

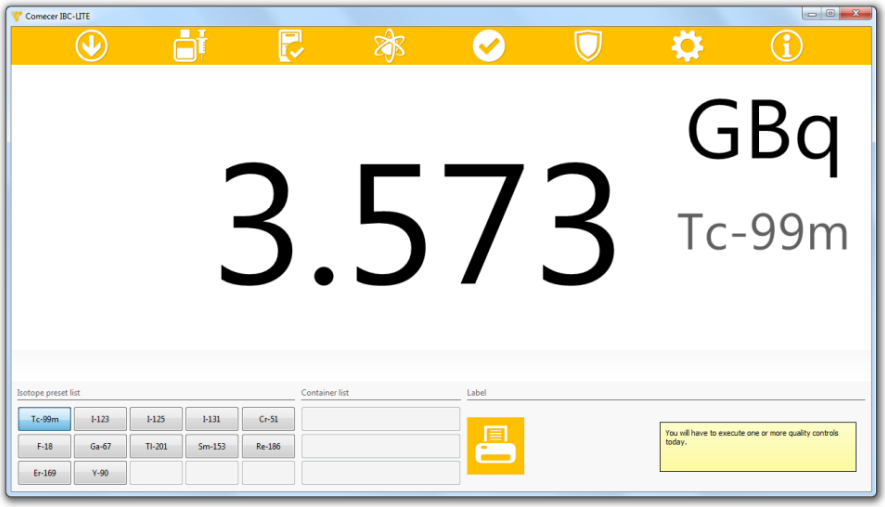


Figure 7.: Main setup of the software on reading unit

The quality controls (QMM-101) appear as grouped into different categories, such as tests to be performed on a daily basis, on a weekly basis or other. Under “Status” you can identify which tests have to be performed and which do not.

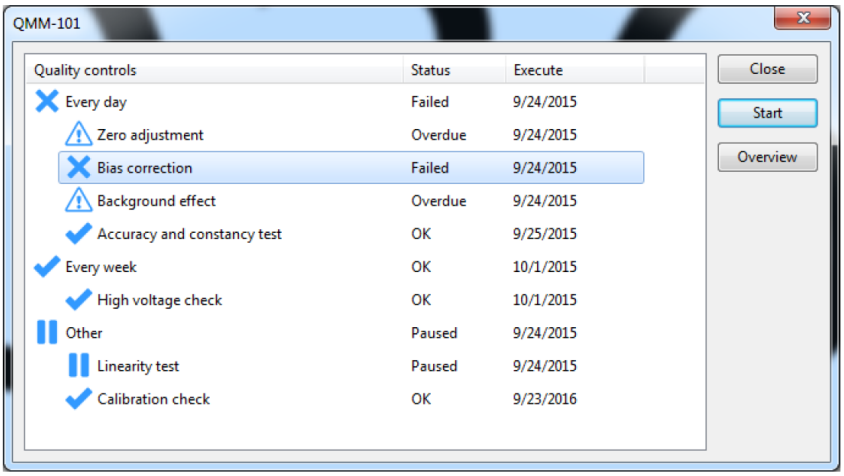


Figure 8.: QMM-101 window with all quality checks and their status

Each test can be started by selecting it and clicking on the start button.

5.2 Every day tests

Most quality control routines that should be performed every day can be completed automatically and without interaction. If not performed daily, they should at least be performed **before each treatment**. For the last routine check (accuracy and constancy test), you require a source; keep this ready.

5.2.1 Zero Adjustment

Step 1: All activity needs to be removed from and near the chamber for a correct measurement of the zero setting. After selecting the Zero Adjustment and clicking on the Start button, a window will open to remind you of this. Click OK.

Step 2: After clicking OK, it takes at most 45 seconds for the result to be shown on the readout unit. Two values will be produced; the PREAMP and the ITOUB value. These two values are dependent on the background and should be between the limits indicated on the calibration sheet (see table below) to pass the test successfully.

	Minimum	Maximum
Pre-amplifier amplification	3100	4500
I-to-Ub-factor	3100	4500

Table 6.: Indication limits for zero adjustment

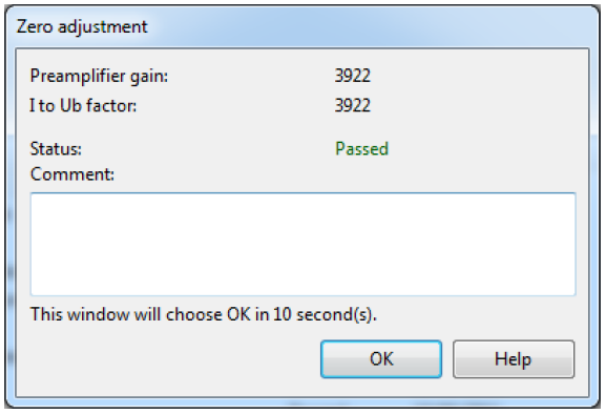


Figure 9.: Zero adjustment results

If the test has failed, the following quality controls may also fail. Your measurements in the main application will, in any case, be less accurate or even inaccurate.

5.2.2 Bias Correction

Adjusting the Bias setting is necessary to obtain a near zero reading from the ionization chamber. Leakage currents that exist in any electronic circuit will be compensated by this.

Step 1: Select Bias correction and click the Start button to perform the test. After a few seconds a new window will appear and show you the results.

The resulting current should be about 0.1 pA. Increasing the Bias setting value will result in a lower current and vice versa. This can be adjusted with the Up, Down and Automatic buttons, if needed. The measured current should be between 0.05 and 0.15 pA to pass the test successfully.

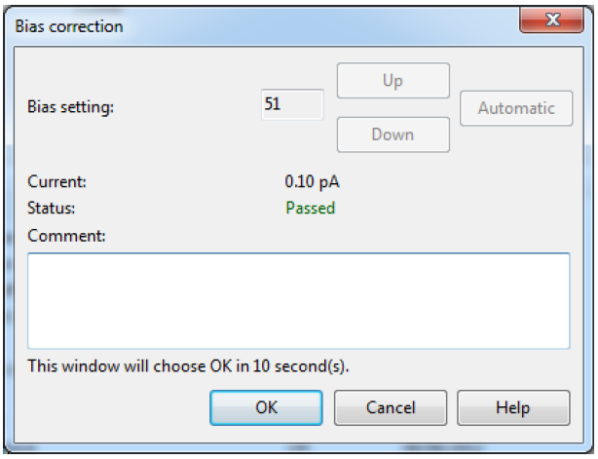


Figure 10.: Bias correction window

5.2.3 Background effect

Background radiation must not be higher than a specific threshold value to ensure the quality of the measured data is kept high.
Step 1: Select “Background effect” and click the “Start” button. This will determine the background radiation and takes approximately 15 to 30 seconds.
The system automatically measures the activity 10 times and averages this. This will also give you the standard variation.
The test will be successful when the average activity is between 0 and 0.4 MBq.

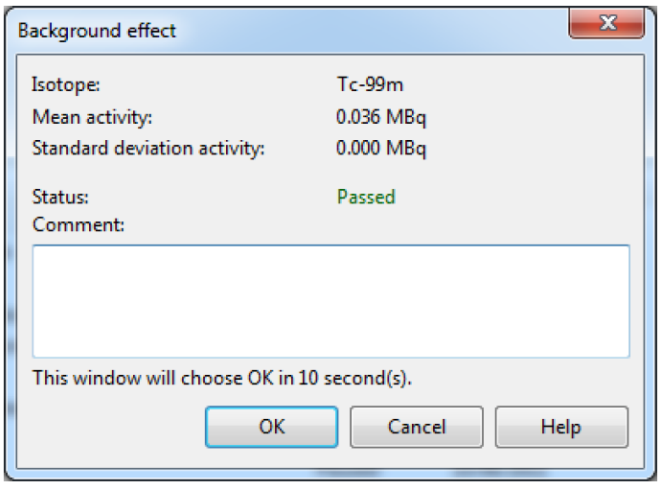


Figure 11.: Background measurement

Step 2: Click “OK” to save the quality control and to accept the background effect.

5.2.4 Accuracy and Constancy test

A dose calibrator must produce the same expected value every time a measurement is performed with a known source. Therefor an accuracy and constancy test is performed on a regular basis.

Step 1: Select “Accuracy and constancy test” and click the “Start” button in the main window to perform the test.

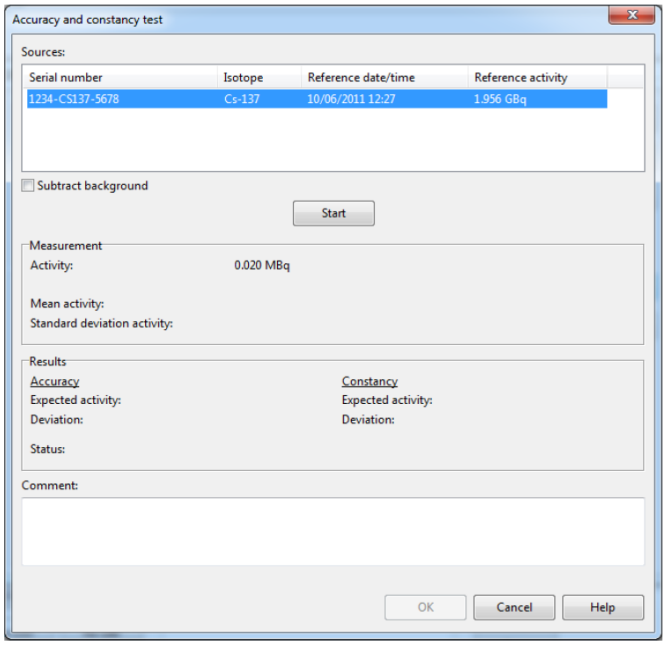


Figure 12.: Interface of the accuracy and constancy test.

Step 2: Select the source to be tested from the list of available sources in the window for the test. Be aware that you have to have a source added to the system in order to select one for this test.

Note: if you see a light background (under the “Measurement”, “Activity” label) and you have a relatively low source activity, you can use the “Subtract background” checkmark to compensate for the background. But do not use the background subtraction when the radioactive source is near the dose calibrator.

Step 3: Place the source in the dipper and into the dose calibrator and click “Start” to start the routine. The system will ask for the correct source to be positioned.
The determination of the accuracy and constancy test will take some time (approximately 15 to 30 seconds); the system will measure the activity 10 times and averages this. In addition, the standard variation is determined.

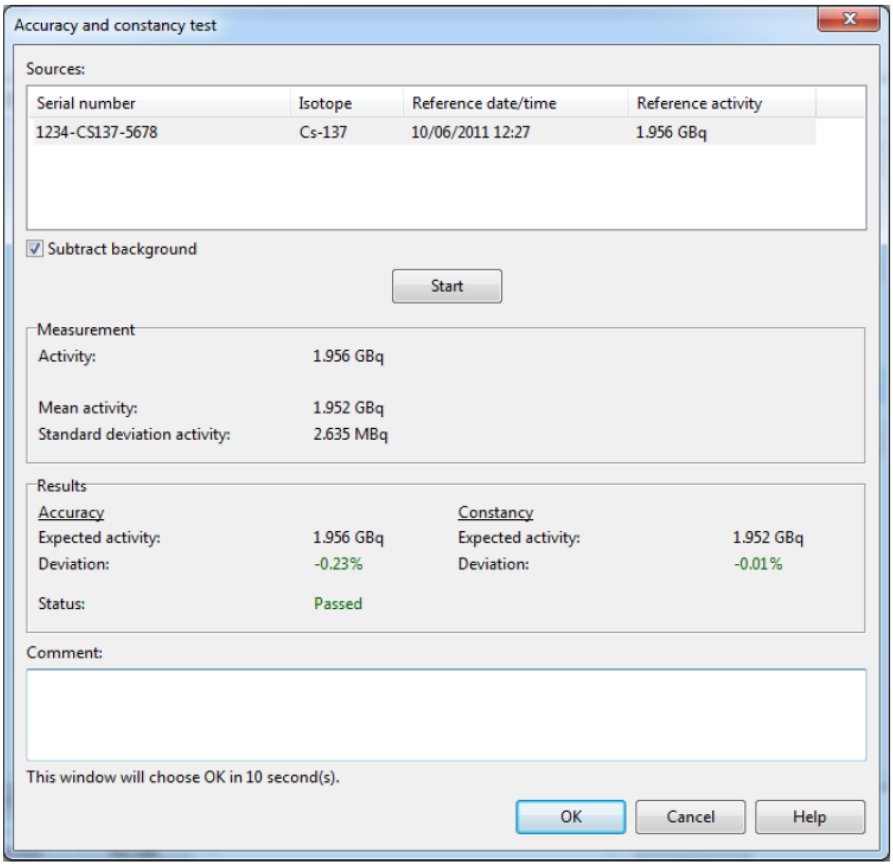


Figure 13.: The results of an accuracy and constancy test.

The accuracy and constancy test is successful when both deviations are between the following values:

	Minimum	Maximum
Accuracy	-5,00%	5,00%
Constancy	-5,00%	5,00%

Table 7.: Limitation values for accuracy and constancy test

Step 4: Click “OK” to save and accept the quality control.

If the test has failed, the measurements in the main application will, in any case, be less accurate or even inaccurate.

Perform the following steps if the test has failed:

1. Check whether the correct source has been selected and has been positioned in the dose calibrator.
2. Check whether the dose calibrator is contaminated. Remove the dipper for investigation.
3. Check the position of the source in the dose calibrator. This must be the same as the position during acceptance.
4. Again, perform the quality control routine. If this fails again, contact your supplier.

5.2.5 Re-188 container test

This test is to ensure the correct functionality of the two different containers used for the Rhenium SCT. This quality check is performed by using the Re-188 measuring setting with the containers for “Not Activated” and “In Use” carpoule.
IMPORTANT: All measurements below will be executed with the same Cs-137 source!

Step 1: Return to the main screen and choose the Cs-137 setting and measure the Cs-137 source available. To do this, introduce the radioactive source into the measurement chamber and let stabilize for a few seconds. Note the value measured.

Step 2: Now select Re-188 as nuclide. Then choose the container **Not Activated**. Again, introduce the **same** radioactive source. Note the value measured.

Step 3: As next step, choose the Re-188 container **In Use**. Again, introduce the same Cs-137 source and note the measured value.

Step 4: After proceeding with the measurements, use the formula below to calculate the two different factors.

$$\frac{Re-188\ Not\ Activated}{Cs-137} = \mathbf{25} \pm \mathbf{1}\%$$

$$\frac{Re-188\ In\ Use}{Cs-137} = \mathbf{24.3} \pm \mathbf{1}\%$$

If the result of the calculated factor is within 1% margin, the test is successful.

In case of failure:

The test has failed if the margin is bigger than 1%.
In this case, check whether any quality checks still must be performed. If this is the case, proceed with the pending quality checks until successfully completed. Then, redo the Re-188 Container test.

If the test still fails, please contact OncoBeta GmbH.

5.3 Quality controls every week:

The following quality controls shall be executed once a week or at least before each treatment.

5.3.1 High voltage check

The electronics has a built-in high voltage source. Without this high voltage the ionization chamber cannot produce a proper output current. It is very important to check the high voltage on a regular basis to ensure a reliable operation of the dose calibrator.

Step 1: Select “High voltage check” in the main window and click the “Start” button. A new window will open and ask you to remove all activity from and around the dose calibrator. To continue click “OK”. The determination of the voltage may take up to 30 seconds.

The high voltage check is successful when the voltage is above 145 V.

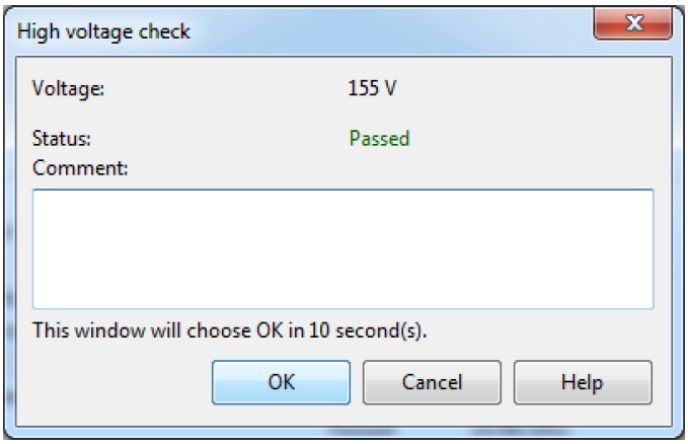


Figure 14.: Results of a high voltage routine

Step 2: Click “OK” to save the quality control result and to accept the high voltage routine.

If the high voltage check result is below 135 Volt, then first perform a Zero adjustment and Bias and perform a new high voltage check.
If the high voltage check result remains too low, please contact OncoBeta® GmbH.

5.4 Other quality controls

5.4.1 Linearity test

All deviations that have been corrected through the zero adjustment, bias correction and calibration have been carried out with a specific activity that is relatively stable. The linearity test is available to ensure that the other activities are also measured correctly: the activity is measured and checked over a broad spectrum of activities.

The linearity test must be performed **every six months**. Tc-99m and/or F-18 are the recommended source for the intended test. With these sources, the test could be initiated on a Friday so that it is completed by the following Monday. The activity range shall cover the activities used during a standard production.

Step 1: Select “linearity test” and click the “Start” button to perform the test. The following window will be displayed.

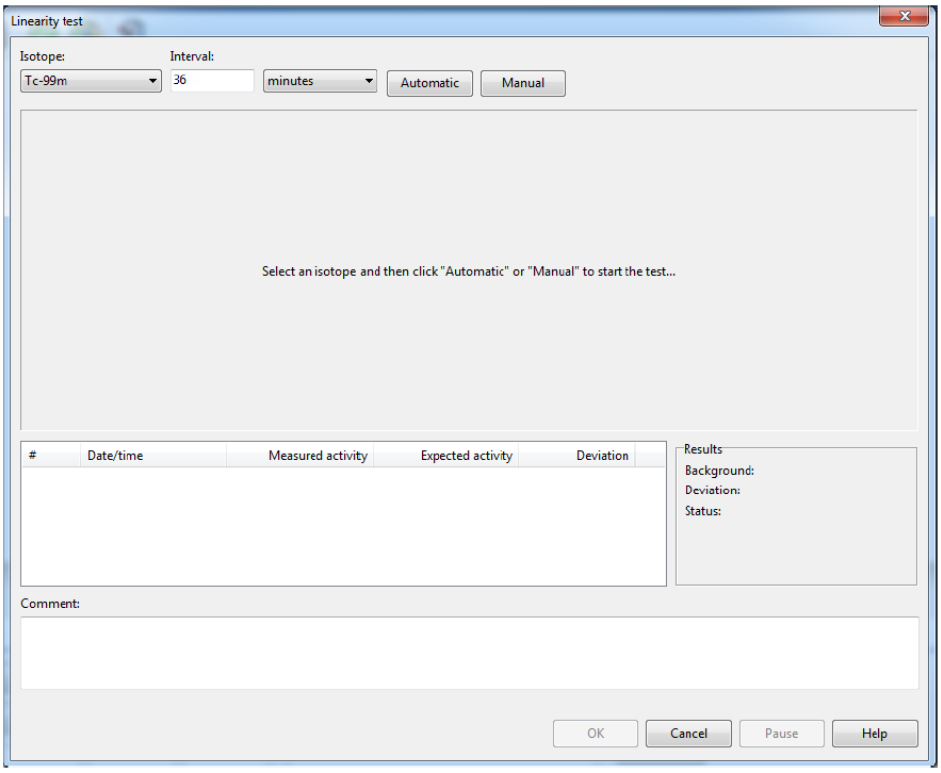


Figure 15.: Linearity test

Step 2: Select the required isotope from the list with isotopes. If you select an isotope, the system will automatically fill in the interval between two measurements. This is used when you wish to perform the test automatically.
The default interval is 10 measurements per half-life with a minimum of 10 seconds and a maximum of 1 day. Change the interval if required.

Performing the test automatically:

Step 3a: Click the “Automatic” button to perform the linearity test automatically. The next window will be displayed, telling you to place the source in the dose calibrator.

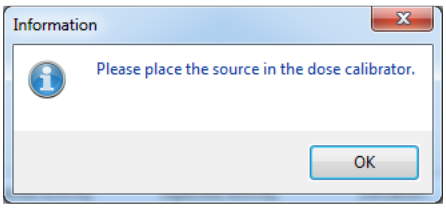


Figure 16.: Position the source

Step 4a: Position the source (the product) in the dose calibrator and click “OK” to perform the first measurement.

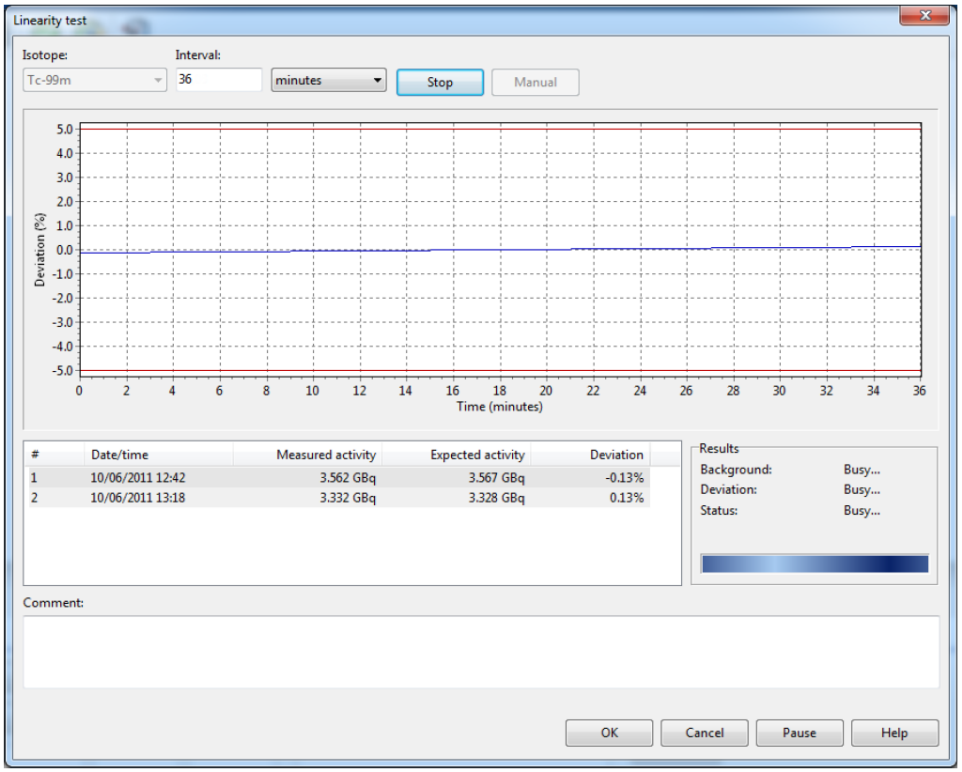


Figure 17.: Performing a linearity test with several measurements.

You will see the diagram where the deviation (between the measured activity and expected activity) is shown compared to time in the test. This is displayed using a large format. The individual measurements will be displayed under the diagram.

Performing the test manually:

Step 3b: Click the “Manual” button to add a new measurement. A new window will open informing about the isotope and its activity.

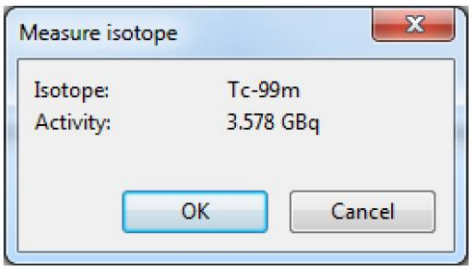


Figure 18.: Measuring Isotope

The screen will retrieve new activity measurements continuously. Therefor there will be sufficient time to introduce the source in the dose calibrator. When the read-out of the activity has stabilized, click “OK” to select the measurement.

Step 4b: The measuring isotope window will close and lead you to the main window of the linearity test. There you will see the first measurement, you just performed, added. Again click “Manual” to add the next measurement.

Step 5: The linearity test will have been completed when the last activity measurement is lower than 1.000 MBq.

Note: When the test passes the threshold value, the background activity will be determined automatically. The background is an activity between -200 kBq and 200 kBq where the maximum deviation will have been minimized. The background will be subtracted from the measurements. Then the reference activity, expected activities and deviations will be redetermined.

The linearity test is successful when the maximum deviation is between -5% and 5%.

Step 6: Click “OK” to save the quality control result and to accept the linearity test.

Note: If necessary, the test can be paused and resumed at a later state. To do so, click the “Pause” button to pause. And “Start” to resume the test.

5.4.2 Calibration Check

The calibration of the dose calibrator means adjusting three parameters that will ensure that the dose calibrator again meets the standard model criteria. Three sources are used for the calibration check: Co-57 (low energy) and Co-60 (high energy). These two first sources are introduced one at a time and the two parameters are calibrated until minimum deviations are obtained. A third source, Cs-137 (medium energy), is introduced as last in the control source.

Note: Only service personnel who are qualified and experienced with the product should calibrate a dose calibrator. Because this group is not available everywhere and a statement must be made anyway about the quality of the dose calibrator, we have the calibration check.

The calibration check uses the same sources as the basic calibration of this device:

- Co-57 (low energy)
- Cs-137 (medium energy)
- Co-60 (high energy)

The three aforementioned parameters cannot be changed during the calibration check. Only deviations are the determining factors for the success or failure of the check.
The check must be performed **every 6 years**, starting from VIK-202 Calibration Certificate date delivered with the device.

Step 1: Select “Calibration check” in the main window and click the “Start” button. The following window will open:

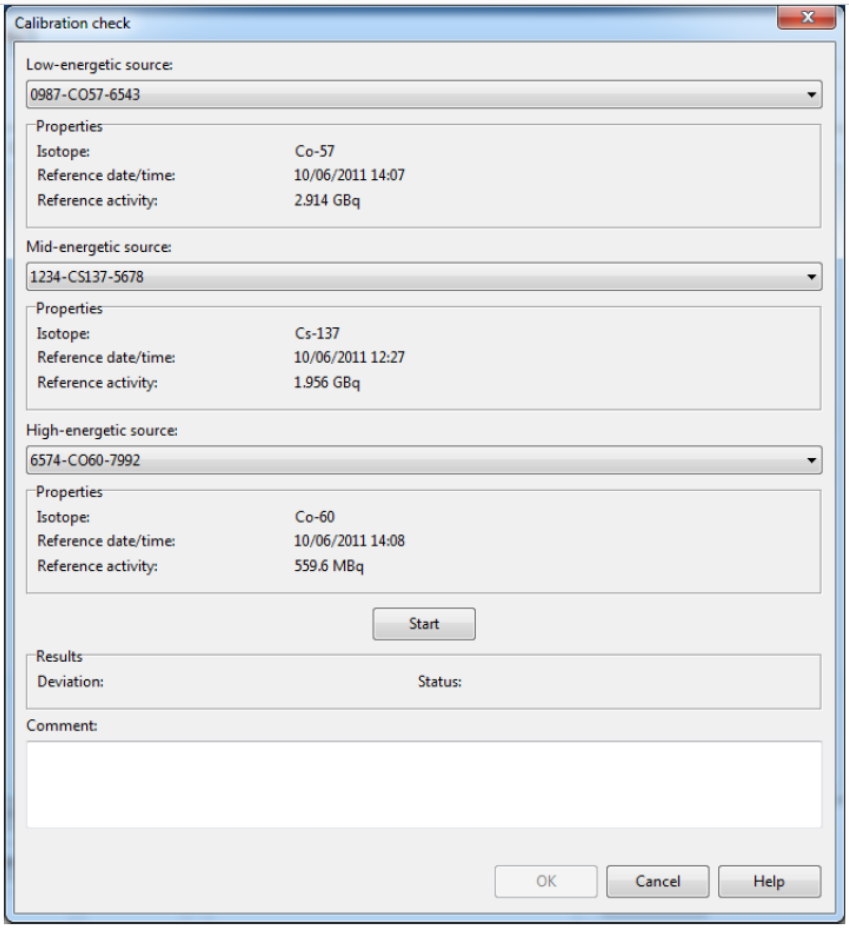


Figure 19.: The calibration check still without results

The window mainly shows the three required sources and the properties.

Step 2: Check carefully that the serial numbers and properties match the ones of the sources that you have prepared for the check. If one or more of the sources in the window do not match the actual source, select the correct source in the window by clicking the serial number.

Step 3: After having checked all sources, click “Start” to start the calibration check. The system will ask you to introduce the correct source in the dose calibrator every time.

Measuring each source will take approximately up to 30 seconds. The system measures the activity 10 times and averages this. In addition, the standard deviation will also be determined for each source.

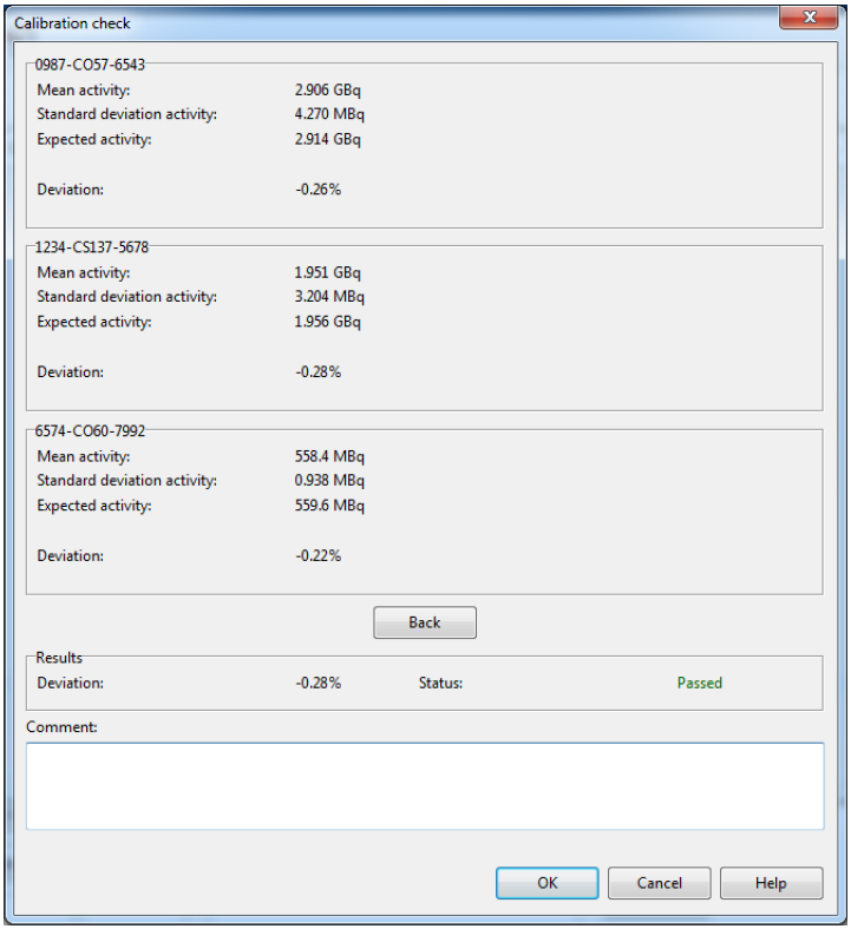


Figure 20.: The results of a calibration check

The calibration check is successful when the maximum deviation is between -5% and 5%.

Step 4: Click “OK” to save the quality control result and to accept the calibration check routine. If you wish to again perform the calibration check, click the “Back” button instead.

5.4.3 Calibration

A re-calibration has to be performed in case of a failure of the calibration check. In this case please contact OncoBeta GmbH.

5.5 Ready for use

The dose calibrator is ready to be used as soon as all quality controls have been successfully completed.

5.6 Sources and configurations

5.6.1 Source management

Long-life sources will be needed for the accuracy and constancy test, calibration check and calibration quality control routines.

To manage the sources, click on the “Sources” button  in the main window of the QMM-101 window. This will require a password. The Setting Password is: **OncoBeta**

The following window will open:

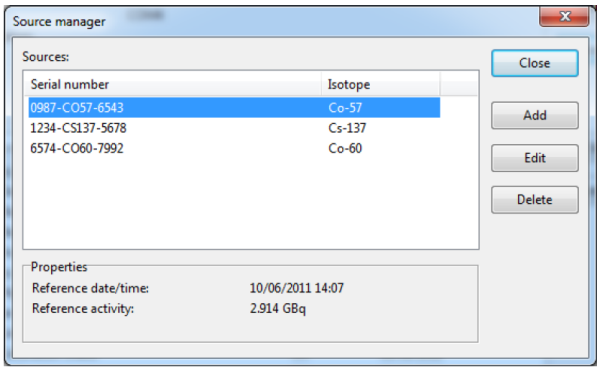


Figure 21.: Source management

All defined sources will be displayed in a list in the window. Click a source to view the reference properties under the list.

5.6.2 Adding a source

Step 1: To add a source to the list with sources, click the “Add” button in the source manager window. The following window will open:

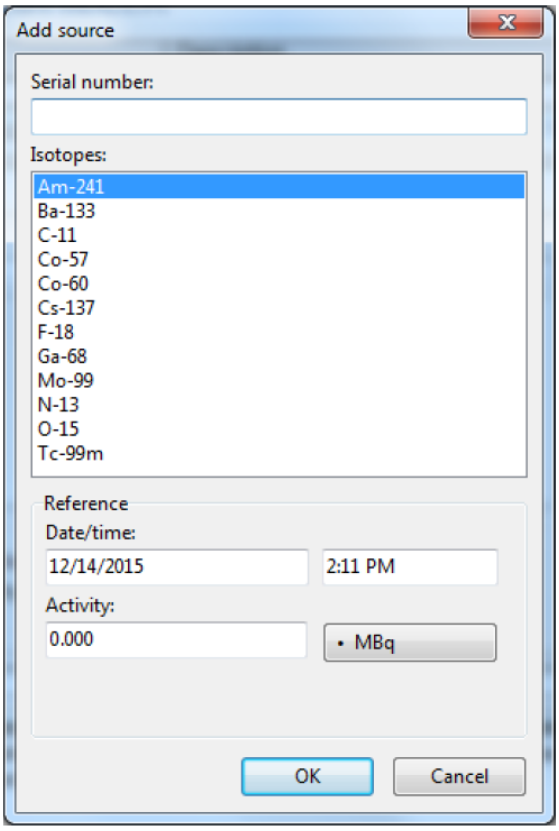


Figure 22.: Add a source

Step 2: Specify the serial number of the source. This is very important and must be unique.

Step 3: Select the isotope followed by the reference data. The manufacturer may refer to this as “calibration” and not as “reference”. In any case, this refers to the date, time and activity that the manufacturer has specified.
Step 4: When all source data has been specified, click “OK” to add the source to the system.

5.6.3 Edit source

Select a source from the list and click the “Edit” button to edit a source. The following window will be displayed:

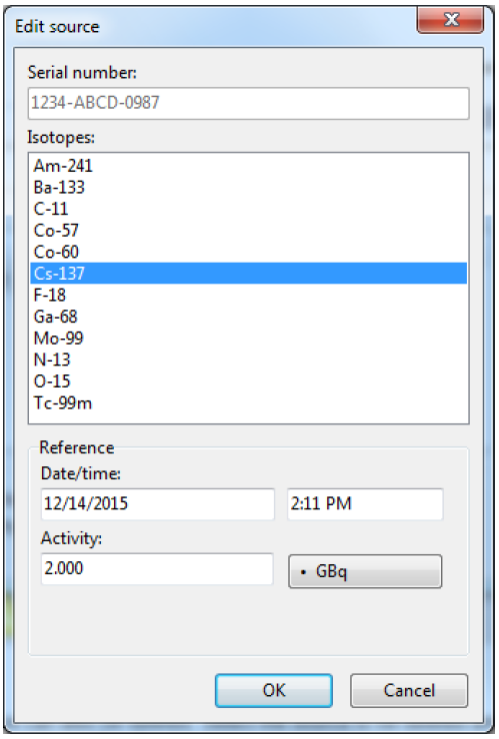


Figure 23.: Edit source

The functionality of the window is the same as when the source is added. The only difference is that the serial number can no longer be changed. Change the required data and click the “OK” button to implement the source change.

5.6.4 Deleting a source

A source can also be deleted. Select the source to be deleted and the click the “Delete” button. The system will require you to confirm the deletion in a new window. Confirm the deletion by clicking “Yes”. If not, click “No”.

6 Errors

6.1 Errors in Use

Errors in use could occur:

- By selecting a wrong nuclide
- After a faulty calibration has been performed
- When the ionization chamber is not connected properly

6.2 Errors in the Equipment

6.2.1 Communication error

The most probable cause is a faulty connection. Please check the cable between the readout unit and the ionization chamber. If the cable is connected correctly, the cable itself has to be checked for wear or damage.

6.2.2 No zero value

If the measured value cannot be adjusted to zero with the Bias adjustment, there are several reasons why this could happen. Below a description and explanation in question - answer form.

Q: The well liner is contaminated.
A: Decontaminate the well liner.
Q: High background value because of a large source in the surrounding of the ionization chamber. Shield or remove this source.
A: If changing the Bias adjustment setting doesn't bring the reading close enough to zero, use the background subtraction option to produce a close to zero value.
Q: The leakage current is too high because of moisture.
A: The desiccant cartridge inside the ionization chamber needs to be changed.

6.2.3 No proper calibration (check) is possible

If no proper calibration is possible, this can be caused by:

- An improper Bias/ zero adjustment
- An excessively high background value
- A defective ionization chamber
- The uncertainty level of the calibration sources is too high

7 Measuring activity

7.1 Overview of the steps

The process of using the Measurement Station together with the applicator is illustrated in the following flow chart:

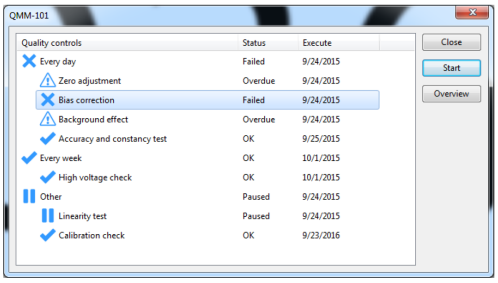
Step	Activity
0	**Turn on the dose calibrator and let stabilize for at least 30min.**
1	Perform quality tests before starting the treatment. (At least a zero adjustment & bias setting has to be performed before every treatment)
2	Starting treatment: Insertion of the loaded Applicator into the MST
3	Lowering of applicator into measurement chamber
4	Measurement

5	Lifting of applicator into end position
6	Continue with treatment
7	Cleaning

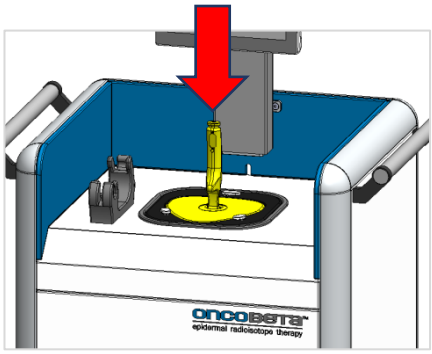
7.2 Description of the steps for measuring the activity

The Measurement Station will be used together with the applicator to measure the activity of the REC-compound inside the carpoule in use. To do so the following steps must be performed:

1 Before starting the treatment, various quality tests must be performed. Those tests can differ depending on the time passed since last tested.
To do so, please follow the instructions as described in chapter 4 of this IFU.

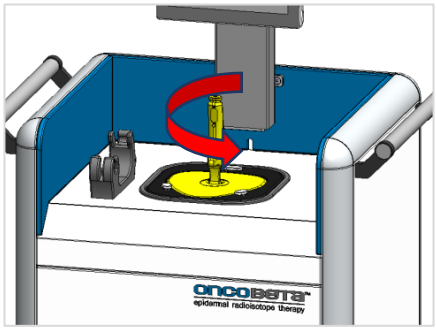


2 Insert the loaded applicator into the deepening of the measurement station. Place the actuator in its holder.

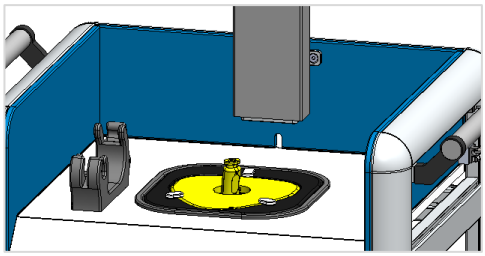


3 To lower the applicator and its carpoule into the measurement station, turn the handle of the applicator counter clockwise until stop. This allows a separation of the handshield and the rest of the applicator. This also locks the shield in its position with help of 3 hooks.

When loosened, let the handle slowly dive into the chamber until it reaches the bottom. The handshield will stay in place.

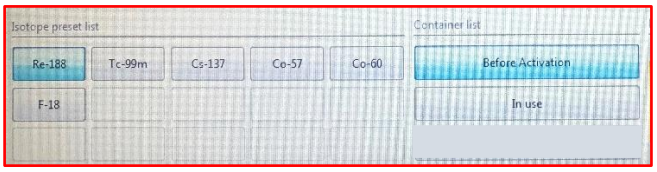


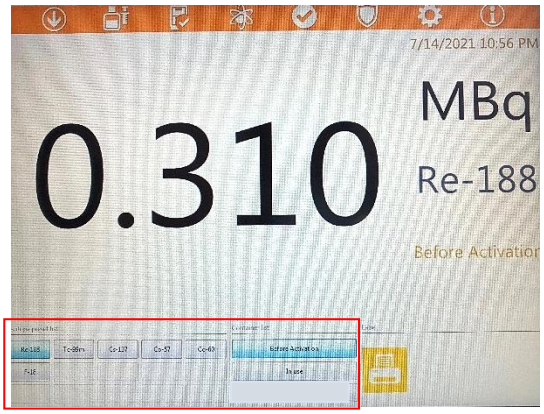
4 To measure the activity, follow the instructions for the dose calibrator and its reading unit. All necessary test needs to be done beforehand.



Before Activation: To measure the activity of the non-activated carpoule, select first Re-188 in the bottom left corner. Then select the container “Before Activation”. The correct value will appear in the main window.

In Use: To measure the activity, when the carpoule already is activated, select first the Re-188 in the bottom left corner. Then select the container “in Use”. The correct value will be displayed in the main window.

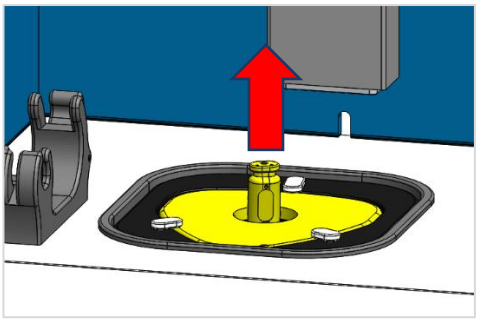




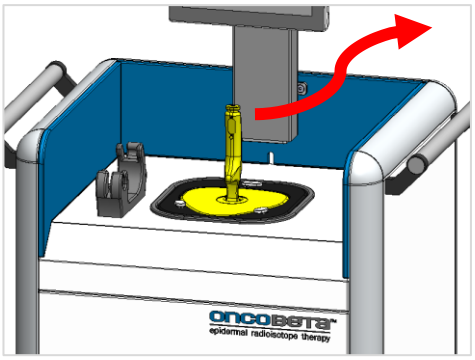
When proceeded, keep record of the measured activity in the treatment protocol to then calculate the treatment time.

5 After the measurement lift the handle back up until a click noise can be heard. That means the handle and its handshield connect to each other again.

Turn the handle clockwise until both parts are locked with each other. The hooks fastening the shield will be opened again.



6 The applicator can now be removed from the MST and the treatment can continue.



7 After the finished treatment the device shall be checked for contamination and all surfaces shall be cleaned.

8 Maintenance

The ionization chamber is, apart from cleaning after each use and its quality control tests, service free for the end user.

8.1 Cleaning the MST

The MST can be cleaned, decontaminated, and disinfected by means of wiping with Kohrsolin® extra tissues. The devices are not suitable for being immersed in water or sterilised. Alcohol-based cleaning products must never be used on acrylic glass surfaces.

Contact OncoBeta® GmbH for an up-to-date list of the suitable cleaning, decontamination and disinfecting agents.

8.2 Procedure to follow in the event of incorporation

For the safety of the patient and all personnel involved in the treatment process, it is important that the contingency plan is followed carefully in the event of incorporation of the radioactive material.
Since the radioactive component of the **OncoBeta® Rhenium-188-Compound** is in the form of a Re_2S_7 colloid with a low solubility, it is generally not expected for the incorporated rhenium-188 to distribute itself systematically throughout the body. The steps taken in the event of incorporation should therefore focus on the localized removal of the incorporated material.

PLEASE NOTE Medical practices are the responsibility of hospital personnel providing the treatment. The clinical procedures described here have been observed in everyday clinical practice; however, they do not constitute mandatory requirements set by OncoBeta® GmbH. Hospital personnel have a duty to keep up to date with the latest medical findings and to choose the most appropriate procedures for their patients.

The extent of the incorporation must be calculated and the possible potential damage estimated. Appropriate measures to be taken must be justified by the potential for damage. Depending on the route of incorporation, measures can be taken to speed up the natural excretion process or attempts can be made to remove remnants of the *compound*, e.g. using tweezers.

8.3 Life time and Disposal

The lifetime of the MST is defined as 6.000 cycles of use. One cycle is defined as one measurement of a REC Carpoule.
For disposal of the Measurement Station please contact OncoBeta GmbH.

Appendix

EMC Information:

Electromagnetic disturbances such as electrostatic discharge, mains supply overvoltage spikes and mains interruptions may cause the following types of degradation of performance:

- Noticeable influences on the screen. These should be discarded because it's clearly not a measurement of the activity of a radioactive source.
- As a result, the VDC-606 product may need to be restarted (recycle power).

Basic safety is not affected by these phenomena.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The VDC-606 is intended for use in the electromagnetic environment specified below. The customer or the user of the VDC-606 should assure that it is used in such an environment.
All tests are executed in combination with ionisation chamber VIK-202</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The VDC-606 uses RF energy only for its internal function.
Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The VDC-606 is suitable for use in all establishments
other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonics emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity		
All tests are executed in combination with ionisation chamber VIK-202		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 4 6 8 kV contact ±2 4 6 8 15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency for power supply lines ±1 kV 100 kHz repetition frequency for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:	U_T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) U_T = 0%; 1 cycle U_T = 70%; 25/30 cycles (@ 0 degrees) U_T = 0%; 250/300 cycle	U_T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) U_T = 0%; 1 cycle U_T = 70%; 25/30 cycles (@ 0 degrees) U_T = 0%; 250/300 cycle
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity		
All tests are executed in combination with ionisation chamber VIK-202		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	6 Vrms 150 kHz to 80 MHz 80% AM modulation @1 kHZ for power supply lines 6 Vrms 150 kHz to 80 MHz 80% AM modulation @1 kHZ for input/output lines	6 Vrms
Radiated RF IEC 61000-4-3	3 V/m80 MHz to 2.7 GHz 80% AM modulation @1 kHZ	3 V/m
Proximity field from RF wireless communications equipment IEC 61000-4-3	TETRA 400, 380-390 MHz, 27 V/m @18 Hz pulse modulation	27 V/m
	GMRS460, 430-470 MHz, 28 V/m @ FM ± 5 kHz deviation 1 kHz sine	28 V/m
	LTE Band, 704-787 MHz 9 V/m @217 Hz pulse modulation	9 V/m
	GSM800/900, 800-960 MHz, 28 V/m @18 Hz pulse modulation	28 V/m
	GSM1800, UMTS, 1700-1990 MHz, 28 V/m @217 Hz pulse modulation	28 V/m
	WLAN, BT, 2400-2570MHz, 28 V/m @217 Hz pulse modulation	28 V/m
	WLAN 802.11, 5100-5800MHz, 9 V/m @217 Hz pulse modulation	9 V/m