



OncoBeta[®] Dosimetry

Rhenium-SCT[®] procedure

**User manual
English**

OncoBeta[®] GmbH



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Contact Information

OncoBeta® GmbH
Schleißheimer Str. 91
D-85748 Garching near München
Germany
Tel. +49 (0) 89 - 32667330
Fax +49 (0) 89 - 3266733099
Email: info@oncobeta.com
Website: www.oncobeta.com
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1 Introduction

This user manual is intended solely for **qualified medical personnel that have been trained** by OncoBeta® GmbH or by sister organizations of OncoBeta® GmbH or by certified sales partners.

PLEASE NOTE

If applicable, national regulations must be taken into account when selecting the personnel who will be authorised to use the product.

This user manual applies to the **OncoBeta® Dosimetry**. The instructions for using the OncoBeta® Rhenium-Skin-Cancer-Therapy (Re-SCT®) Dosimetry, as well as the instructions for the other **Rhenium-SCT®** products needed to carry out the procedure, must be considered before any Rhenium-SCT® procedure takes place.

BEFORE using this manual:

- Check the page numbers to ensure that the document is complete
- Make sure that you have the latest version of the OncoBeta's Re-SCT Dosimetry

IMPORTANT: Please contact the manufacturer if this manual is incomplete or the dosimetry file is not up to date.

1.1 The Rhenium-SCT® procedure

The Rhenium-SCT® with Rhenium-188 is used as a non-invasive method for treating non-melanocytic skin cancers. Prior to the treatment, the depth of the lesion is determined by the dermatologist and the area to be treated must be accurately marked, including the evident lesion and a healthy tissue border of 5 mm beyond the lesion. The surface of this area must be then determined accordingly.

During the treatment, the treatment area of the skin is covered with the sterile protective foil. The **OncoBeta® Rhenium-188-paste** is then applied over the foil above the tumour tissue including the safety margin. The treatment time required to achieve the desired target dose at the defined penetration depth is calculated taking into account the total activity of the applied substance and the surface of the area to be treated. The paste hardens during the treatment process and forms a flexible film on the foil. After the treatment time, the radioactive paste is removed by pulling the foil from the skin.

The beta radiation means that the dose decreases exponentially as the penetration depth increases, protecting deeper layers of tissue. This generally makes it possible to administer a lethal dose to the tumour in a single course of radiation without damaging deeper layers of skin tissue.

Rhenium-188 has a half-life of 17 hours and radiates with a beta decay energy of maximum 2.12 MeV, which allows for the treatment of lesions with a depth of up to 3 mm. Due to the relatively fast decay of Rhenium-188, the activity of the **OncoBeta® Rhenium-188- paste** on delivery changes depending on the production and the requested delivery time of the

clinic. Additionally, the activity might be limited to a certain value on delivery, if the institute receiving the activity has a limited license for handling Rhenium-188. The treatment time is calculated during the treatment depending on the activity of the applied Rhenium-188-paste on the lesion, target radiation dose (commonly 50 Gy), target treatment depth and area of the lesion. A delivered REC Carpoule will have an activity within specifications, which generally provide for a treatment time ranging between 45-180 min. In exceptional cases, however, treatment times of significantly less than 45 minutes are also possible. This is especially the case when the lesions are particularly shallow or very small areas are treated.

1.2 Activating and saving OncoBeta Dosimetry

OncoBeta Dosimetry is automatically saved to prevent data loss. If you receive OncoBeta Dosimetry as an email attachment, please save it to your computer first to prevent Error 9 (see Chapter 1.5).

When OncoBeta Dosimetry is opened for the first time, Excel will most likely display a security warning. This warning is expected and is intended to protect the computer from malware and viruses. This disables the Excel file and the macros (functions in the file) are automatically disabled. To use OncoBeta Dosimetry, please click on **"Enable Content"** to activate the macros.

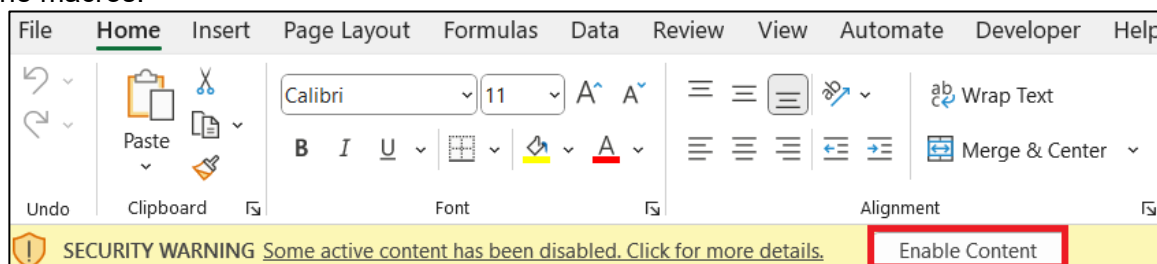


Figure 1. Macro activation: Message Bar

Alternatively, you can click on "Click for more details" first. Excel will then redirect you to the security warning. You can then click the drop-down arrow and activate OncoBeta Dosimetry under **"Enable all content"**:

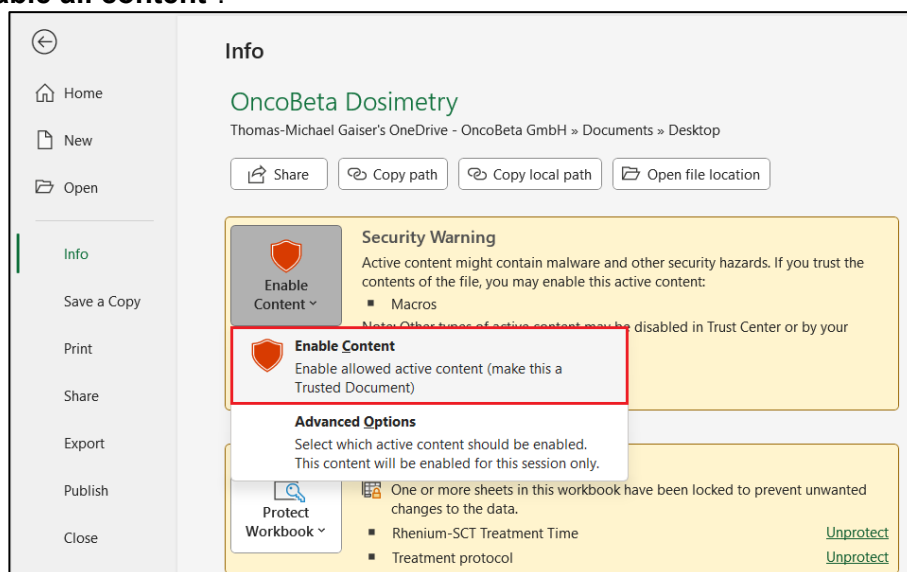


Figure 2. Macro activation: Microsoft Office Backstage

OPTIONAL:

In OncoBeta Dosimetry, **Comma ","** is set as the **decimal separator** and **Point "."** as **thousands separator**. If the reverse notation is preferred, please change the Excel file accordingly. To do so, please go to **File → Options → Advanced** and uncheck **"Use systems separators"**. Now you can exchange "." and ",". Confirm the process with **"Ok"**.

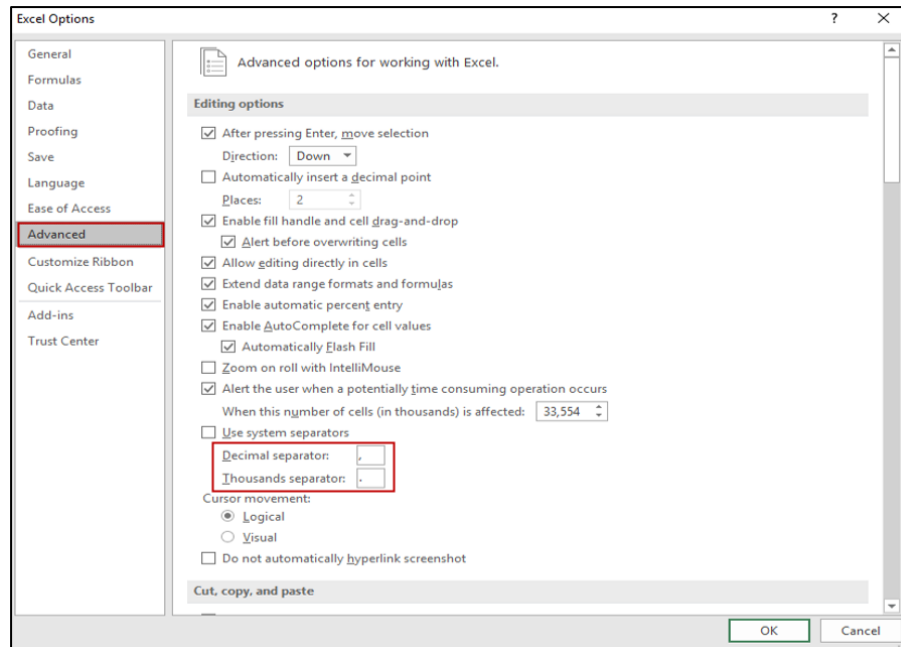


Figure 3. Comma (,) as a decimal separator and point (.) as an optional thousands separator

The file can now be operated. Please read the first page carefully. Then check all three boxes if you agree and select **"Start"** to proceed to enter the data.

OncoBeta® Dosimetry

oncoBeta
epidermal radioisotope therapy

The possible values for the **activity per area** (MBq/cm²) range from 12 MBq/cm² to 200 MBq/cm²

The smallest area (cm²) that can be introduced: 0,5 cm²; the largest one: 100 cm²

Treatment times over 6 hours will be highlighted to warn the user about this situation

The values recorded for the different measurements of the activities should always be within the specifications

All the data is saved when the file is closed. If you want to save the file with a different name use **Save as** command before closing the file

Version: 2.0
Latest version available in the OncoBeta website: <https://www.oncobeta.com/>

☐
Click here to indicate that you have read the message above

☐
Click here to confirm that macros have been enabled

☐
Click here to certify that the OncoBeta Dosimetry file has been validated in the laptop and that the personnel using it has been thoroughly trained by OncoBeta

Start

Figure 4: Activating OncoBeta Dosimetry

1.3 Determination of the treatment time

The irradiation time required must be calculated by a qualified member of staff with specialist knowledge in this area. The information required for this calculation and the irradiation time charts for checking the plausibility of the treatment time (including a dedicated instruction for use) are provided by OncoBeta® GmbH, a sister company or its certified sales partners.

The recommended target radiation dose to be delivered for the desired clinical effect of the Rhenium-SCT® procedure would be 50 Gy at the thickest part of the lesion. The material provided by OncoBeta® GmbH, sister companies or its certified sales partners already includes this target radiation dose explicitly.

The required treatment time for the **Rhenium-188- paste (REC)** to remain on the lesion depends on three different parameters:

- depth of the lesion (µm)
- surface of the area to be treated (cm²)
- activity applied (MBq)

The determination of the treatment time is performed by the qualified member by means of the OncoBeta® Re-SCT Dosimetry, which shall be validated prior to its use as per OncoBeta® Dosimetry Validation Manual. The previously mentioned parameters must be determined by the user and subsequently transferred to the dosimetry's interface (Figure 6). This interface is divided into *Input* and *Output* values, differentiating thus between the values that need to be introduced by the user, and the ones determined by OBG Re-SCT Dosimetry.

Once the lesion has been prepared, as stated in the "OncoBeta® Application System User Manual", the following steps need to be performed and the correspondent values need to be determined and transferred to the OncoBeta® Re-SCT Dosimetry:

1. Number the lesions in the **Lesion Nr.** field (optional)
2. Introduce the area of the lesion to be treated in the correspondent **Area (cm²)**
3. To identify the different lesions, the anatomical location of each one of them can also be specified in **Location**
4. Select the penetration depth of the lesion from the drop-down list **Depth (µm)**
5. Write down the activity of the REC Carpuole recorded in the initial measurement (**1st Measurement (MBq)**)
Apply the paste over the area and measure the remaining activity
6. Fill in the **2nd Measurement (MBq)** field with the recorded value
7. Write down the time when the paste was applied in **Start Time (hh:mm)**

NOTE: Before introducing the measurements of the activities in the dosimetry file (1st and 2nd Measurement values), make sure that all the previous fields have been filled in, specially the area and the depth of the lesion.

A definition of the different required parameters can be found in Table 1.

Table 1. Parameters required for the Rhenium-SCT treatment time determination.

Input values defined by the user		
1	Lesion Nr.	Lesion identification number
2	Area (cm ²)	Surface of the area needed to treat in cm ²
3	Location	Anatomical location of the lesion
4	Depth (µm)	Depth of the lesion in µm
5	1 st Measurement (MBq)	Initial activity before applying the paste in MBq
6	2 nd Measurement (MBq)	Remaining activity after applying the paste in MBq
7	Start Time (hh:mm)	Time at which the paste is applied
8	Comments	Additional possible comments
Output values		
9	Activity applied (MBq)	Total activity applied to the area to treat in MBq
10	Activity per area (MBq/cm ²)	Total activity applied per unit area in MBq/cm ²
11	Time (min)	Treatment time for the paste to remain on the lesion in minutes
12	End Time (hh:mm)	Time at which the foil must be removed
Dose		
13	Actual Time (min)	In case the given time (11) has not been followed and the dose must be recalculated. Treatment time in minutes.
14	Actual Dose (Gy)	The dose that resulted from not following the specified treatment time (11) in Gray.

Once these values have been introduced, the **Activity applied (MBq)**, **Activity per area (MBq/cm²)**, **Time (min)** and the **End Time (hh:mm)** will be automatically determined (Figure 6). The activity per area can be calculated based on the difference of the initial (first measurement of the activity at the carpoule) and the remaining radioactivity (second measurement of the activity) divided by the correspondent surface area.

Activity applied (MBq), Activity per area (MBq/cm²), Time (min) and End Time (hh:mm) values will automatically be determined by OBG Re-SCT Dosimetry and therefore no access to these fields is permitted and no values can consequently be introduced.

IMPORTANT: **Area (cm²) = Lesion Area + 5 mm Safety Margin**

Taking into account the 5 mm security margin around the area needed to treat, the smallest surface area that can be introduced in the calculator is 1 cm² (lesion with a diameter of d = 2 mm); the largest one 100 cm². However, for special cases OBG Re-SCT Dosimetry is accepting values from 0,5 cm² upwards. Depth input values can be selected from 0,2-3 mm. The possible values for the activity per area (MBq/cm²) range from 12 MBq/cm² to 200 MBq/cm². Should the input/output values be out of range, a message box will appear indicating that an error has occurred with a short description on how to proceed (Figure 5).

NOTE: Use the comma (,) as a decimal separator and the point (.) as an optional thousands separator.

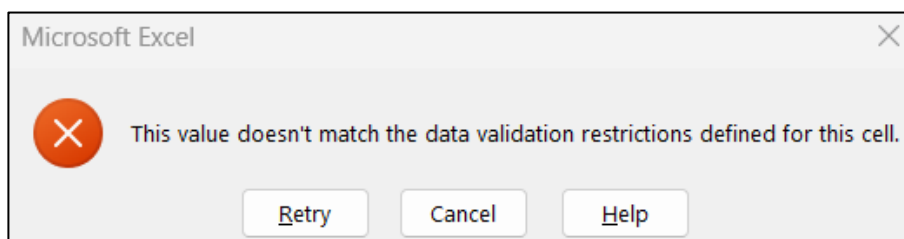


Figure 5: Error message box describing the problem.

Example:

A patient with a lesion on the **forehead** is being treated. The lesion is very small, so the treatment area, including the 5mm safety margin, is only **1cm²** and **0,2mm** deep.

1. Preparation:

Before treatment, it is recommended to enter the following lesion data into OBG Dosimetry (see Figure 6): Lesion Number (1), Area (2), Location (3) and Depth (4).

2. Treatment:

After the patient has been prepared, the treatment can start. The transport unit is placed in the base station, the carpoule is mixed and collected with the applicator. Then the first measurement of the carpoule is taken with the measuring station. The first measurement results show an activity of **1000MBq**. The First Measurement (5) is now entered in OBG Dosimetry.

The applicator is returned to the base station. The carpoule is activated, the cap is removed and a layer of paste is applied to the lesion. The applicator is placed back into the base station and the cap is put back on. Now the second measurement is carried out with the measuring station (change the measurement setting because the geometry has changed due to the activation of the Carpoule). The second measurement result shows **850MBq**. The time when the paste was fully applied was **10:00 am**. Both the Second Measurement (6) and the Start Time (7) are now entered in OBG Dosimetry. As only one patient is being treated that day, the carpoule can now be disposed of.

With the data entered, OBG Dosimetry now automatically calculates the Activity applied (9), the Activity per area (10), the Treatment Time (11) and the End Time (12). The physician now knows that the treatment takes 19 minutes and that he/she has to remove the foil at 10:19 am. He also double checks that the activity per area (10) is within the permitted limits. At the End Time (12), the foil is removed and the treatment is over.

In the Dose table, one could now enter the Actual Time (13) of 19 min and would get a Actual Dose (14) of exactly 50 Gy. For any treatment time other than the recommended one, the actual dose would not be equal to 50 Gy

1	2	3	4	5	6	7	8
Input values defined by user							
Lesion Nr.	Area (cm ²)	Location	Depth (µm)	1st Measurement (MBq)	2nd Measurement (MBq)	Start Time (hh:mm)	Comments
Example	1,00	Forehead	200	1000,00	850,00	10:00	N/A

9	10	11	12
Output values			
Activity applied (MBq)	Activity per area (MBq/cm ²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19

13	14
Dose	
Actual Time (min)	Actual Dose (Gy)
19	50,00

Figure 6: OncoBeta® Dosimetry interface

1.4 Procedure for using multiple layers with one carpoule

In extraordinary cases, a second layer of **Rhenium-188-Paste (REC)** can be applied right after the first application. These cases correspond with the ones where the activity initially applied is less than 12 MBq/cm² (Activity per area < 12 MBq/cm²) or cases with really long treatment times. For this purpose, correct the value recorded in the 2nd Measurement (MBq) field with the last one measured. Should the second application take place with a new REC Carpoule, proceed as follows:

1. Note the already Activity applied (MBq) value
2. Take the new carpoule and proceed as usual: perform the correspondent 1st and 2nd Measurements (MBq)
3. Correct the 1st Measurement (MBq) by adding the initial Activity applied (MBq) value noted in step 1

NOTE: For treatment times over 6 hours, Time (min) will be highlighted to make sure that the user notices; a new layer of Rhenium-188- paste will be required.

1.5 Procedure for using multiple carpoules for one lesion

In some cases, e.g. with very large lesions, it may happen that one carpoule does not achieve high enough activity per area or that the treatment would take longer than 6 hours. In these cases, a second carpoule must be used. The correct utilisation of OBG Re-SCT Dosimetry for such a situation is described below.

1. Fill in the data for the first carpoule as described in chapter 1.2. It is recommended to note the treatment with the first carpoule in the comments as "First Carpoule" to avoid mistakes.

Input values defined by user							
Lesion Nr.	Area (cm ²)	Location	Depth (µm)	1st Measurement (MBq)	2nd Measurement (MBq)	Start Time (hh:mm)	Comments
Example	1,00	Forehead	200	1000,00	850,00	10:00	N/A
1	40,00	Back	1250	1000,00	250,00	9:00	First Carpoule

Output values			
Activity applied (MBq)	Activity per area (MBq/cm ²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19
750,00	18,75	371,00	15:11

Figure 7: Procedure with Multiple Carpoules - Step 1

NOTE: This might trigger an error or highlight the treatment time red. This error can be ignored, since only the total activity per area and time of carpoule 1 and carpoule 2 are relevant.

2. For the second carpoule please proceed as described in chapter 1.2. and fill in the data in a new row. It is recommended to note the treatment with the second carpoule in the comments as "Second Carpoule" to avoid mistakes.

Input values defined by user							
Lesion Nr.	Area (cm ²)	Location	Depth (µm)	1st Measurement (MBq)	2nd Measurement (MBq)	Start Time (hh:mm)	Comments
Example	1,00	Forehead	200	1000,00	850,00	10:00	N/A
1	40,00	Back	1250	1000,00	250,00	9:00	First Carpoule
	40,00	Back	1250	1200,00	500,00	9:10	Second carpoule

Output values			
Activity applied (MBq)	Activity per area (MBq/cm ²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19
750,00	18,75	371,00	15:11
700,00	17,50	408,00	15:58

Figure 8: Procedure with Multiple Carpoules - Step 2

NOTE: This might trigger an error or highlight the treatment time red. This error can be ignored, since only the total activity per area and time of carpoule 1 and carpoule 2 are relevant.

- To calculate the correct treatment time for the treatment with two carpoules please check that the area and depth input from the "First Carpoule" and "Second Carpoule" are identical. If so, continue as follows.

In a third row fill in the same area and depth as for carpoule 1 and carpoule 2. The 1st measurement, 2nd measurement and start time has to be calculated:

1st Measurement (total) = 1st Measurement (First Carpoule) + 1st Measurement (Second Carpoule)

2nd Measurement (total) = 2nd Measurement (First Carpoule) + 2nd Measurement (Second Carpoule)

Start Time (total) = Start Time (Second Carpoule)

NOTE: While the treatment time for carpoule 1 and carpoule 2 respectively is over 6 hours, the total time has been significantly reduced. The output data of carpoule 1 and carpoule 2 can therefore be ignored. The third row shows the correct output data for the treatment with two carpoules.

Input values defined by user							
Lesion Nr.	Area (cm²)	Location	Depth (µm)	1st Measurement (MBq)	2nd Measurement (MBq)	Start Time (hh:mm)	Comments
Example	1,00	Forehead	200	1000,00	850,00	10:00	N/A
1	40,00	Back	1250	1000,00	250,00	9:00	First Carpoule
	40,00	Back	1250	1200,00	500,00	9:10	Second carpoule
	40,00	Back	1250	2200,00	750,00	9:10	First Carpoule + Second Carpoule

Output values			
Activity applied (MBq)	Activity per area (MBq/cm²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19
750,00	18,75	371,00	15:11
700,00	17,50	408,00	15:58
1450,00	36,25	181,00	12:11

Figure 9: Procedure with Multiple Carpoules - Step 3

1.6 Calculating the applied dose for unplanned foil removal

If the foil is removed at a time other than that specified by OncoBeta Dosimetry, the patient will NOT be exposed to the intended 50 Gy. To calculate the applied radiation dose, there is third "Dose" table next to the "Output values" table. Please enter the actual time the paste was on the patient, and you will automatically receive the applied dose. Figure 10 shows an example where the paste was accidentally left on the patient for longer than the specified 118min. After 130 min, this resulted in a dose of 54,86 Gy.

NOTE: Please use the table "Dose" ONLY if you remove the foil too early or too late. Otherwise, please stick to the given treatment time shown in the "Output values" table.

Input values defined by user							
Lesion Nr.	Area (cm²)	Location	Depth (µm)	1st Measurement (MBq)	2nd Measurement (MBq)	Start Time (hh:mm)	Comments
Example	1,00	Forehead	200	1000,00	850,00	10:00	N/A
1	10,00	Forehead	800	1000,00	600,00	9:00	N/A

Output values			
Activity applied (MBq)	Activity per area (MBq/cm²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19

Dose	
Actual Time (min)	Actual Dose (Gy)
19	50,00

Figure 10: Calculating the Applied Dose for Unplanned Foil Removal

1.7 Errors and Warnings

Table 2: Potential Errors

Nr.	Error	Solution
1	The excel sheet cannot be operated.	Please make sure you have enabled the Macros first. Macros can be enabled as follows: 1. By clicking the Enable Content button when the Message Bar appears (Figure 1) 2. Via the Microsoft Office Backstage view that appears after clicking the File tab. In the Security Warning area, click Enable Content; under Enable All Content, click Always enable this document's active content (Figure 2)
2	The Start button does not work.	Please make sure you read and accept all conditions shown on the first page of OBG Re-SCT Dosimetry. All boxes must be clicked to enable the start button. (Figure 4)
3	Data Missing	Please make sure you filled in all mandatory input values. (Figure 16)
4	Too high	The achieved activity is too high! Please remove the foil with the Rhenium-188-Paste upon it immediately (Figure 17 & Figure 18)
5	Too low	The achieved activity is too low. Please follow instructions of Figure 19 & Figure 20.
6	Wrong Values	Please review the Data. The Value of Measurement 2 cannot be smaller than that of Measurement 1. (Figure 21)
7	The value doesn't match data validation restrictions defined for this cell.	Please make sure you are using the correct format and/or the value is within the defined range. (Figure 22)
8	Please select a valid number for the surface area.	Data input for surface area is out of range. Please use a value in the range of 0,5-100cm ²
9	A file named 'OncoBeta Dosimetry 2.0.xlsm' already exists in this location. Do you want to replace it? (Figure 24) or Run time error '1004' (Figure 25)	OncoBeta Dosimetry usually saves changes automatically. If OncoBeta Dosimetry is opened directly from an e-mail attachment this automatic save function is not possible because your computer does not know where to save the file. Please continue as described below: 1. Click "No". 2. Run time error '1004' will pop up (Figure). Click "End". 3. "Save your changes to this file?" window will pop up (Figure 26). Choose a location where you want to save the file and click "Save". 4. If this file has already been saved in this location, Excel will ask you if you want to overwrite the file Figure 27. Click "Yes" if you want to replace the file.

1.8 Treatment Protocol

The treatment protocol serves as a support for both the physician and OncoBeta GmbH to document the treatment. The input values defined by the user on the “Rhenium-SCT Treatment Time” sheet are automatically transferred to the “Treatment Protocol” sheet. The input data in the following tables and illustrations should only be seen as an example.

1.8.1 General Information

Table 3: General Information Input Values

Input Values	Description
Hospital / Clinic Name	Name of the hospital where the treatment is performed.
Nuclear medicine physician	Name of the physician in charge.
Date of treatment / therapy	Date on which the treatment is performed.
Hospital/clinic name	Skin Cancer Hospital Melbourne
Nuclear medicine physician	Dr. Sophia Reynolds
Date of treatment / therapy	17.03.2023

Figure 11: Treatment Protocol - General Information

1.8.2 Patient Information

Table 4: Patient Information Input Values

Input Values			Description	
Patient ID Lesion Nr			Data automatically copied from sheet “Rhenium-SCT Treatment Time”	
Anatomical Lesion Location			Data automatically copied from sheet “Rhenium-SCT Treatment Time”	
Histology / Indication			More detailed information about the lesion.	
Lesion Depth			Data automatically copied from sheet “Rhenium-SCT Treatment Time”	
Lesion Area			Data automatically copied from sheet “Rhenium-SCT Treatment Time”	

Patient ID Lesion Nr	Anatomical Lesion Location	Histology/Indication	Lesion Depth (µm)	Lesion Area (cm²) incl. the 5 mm safety margin
1	Forehead	BCC	1250	5,00
2	Nose	SCC	400	4,00
0	0		0	0,00
0	0		0	0,00

Figure 12: Treatment Protocol - Patient Information

1.8.3 Data Verification

Table 5: Data Verification Input Values

Input Values	Description
Serial Number (SN)	The serial number can be found in the CoC.
Activity (MBq) at Calibration Time	Activity at calibration time can be found in the CoC.
Initial Activity Measured (before activation)	1 st measurement of the carpoule activity.
Time (hh:mm) at Measurement	Time at which 1 st measurement was performed.
Does the measured activity match the activity values as stated in the CoC (activity at calibration time)?	If selected No , please contact OncoBeta immediately.
Is the activity value in permissible range (refer to the CoC) as determined by the manufacturer?	If selected No , please contact OncoBeta immediately.
No. of Carpoules received	Number of carpoules supplied for treatment.
Did you receive a Declaration of Conformity (DoC)	If selected No , please contact OncoBeta immediately.

Did you receive a Certificate of Compliance (CoC)?	If selected No , please contact OncoBeta immediately.		
Calibration time stated in the Certificate of Compliance (CoC)	Please use format yyyy-mm-dd hh:mm (UTC)		
No. of Carpoules received	2		
Did you receive a Declaration of Conformity (DoC)?	☒ Yes	☐ No	
Did you receive a Certificate of Compliance (CoC)?	☒ Yes	☐ No, then contact the manufacturer immediately	
Calibration time stated in the Certificate of Compliance (CoC)	Calibration Time: 2023-03-17 09:00 (UTC)		

Certificate of Compliance (CoC) Information		Treatment Information	
Serial Number (SN)	Activity (MBq) at Calibration Time	Initial Activity Measured (MBq) (before activation)	Time (hh:mm) at Measurement
SN 001650	1200	1000	09:00
SN 001651	1100	950	09:25
Does the measured activity of the Carpoule(s) match the activity value as stated in the CoC (activity at calibration time)?		☒ Yes	☐ No
If 'yes', continue with the treatment.			
If 'no', answer the question below to make a decision.			
Is the activity value in permissible range (refer to the CoC) as determined by the manufacturer?		☒ Yes	☐ No
If 'yes', continue with the treatment.			
If 'no', then stop the treatment and contact the manufacturer immediately.			

Figure 13: Treatment Protocol - Data Verification

1.8.4 Treatment Data

Table 6: Treatment Data Input Values

Input Values		Description				
Patient ID Lesion Number		Data automatically copied from sheet "Rhenium-SCT Treatment Time"				
Carpoule Serial Number		The serial number can be found in the CoC.				
1 st Measurement (MBq)		Data automatically copied from sheet "Rhenium-SCT Treatment Time"				
2 nd Measurement (MBq)		Data automatically copied from sheet "Rhenium-SCT Treatment Time"				
Time (min)		Data automatically copied from sheet "Rhenium-SCT Treatment Time"				
Start Time (hh:mm)		Data automatically copied from sheet "Rhenium-SCT Treatment Time"				
End Time (hh:mm)		Data automatically copied from sheet "Rhenium-SCT Treatment Time"				

Patient ID Lesion Nr	Carpoule SN ²	1st Measurement (MBq)	2nd Measurement (MBq)	Time (min)	Start Time (hh:mm)	End Time (hh:mm)
1	SN 001650	1000,00	300,00	49,00	09:05	09:54
2	SN 001651	950,00	600,00	37,00	09:30	10:07
0		0,00	0,00		00:00	
0		0,00	0,00		00:00	

Figure 14: Treatment Protocol - Treatment Data

1.8.5 Comments

Comments are optional and may provide information about any complications or changes in treatment. Please note here if multiple layers or multiple carpoules were used for the same lesion.

1.8.6 Document Release

After filling out this form completely, a copy of the completed Excel file will be automatically sent to OncoBeta GmbH by clicking the submit button.

2 Validation

2.1 Objective

Validation of the OncoBeta® Re-SCT Dosimetry holds only for Microsoft Excel installed on Windows! A validation of the OncoBeta® Re-SCT Dosimetry shall be performed before it can be implemented in any Rhenium-SCT® procedure. A copy of the validation documents shall be handed over to OncoBeta GmbH after the successful validation of OncoBeta® Re-SCT Dosimetry.

IMPORTANT: In an event of not providing the validation documents before a Rhenium-SCT® procedure, OncoBeta GmbH takes no responsibilities for the consequences.

The validation process is required to be carried out in cases where one of the following situations apply:

- First implementation of the OncoBeta® Re-SCT Dosimetry
- Updates/changes in the OncoBeta® Re-SCT Dosimetry
- Update of the user's Excel version
- Replacement/substitution of the computer used for OncoBeta® Re-SCT Dosimetry
- Problems by previous uses

2.2 Associated Documents

- OncoBeta® Dosimetry User Manual
- OncoBeta® Re-SCT Dosimetry
- OncoBeta® Re-SCT Dosimetry Validation Form

2.3 Validation Protocol

The validation must be accordingly documented in the OncoBeta® Re-SCT Dosimetry Validation Form.

The required steps of the validation process need to be followed as written below in the tables. The steps are described as **Actions** and their acceptance criteria can be found in the **Value** field. Additional explanations are given to assist the user in the validation process.

2.3.1 Documentation

Nr.	Action	Value	Comments
1.1	Validation Manual	Title and version of validation manual used	See footnote of the referred document
1.2	Computer	Computer name, Operating System and version	
1.3	Excel Version	Enter excel version	► Explanation 1
1.4	Macros Activation	Macros need to be activated	► Explanation 2
1.5	Excel Options: Decimal Separator	Comma (,)	► Explanation 3
1.6	Activate OBG Re-SCT Dosimetry	Read and accept the conditions.	► Explanation 4

- Explanation 1: The Excel Version can be found under: File/Account/About Excel (Figure 15)
- Explanation 2: Macros can be enabled as follows:
- By clicking the Enable Content button when the Message Bar appears (Figure 1)
 - Via the Microsoft Office Backstage view that appears after clicking the File tab. In the Security Warning area, click Enable Content; under Enable All Content, click Always enable this document's active content (Figure 2)
- Explanation 3: As a decimal separator, a comma should be selected to avoid formatting issues (Figure 3)
- Explanation 4: To activate the OBG Re-SCT Dosimetry read the warning information on the first page carefully. Click all three boxes to confirm that you agree with all conditions. (Figure 4)

2.3.2 Data Validation

This step consists of a general validation to confirm that the OBG Re-SCT Dosimetry works as intended. Data (input values) will be filled in to check different scenarios and the resulting values will be validated.

A validation of OBG Re-SCT Dosimetry can only be completed if all applicable points have been answered with yes.

Nr.	Action	Value	Comments
2.1	Test Configuration 1	Input values according to Figure 28	---
2.2	Activity applied (MBq)	500,00	Error message Figure 17: Error 4 Warning
2.3	Activity per area (MBq/cm ²)	250,00	Output values to be found in Figure 29.
2.4	Time (min)	Too high	Test configuration 1 – Output values
2.5	End Time (hh:mm)	---	Error cause: Activity per area (MBq/cm ²) > 200
2.6	Test Configuration 2	Input values according to Figure 30	---
2.7	Activity applied (MBq)	20,00	Error message Figure 19
2.8	Activity per area (MBq/cm ²)	10,00	Output values to be found in Figure 31
2.9	Time (min)	Too low	Error cause:
2.10	End Time (hh:mm)	---	Activity per area (MBq/cm ²) < 12
2.11	Test Configuration 3	Input values according to Figure 32	---
2.12	Activity applied (MBq)	---	Error message Figure 23
2.13	Activity per area (MBq/cm ²)	---	Error cause: Area (cm ²) < 0,5
2.14	Time (min)	---	
2.15	End Time (hh:mm)	---	
2.16	Test Configuration 4	Input values according to Figure 33	---
2.17	Activity applied (MBq)	---	Error message Figure 23

2.18	Activity per area (MBq/cm ²)	---	Error cause: Area (cm ²) > 100
2.19	Time (min)	---	
2.20	End Time (hh:mm)	---	
2.21	Test Configuration 5	Input values according to <i>Figure 34</i>	---
2.22	Activity applied (MBq)	25,00	
2.23	Activity per area (MBq/cm ²)	12,50	Output values to be found in <i>Figure 35</i>
2.24	Time (min)	1782,00	Notice that Treatment Time (min) is over 6 h
2.25	End Time (hh:mm)	17:42	
2.26	Test Configuration 6	Input values according to <i>Figure 36</i>	---
2.27	Activity applied (MBq)	500,00	Output values to be found in <i>Figure 37</i>
2.28	Activity per area (MBq/cm ²)		Notice that without Area input, treatment time cannot be calculated.
2.29	Time (min)	Data missing	
2.30	End Time (hh:mm)		
2.31	Test Configuration 7	Input values according to <i>Figure 38</i>	---
2.32	Activity applied (MBq)	200,00	
2.33	Activity per area (MBq/cm ²)	20,00	Output values to be found in <i>Figure 39</i>
2.34	Time (min)	Data missing	Notice that without Depth input, treatment time cannot be calculated.
2.35	End Time (hh:mm)		
2.36	Test Configuration 8	Input values according to <i>Figure 40</i>	
2.37	Activity applied (MBq)	600,00	
2.38	Activity per area (MBq/cm ²)	60,00	Output values to be found in <i>Figure 41</i>
2.39	Time (min)	Data missing	Notice that without Start Time input, treatment time cannot be calculated.
2.40	End Time (hh:mm)		
2.41	Test Configuration 9	Input Values according to <i>Figure 42</i>	Output values to be found in <i>Figure 43</i>
2.42	Activity applied (MBq)	1450	Note that the treatment time has been significantly reduced. The first two output rows can be ignored. Only the output data of Carpoule 1 + Carpoule 2 are relevant.
2.43	Activity per area (MBq/cm ²)	36,25	
2.44	Time (min)	181,00	
2.45	End Time (hh:mm)	15:16	
2.46	Test Configuration 10	Input Values according to <i>Figure 44</i>	
2.47	Activity applied (MBq)	200,00	Output values to be found in <i>Figure 45</i>
2.48	Activity per area (MBq/cm ²)	100,00	
2.49	Time (min)	38	Note that the Actual Time is higher than the given Treatment Time. The Actual Dose is therefore higher than the recommended 50 Gy!
2.50	End Time (hh:mm)	12:38	
2.51	Actual Dose (Gy)	52,60	
2.52	Test Configuration 11	Input values according to <i>Figure 46</i>	---
2.53	Activity applied (MBq)	100,00	
2.54	Activity per area (MBq/cm ²)	50,00	Output values to be found in <i>Figure 47</i>
2.55	Time (min)	78	
2.56	End Time (hh:mm)	13:18	

2.3.3 Treatment Protocol Validation

Before proceeding with the treatment protocol, make sure to use the input data of **Test Figure 11** as starting point.

Nr.	Action	Value	Comments
2.57	Treatment Protocol	Treatment Protocol sheet is available	The Excel File has 2 sheets (Rhenium SCT-Treatment time & Treatment protocol)
2.58	General Information	Cells are enabled	---
2.59	Patient Information	Data was copied from sheet "Rhenium-SCT Treatment Time" and "Histologie/Indication" is enabled	Output values to be found in Figure 48
2.60	Data Verification	Cells and check boxes are enabled	---
2.61	Treatment Data	Data was copied from sheet "Rhenium-SCT Treatment Time" and "Carpoule SN" is enabled	Output values to be found in Figure 49
2.62	Comments	Cell is enabled	---
2.63	Document Release	Submit button triggers e-mail program	Note 1

Note 1: Emails are only triggered if the program **Outlook** is used. If you do not have access to this program, please save the protocol as a PDF and send it as an email to OncoBeta GmbH.

3 Appendix

3.1 Microsoft Excel Version

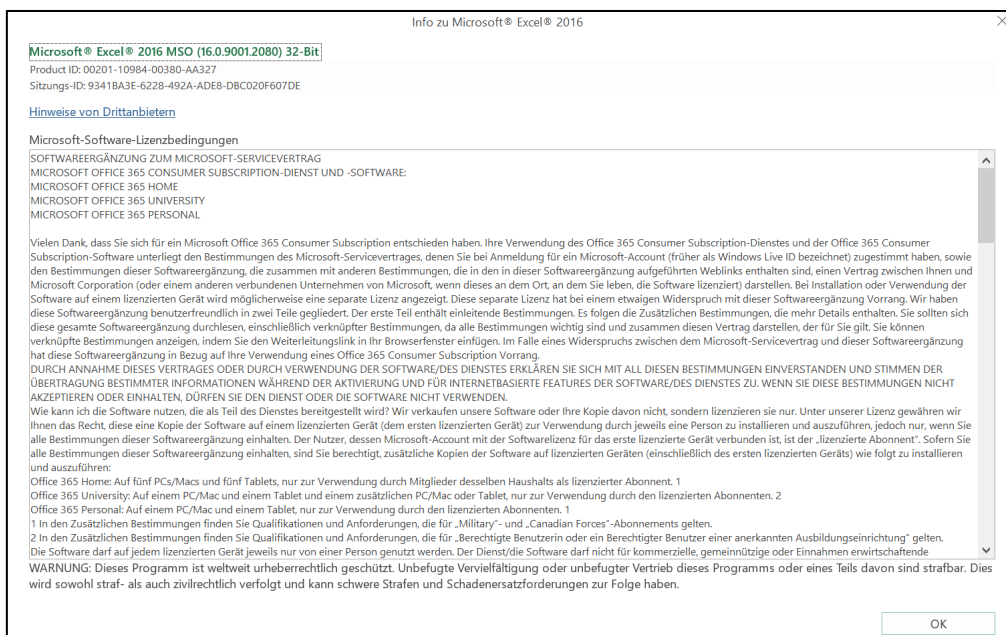


Figure 15: Excel Version Documentation

3.2 Error Messages & Warnings

Output values			
Activity applied (MBq)	Activity per area (MBq/cm²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19
300,00		Data missing	

Figure 16: Error 3 - Data Missing

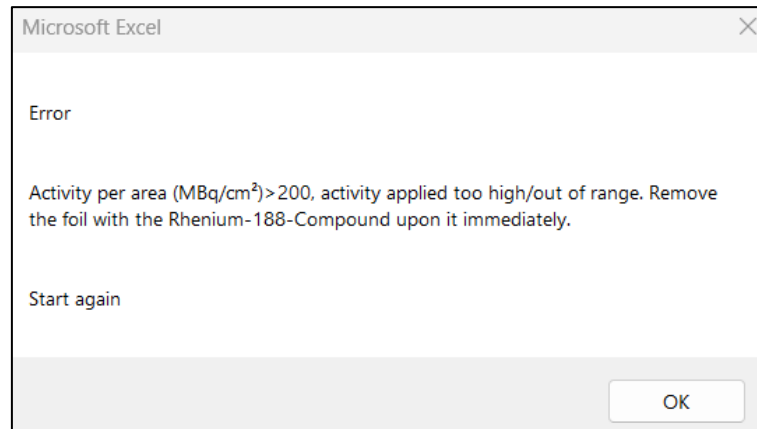


Figure 17: Error 4 Warning

Output values			
Activity applied (MBq)	Activity per area (MBq/cm²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19
990,00	990,00	Too high	

Figure 18: Error 4 – Activity too high

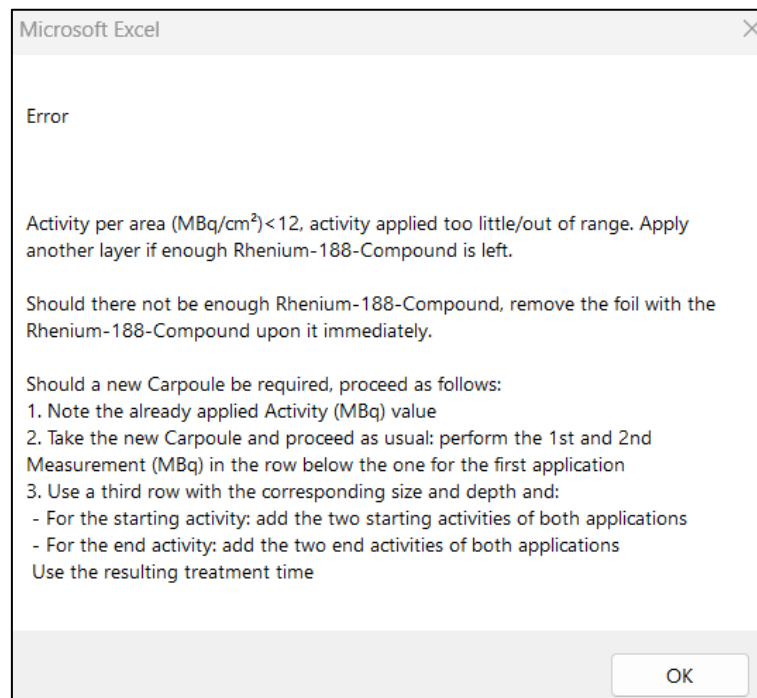


Figure 19: Error 5 Warning

Output values			
Activity applied (MBq)	Activity per area (MBq/cm²)	Time (min)	End Time (hh:mm)
150,00	150,00	19,00	10:19
1,00	1,00	Too low	

Figure 20: Error 5 – Activity too low

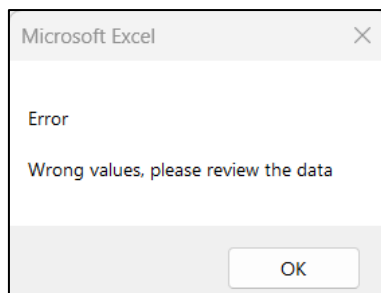


Figure 21: Error 6 Warning

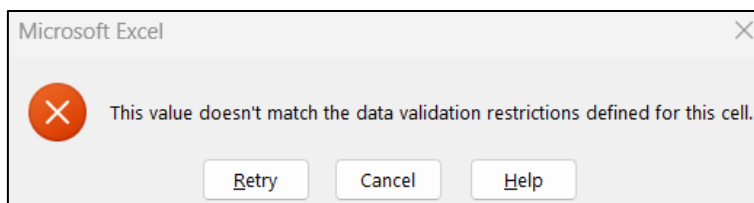


Figure 22: Error 7 Warning

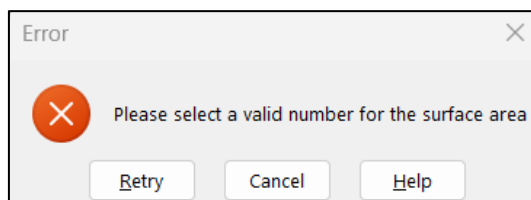


Figure 23: Error 8 Warning

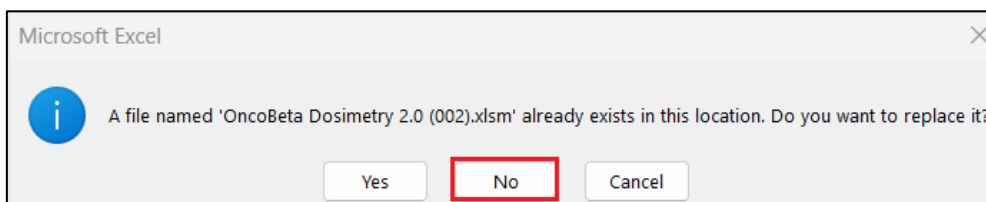


Figure 24: Error 9 Warning - Step 1

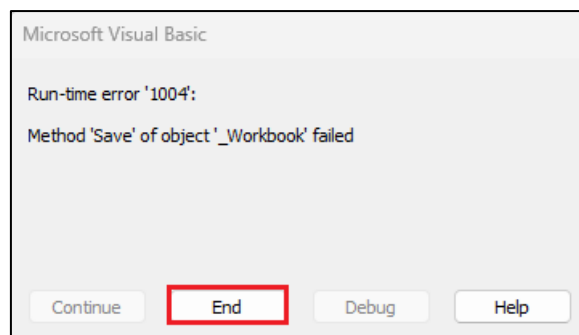


Figure 25: Error 9 Warning - Step 2

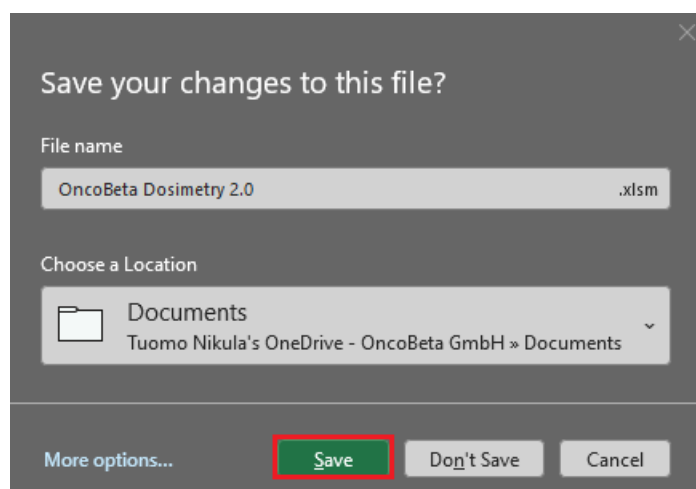


Figure 26: Error 9 Warning - Step 3

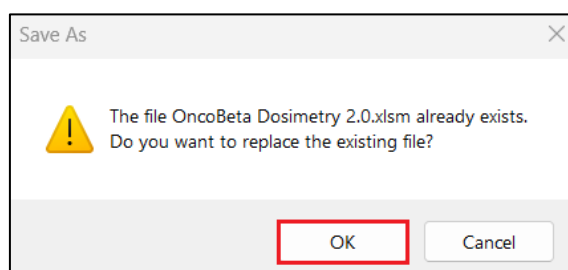


Figure 27: Error 9 Warning - Step 4

3.3 Data Validation - Test Configurations

[illegible]

1	Lesion Nr.	1
2	Area (cm ²)	2,00
3	Location	Forehead
4	Depth (µm)	500
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	500,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

Figure 28. Test configuration 1 – Input values

[illegible]

9	Activity applied (MBq)	500,00
10	Activity per area (MBq/cm ²)	250,00
11	Time (min)	Too high
12	End Time (hh:mm)	-

Figure 29. Test configuration 1 – Output values

1	Lesion Nr.	1
2	Area (cm ²)	2,00
3	Location	Forehead
4	Depth (µm)	500
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	980,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

[illegible]

Figure 31. Test configuration 2 – Output values

1	Lesion Nr.	1
2	Area (cm ²)	0,4
3	Location	Forehead
4	Depth (µm)	500
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	990,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

Figure 32. Test configuration 3 – Input values

1	Lesion Nr.	1
2	Area (cm ²)	110,00
3	Location	Forehead
4	Depth (µm)	500
5	1 st Measurement (MBq)	3000,00
6	2 nd Measurement (MBq)	990,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

Figure 33. Test configuration 4 – Input values

1	Lesion Nr.	1
2	Area (cm ²)	2,00
3	Location	Forehead
4	Depth (µm)	2000
5	1 st Measurement (MBq)	100,00
6	2 nd Measurement (MBq)	75,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

[illegible]

Figure 35. Test configuration 5 – Output values

1	Lesion Nr.	1
2	Area (cm ²)	
3	Location	Forehead
4	Depth (µm)	1000
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	500,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

[illegible]

Figure 37: Test configuration 6 – Output values

1	Lesion Nr.	1
2	Area (cm ²)	10,00
3	Location	Forehead
4	Depth (μm)	
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	800,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

[illegible]

9	Activity applied (MBq)	200,00
10	Activity per area (MBq/cm ²)	20,00
11	Time (min)	Data missing
12	End Time (hh:mm)	

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[illegible]

1	Lesion Nr.	1
2	Area (cm ²)	10,00
3	Location	Forehead
4	Depth (µm)	500
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	400,00
7	Start Time (hh:mm)	
8	Comments	N/A

Figure 40: Test configuration 8 – Input values

[illegible]

9	Activity applied (MBq)	600,00
10	Activity per area (MBq/cm ²)	60,00
11	Time (min)	Data missing
12	End Time (hh:mm)	

Figure 41: Test configuration 8 – Output values

1	Lesion Nr.	1		
2	Area (cm ²)	40,00	40,00	40,00
3	Location	Back	Back	Back
4	Depth (µm)	1250	1250	1250
5	1 st Measurement (MBq)	1000,00	1200,00	=1000+1200
6	2 nd Measurement (MBq)	250,00	500,00	=250+500
7	Start Time (hh:mm)	12:00	12:15	12:15
8	Comments	1. Carpoule	2. Carpoule	1. Carpoule + 2. Carpoule

[illegible]

Figure 43: Test configuration 9 – Output values

[illegible]

1	Lesion Nr.	1
2	Area (cm ²)	2,00
3	Location	Forehead
4	Depth (µm)	500
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	800,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

Figure 44: Test configuration 10 – Input values

[illegible]

9	Activity applied (MBq)	200,00
10	Activity per area (MBq/cm ²)	100,00
11	Time (min)	38,00
12	End Time (hh:mm)	12:38

13	Actual Time (min)	40
14	Actual Dose (Gv)	52.60

Figure 45: Test configuration 10 – Output values & Dose

1	Lesion Nr.	1
2	Area (cm ²)	2,00
3	Location	Forehead
4	Depth (μm)	500
5	1 st Measurement (MBq)	1000,00
6	2 nd Measurement (MBq)	900,00
7	Start Time (hh:mm)	12:00
8	Comments	N/A

[illegible]

Figure 47. Test configuration 11 – Output values

3.4 Treatment Protocol Validation

2. Patient information

Patient ID Lesion Nr	Anatomical Lesion Location	Histology/Indication	Lesion Depth (µm)	Lesion Area (cm ²) incl. the 5 mm safety margin
1	Forehead		500	2,00
0	0		0	0,00

Figure 48: Patient Information - Automatically Copied Data

4. Treatment data

Patient ID Lesion Nr	Carpoule SN ²	1st Measurement (MBq)	2nd Measurement (MBq)	Time (min)	Start Time (hh:mm)	End Time (hh:mm)
1		1000,00	900,00	78,00	12:00	13:18
0		0,00	0,00		00:00	

Figure 49: Treatment Data - Automatically Copied Data

3.5 Validation Form

Documentation

Date:				Responsible:	
1.1 Validation Manual:					
1.2 Computer:				1.3 Excel Version ¹ :	
1.4	Yes ☐	No ☐	N/A ☐	Comments:	Signature:
1.5	Yes ☐	No ☐	N/A ☐	Comments:	Signature:
1.6	Yes ☐	No ☐	N/A ☐	Comments:	Signature:

Data validation

	Yes	No	N/A	Remarks	Signature ²
2.1	☐	☐	☐		
2.2	☐	☐	☐		
2.3	☐	☐	☐		
2.4	☐	☐	☐		
2.5	☐	☐	☐		
2.6	☐	☐	☐		
2.7	☐	☐	☐		
2.8	☐	☐	☐		
2.9	☐	☐	☐		
2.10	☐	☐	☐		
2.11	☐	☐	☐		
2.12	☐	☐	☐		
2.13	☐	☐	☐		
2.14	☐	☐	☐		
2.15	☐	☐	☐		
2.16	☐	☐	☐		
2.17	☐	☐	☐		
2.18	☐	☐	☐		
2.19	☐	☐	☐		
2.20	☐	☐	☐		
2.21	☐	☐	☐		
2.22	☐	☐	☐		
2.23	☐	☐	☐		

¹ Please note that the validation is not valid for Excel installed in macOS

² Short name can be used instead of signature

	Yes	No	N/A	Remarks	Signature ²
2.24	☐	☐	☐		
2.25	☐	☐	☐		
2.26	☐	☐	☐		
2.27	☐	☐	☐		
2.28	☐	☐	☐		
2.29	☐	☐	☐		
2.30	☐	☐	☐		
2.31	☐	☐	☐		
2.32	☐	☐	☐		
2.33	☐	☐	☐		
2.34	☐	☐	☐		
2.35	☐	☐	☐		
2.36	☐	☐	☐		
2.37	☐	☐	☐		
2.38	☐	☐	☐		
2.39	☐	☐	☐		
2.40	☐	☐	☐		
2.41	☐	☐	☐		
2.42	☐	☐	☐		
2.43	☐	☐	☐		
2.44	☐	☐	☐		
2.45	☐	☐	☐		
2.46	☐	☐	☐		
2.47	☐	☐	☐		
2.48	☐	☐	☐		
2.49	☐	☐	☐		
2.50	☐	☐	☐		
2.51	☐	☐	☐		
2.52	☐	☐	☐		
2.53	☐	☐	☐		
2.54	☐	☐	☐		
2.55	☐	☐	☐		
2.56	☐	☐	☐		
2.57	☐	☐	☐		
2.58	☐	☐	☐		
2.59	☐	☐	☐		
2.60	☐	☐	☐		

	Yes	No	N/A	Remarks	Signature ²
2.61	☐	☐	☐		
2.62	☐	☐	☐		
2.63	☐	☐	☐		

Validation

Validation of the OncoBeta® Dosimetry can only be completed if all applicable points have been answered with 'yes'.

The OncoBeta® Dosimetry has been:	☐ Validated ☐ Not validated
Date, Signature	