INSTRUCTIONS FOR USE

OLINDA/EXM®

Version 2.3.0

HERMES
MEDICAL
SOLUTIONS

Document Name: P58-044 Instructions For Use OLINDA EXM 2.3.0 Rev.5_EN
Document revision date: 2025-04-30

This Instructions For Use (IFU) informs the user of the software's intended purpose, proper use, and any precautions that need to be taken and includes general product information and the information needed to identify the device and its manufacturer.

Any safety and performance information relevant to the user is stated in this IFU and residual risks are described. Study this manual carefully before using the software.

This is an electronic document, a copy of which can be downloaded from www.hermesmedical.com/ifu. Hard copies of Instructions for Use, System Environment Requirements, and Release Notes are available for free (as many as number of purchased licenses) upon request.

This IFU contains WARNINGS concerning the safe use of the product. These must be followed.

 This is the general warning sign.

NOTE: A note provides additional information to be aware of, for example, things to consider when performing a certain procedure.

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*Subject to registration in some markets

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1 INTRODUCTION

1.1 General notes

Modification of the product is not allowed and may result in hazardous situations.

All users need to be trained in the basic functionalities of the software before use. See list of basic functionalities in *Appendix 1 - User Training Required Content.*

User provided protocols, scripts and programs are not validated nor warranted by Hermes Medical Solutions. The party using such programs is solely responsible for the results.

Hermes Medical Solutions takes no responsibility for loss of data.

The users of the software are solely responsible for its use and for the resulting decisions regarding patient radionuclide therapy treatments or radiation protection measures. Hermes Medical Solutions takes no responsibility for any results and diagnoses derived from using the program described or from information in this Instructions For Use.

1.2 Regulatory information

Europe - This product complies with Medical Device Regulation (MDR) 2017/745. A copy of the corresponding Declaration of Conformity is available on request.

European SRN number: The single registration number (SRN) = SE-MF-000023032 has been issued to Hermes Medical Solutions, as required by the EU MDR – Regulation (EU) 2017/745.

⚠️

United States - Use of radiopharmaceuticals not approved by the FDA, and/or off-label use of such by-product material is restricted to investigational use only.

Canada - the Device identifier, as defined with Health Canada, is the first two numbers in the release version number.

1.3 Associated documentation

- P58-045 Release Notes OLINDA 2.3.0 Rev.5_EN

User guidance, intended to assist users in using the software, is available from the Help function in the software itself.

2 PRODUCT INFORMATION

2.1 Intended purpose

Intended Use

OLINDA/EXM® is a software application for nuclear medicine. Based on user input of time integrated activity in separate organs, OLINDA/EXM® calculates the organ dose and the whole-body dose and presents the results to the user. The results can be stored for future analysis.

The dose estimates provided by OLINDA/EXM® may guide the decision making for future patient radionuclide therapy treatments or inform radiation protection measures for diagnostic radiopharmaceuticals.

Intended User

The intended users of OLINDA/EXM® are medical professionals trained in using the system.

2.2 Intended patient population and medical conditions

Patients of any age and gender undergoing molecular imaging or radionuclide therapy.

Intended medical indication is any for which molecular imaging or radionuclide therapy is performed. Examples of indications for which OLINDA/EXM® 2.3 may inform treatment management are neuroendocrine tumours treated with peptide receptor radionuclide therapy such as Lu-177 DOTATATE or Y-90 DOTATOC, prostate cancer tumours treated with Lu-177 PSMA, and metastatic thyroid cancer treated with I-131 iodide.

2.3 Contraindications

There are no contraindications.

2.4 Product label

The version number, the Unique Device Identification (UDI) and other product data of installed OLINDA/EXM® software can be found by clicking on the Help menu and select About.

The following information can be identified in the product label (About box):

Product name = OLINDA/EXM
Release Version = 2.3.0
Marketing name = Hermia OLINDA
Software build no = 7

R̲X Only   Prescription only - device restricted to use by or on the order of a physician

[factory symbol]   Date of Manufacture (YYYY-MM-DD)

UDI   Unique Device Identifier

CE 2862 CE mark and the Notified Body number

MD   Indicates that the product is a medical device

📖ℹ️   Consult Instructions for Use (IFU)

@   The support email addresses

🏭   Manufacturer's contact information

CH|REP   Swiss authorized representative

About this application   ✕

Product Name: OLINDA/EXM

Release Version: 2.3.0
Marketing name: Hermia OLINDA
Software build no: 7

$C \epsilon$ 2862

Rx   only

MD   Medical device

📈   2023-08-22

📖ℹ️   eIFU indicator
https://www.hermesmedical.com/ifu

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4052 Basel, Switzerland

2.5 Product Lifetime

 The lifetime of OLINDA/EXM® 2.3 is 5 years.

The lifetime of 5 years starts when OLINDA/EXM® 2.3.0 is manufactured (5 years from Manufacturing date of 2.3.0). Possible patches for OLINDA/EXM® 2.3 will have new manufacturing dates, but the lifetime will not restart from these dates.

During the stated lifetime, Hermes Medical Solutions will maintain the safety and performance of OLINDA/EXM® 2.3. Patches will be provided when necessary to maintain the safety and performance of the product.

2.6 Complaints and serious incidents

Any serious incident that has occurred in relation to the device must be reported to our support, see Contact Information.

Depending on applicable regulations, incidents may also need to be reported to national authorities. For the European Union, serious incidents must be reported to the competent authority of the European Union Member State in which the user and/or patient is established.

Hermes Medical Solutions welcomes feedback from readers of this Instructions For Use. Please report any errors in content or typography and suggestions for improvements to our support, see *Contact Information*.

2.7 System Environment Requirements

OLINDA/EXM® version 2.3.0 has been verified on systems with the specifications described below. For questions regarding other combinations, please contact the support service, see Contact Information.

Operating Systems	Microsoft® Windows 10, Microsoft® Windows 11, Microsoft® Server 2016 and Microsoft® Server 2019
Memory	Minimum 1GB Recommended 2GB
CPU	1.0GHz CPU

2.7.1 Interoperability with Hybrid Viewer

OLINDA/EXM® 2.3 is interoperable with Hybrid Viewer, version 4.0 or later. See Instructions For Use for Hybrid Viewer for further details.

When used with Hybrid Viewer, OLINDA/EXM® is doing calculations in the background, initiated by Hybrid Viewer.

2.8 Installation

Installation must comply with applicable requirements such as, but not limited to, system requirements, configuration, and licensing.

For stand alone installations performed by the customer, installation instructions provided by Hermes Medical Solutions must be followed. Please see installation instructions in the Installation Manual.

NOTE: It is the customer's responsibility to install and maintain anti-virus software in the server and client computers, and apply the necessary protection against potential threats.

2.8.1 Warnings

⚠️ Modification of the product is not allowed and may result in hazardous situations.

⚠️ User provided protocols, scripts and programs are not validated nor warranted by Hermes Medical Solutions. The party using such programs is solely responsible for the results.

⚠️ Unauthorised users should not modify protocols.

3 SAFETY AND PERFORMANCE INFORMATION

3.1 Limitations of OLINDA/EXM®

The dose estimates calculated by the program will only be as good as the values for number of disintegrations for source organs entered and will always be only estimates of the radiation dose for a population or individual. These numbers should be studied critically before they are used for decision making in a medical, clinical, regulatory, or other environment. It is absolutely essential to understand the assumptions used to determine any dose estimates generated with this application. The dose estimates themselves are of little value without the accompanying assumptions.

Some important assumptions and limitations of the use of OLINDA/EXM®:
- The doses estimated by this application should not be used to evaluate risk to an individual patient, as the risk weighting factors are meant to be applied to population averages. The quantity Effective Dose should most certainly not be used in situations involving radiation therapy, as non-stochastic effects are more important, and it should never replace the consideration of the individual absorbed doses to separate organs.
- Radionuclides may have chemical/biological interactions besides pure decay of the radioisotope, but the software is not designed to incorporate them.
- A uniform distribution of activity in source organs and uniform energy absorption in target organs.
- The sphere model applies to approximately spherical structures unit density material, and is an appropriate model for lesions, such as tumors with approximately unit density. For any approximately spherical structure of non-unit density such as bony tumor, the model is not applicable.
- For the sphere model, it is important to note that linear interpolation between sphere masses may not produce a correct result for intermediate sphere sizes. As the dose factors usually decrease in an exponential fashion, a semi logarithmic interpolation is always recommended. In some cases, a linear interpolation is not markedly different, but it is not possible to state regions in which this may or may not work.

OLINDA/EXM® also provides tables of dose conversion factors (Dose Factors, like MIRD S-values) for all source and target organs for a given phantom and radionuclide, so that the user may do other calculations, and check the estimates generated by the application.

3.2 Terminology

Number of disintegrations per unit activity administered (µCi·hr/µCi or Bq·hr/Bq) has previously been known as 'Residence time'. It is the integral of a time activity curve for a source region. In units separated by a dash as in Bq·hr or µCi·hr the – indicates an integral of a function having the first unit integrated over the variable associated with the second Unit. In these examples Activity, which varies with time and has units Bq or µCi, is integrated over the timespan over which it is active.
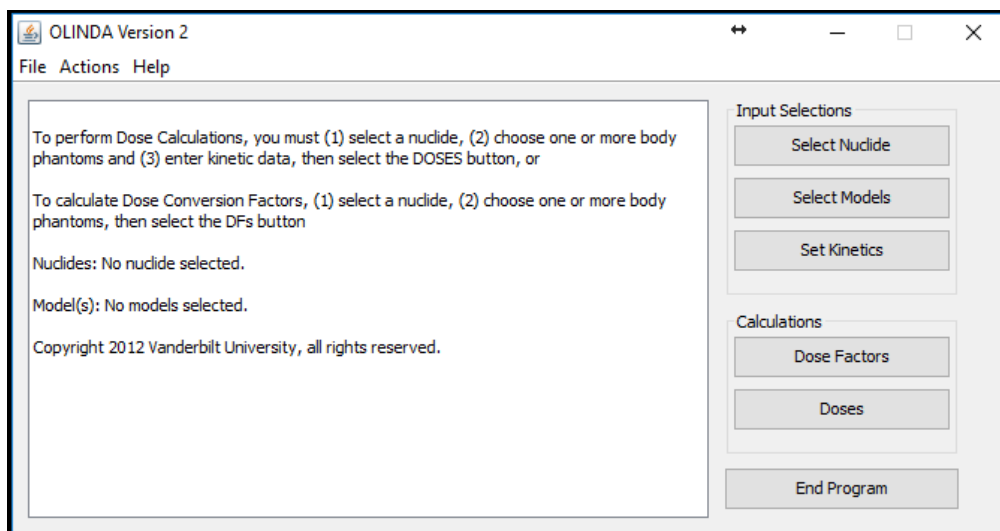
'Phantoms' are models of human or animal bodies.

A Dose Factor is mathematically the same as an S-value as defined in the MIRD system.

The dose absorbed from a source organ to a target organ is called the Absorbed Fraction (AF).

The absorbed fraction divided by the mass of the target region is called the Specific Absorbed Fraction (SAF).

3.3 Workflow overview

The main application window has 3 input selections. The workflow in OLINDA/EXM® is as follows:
1.   Select a Nuclide
2.   Select Models (Phantoms)
3.   Set Kinetics

If the user neglects to enter any required data, the application will stop and notify the user that data are missing. The user will then be able to add any missing information.

Once all the required information has been entered, calculations of Dose and Dose Factors can be performed.

Only steps 1 and 2 are needed if a set of Dose Factors only is required.
All steps are needed if a set of Absorbed Doses and Effective Doses is required.

3.4 Dose and Dose Factor reports

OLINDA/EXM® generates two reports – Doses and Dose Factors.
They can be generated either by clicking on Dose or Dose Factors on the main menu or using the Report dropdown in the Report Viewer.

Using the options in the Files menu at top left of the Report Viewer, the information in both reports can be printed to any available printer and/or output to a CSV file for input into software such as Excel. It may be necessary to change Excel configuration options to read the CSV files correctly.

Both reports can display information additional to the default report, which can be selected from the Options menu.

If more than one model has been selected, the information may be viewed by clicking Next/Prev Model.
Target organ masses and radiation weighting factors can be modified by clicking on Modify Data.

Any model assumptions entered regarding the Dynamic Bladder Model, ICRP HAT or ICRP 30 GI Tract Models, or bone activity attributed to surface or volume are shown at the bottom of the page in both Dose and Dose Factor reports.

3.5 Security

Hermes Medical Solutions actively works with cyber security during manufacturing to ensure the highest level of security. To increase security further, the software supports customer's own security measures, such as, but not limited to, access control and authorization, antivirus, operating system patching, and disk encryption. For more information, please contact support@hermesmedical.com.

It is the customer´s responsibility to install and maintain anti-virus software on the server and client computers and apply the necessary protection against threats.

4 WARNINGS

For alpha-particles the uncertainty in the dose equivalent is directly proportional to the uncertainty in the weighting factor. It is the user's responsibility to determine the appropriate weighting factor for their application.

The software includes radionuclides that are not associated with any approved radiopharmaceuticals. Such radionuclides can only be used for calculating exposures, research and development purposes.

OLINDA/EXM® is configured for the English language, so all values with decimal points should be entered with a dot (.) not a comma (,) as a decimal separator. If a comma is used, the digits after the comma will be ignored.

ENTER must be pressed after entering a value for **# of Dis**. for all the special models.

If the sum of all of the number of disintegrations entered exceeds the radionuclide's physical half-life, the user will be notified of this, and asked if the application should continue. There are situations in which this may occur legitimately, and the program will continue if the user wishes.

If you utilize either GI model, utilize it before entering GI organ kinetics elsewhere. The GI models are age specific and to keep from misplacing data, all GI organs are reset to zero elsewhere when using the GI models.

The application will notify the user if the sum of the fractions of the administered activity passing through the GI tract or the urinary tract exceeds 1.0. For example, if the GI tract model is used, with a fraction of 1.0 entering the stomach and absorption from the small intestine into the blood of 0.4 (meaning that 0.6 continued through the GI tract), and fractions totaling greater than 0.4 are assigned to compartments in the urinary bladder model, the user will be warned and asked if the application should continue. The user is free to continue if this is acceptable. The dose estimates generated by this program are only as good as the input data provided by the user. These checks have been included to aid the user, but the ultimate responsibility for the quality of the data is left with the user.

The use of this Effective Dose is controversial, and some do not think it should be used in medicine (Poston 1993). It certainly should not be used to evaluate risk to an individual patient, as the risk weighting factors are meant to be applied to population averages. The number most certainly should not be used in situations involving radiation therapy, as non-stochastic effects have more impact, and it should never replace the consideration of the individual absorbed doses to separate organs. Most, however, believe that it is far more meaningful than dose to Total Body (the average of all energy absorbed by all tissues divided by the mass of the entire body).

⚠️ OLINDA/EXM® only calculates whole organ Equivalent Doses and whole-body Effective Doses. It does not calculate Biological Equivalent Dose (BED) or Equivalent Uniform Dose (EUD).

⚠️ Normally the ten 'Remainder' organs (Adrenals, Brain, Upper Large Intestine, Small Intestine, Kidney, Muscle, Pancreas, Spleen, Thymus and Uterus) specified in the ICRP60 standard have a total tissue weighting factor of 0.05 which is divided equally amongst the 10 organs, giving a weighting factor of 0.005 each.

However, if one of the 'Remainder' organs receives a higher Equivalent Dose than any of the 'non-Remainder' organs, the ICRP Publication 60 specifies that a 'splitting rule' should be used. This states that half of the tissue weighting factor for 'Remainder' organs (0.025) should be applied to the single most exposed 'Remainder' organ and the remaining 0.025 should be shared among the other 'Remainder' organs.

ICRP60 tissue weighting factors have been superseded by ICRP103 weighting factors. This statement is only relevant if 'Show legacy effective doses' has been selected in the OLINDA Report Viewer.

The table of tissue weighting factors for ICRP60 is given in the Appendix 2.

⚠️ The ICRP26 standard states that the tissue weighting factor of 0.06 be allocated to each of the 5 'Remainder' organs which have the highest Equivalent Dose. The table of tissue weighting factors for ICRP26 is given in the Appendix 2. **This is not operational in the Dose Factors report.**

⚠️ If only the total body mass is altered, the organ masses remain the same, but if a value is entered for **Multiply all masses by a factor of:**, the total body AND all the internal organs will be scaled by the same value. The former is useful for individuals who are simply obese, and whose organ masses may be similar to the model, and the latter for people who are overall larger than the model.

⚠️ If it is not possible to retrieve the data for xx nuclide, the legacy data for this nuclide will be used.

5 CONTACT INFORMATION

Contact any of the addresses below for service, support or if you have any other questions.

5.1 Manufacturer contact information

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5.2 Representatives

 Authorized representatives

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6 APPENDIX 1 - USER TRAINING REQUIRED CONTENT

Launch
- About box and link to IFU's
- User Handbook

Limitations
- OLINDA/EXM® is a statistical model of average human response to defined activity distribution. The dose derived is approximated to be uniformly distributed in each organ, and tumors are not considered in cross dose values.

Workflows
- Select appropriate Nuclide.
- Select appropriate Model, if any of the special models are intended to be used, select them first.
- Input kinetics directly when appropriate. Use model fitting functions or bladder/ingestion models if required.
- Review dose factors if needed.
- Review doses.

Calculations
- A table for every phantom/isotope combination exists. When a user defines the total disintegrations occurring in an organ the contribution from that source organ to all target organs is the product of the source organ activity multiplied by the table value corresponding to the source->target value. Contribution to all targets from all sources are summed. Equivalent doses are calculated by multiplying by the appropriate tissue weighting factor. Effective dose is the sum of all the equivalent doses.

Dose and Dose Factor reports
- Doses are given per injected MBq. They are divided into the Alpha component, Beta component, and Gamma component. Each particle component is multiplied by the particle effective weighting value. The Total column represents the sum of the particle components. Equivalent dose is total dose weighted to reflect the probability of long-term effects and organ vulnerability. The sum of these per organ equivalent doses gives an effective dose to reflect the overall dose impact on a patient.

Saving/Printing Reports
- OLINDA/EXM® can save two separate formatted files. The first, with default extension .CAS is a text format file that records all the choices selected in the process of filling in the OLINDA/EXM® options. The second is a file in standard Java file format in which the kinetic data entered in the Fit Data to Model (Disintegrations Calculator) window can be saved.
  Reports of the final dose results can be saved in CSV or text format, and they can be printed.

NOTE: For stand alone installations performed by customers themselves, the required training before use is to read through the User Handbook, which can be found in the Help menu in the application, under option "Help". For questions or further training, please contact Hermes Medical Solutions support, see *Contact Information*.

7 APPENDIX 2 - LEGACY TISSUE WEIGHTING FACTORS

The tissue weighting factors specified in ICRP26/30 which are to calculate Legacy EDE (Effective Dose Equivalent) in the Dose Report and the revised tissue weighting factors specified in ICRP60, which are used to calculate ED (Effective Dose) in the Dose report, are listed below.

ICRP26/30

Organ	Tissue Weighting Factor (WF) per organ
Red Marrow Lung	0.12
Gonads (Testes or Ovaries)	0.25
Breast	0.15
Remainder Tissues: Adrenals, Liver, Kidneys, Pancreas, Small intestine, Spleen, Stomach, Thymus, Upper Large Intestine, Lower Large Intestine	0.3 A WF of 0.06 to be allocated to each of the 5 remainder organs with the largest Equivalent Dose and a factor of 0 to the rest. This is called the 'Splitting Rule'
Total	**1.0**

ICRP60

Organ	Tissue Weighting Factor (WF) per organ
Red Marrow Lung Colon Stomach	0.12
Gonads (Testes or Ovaries)	0.20
Urinary Bladder, Breast, Liver, Esophagus, Thyroid	0.05
Skin Bony Surface	0.01
Remainder Tissues: Adrenals, Brain, Kidneys, Pancreas, Muscle, Small intestine, Spleen, Thymus, Upper Large Intestine, Uterus	0.05 A WF of 0.05/10 is normally applied to each of the remainder organs. An exception is when a remainder organ receives the largest Equivalent Dose of all organs, in which case a WF of 0.025 is applied to that organ and 0.025/9 to the other 9 remainder organs
Total	**1.0**