CoLumbo

AI SPINE ASSISTANT

INSTRUCTIONS FOR USE

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Issue: 1

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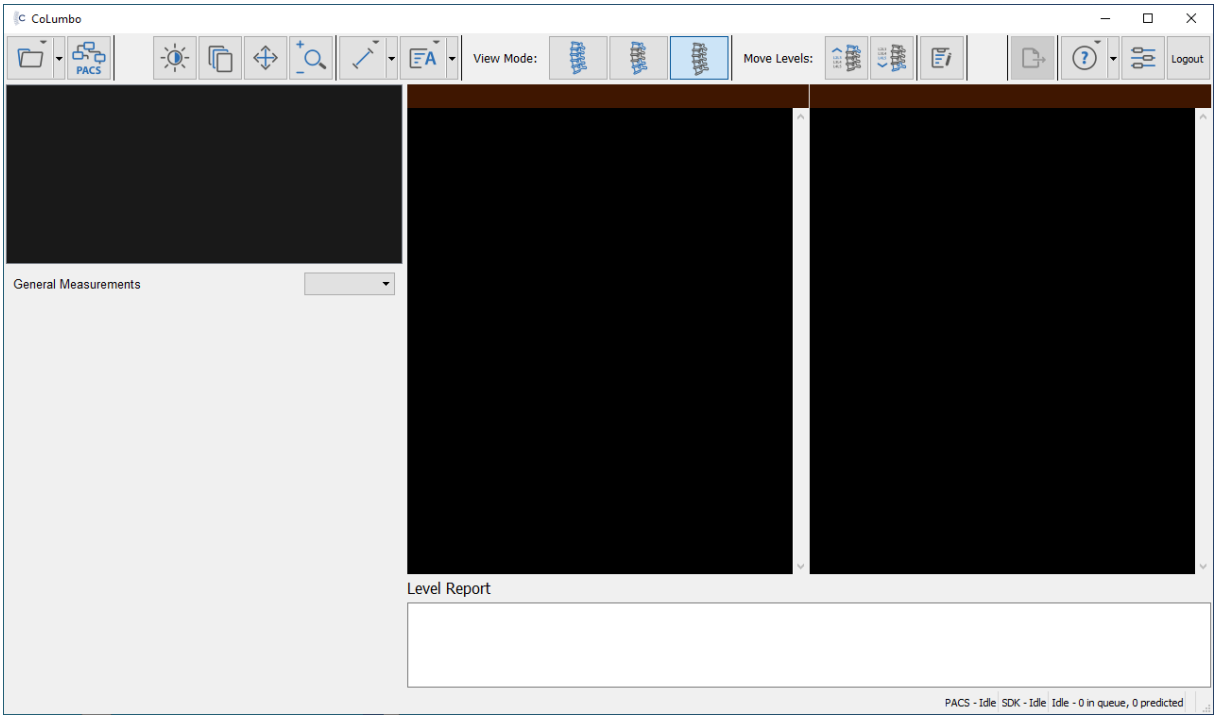
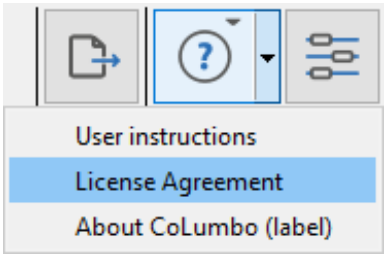
Introduction

CoLumbo version 3 is a medical device (software) for viewing and interpreting magnetic resonance imaging (MRI) of the lumbar spine. The software is an assistive tool that helps radiologists and neuro- and spine surgeons ("users") to identify and measure lumbar spine features in medical images and record their observations in a report. The users then confirm whether the out-of-range measurements should be reported or not. The segmentation and measurements are based on rule-based algorithms and thresholds set by each software user and stored in the user's individualized software settings. The user also identifies and classifies any other observations that the software may not annotate.



Additional information about the software (instructions for use in different languages in electronic format, license agreement and product label) is available from button (Help):



User Safety

The product is software without a physical device. It does not come into contact with the patient. Besides, CoLumbo is used for post-MRI analysis. The product itself does not control the MRI process, nor does it control another device or substance that comes into contact with or directly affects the patient.

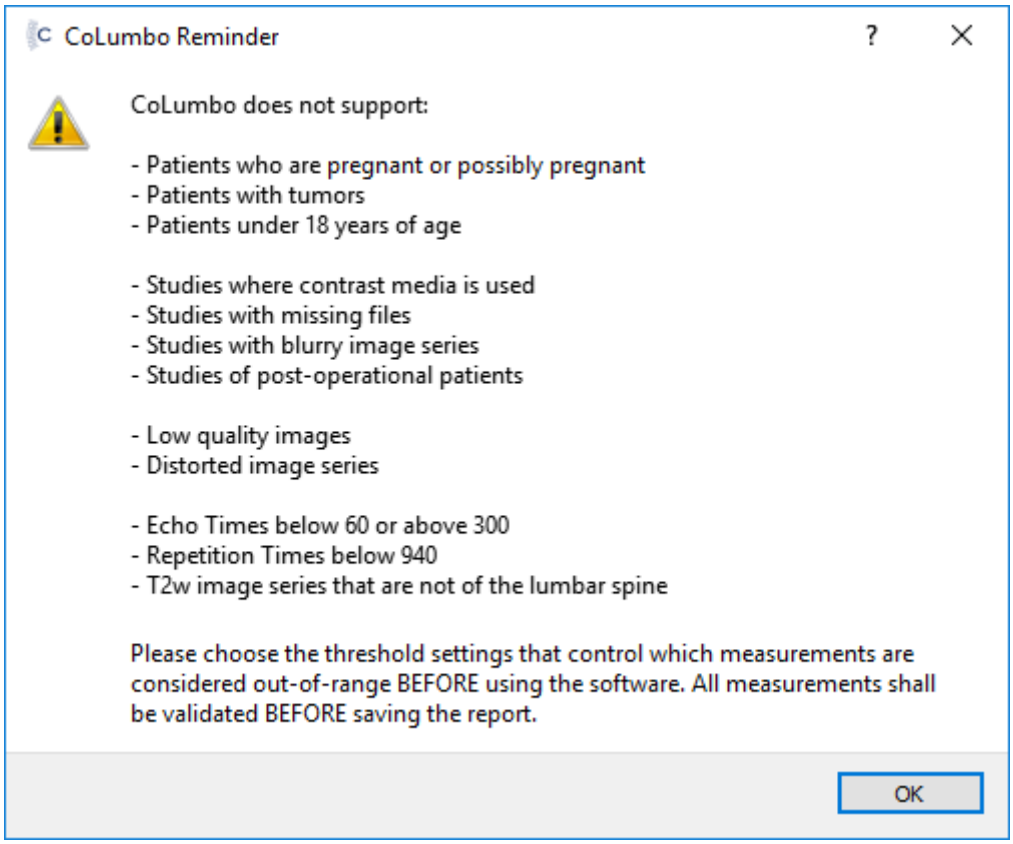
The software itself does not pose a danger to either users or patients, but it can contribute to dangerous situations. The risk analysis shows that after the measures taken to reduce the risk, the residual risk is minimal.

Caution: Federal law restricts this device to sale by or on the order of physician

Warnings

CoLumbo **does not support**:

- Studies, other than of the lumbar spine;
- Patients under 18 years of age;
- Patients who are probably pregnant;
- Post-operational patients (with surgeries, spine implants, etc)
- Patients with tumors;
- Studies using contrast media;
- Studies with missing files and/or images;
- Echo Times below 60 or above 300;
- Studies with Repetition time under 940.



IT Security Information

To learn more about the security of the CoLumbo software, contact your Smart Soft Healthcare sales representative and ask for the respective documentation.

Overview

Indications for use

CoLumbo is an image post-processing and measurement software tool that provides quantitative spine measurements from previously-acquired DICOM lumbar spine Magnetic Resonance (MR) images for users' review, analysis, and interpretation. It provides the following functionality to assist users in visualizing, measuring and documenting out-of-range measurements:

- Feature segmentation;
- Feature measurement;
- Threshold-based labeling out-of-range measurement; and
- Export of measurement results to a written report for user's review, revise and approval.

CoLumbo does not produce or recommend any type of medical diagnosis or treatment. Instead, it simply helps users to more easily identify and classify features in lumbar MR images and compile a report. The user is responsible for confirming/modifying settings, reviewing and verifying the software-generated measurements, inspecting out-of-range measurements, and approving draft report content using their medical judgment and discretion.

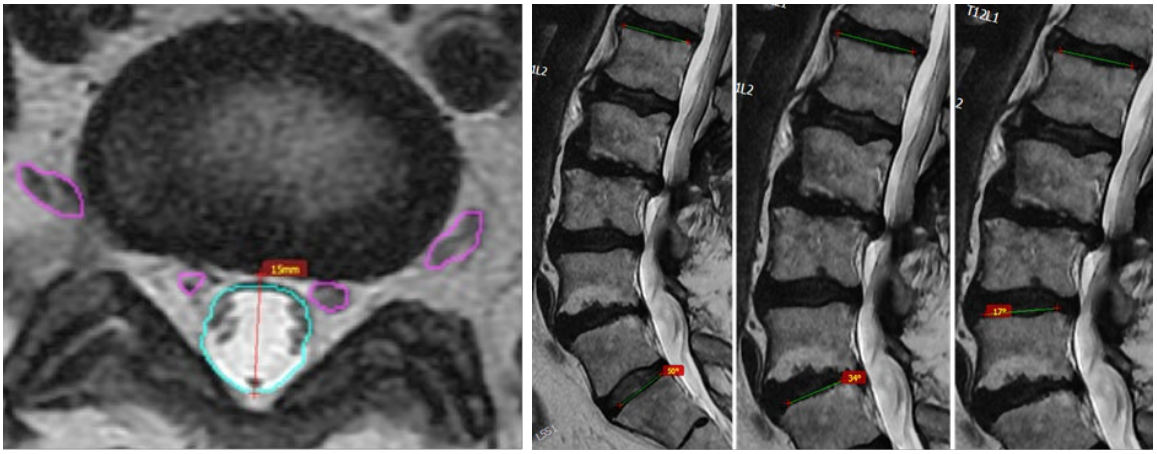
The device is intended to be used only in hospitals and other medical institutions.

Only DICOM images of MRI acquired from lumbar spine exams of patients aged 18 and above are considered to be valid input. CoLumbo does not support images of patients that are pregnant, undergo MRI scan with contrast media, or have post-operational complications, tumors and infections.

Target Population Information

Patient population	Adults (age 18 and above), not pregnant, without tumors, infections, or previous spinal surgeries and/or implants
Organs of interest	Lumbar spine (L-spine) MRI
Measurements of interest	• Focal Disk Material Outside VB Projection; • Descending (Caudal) and Ascending (Cranial) Disk Material Outside of the Intervertebral Space; • Disk Outside VB Projection; • Dural Sac Cross-Sectional Area; • Dural Sac Anterior-Posterior Diameter; • Nerve Root Deviation; • Lordotic and Lateral Spinal Curvature Angle; • Spondylolisthesis Slippage; • Vertebral Body Height; • Disk Height;

- Facet Joint Diameter;
- Posterior Epidural Fat Size;
- Muscle Fat Infiltration Percentage;
- Foramen Diameter;
- Lateral Recess Diameter;
- Spinal Canal Diameter;
- Disk Material Outside of Endplate Margins Size;
- Ligament Flavum Thickness;
- Vertebral Body Zone with Changed Intensity Size;
- Vertebral Body Width Difference AP Size.



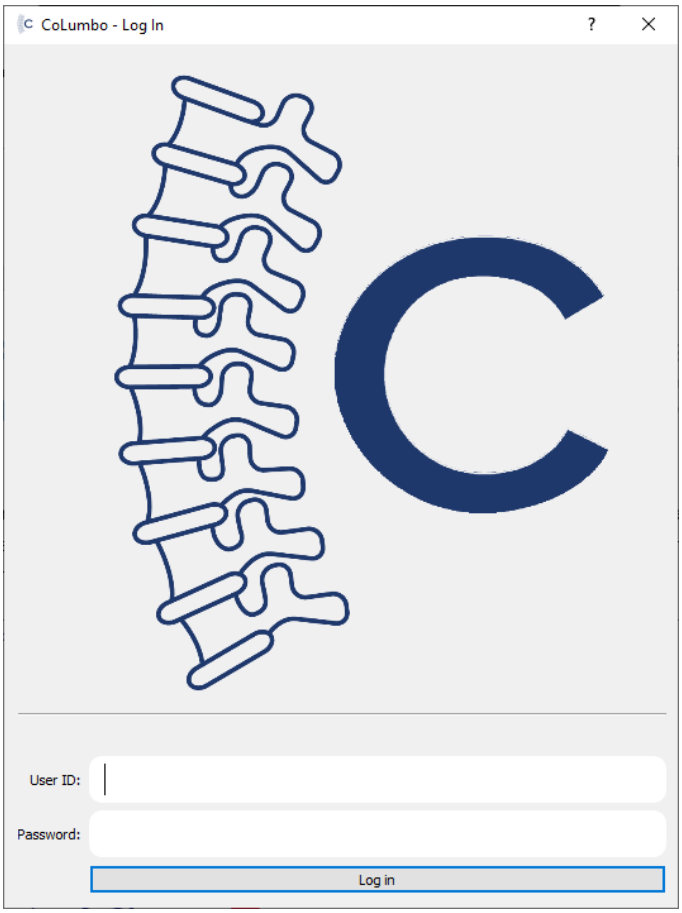
Supported Input Data

File Type(s)	DICOM (.dcm)
Modality	MR (Magnetic Resonance)
Pulse sequence	T2w
Magnetic Field Strength	1,5T or 3T
MR Acquisition Type	2D or 3D
Scanning Sequence	SE, FSE/TSE
Minimum Required Input Series	At least one sagittal T2w sequence with a minimum of 5 slices; At least one axial T2w sequence
Repetition Time	at least 940 ms
Echo Time	from 45 ms to 300 ms
Maximum slice (axial and sagittal) thickness	5 mm
Min Sagittal Resolutions (Cols x Rows)	280 x 280

Min Axial Resolutions (Cols x Rows)	192 x 192
Maximum voxel volume	3 mm^3 for 2D sagittal series, and 1 mm^3 for 3D sagittal series
Maximum voxel volume	1.6 mm^3 for axial series

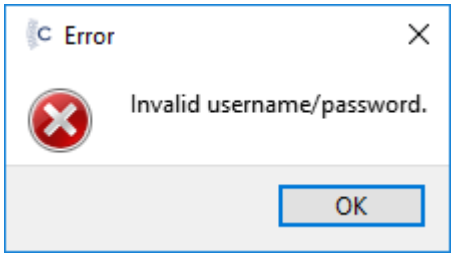
Authorization and Authentication

When starting the software, a login form appears on the screen:



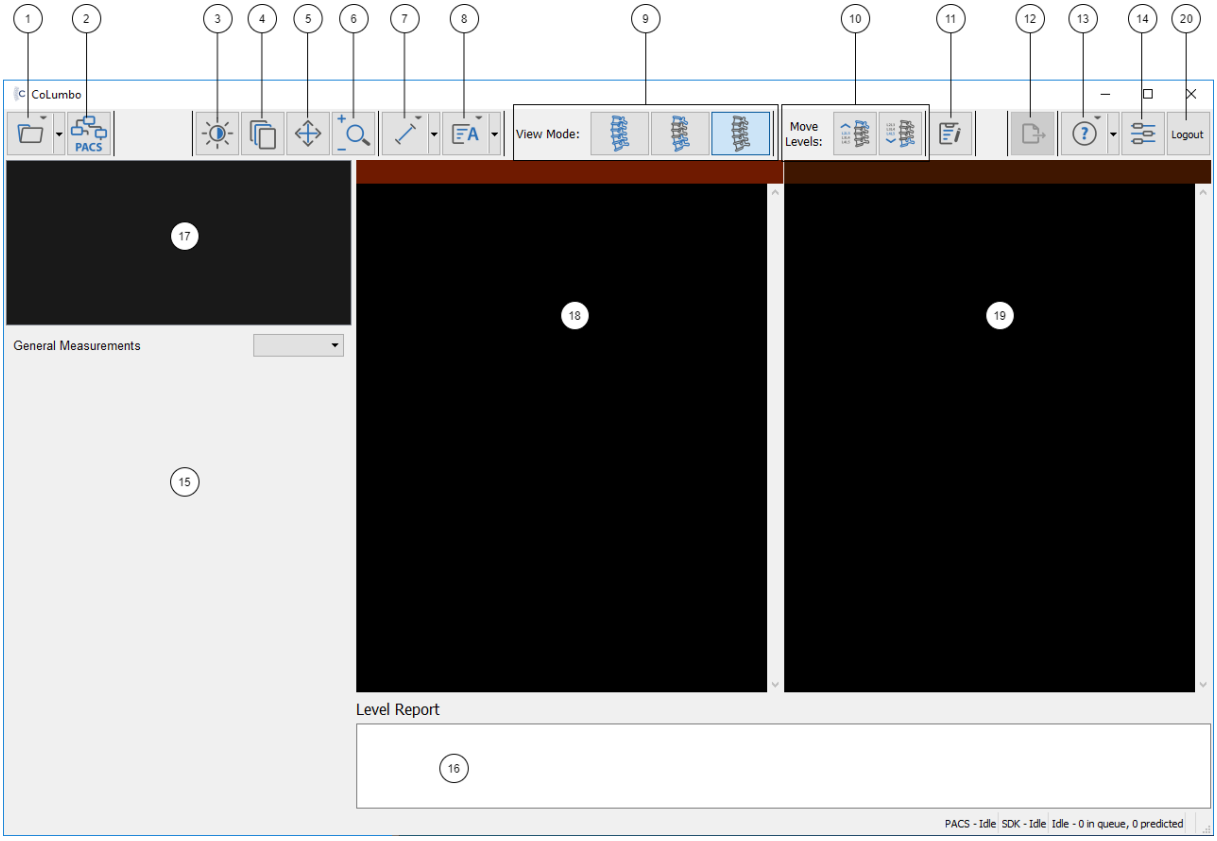
Users must enter their username and password, which are provided by the clinic's IT department.

When entering invalid username or password, an error message pops up:



Main Features

In order to facilitate navigation on the interface of the application, as well as in this user manual, the following numerical designations of each of the components have been introduced:

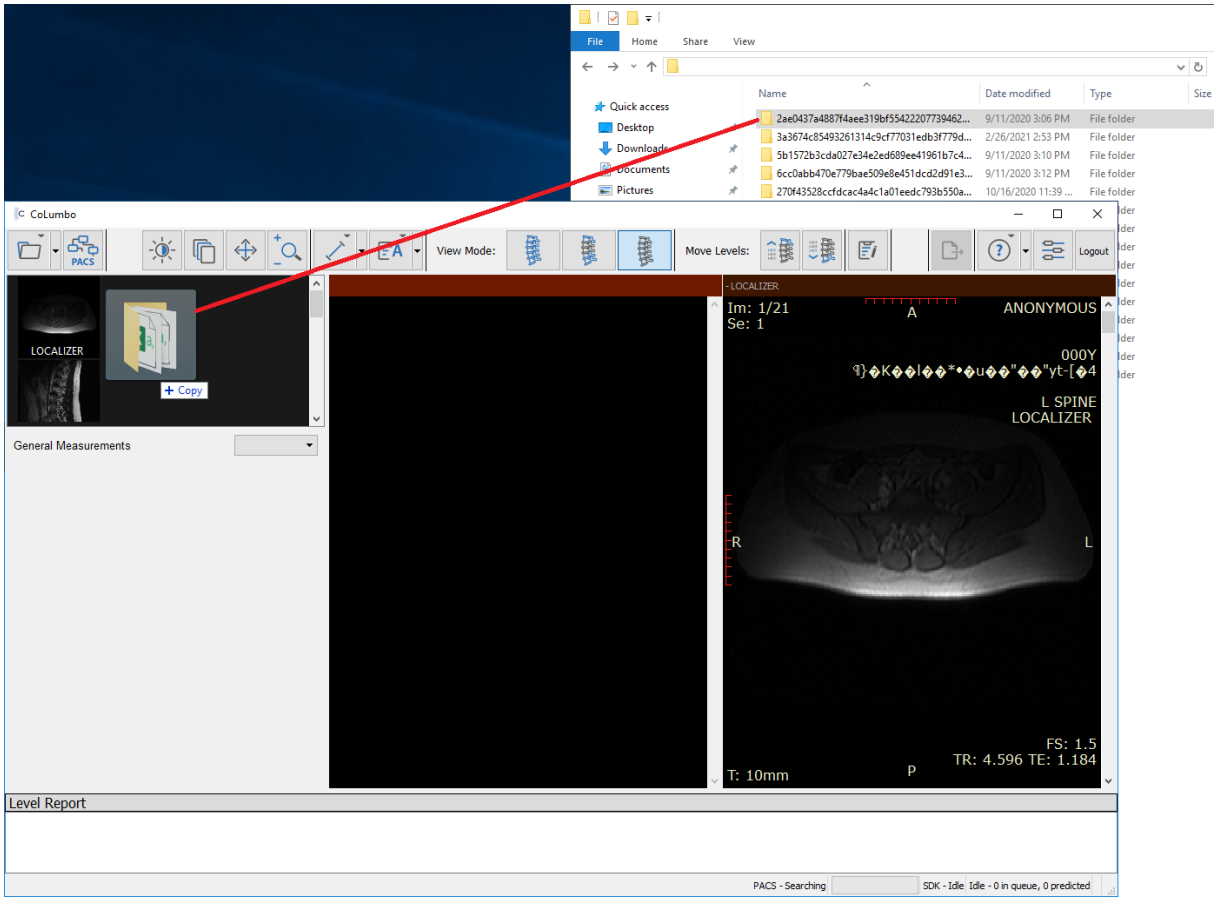


They will be used in further clarifications on the functionalities.

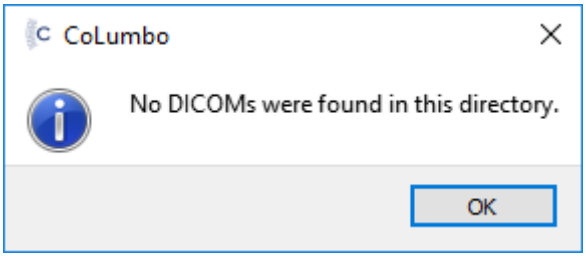
Visualization of MR Images

In order to visualize a study and the images in it, the corresponding files in DICOM (Digital Imaging and Communications in Medicine) format must be opened in the software. This is done in 3 ways:

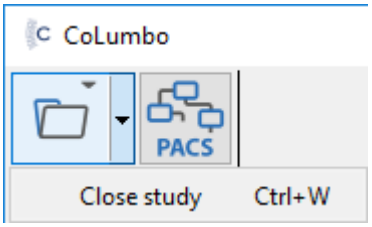
- Open a study from the folder with the button (1)
- Open a study from a folder using the keyboard shortcut ctrl + shift + O
- Open a study by drag-and-drop of the folder in the series panel (16)



If the user tries to load an empty folder or folder in which there are no images in DICOM format, a message is displayed on the screen that no DICOM files have been found in the folder:



The software allows visualization of only one study at a time. In case the user tries to load several studies at once, they are put in a queue, ordered by the date the images were taken (descending, from newest to oldest) and analyzed in the same order. The maximal number of studies in the queue is 150.

Closing of the current study is done by clicking the button 

or with the shortcut keyboard combination ctrl + w. If more than one study has been loaded, after closing the current in CoLumbo, the next one in the queue is visualized and 1 position is released in it.

Processing and analysis of MR images

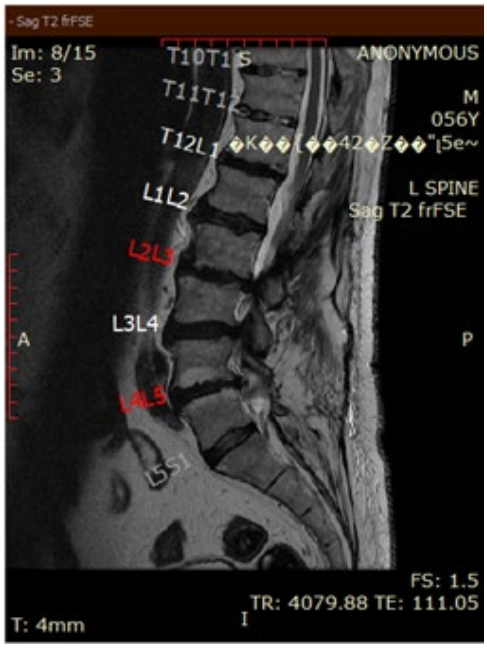
In addition to visualization of magnetic-resonance images, the software performs image processing and analysis – segmentation of various tissues (vertebrae, discs, dural sac, nerve roots, etc.) and measurements. These segmentations are contours on given tissues that have certain colors associated with them:

Tissue	Color
Vertebra	Green
Disc	Blue
Extruded/protruded disk material	Red
Nerve roots	Magenta
Dural sac	Turquois
Aorta/iliac arteries	Purple
Ligamentum flavum	Brown
Processus spinosus	Dark purple
Multifidus and erector spinae muscles	Light violet
Foramen	Soft orange

They serve to guide the user to the tissue, thus helping them to focus on the more important out-of-range measurements that may be present in the patient.

Once the study is opened, the image series are loaded in the series panel (17). By default, T2 sagittal and T2 axial series are visualized when a study is loaded, if available. A series can be opened in panel (18) or (19), regardless there is already another open series, by drag-and-drop from the series panel (17) or by double-clicking with the left mouse button on the series. It will open in the currently selected panel (18 or 19).

If the software calculates an out-of-range measurement, the label on the disc where the measurement is located is colored in red (to attract attention).

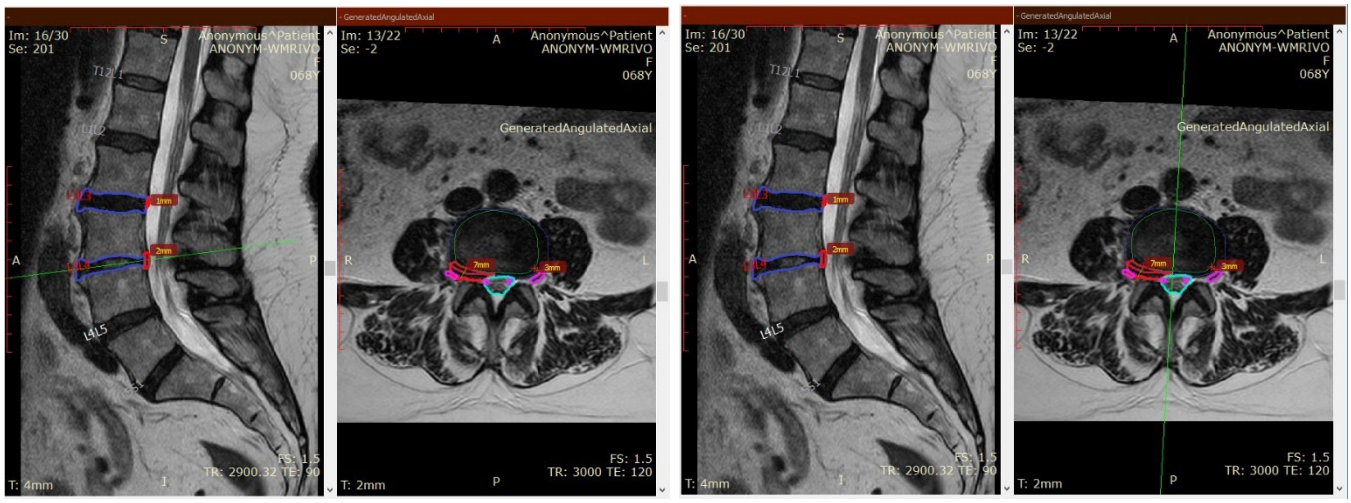


CoLumbo has set minimums for the measurements it makes in order to distinguish when a deviation from the norm is a real out-of-range measurement. These values can be changed from the software settings.

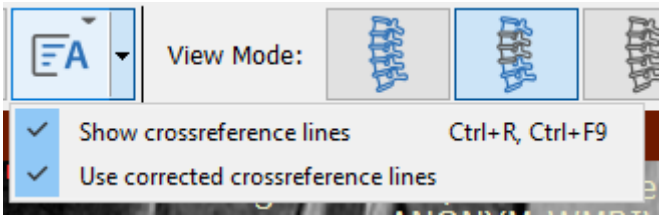
Annotation of MR images

CoLumbo automatically annotates (shows the patient's name, age, level labels, segmentations and measurements) images of all supported studies. The user can turn off or change the visualizations of these annotations by clicking (8)

In case the two open series correspond (e.g. sagittal and axial), the software also draws a cross-reference line that shows exactly where one slice is relative to the other. Depending on which panel is active, the cross-reference line is displayed in the inactive/unselected one.



By default, the cross-reference line is always displayed. The user can hide it from the button (8), as well as choose whether to use a normal cross-reference line or correct cross-reference line:



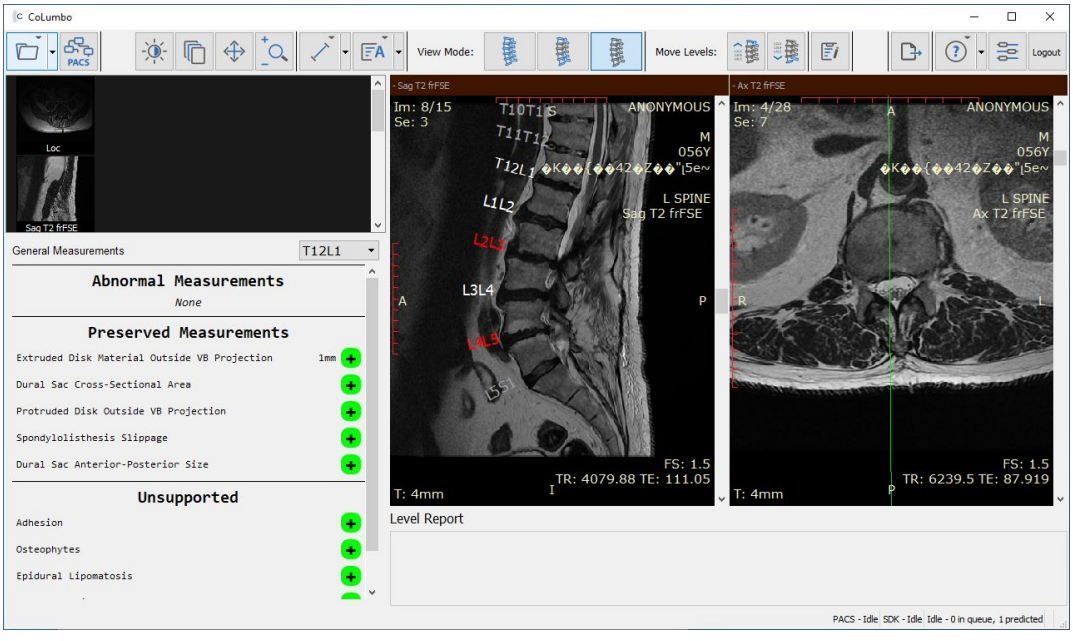
The corrected cross-reference line is an improvement on the normal cross-reference line, which is useful in studies in which the patient has moved and the images have shifted. This allows a better correlation between the different series which the user wants to view, in cases when the normal reference line is not accurate enough.

Reporting MR Images

After the software analyses the images and segments the tissues, it generates a draft report. All calculated out-of-range measurements must be validated by the user. The physician is fully responsible for preparing the final reading. The user can edit the draft report in 2 ways in case of disagreement between their opinion and the values calculated by CoLumbo – by adding and removing out-of-range measurements from the general measurements list (15) for each level and editing their values and modifiers, if any, from the level report (16), or by editing the full report.

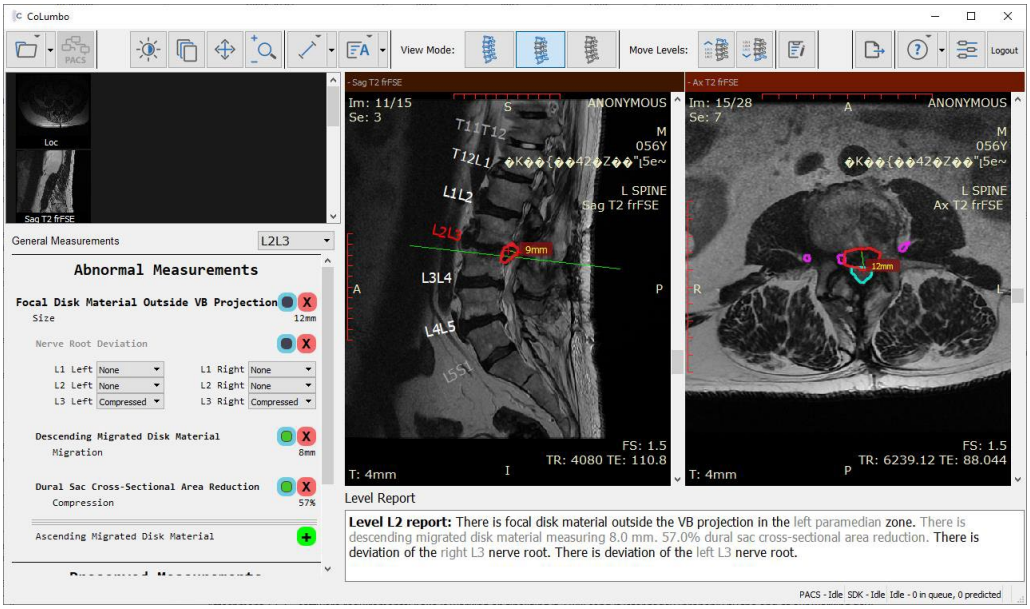
General Measurements Panel

In the general measurements panel, also called general measurements list (15), all out-of-range measurements supported by the software, as well as some additional (unsupported and not calculated by CoLumbo) measurements are listed.



From this panel the user can add from the button + or remove from the button X out-of-range measurements for each level to the final report. If the user believes that an out-of-range measurement is present at any of the levels, it is enough to be at the respective level axially and click + next to the name of the measurement. **We advise the user to click on the measurement label in the panel before adding it and see the calculated by CoLumbo value so that they can make sure that the measurement is out-of-range.** Once it is added as present at the appropriate level, different modifiers and measurements are added to it, which the user can correct (or fill in if they are empty).

The user can see the segmentation and measurements associated with each out-of-range measurement by hovering the mouse over the label with its name:

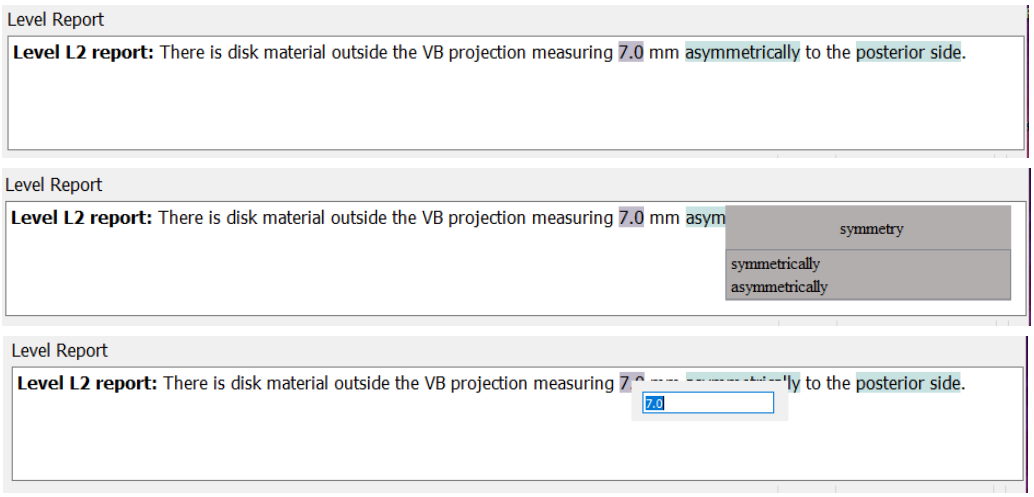


The user explicitly validates the measurements by clicking the checkbox ● next to the X button. The checkbox turns dark purple ● when checked.

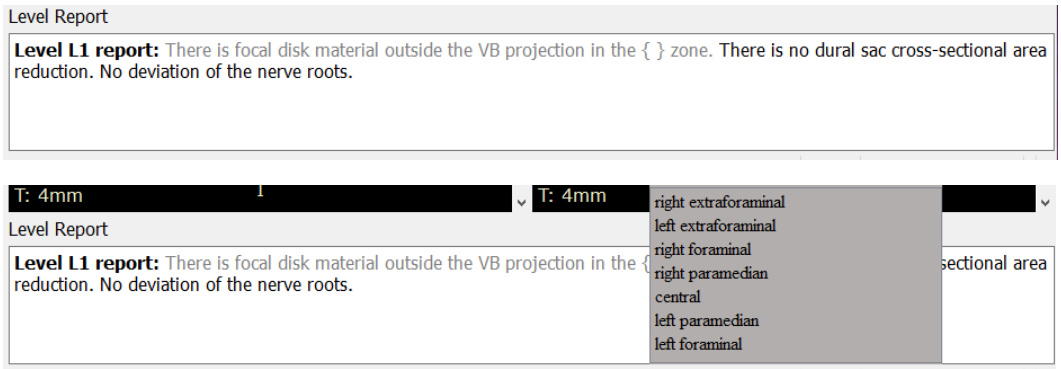
All changes in the measurements are automatically transferred to the full draft report, as well as to the level report panel.

Level Report Panel

The user can edit the modifiers and measurements made by CoLumbo in the level report (16). Editing modifiers that are marked in light green is done by left-clicking on the respective modifier and selecting the correct value. All values for modifiers are taken from the so-called dictionary of terms that the user can edit or change entirely from the software settings ⚙ (14). Measurements marked in a light purple can also be edited manually and new values can be entered again by left-clicking on the numerical value of the measurement. All calculated out-of-range measurements, their modifiers and values must be validated by the user. The responsibility for preparing the final report is entirely his/hers.



If the user adds an out-of-range measurement that is not visible on the slice, or the software does not report it as present, the text related to it is colored in gray. If a measurement for which the software failed to measure values for any of the modifiers is added, modifiers are empty and displayed with parenthesis {}.



Full Report

Full report is available from the button (11).

The full report contains the information on all out-of-range measurements arranged by levels (from L1 to L5). The report is empty if the user has not added and confirmed any measurements and/or impressions. If no out-of-range measurement is present, the software does not generate any information about the corresponding level. The user can save reports on a computer in .pdf format using the “Save” button, to copy the text of the report and put it a clinic’s form, as well as direct printing. The full report can also include specific screenshots of the images of the study, similar to those on page 7, depending on the user preferences.

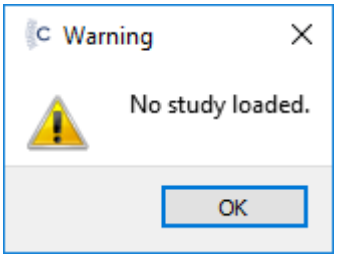
The report template looks like this:

```
Patient name: [patient_name] , Age: [age]
Exam date: [date_of_exam]
Exam type: Lumbar Spine
Contrast: [contrast]
MRI pulse sequence: [list_of_sequence_names]
```

```
Measurements:
[lordosis]
[absent_stenosis]
     [normal_disc_height]
     [normal_vert_height]

Per-level measurements:
Level L1 report: [L1L2]
Level L2 report: [L2L3]
Level L3 report: [L3L4]
Level L4 report: [L4L5]
Level L5 report: [L5S1]

Impression:
[impression]

Information for the patient:
[information_for_the_patient]

Report date: [date_of_report]
```

The template can be edited and adjusted to the user's preferences.

In case the user tries to generate a report when no study is loaded or before the software has been able to analyze the open one, the following messages are displayed on the screen:



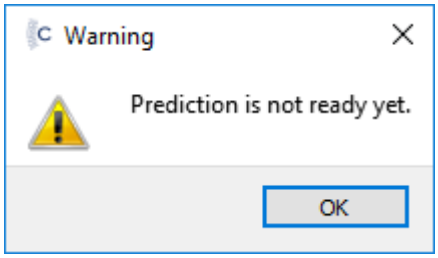
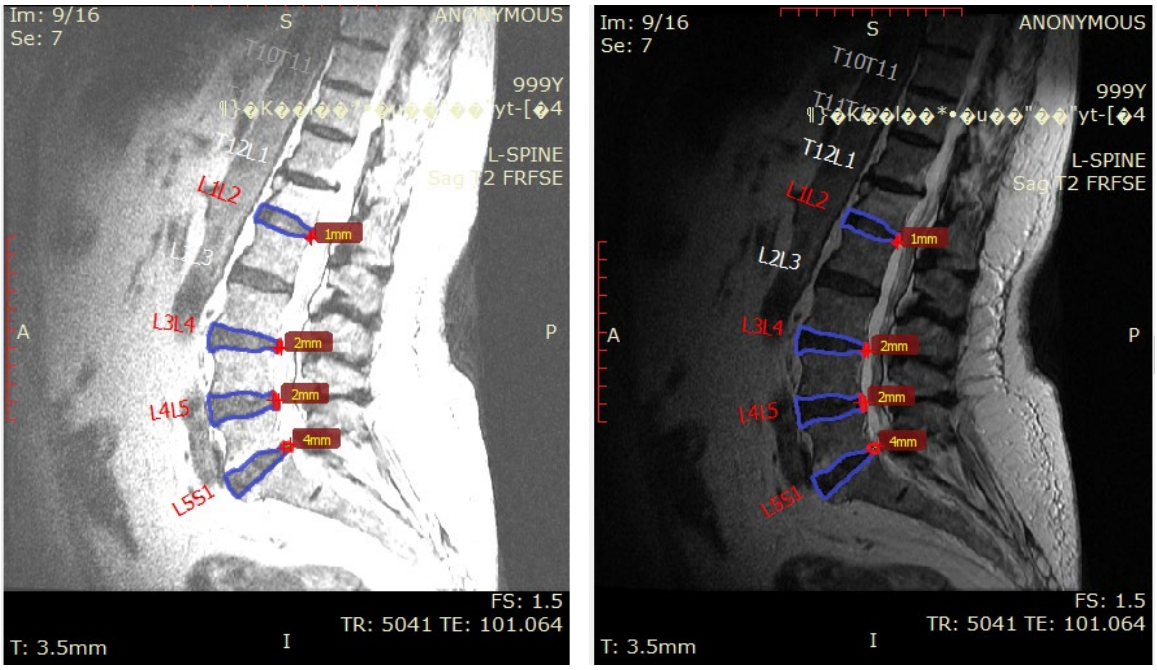


Image Contrast and Brightness Change

The user can change the brightness and contrast of a series by clicking the button (3) and moving the mouse over the series with the left button held:

- up to increase the brightness
- down to reduce the brightness
- left to increase the contrast

- right to reduce the contrast



Switching Slices

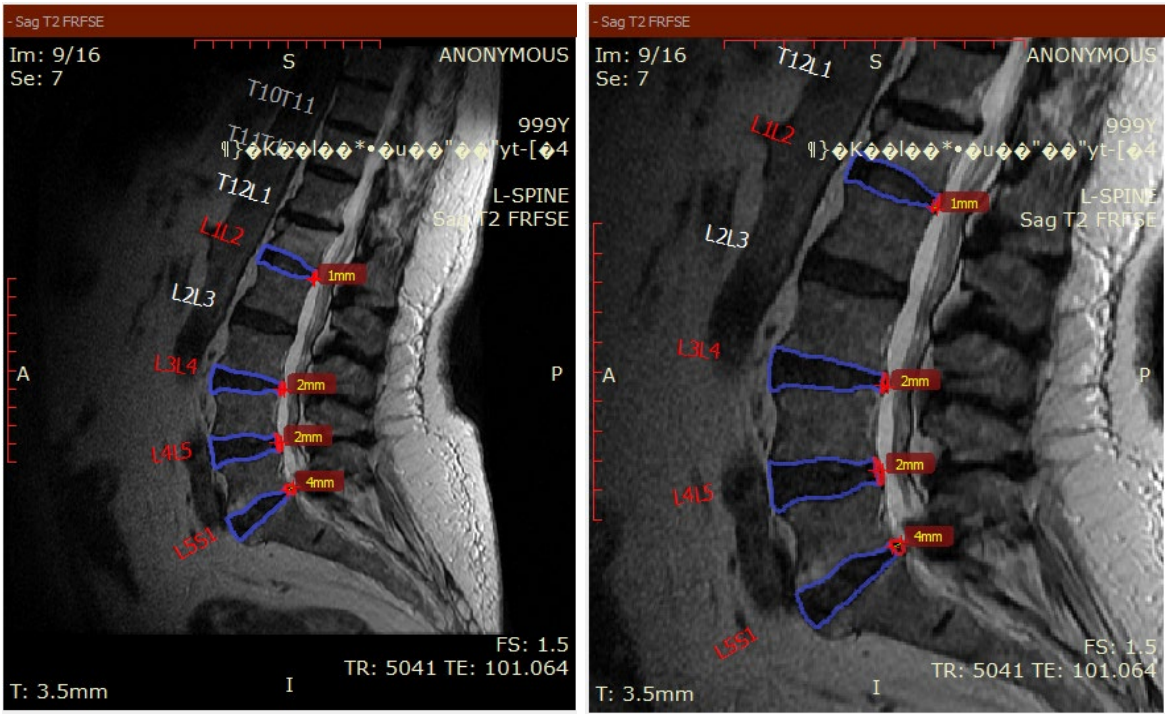
By pressing the button (4) with a certain mouse button and dragging through the series, using *this* button or scrolling with the mouse, the images with the sections of the selected panel are changed. This functionality can be used by default by scrolling through the images using the left mouse button, or with the ← and → arrows on the keyboard.

Moving Images

By pressing (5) with a certain mouse button, holding down this button and moving it, or by pressing the P key while holding down a certain mouse button, you can move the given image from the corresponding panel. This functionality can be used by default by holding down the middle mouse button and moving the image.

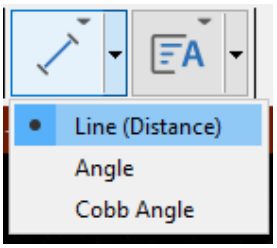
Zooming Images

By pressing (6) with a certain button, holding down this button and moving the mouse or by pressing the Z key while holding down a certain mouse button, and moving the mouse up and down, the image is enlarged or reduced accordingly. This functionality can be used by default by holding down the right mouse button and moving the image up or down.

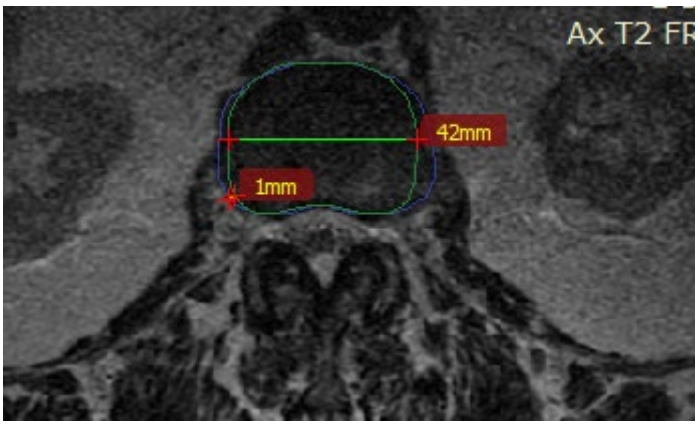


Measurements

Length Measurements



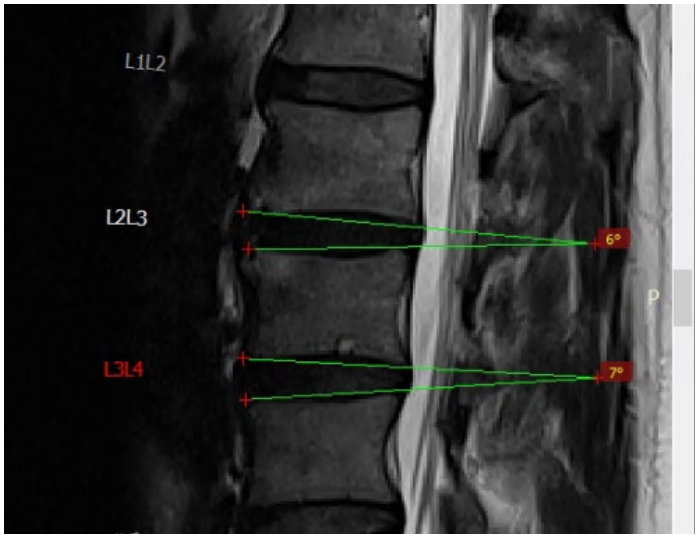
The instrument for measuring the length between two points in millimeters is accessible from the button (7) and selecting a line from the list. The measurement is done manually. They are marked with the mouse at the two points between which it is necessary to make the measurement. It is possible to move any of the endpoints. The measurement result is recalculated in real time.



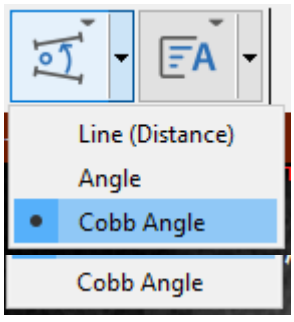
When a line is selected, it's colour turns from green to red (yellow when it's hovered). A line can be moved and deleted by pressing Delete button on the keyboard.

Angle Measurements

The tool for measuring an angle between two lines in degrees is accessible from the button (7) and selecting angle from the list. The measurement is done manually. Two points are marked with the mouse. These points create the first side of the angle. The vertex of the angle is at the second point. A third point is drawn towards it, which forms the second side of the angle. The value in degrees appears next to the vertex. It is possible to move any of the points that form the angle. The measurement result is recalculated in real time.



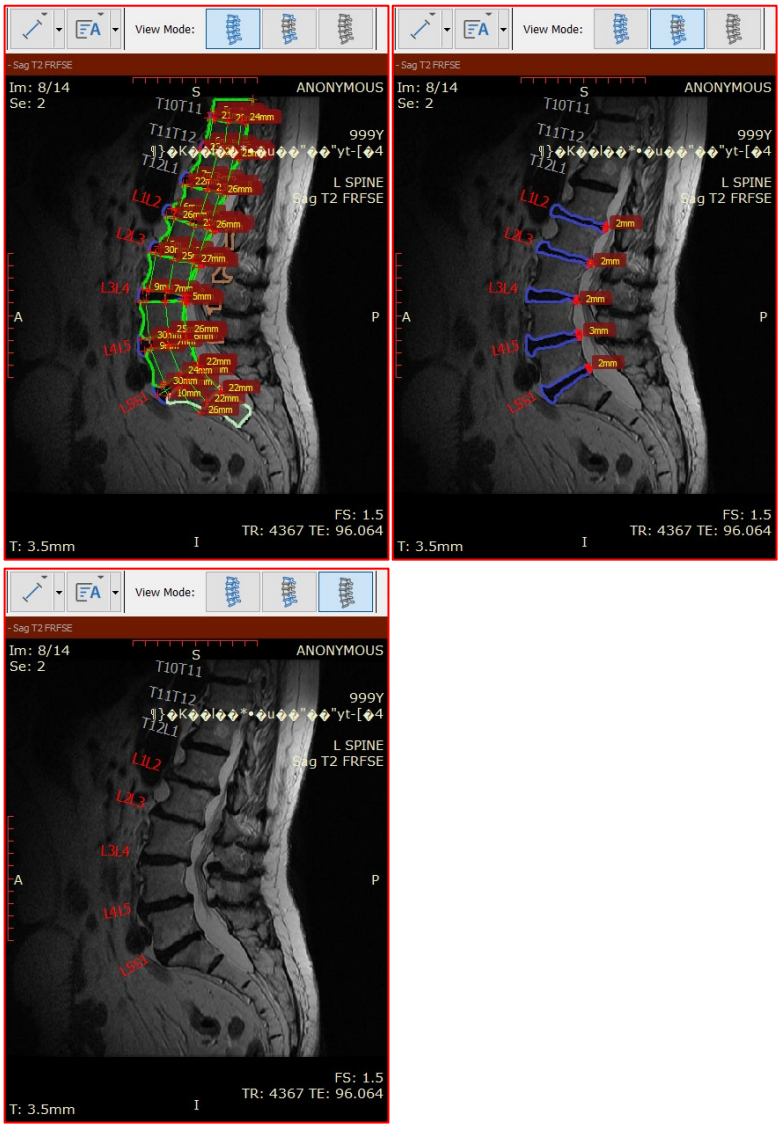
Cobb Angle Measurement



The tool for measuring the Cobb angle in degrees is accessible form the button (7) and selecting Cobb Angle from the list. The measurement is done manually. Two points are marked with the mouse, forming a line part of the first side of the angle. Then two other points are marked, forming a line, part of the second side of the angle. The vertex of the angle is visualized next to the first drawn point on the first line. It is possible to move any of the points on the angle. The measurement result is recalculated in real time.

Visualization mode change

The user has the opportunity to choose between three modes of visualization (9) of the segmentations and measurements of a study supported by CoLumbo:



All Out-of-range None

By selecting **All** , all possible segmentations and measurements that the software makes are visualized on the axial and sagittal images.

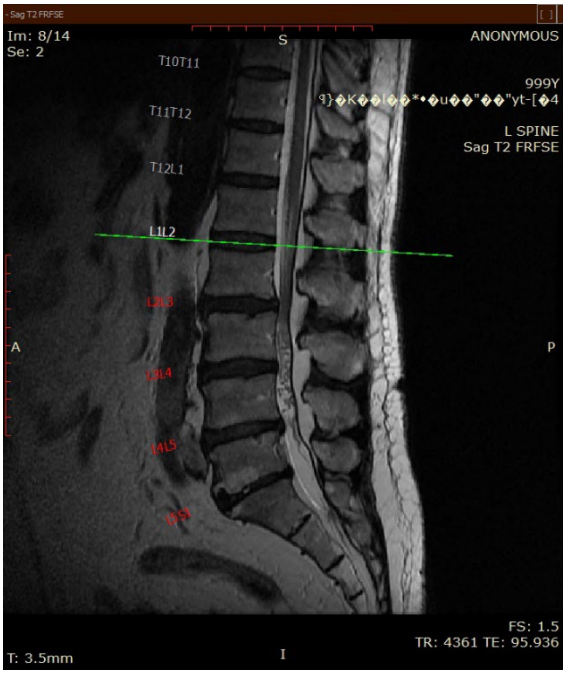
By selecting **Out-of-range** , only the segmentations and measurements that are present in the list of out-of-range measurements are visualized on the axial and sagittal images.

By selecting **None** , no segmentations or measurements are visualized on the axial and sagittal images. Only the level labels remain.

Move levels

In case CoLumbo does not correctly determine the disc levels, the user has the option to move the labels on all levels (10) one level up from the button or one level down from the button . This moves and changes the levels both visually and in the reports. For example, if the out-of-range measurement is calculated at the L4L5 level, but the levels are not correctly defined and is actually L3L4, then clicking the button will move the levels up one level and the measurement is already at the L3L4 level.

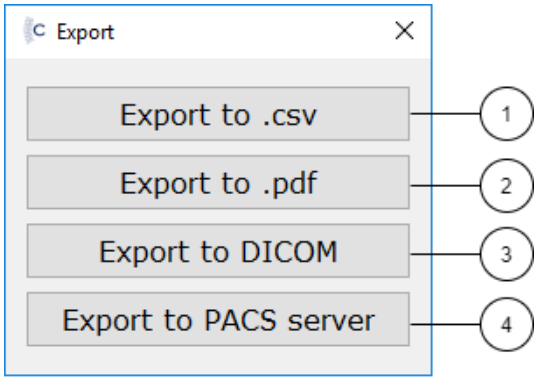
When using either of the two options, the software deactivates all functionalities of the general measurements panel and reports (by level and full report). At this point, the software recalculates the levels and out-of-range measurements and can only be used to view images.



Study Export

There are four study export options. The user can choose to use only one of them each time or select a different one at different times.

The button (12) on the screen opens a new window from which the user can choose how to export a study:



1) Choosing the option to export to .csv opens a new window in which the user must choose where to create and save a folder with a .csv file. The folder name is generated automatically and corresponds to the study identification number (ID). The language of the table is the same with the language of the report.

The table contains two columns – “Measurements” and “Results”.

The first two rows of the table are “Study ID” and “Date”.

The following rows for each level (L1 to L5) are present in the “Measurements” column:

- Size of out-of-range disc material outside VB projection with circumference above a threshold;
- Symmetry of out-of-range disk outside VB projection;
- Position of out-of-range disk outside VB projection;
- Size of out-of-range disc material outside VB projection with circumference below a threshold (focal);
- Position of out-of-range disk material outside VB projection;
- Ascending/Descending size of the disk material outside VB projection;
- Nerve root center difference measurement;
- Dural sac anterior-posterior diameter measurement;
- Dural sac cross-sectional area measurement;
- Value of spondylolisthesis slippage;
- Direction of spondylolisthesis slippage;

In addition, “Lordotic angle” that is not associated with a certain level, and “Correct determination of levels” are listed after the L5 level. By default, the result against “Correct

level definition" is always "Yes". If the user clicks the or buttons, the value changes to "No".

Study ID:	2L7BM7X364CKJROOMMJ5XAQBJB7CXZ7C2DKWUZPUX4SQ2===
Date:	XXXX-XX-XX.XX:XX:XX
Measurements	Results
Size of out-of-range disk material outside VB projection with circumference above a threshold - L1L2	
Symmetry of out-of-range disk outside VB projection - L1L2	
Position of out-of-range disk outside VB projection - L1L2	
Size of out-of-range disk material outside VB projection with circumference below a threshold (focal) - L1L2	
Position of out-of-range disk outside VB projection (focal) - L1L2	
Ascending/Descending size of the disk material outside VB projection - L1L2	
Nerve root center difference measurement - L1L2	
Dural sac anterior-posterior diameter measurement - L1L2	
Dural sac cross-sectional area measurement - L1L2	
Value of spondylolisthesis slippage - L1L2	
Direction of spondylolisthesis slippage - L1L2	

In the column "Results" value/measurement – according to the settings selected by the user, is marked for each of the measurements for each level.

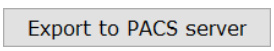
Adding or removing measurements and changing a modifier from the general measurements panel (15) or full report (11) is transferred to the "Results" column.

In case the open study is not supported or is currently being analyzed, the button (12) is not active.

2) Choosing the option to export to .pdf provides the same functionality as the "Save" button on full report, but in .pdf format. The user must select where to save the report as well as the file name. If the study is not supported, the user can save the report, but information about the measurements will not be filled-in automatically, i.e. the fields will be empty.

3) Choosing the option to export to DICOM opens a new window, allowing the user to select a directory where the study should be exported in standard DICOM format. All series of the study are exported – the original, and the generated by the software ones with segmentations and measurements, if the user has added any on them. The last directory to which the study was exported opens each time the option is selected. By default, the directory from which the study was loaded opens. The user can set exactly what to export in the study from the software settings from the button (14) – DICOM Export Settings.

The software retains all mandatory standard DICOM tags. All information in them is validated in accordance with the DICOM standard.

4) Clicking on the option 

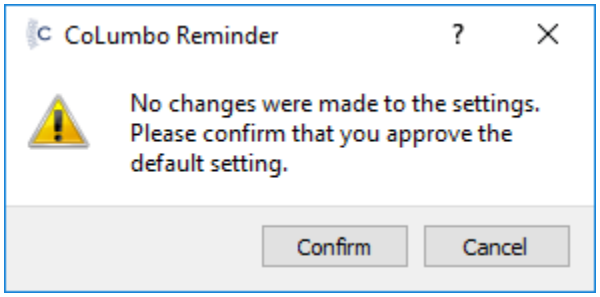
exports the report and series generated by the software to the hospital's PACS server.

In case the study is not supported by the software, the original series, together with a .pdf file with information about why the study is not supported, are exported to the PACS server without a report. A report is exported only if the user has written it manually. The collection of out-of-range mini reports have to be explicitly confirmed by the user one by one.

Settings

The settings are available from the button (14).

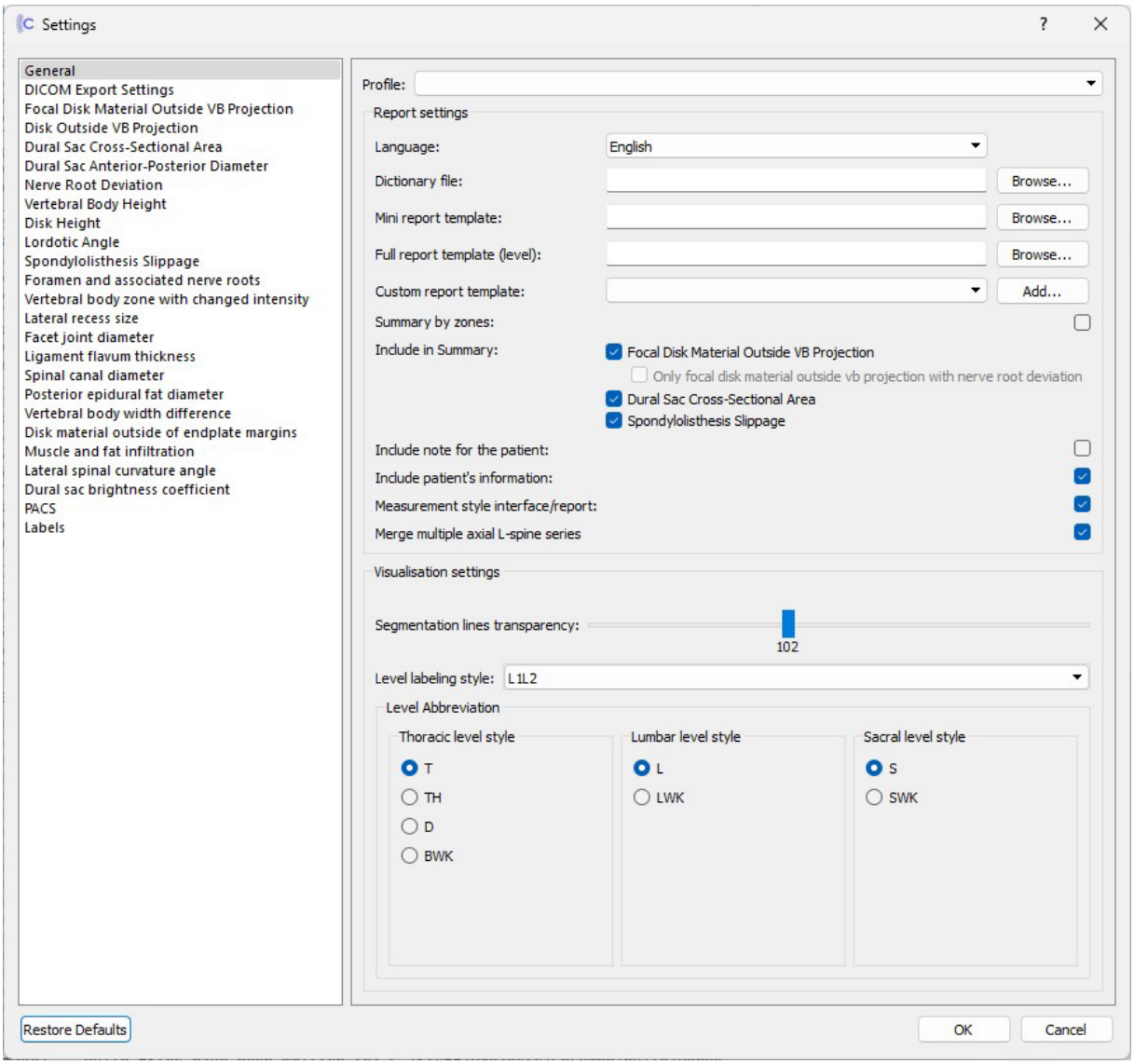
When the user logins for the first time after installation of the software, the settings menu pops-up. The user shall customize the measurement-related settings of CoLumbo before starting using it. After the user adjusts their settings, they shall click the button Save and Continue which will automatically open the next menu from the settings screen. If no changes are made in the current menu, the following warning message pops-up:



If the user clicks Cancel they will not be able to start and use the software until they finish up their settings adjustments.

The user can change their settings later and click OK to save the changes.
Other parts of CoLumbo's functionality can be configurated, too.

General settings



(1) Profile: Select a profile with pre-saved user settings

(2) Language: Select report language:

- English
- Bulgarian
- French
- German
- Italian
- Spanish
- Romanian
- Dutch

(3) Dictionary file: Select or add dictionary with terms used.

(4) Mini report template: Select or add mini report template.

(5) Full report template (level): Select or add full report template.

(6) Custom report template: Select or add custom report template.

(7) Include in Summary: *Select what to include in the summary of report:*
- Focal Disk Material Outside VB Projection
- Only Focal Disk Material Outside VB Projection with Nerve Root Deviation
- Presence Dural Sac Cross-Sectional Area
- Presence of Spondylolisthesis Slippage

(8) Include note for the patient: Select to include note for the patient "The following measurements are so common in people without low back pain that while we report their presence, they must be interpreted with caution and in the context of the clinical situation. Measurements: (prevalence in patients without low back pain), Disk degeneration (decreased T2 signal, height loss, bulge) (91%), Disk T2-signal loss (83%), Disk height loss (56%), Disk bulge (64%), Disk protrusion (32%), Annular tear (38%)."

(9) Patient Information:
- Patient name
- Age
- Date of examination
- Type of study
- Contrast
- MRI pulse sequence

(10) Measurement style interface/report: select whether to enable measurement style interface/report

(11) Merge multiple axial L-spine series: select whether to merge multiple axial L-spine series

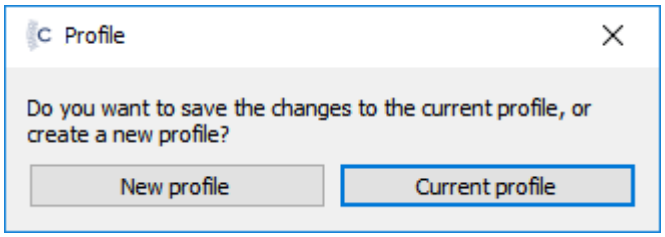
(12) Segmentation lines transparency: Segmentation transparency – 0% is a completely transparent contour, and 100% is a completely dense contour.

(13) Level labeling style: Select style of level labeling:
- with the name of the vertebra above the disk
- with the names of the vertebrae between which the disk is located

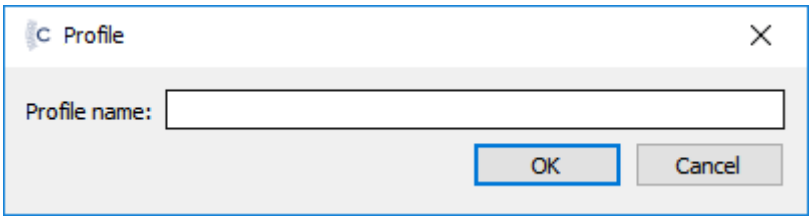
(14) Statistics for the analyzed studies of the currently selected CoLumbo profile:
- Study ID – study identification data
- Date – the date on which the study was uploaded to CoLumbo
- FN (false negative) – number of misidentified non-existent / unavailable out-of-range measurements that are actually present in the given study
- FP (false positive) – number of incorrectly identified existing / available out-of-range measurements that are not actually present in the given study
- TP (true positive) – number of correctly identified existing / available out-of-range measurements of the given study
- TN (true negative) – number of correctly calculated non-existent / non-available out-of-range measurements of the given study
- Session duration (sec.) – the time during which the study was opened in CoLumbo, in seconds

(15) Level Abbreviation – select abbreviation style of thoracic, lumbar and sacral levels:
- Thoracic level style: T, TH, D, BWK
- Lumbar level style: L, LWK
- Sacral level style: S, SWK

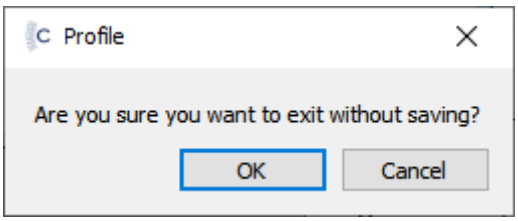
After the user enters his personal settings and clicks the “OK” button in the lower right corner, a window appears on the screen from which he/she must choose whether to save the settings in the currently selected profile or create a new one. If no profile is created and the default settings are edited, the Current profile button is inactive.



If the option New profile is selected and another window opens on the screen, in which the user must enter a name for his account:

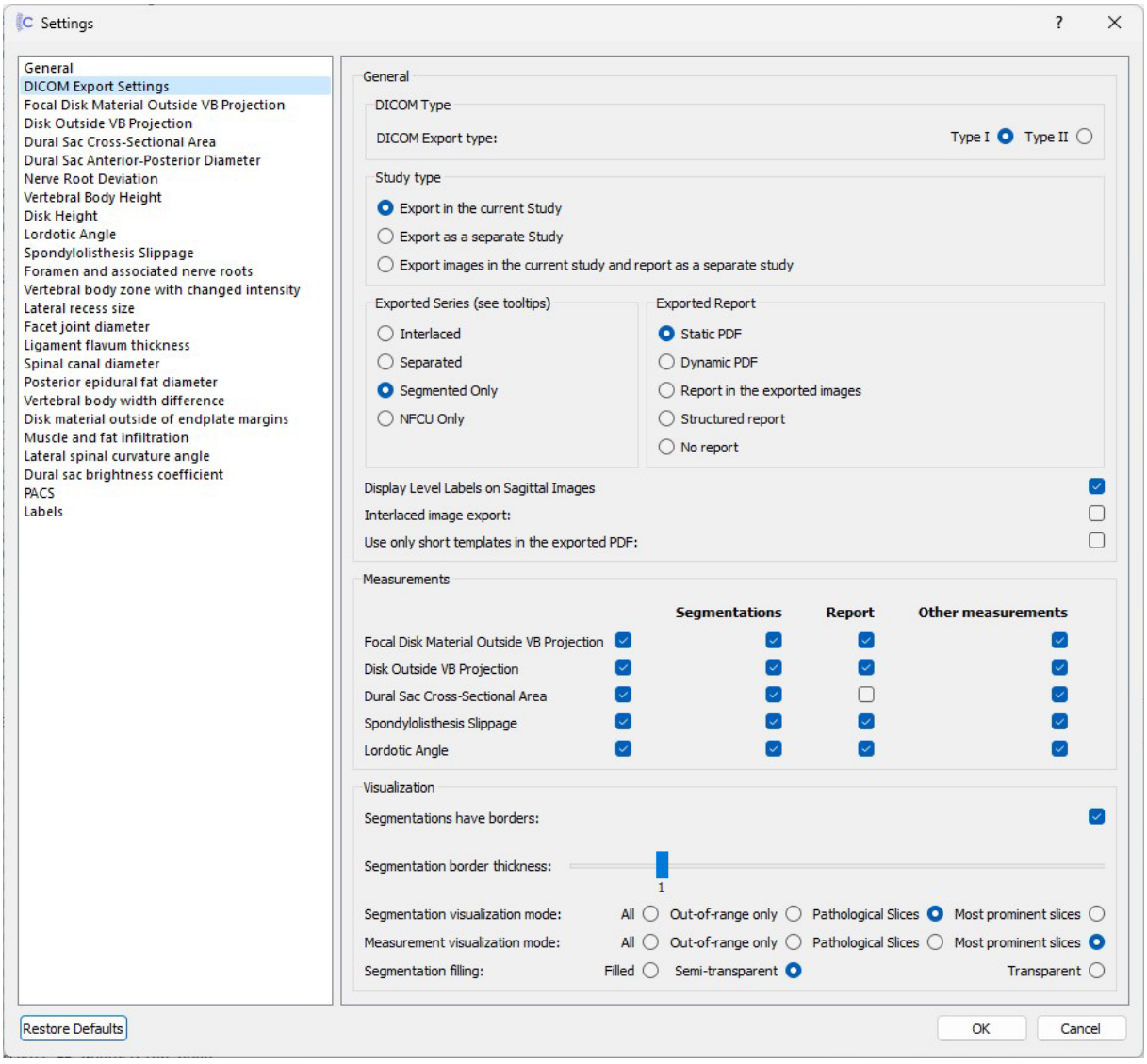


If the user does not want to save the changes he has made, or close the settings window, he must press the X button in the upper right corner. If changes have been made, another window will appear on the screen to confirm that the user wants to leave the menu without saving their changes:



DICOM Export Settings

DICOM Export is CoLumbo's functionality for exporting studies or specific series of them with added segmentations and measurements, and draft report in .pdf format. By configuring it, the user can select what the result of the export should be, e.g. what tissues and out-of-range measurements to include, how segmentations should look like, etc.



(1) Type DICOM Export:
- Type I: secondary capture images with either a PDF, SR or report in the DICOM tags
- Type II: layered images where each layer represents a certain pathology, with a structured report, where each node is connected to a pathology layer

(2) Study type: Select the type of study export:
- Export in the current study
- Export as a separate study
- Export images in the current study and report as a separate study

(3) Exported Series - Select mode of visualization of exported studies:

- Interlaced
- Separated
- Separated Only
- NFCU Only

(4) Exported Report: Select the type of exported report:
- Static PDF
- Dynamic PDF
- Report in the exported images
- Structured report
- No report

(5) Display Level Labels on Sagittal Images: Select whether to include labels with measurements on the segmentations only of measurements included in the report

(6) Interlaced image export: Select whether the exported images to be interlaced (the original series without segmentation is used, duplicating the sections where the software has calculated out-of-range measurements and intertwining with the original images, alternating original and segmented image)

(7) Use only short templates in the exported PDF: Select whether to use only short templates in the exported PDF

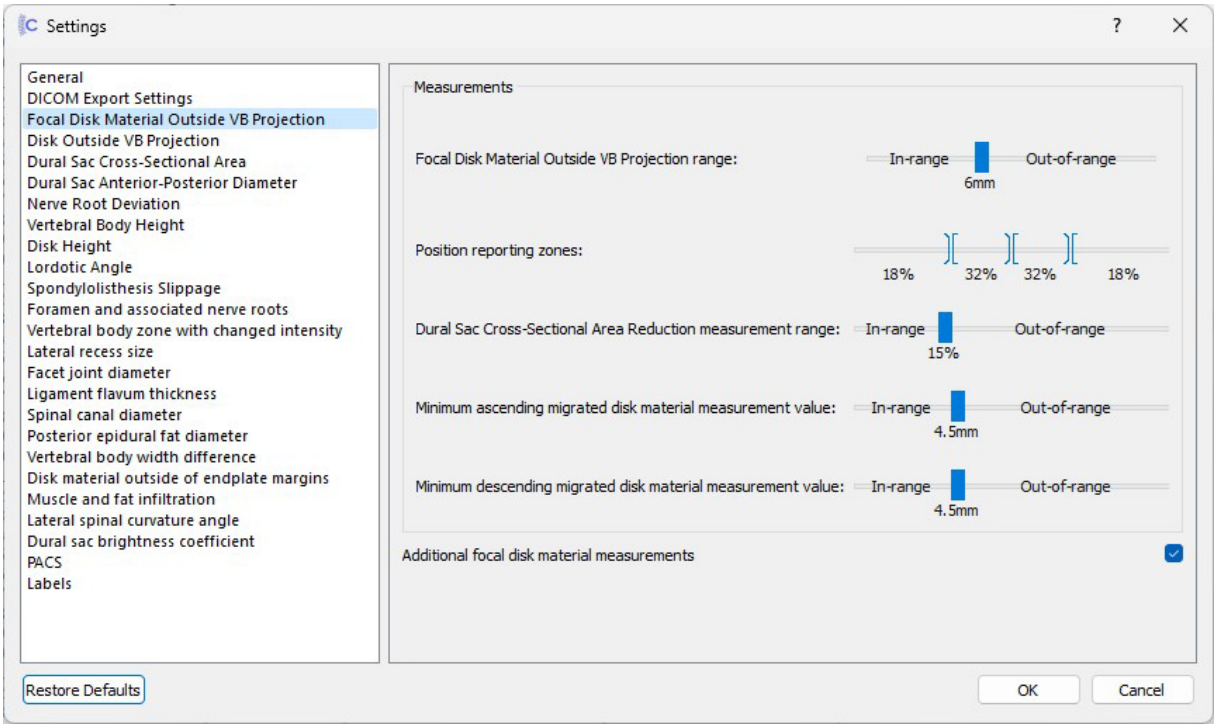
(8) Measurements: Selection of information for which out-of-range measurements to be included:
a. Focal Disk Material Outside VB Projection – select whether to include segmentations, report or other measurements
b. Disk Outside VB Projection - select whether to include segmentations, report or other measurements
c. Dural Sac Cross-Sectional Area - select whether to include segmentations, report or other measurements
d. Spondylolisthesis Slippage - select whether to include segmentations, report or other measurements
e. Lordotic Angle - select whether to include segmentations, report or other measurements

(9) Select whether the segmentations of the exported study to have a contour

(10) Select contour thickness of segmentations (in pixels): 1 to 3 px

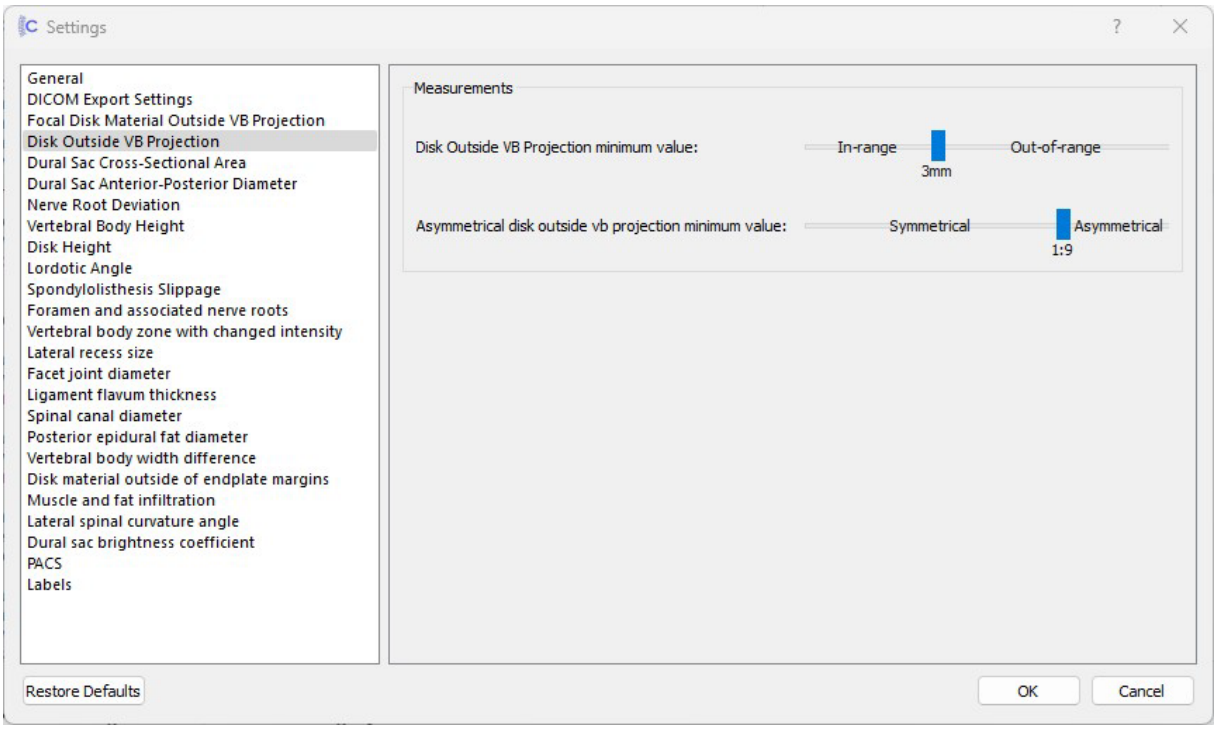
(11) Select:
- segmentation visualization mode: all, out-of-range only, pathological slices, most prominent slices
- mode of visualization of measurements: all, out-of-range only, pathological slices, most prominent slices
- fill of segmentations: filled, semi-transparent, transparent

Focal Disk Material Outside VB Projection Settings



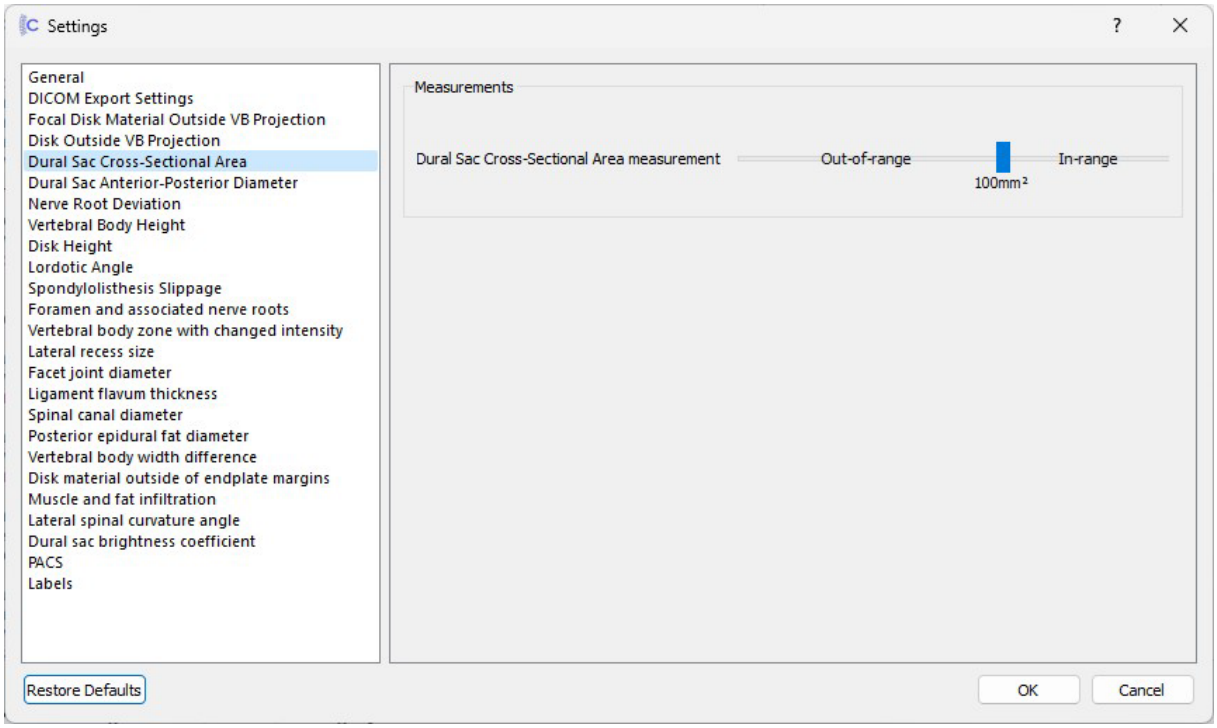
(1) Focal Disk Material Outside VB Projection range: Select the boundaries for reporting focal disk material outside vb projection
(2) Select the boundaries between the different levels of a focal disk material outside vb projection (in millimeters)
(3) Position reporting zones: Select the limits for reporting the position of the focal disk material outside vb projection (as a percentage of the size of the canal)
(4) Dural Sac Cross-Sectional Area Reduction measurement range: Select a lower limit above which reduction of a dural sac cross-sectional area will be reported
(5) Minimum ascending migrated disk material measurement value: Select a minimum value for reporting ascending migrated disk material (in millimeters)
(6) Minimum descending migrated disk material measurement value: Select a minimum value for reporting descending migrated disk material (in millimeters)

Disk Outside VB Projection Settings



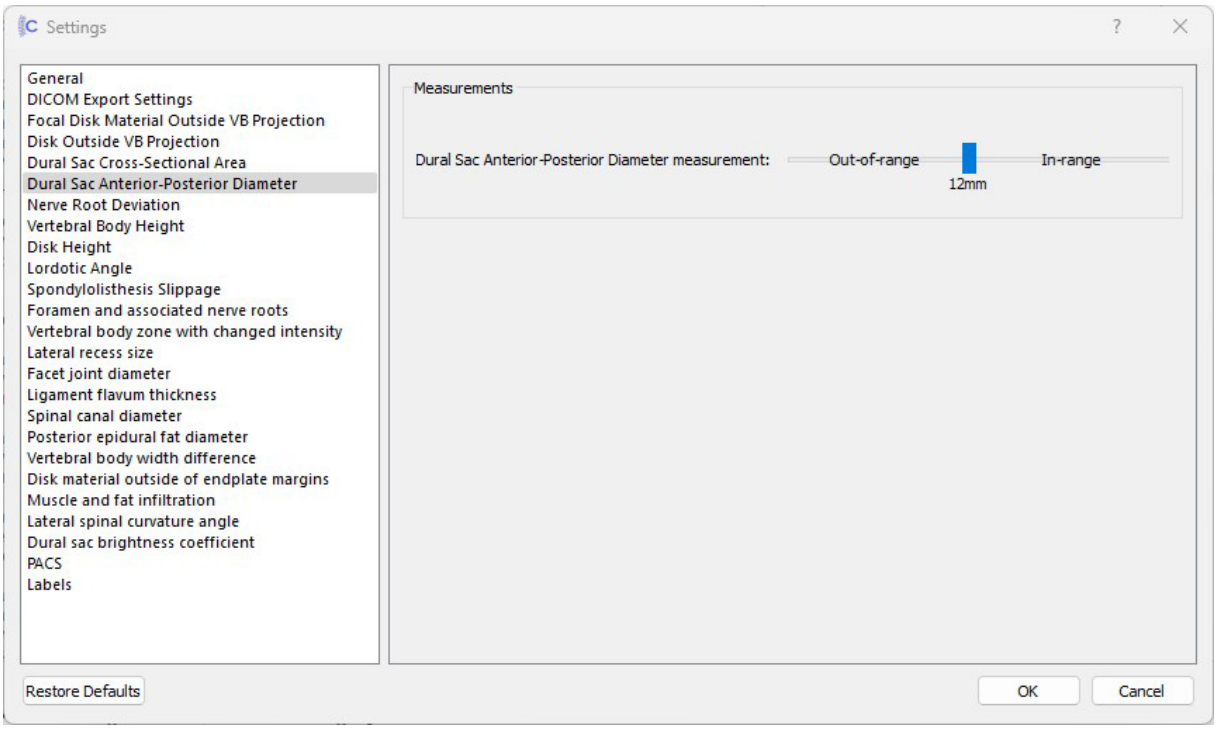
(1) Disk Outside VB Projection minimum value: Select a lower limit above which the presence of disk outside of vb projection will be reported (in millimeters)
(2) Asymmetrical disk outside vb projection minimum value: Select a minimum value above which a present disk outside of vb projection will be reported as asymmetric in a given direction (as ratio)

Dural Sac Cross-Sectional Area Settings



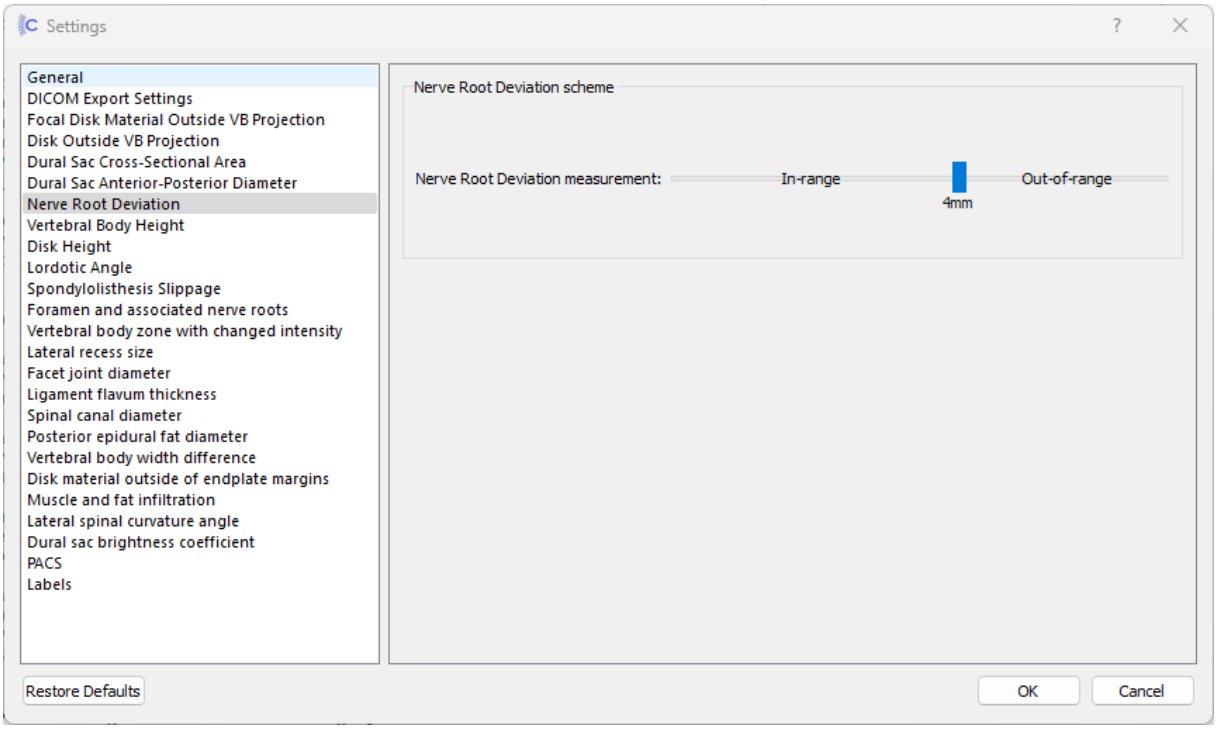
(1) Dural Sac Cross-Sectional Area measurement: Select a lower limit above which the presence of dural sac cross-sectional area will be reported (in millimeters)

Dural Sac Anterior-Posterior Diameter Settings



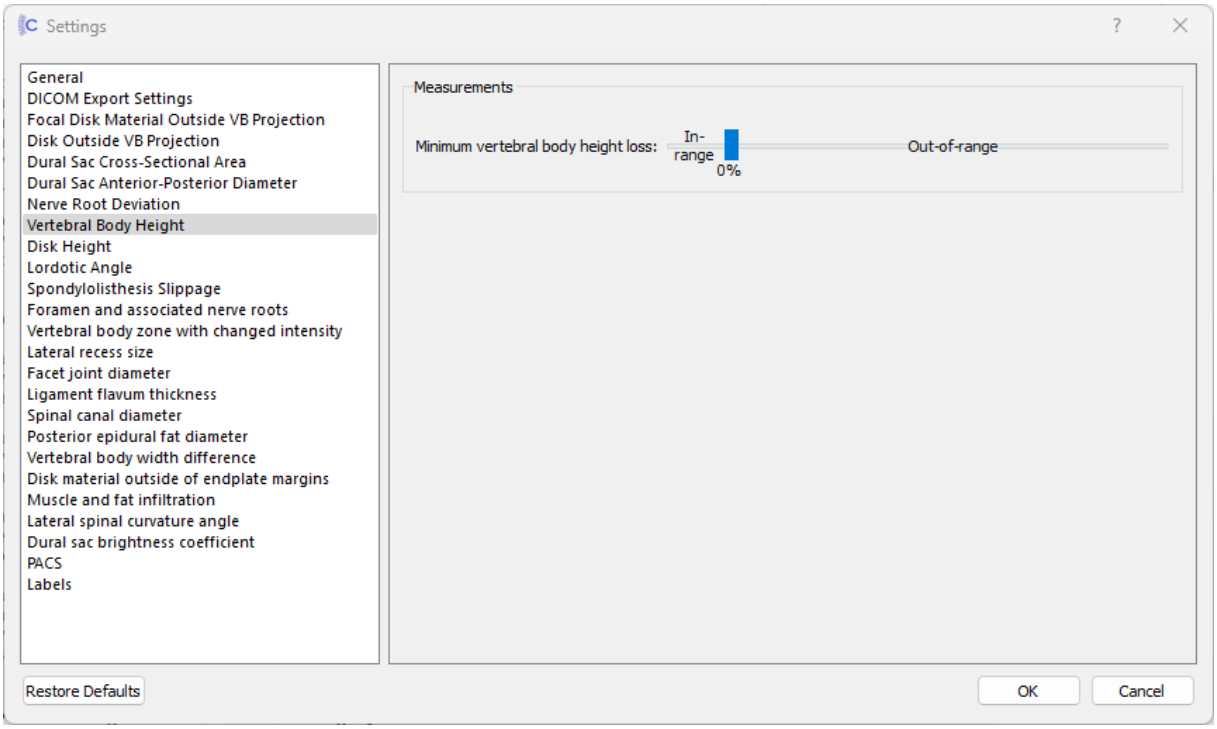
(1) Dural Sac Anterior-Posterior Diameter measurement: Select a lower limit above which the presence of dural sac anterior-posterior diameter will be reported (in millimeters)

Nerve Root Deviation Settings



1) Nerve Root Deviation measurement: Select a lower limit above which the presence of nerve root deviation will be reported (in millimeters)

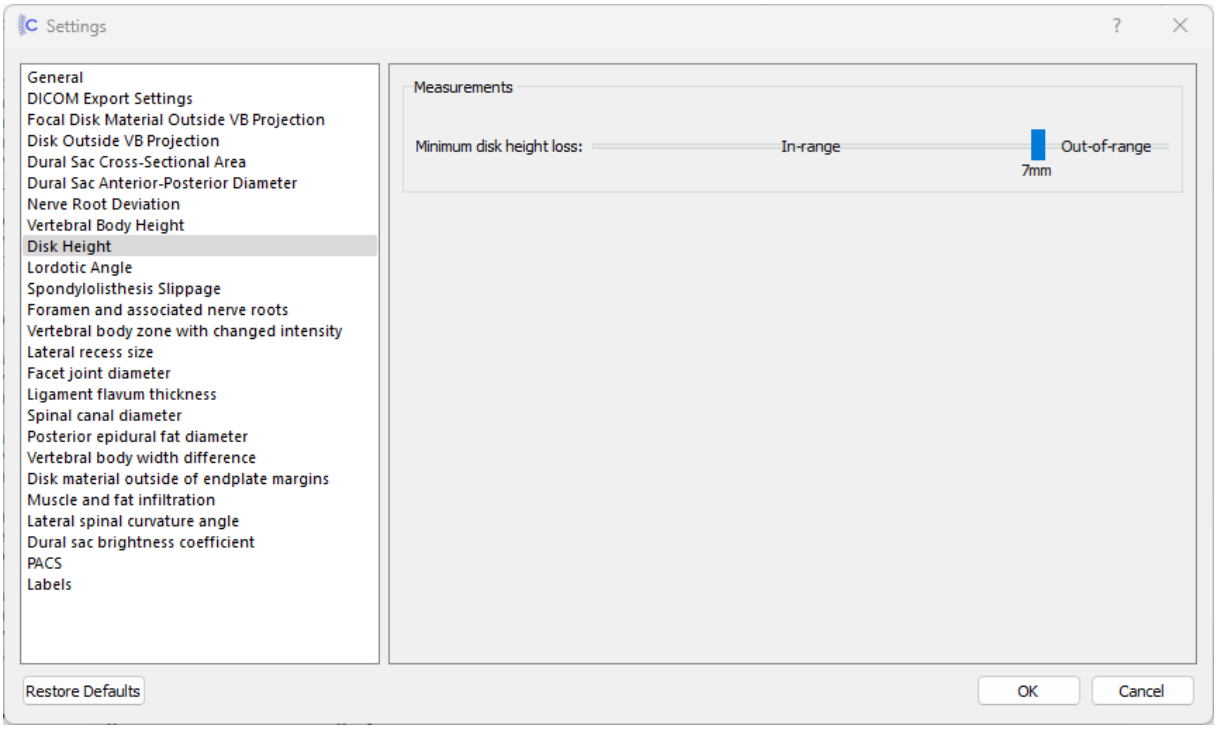
Vertebral Body Height Settings



Minimum vertebral body height loss: Select a minimum reduction percentage to reduce the height of the vertebral body in order to take into account the reduced height of the vertebrae body. *

* The height of the vertebrae body is defined as reduced when the difference between the largest and smallest height (of a total of three heights – anterior, posterior and average) is greater than the set value (20%).

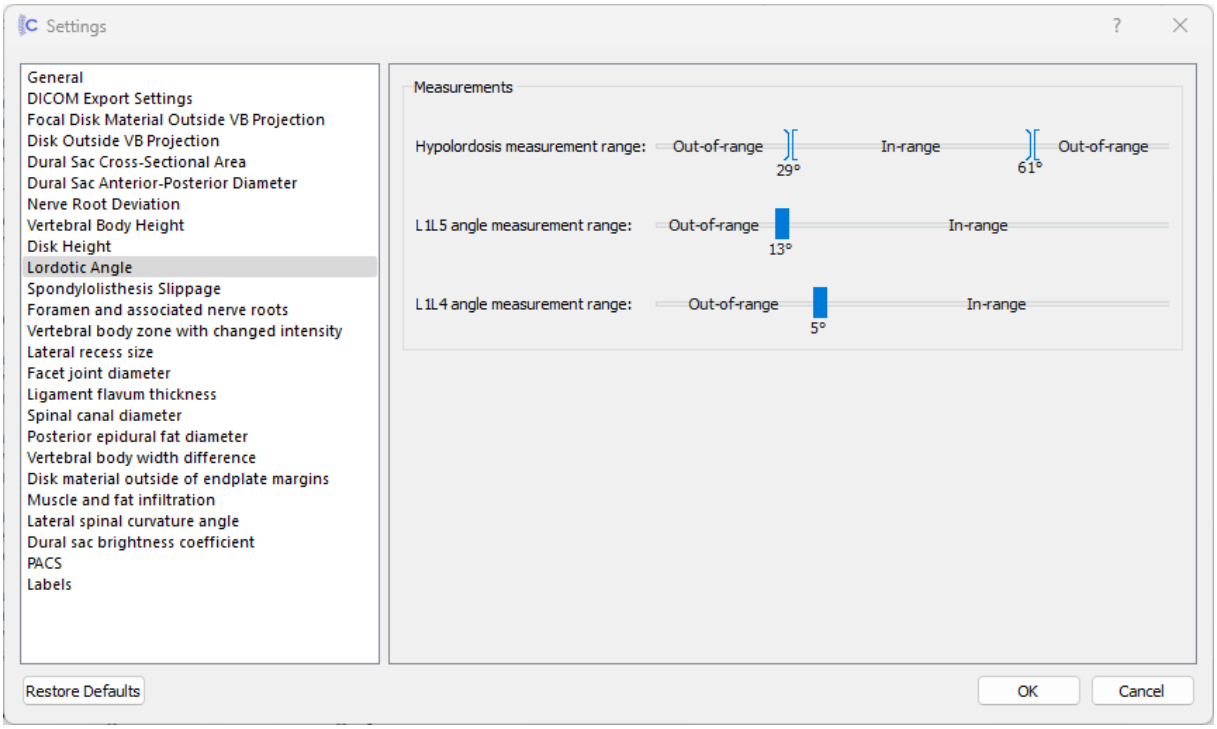
Disc Height Settings



(1) Minimum Disk heigh loss: Select the minimum value by which the disc height is reduced to report the reduced disc height (in millimeters)*

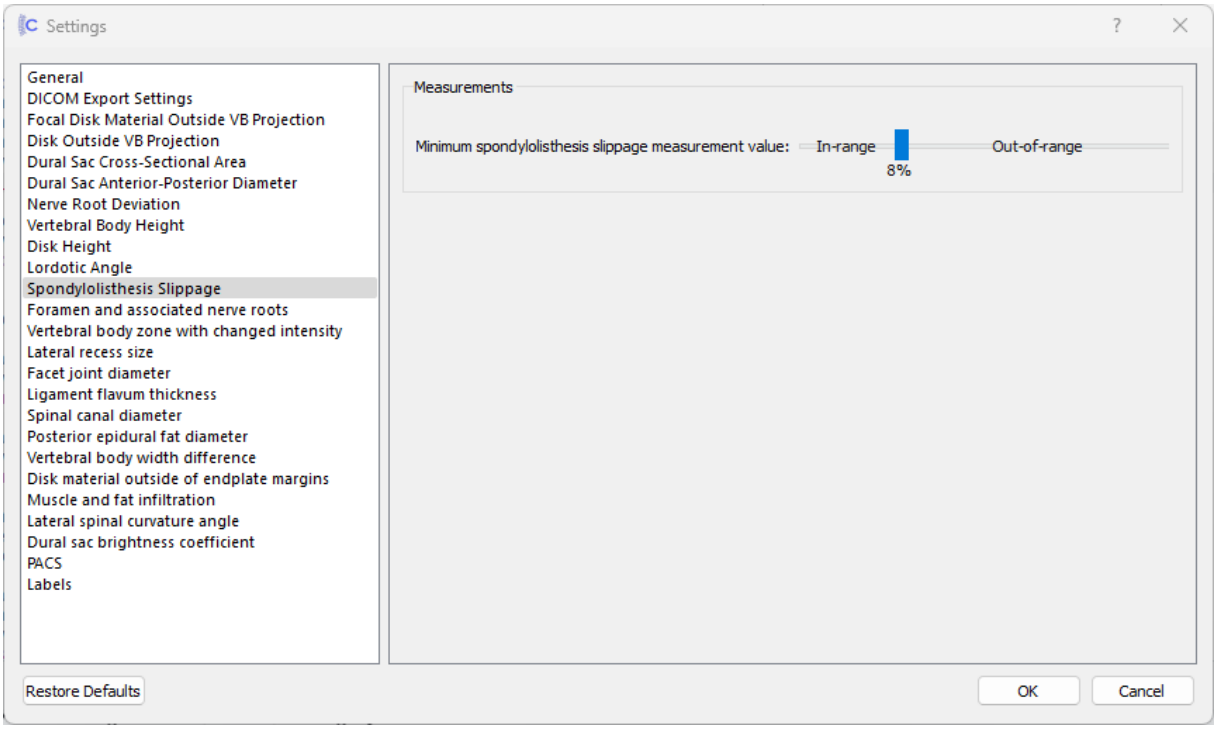
** For example, if the user sets a value of 5 mm, at least one of the heights of a disc must be reduced by at least 5 mm to report a reduced disc height.*

Lordotic Angle Settings



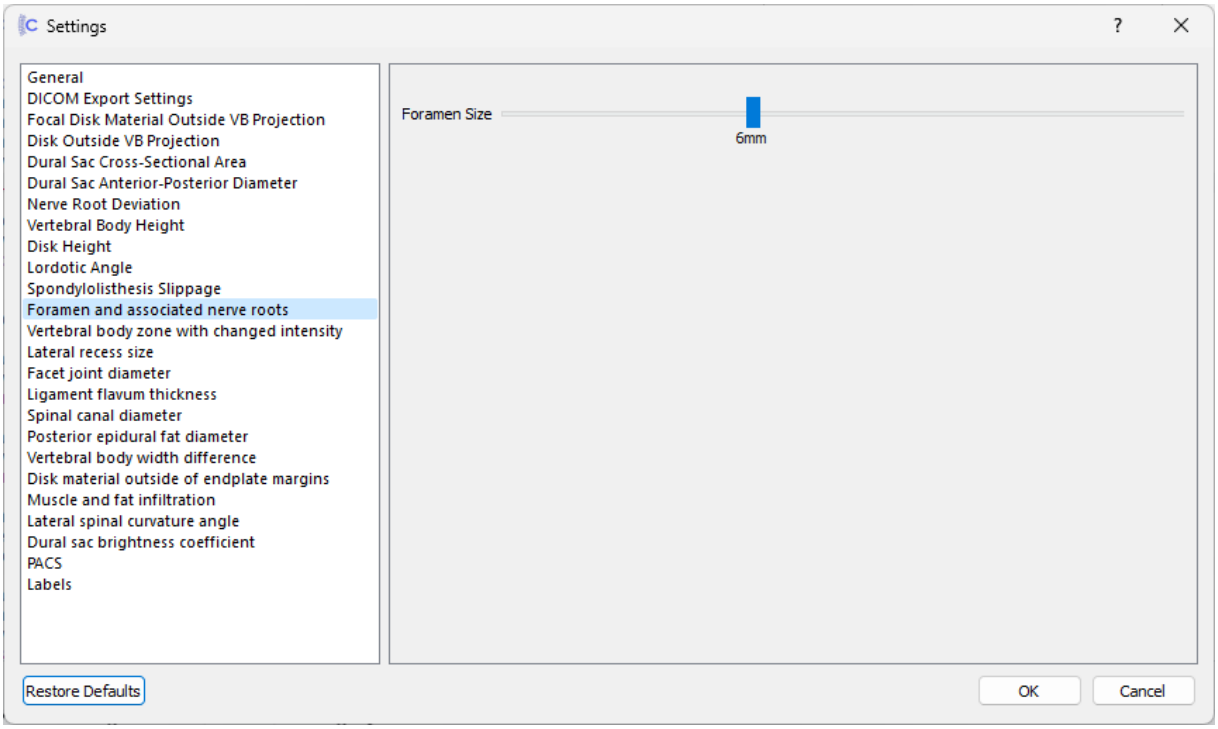
(1) Out-of-range lordotic angle measurement range: Select a minimum and a maximum angle for reporting out-of-range lordotic angle
(2) L1L5 angle measurement range: Select a maximum L1L5 angle for reporting out-of-range lordotic angle
(3) L1L4 angle measurement range: Select a maximum L1L4 angle for reporting out-of-range lordotic angle

Spondylolisthesis Slippage Settings



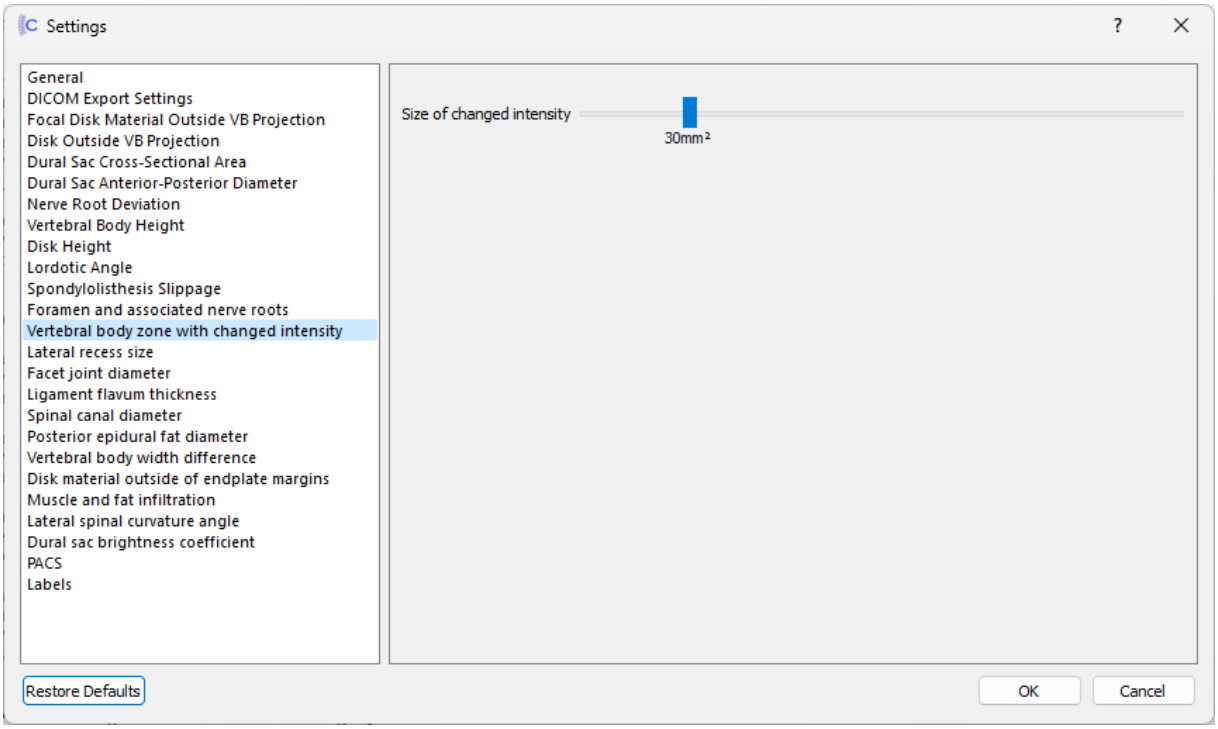
Minimum spondylolisthesis slippage measurement value: Select a minimum vertebral slippage value percentage for reporting spondylolisthesis. The minimum value is 10% and the maximum is 25%.

Foramen And Associated Nerve Roots Settings



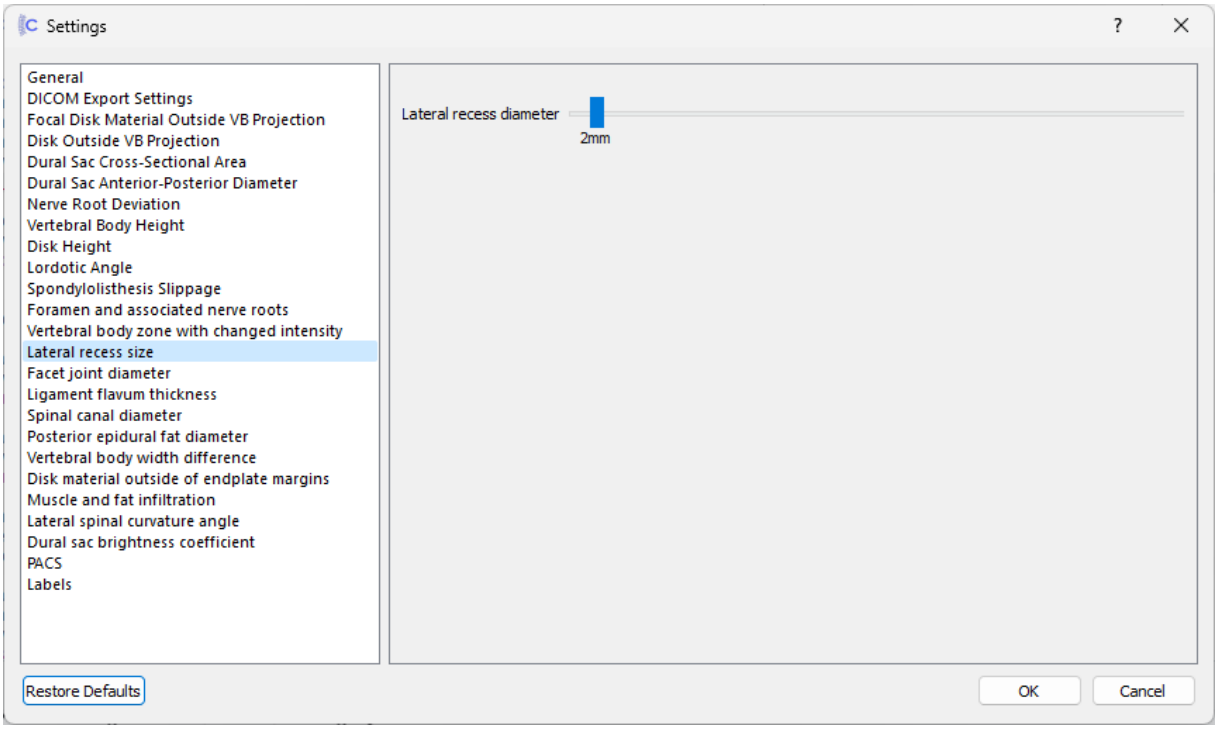
(1) Foramen size: Select the threshold for reporting foramen and associated nerve roots (in millimeters)

Vertebral Body Zone With Changed Intensity Settings



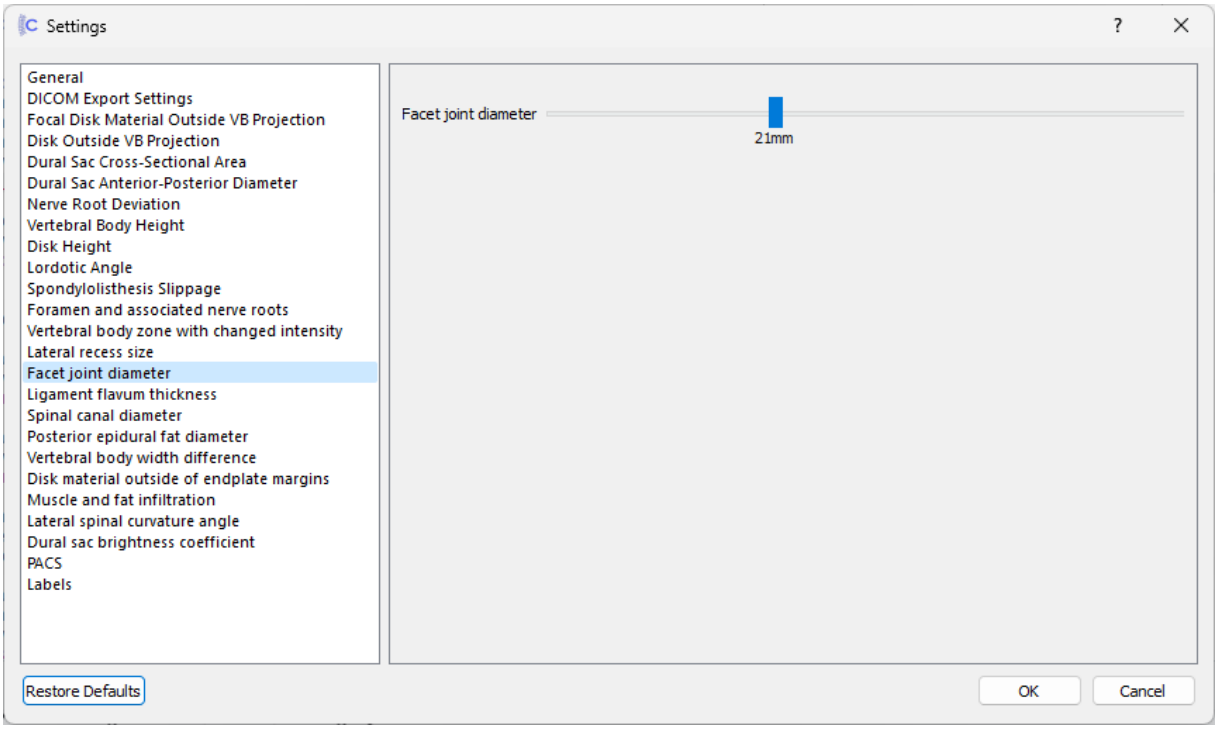
(1) Size of changed intensity: Select the threshold for reporting vertebral body zone with changed intensity (in millimeters)

Lateral Recess Size Settings



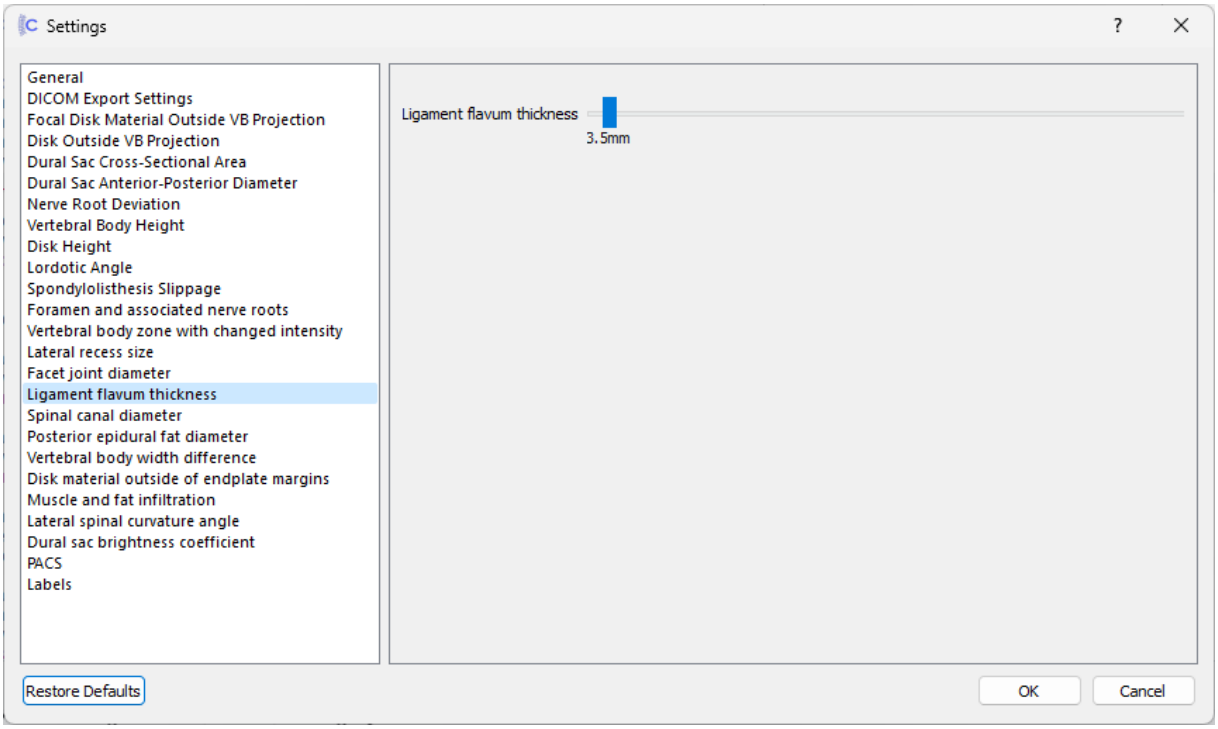
(1) Lateral recess diameter: Select the threshold for reporting lateral recess diameter (in millimeters)

Facet Joint Diameter Settings



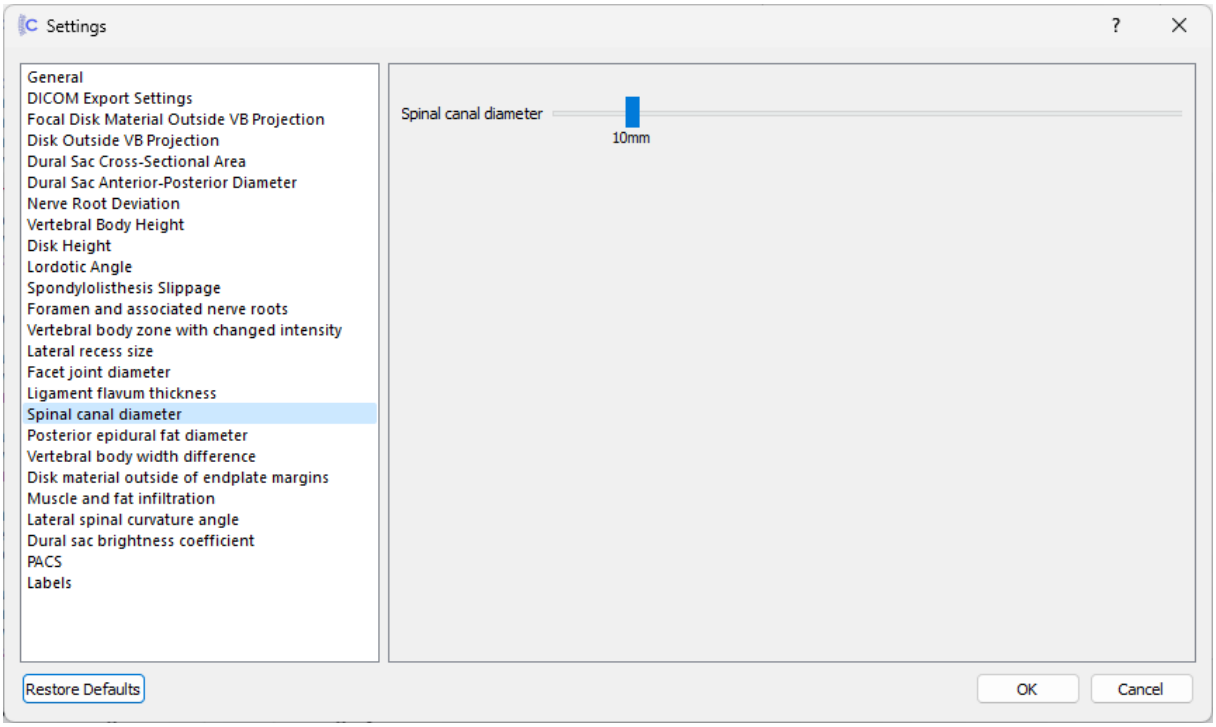
(1) Facet joint diameter: Select the threshold for reporting facet joint diameter (in millimeters)

Ligamentum Flavum Thickness Settings



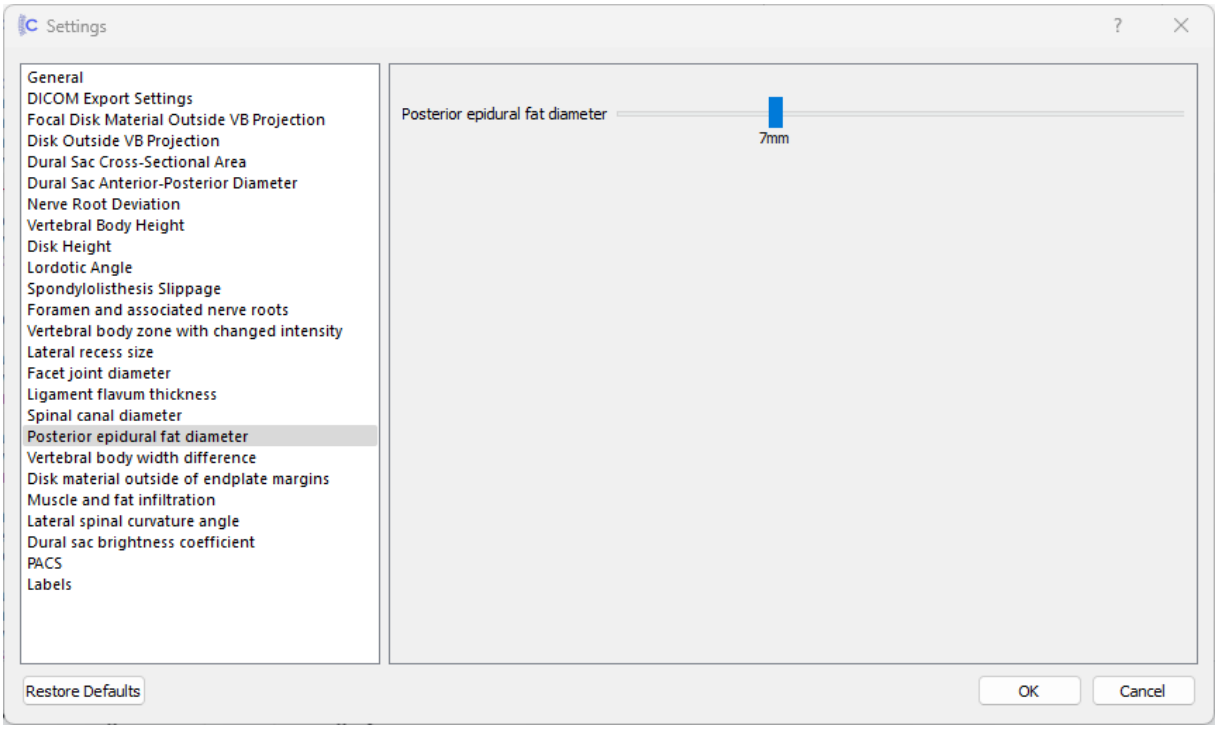
(1) Ligamentum flavum thickness: Select the threshold for reporting ligamentum flavum thickness (in millimeters)

Spinal Canal Diameter Settings



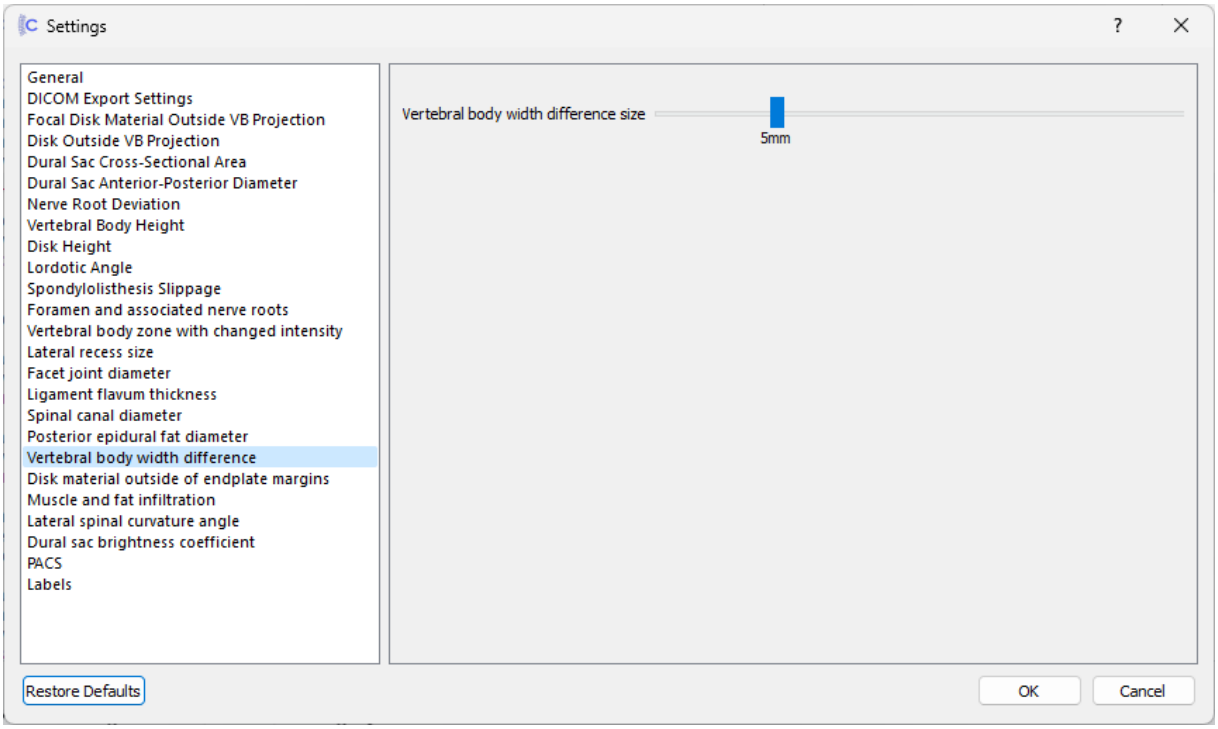
(1) Spinal canal diameter: Select the boundaries for reporting spinal canal diameter (in millimeters)

Posterior Epidural Fat Diameter Settings



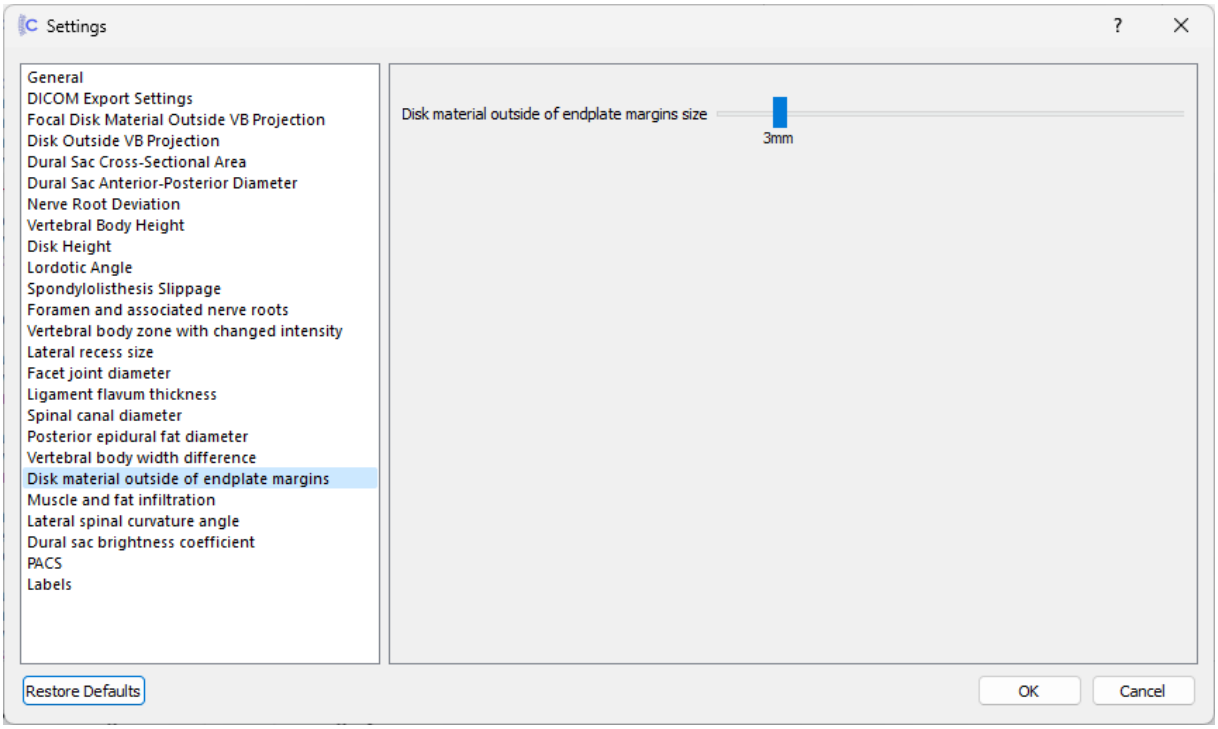
(1) Posterior epidural fat diameter: Select the threshold for reporting posterior epidural fat diameter (in millimeters)

Vertebral Body Width Difference Settings



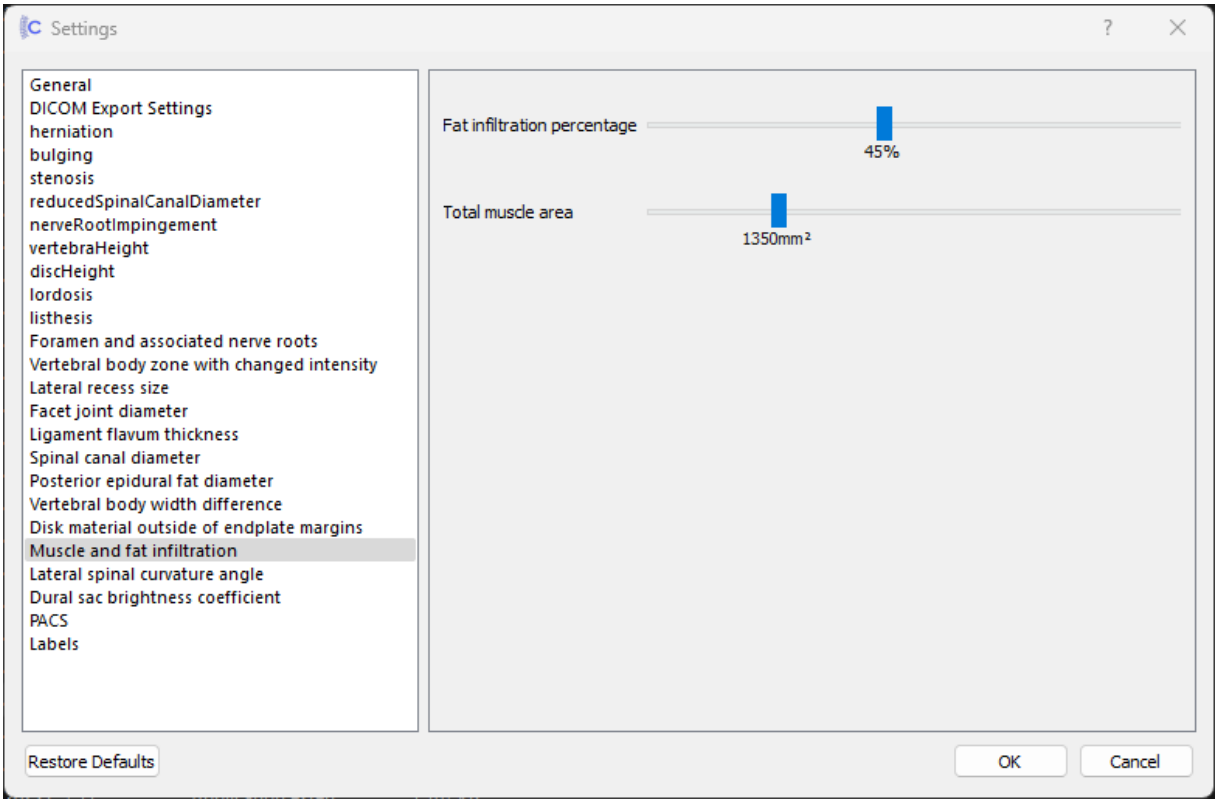
(1) Vertebral body width difference size: Select the threshold for reporting vertebral body width difference (in millimeters)

Disk Material Outside of Endplate Margins Settings



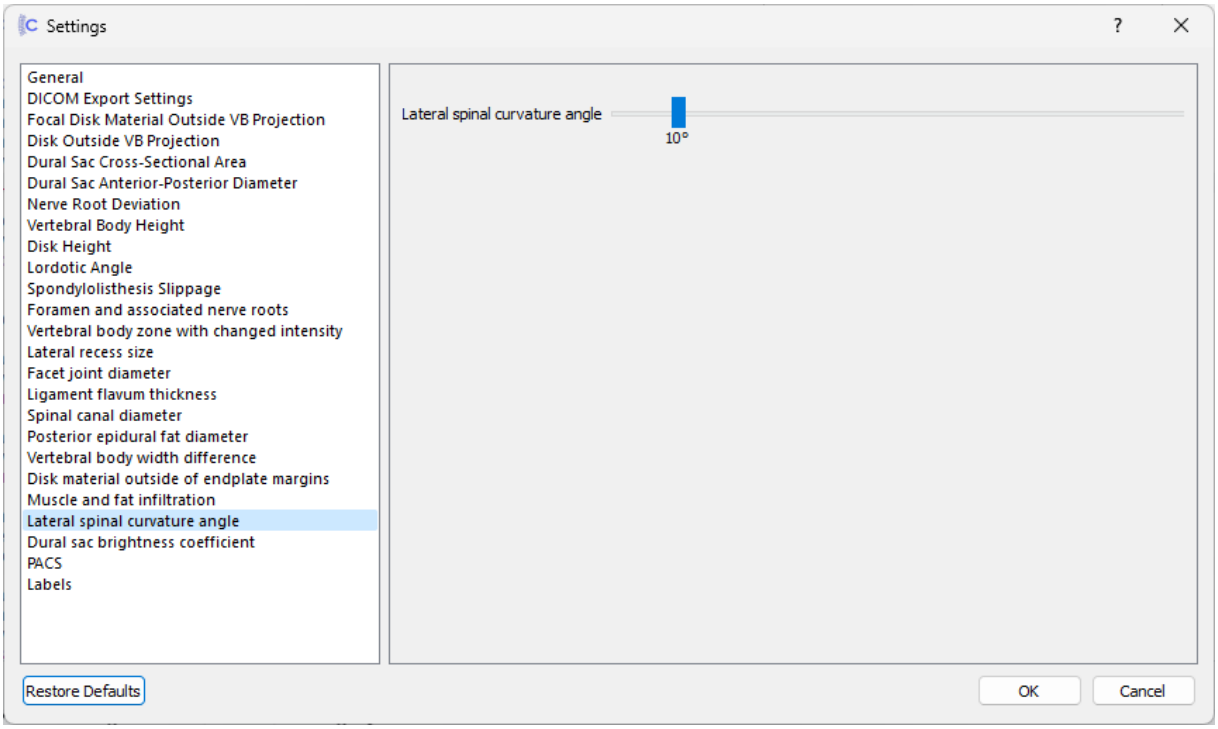
(1) Disk material outside of endplate margins size: Select the threshold for reporting disk material outside of endplate margins (in millimeters)

Muscle And Fat Infiltration Settings



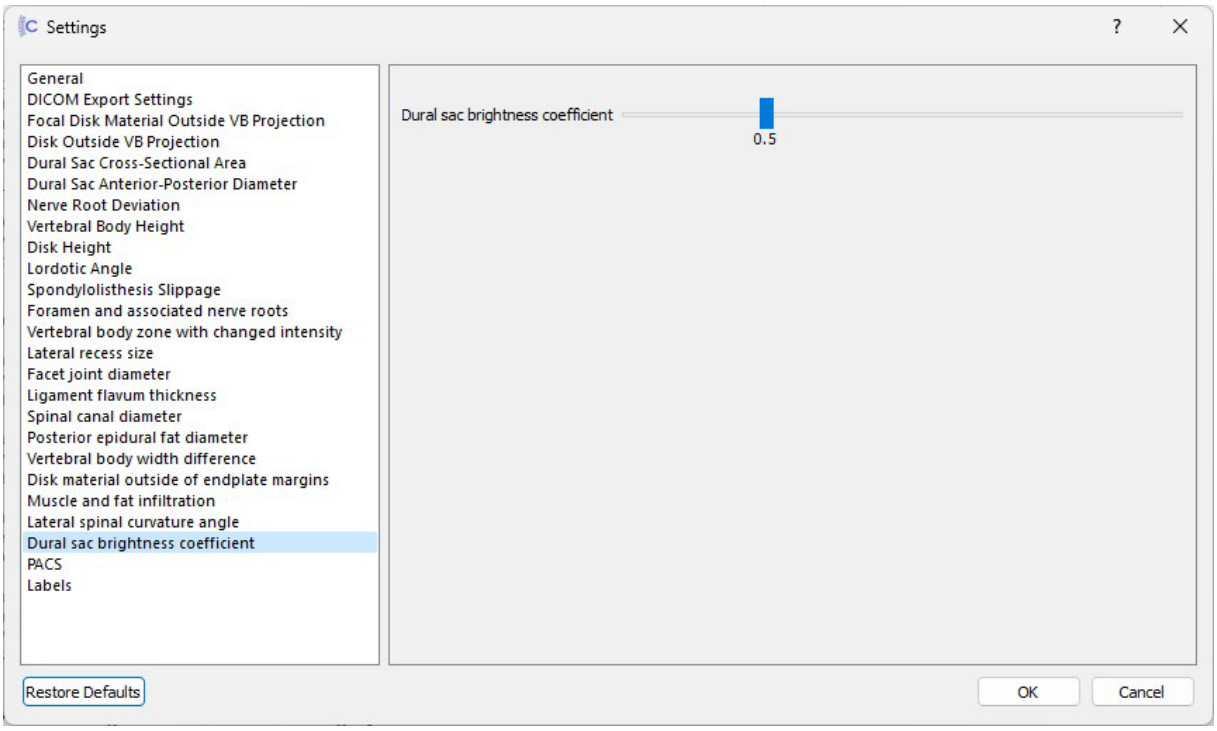
(1) Fat infiltration percentage: Select a minimum percentage for reporting the presence of fat infiltration
(2) Total muscle area: Select a lower limit above which the presence of muscle and fat infiltration area will be reported (in millimeters)

Lateral Spinal Curvature Angle Settings



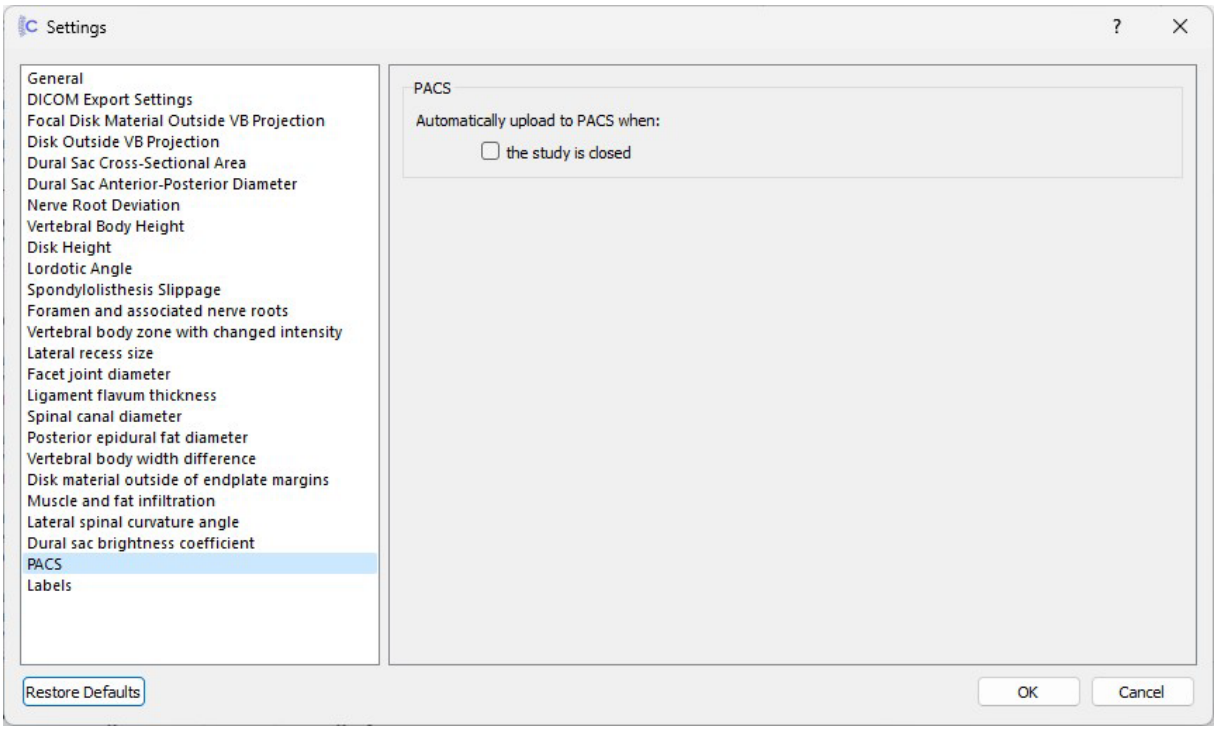
(1) Lateral spinal curvature angle: Select a minimum angle for reporting lateral spinal curvature

Dural Sac Brightness Coefficient



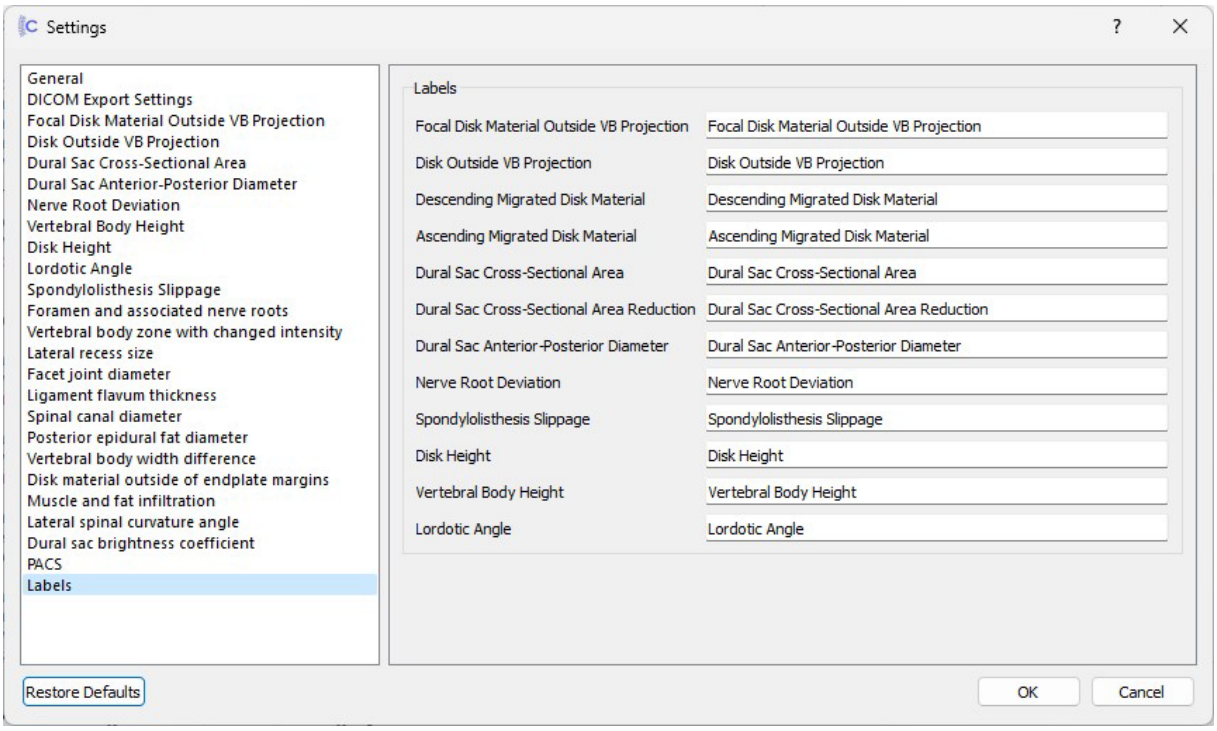
(1) Dural sac brightness coefficient: Select to determine the brightness of the dural sac.

PACS



(1) Automatically upload to PACS when: Select to automatically upload to PACS after the study is closed

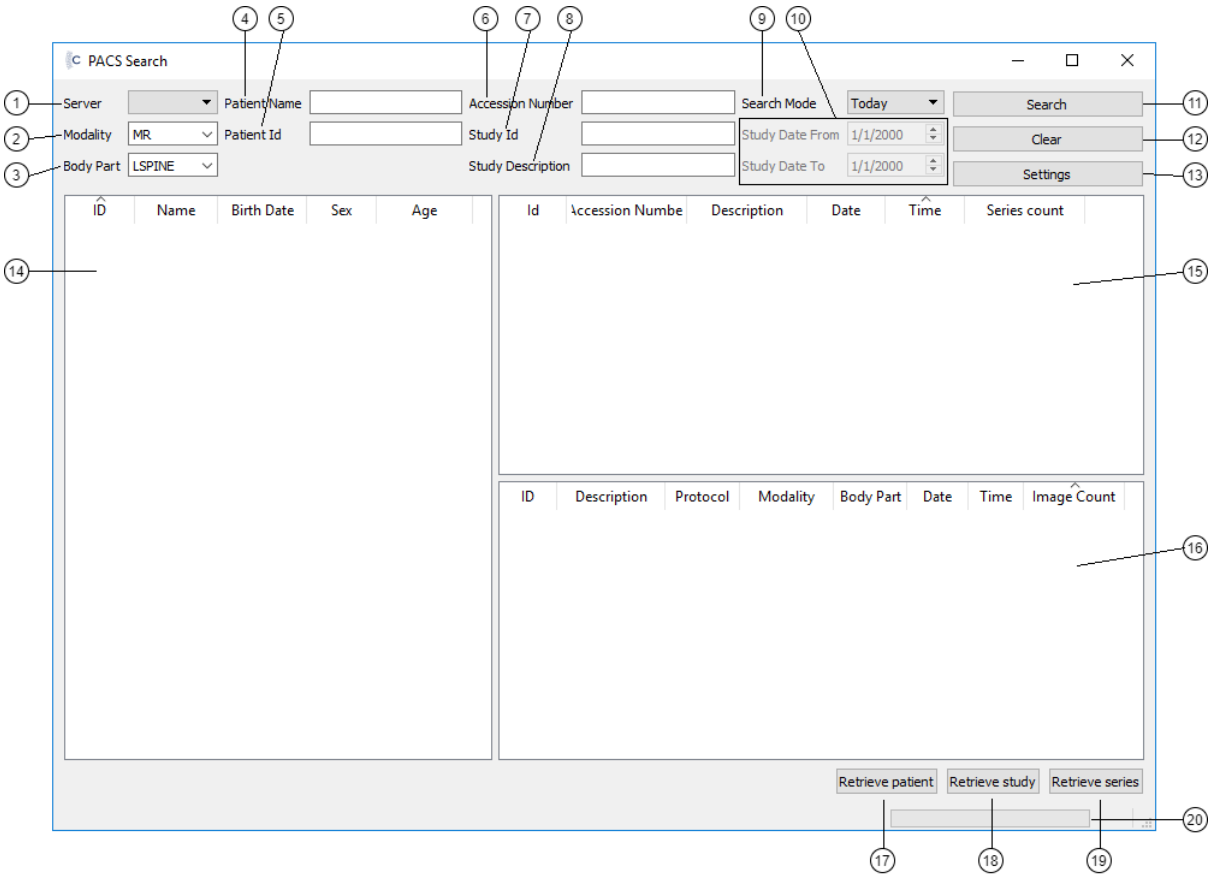
Labels



(1) Focal Disk Material Outside VB Projection: Select a name for focal disk material outside vb projection in the report.
(2) Disk Outside VB Projection: Select a name for disk outside vb projection in the report.
(3) Descending Migrated Disk Material: Select a name for descending migrated disk material in the report.
(4) Ascending Migrated Disk Material: Select a name for ascending migrated disk material in the report.
(5) Dural Sac Cross-Sectional Area: Select a name for dural sac cross-sectional area in the report.
(6) Dural Sac Cross-Sectional Area Reduction: Select a name for dural sac cross-sectional area reduction in the report.
(7) Dural Sac Anterior-Posterior Diameter: Select a name for dural sac anterior-posterior diameter in the report.
(8) Nerve Root Deviation: Select a name for nerve root deviation in the report.
(9) Spondylolisthesis Slippage: Select a name for spondylolisthesis slippage in the report.
(10) Disk Height: Select a name for disk height in the report.
(11) Vertebral Body Height: Select a name for vertebral body height in the report.
(12) Lordotic Angle: Select a name for lordotic angle in the report.

DICOM Server Configuration

The PACS (2) button on the main screen opens a new window for searching in PACS server:



1) Server - the user can select from a dropdown menu the server, which he wants to connect to
2) Modality - the user can choose the type of examination (CT, CR, MG, MR, US, XA), from the dropdown menu with the default being "MR"
3) Body Part - the user can select the body part of which the images were taken (abdomen, chest, cspine, breast, head, hand, hip, knee, lspine, pelvis), with the default being "lspine".
4) Patient Name - the user can input a patient name to use as a search option
5) Patient ID - the user can input a patient ID to use as a search option
6) Accession Number - the user can input the acquisition number of the study to use as a search option
7) Study ID - the user can input a study ID to use as a search option
8) Study Description - the user can input data, included in the study (e.g. info from tags) as a search option
9) Search Mode - allows the user to select a search mode (Today, All Time, Range), with the default being "Today"
10) Study Date From/Study Date To - disabled by default, selecting "Range" from "Search Mode" enables both fields and allows the user to input the desired data

11) Search - for manually search with the given information from the fields
12) Clear - clears the results of the search
13) Settings – opens up new window for server configuration

Opening the PACS search interface automatically searches for studies with the default values.

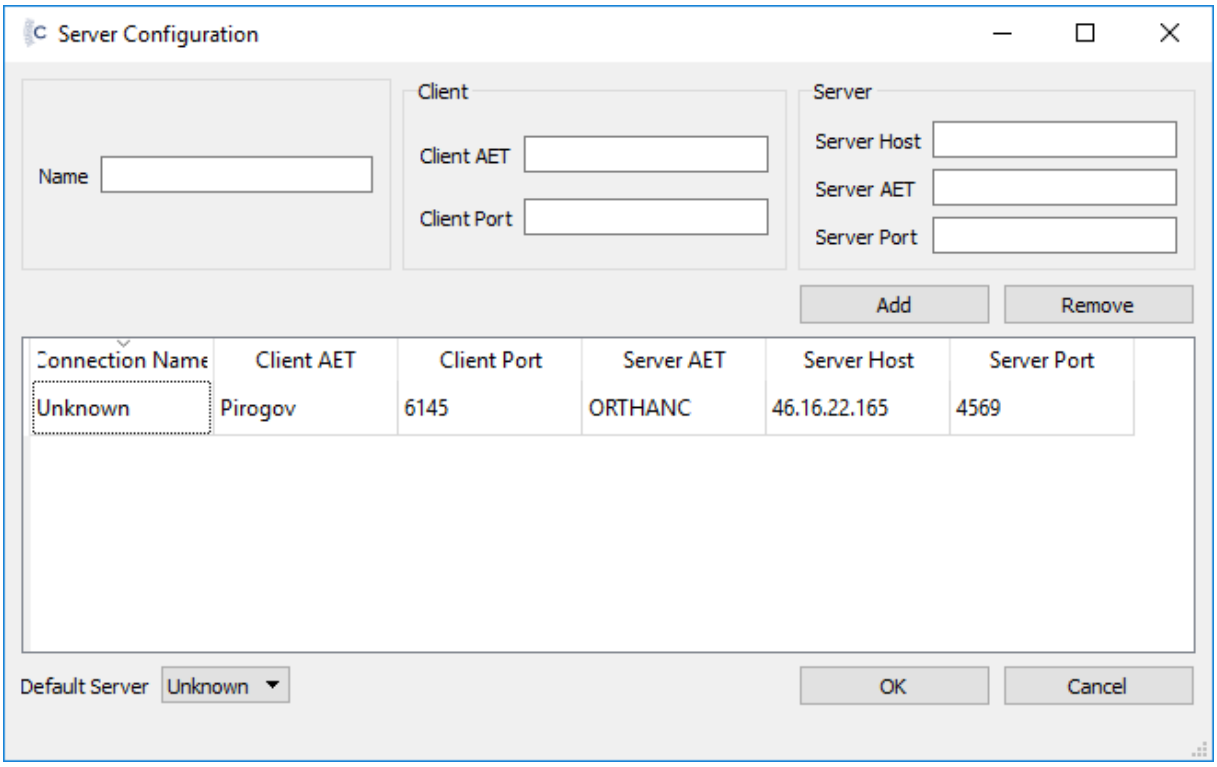
14) Patient panel:
    - Patient ID
    - Name
    - Birth Date
    - Sex
    - Age

15) Study panel:
    - ID - the ID of the study
    - Accession Number – an identifier generated by the information system
    - Description - description of the study, e.g. tag information
    - Date of the study
    - Time - the time of the study acquisition
    - Series Count - the amount of series in a certain study

16) Series panel:
    - ID - the ID of the study
    - Description - the name of the series
    - Series Protocol - (e.g. l-spine, c-spine, etc.)
    - Series Modality - (e.g. MR, CT, etc.)
    - Body Part - the body part of which the series was taken
    - Time - the time of acquisition of the series
    - Image Count - the number of images in a certain series

17) Save a file with all patient data
18) Save a file with the corresponding study
19) Save a file with a specific series
20) Progress bar, which shows when a search or download is in progress or has ended.

The "Settings" button (13) opens the "Server Configuration" window. It is used to configure the servers that CoLumbo will work with:



- Name – server name
- Client AET - Application Entity Title (AET) of the client
- Client Port - TCP/IP port of the client
- Server Host - IP address of the server, which the user wants to connect to
- Server AET - Application Entity Title (AET) identifier of the server
- Server Port - TCP/IP port of the server

The Add button allows the user to add a server with the entered data to the list, and Remove - to remove a selected server form the list of servers.

From the list Default Server Unknown the user can select a default server to which CoLumbo can connect.

OK saves all changes, and Cancel rejects them.