14 CT Pulmo Auto Results

Introduction

The CT Pulmonary Auto Results application segments and quantifies lung volume, as well as regions suggestive of pneumonia in adults.

Regions suggestive of pneumonia are classified as ground glass opacities (GGO) and consolidation areas. A quantitative assessment of the disease burden is performed and results are calculated and included in the generated images in a tabular format, automatically available for review on PACS.

CT Pulmo Auto Results is an automatic processing application, without a user interface. The application is applied automatically (based on user defined rules) on the input series, and generates a set of images which are then saved back to the defined location (which can be the PACS).

NOTICE

The CT Pulmo Auto Results application is not commercially available in China market.

Indications for Use

CT Pulmo Auto Results is a fully automatic image analysis application that identifies several radiological findings (e.g. consolidation and ground-glass opacity) to support the management of adult patients with suspected or diagnosed COVID-19 pneumonia.

Intended Users

Advanced Visualization Workspace CT Pulmo Auto Results Application is intended to be used by adequately trained and qualified medical professionals, including but not limited to physicians and medical technicians. The main clinicians or medical and para-medical professionals, who use the Philips Advanced Visualization Workspace CT Pulmo Auto Results Application, are listed below:

- Radiologists in the radiology department/clinic
- 3D technologists in the radiology department

Intended Patient Population

The CT Pulmo Auto Results application is intended to be used in suspected or diagnosed COVID-19 pneumonia adult patients with chest CT imaging.

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Benefits

When used as specified in the Intended Use, under the circumstances and conditions as specified in the Indications for Use, the CT Pulmo Auto Results application assists the user in assessing the chest CT scans for lesions indicative of pneumonia on par with the state of the art, thus realizing a positive impact on diagnosis or patient management.

Contraindications

None.

Key Features

The CT Pulmo Auto Results imaging application includes the following key features:

- Automatic lung segmentation (left and right lungs)
- Automatic segmentation of regions suggestive of pneumonia
- Automatic color-coded classification of findings
- Quantitative results in a table format
- Rotating batch of a volumetric rendered lungs (optional)
- Result series of segmentation in Advanced Visualization Workspace proprietary format (optional)
- Images are automatically sent to PACS, as additional series in the original study.
- Segmentation results are saved in proprietary format that can be further processed in Advanced Visualization Workspace.

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Limitations for Use

NOTICE

- The physician retains the ultimate responsibility for making the final diagnosis based on image visualization, as well as any segmentation and measurement results obtained from the application. CT Pulmo Auto Results should not be used as the sole basis for clinical diagnosis.
- Depending on your Advanced Visualization Workspace configuration, this application may not be available.
- Only the original chest CT series should be used for diagnostic interpretation by physicians. CT Pulmo Auto Results output, including lung volume segmentation, findings volume segmentation, findings classification and quantitative results, should be verified and only used as an aid to interpretation.
- Incorrect DICOM headers or other factors can cause CT Pulmo Auto Results to reject an input CT series for processing, in which case no result is returned for viewing and there is a page with a failure notification. Physicians reading the original CT series should not be delayed based on the availability of the automated results.
- The CT Pulmo Auto Results application uses the DICOM header tags referring to Patient Position and Patient Orientation information. If the header tags are incorrect, the CT Pulmo Auto Results application might fail to process the series or might create results that are not optimal. If a failure occurs, additional information is provided as part of the automatic results.
- Users of the CT Pulmo Auto Results application should review all findings, even if not identified or segmented by the CT Pulmo Auto Results application.
- In the United States of America, the CT Pulmo Auto Results can only be used under the National Emergency Concerning the Novel Coronavirus Disease (COVID-19), and is not cleared by the FDA.
- CT Pulmo Auto Results is not yet approved in all markets. Please consult your Philips representative for more details.

CAUTION

- **The CT Pulmo Auto Results application is not intended to be used for COVID-19 screening or as a sole basis for COVID-19 diagnosis.**
- **Chest CT scans cannot be used as the sole basis for COVID-19 diagnosis due to the non-specific nature of the targeted radiological findings.**
- **Please consider the latest COVID-19 patient management and diagnosis guidelines when using this software.**

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Main User Workflow

Valid Studies for CT Pulmo Auto Results

For optimal results in the CT Pulmo Auto Results application, the following acquisition parameters are recommended:

- Slice thickness ≤ 3 mm
- Standard dose
- Supine patient orientation (FFS and HFS)
- Both lungs should be included in the scanned FOV

CAUTION

The CT Pulmo Auto Results AI algorithms were trained with the data as specified in the intended data type. Using other acquisition parameters may lead to failed processing or inaccurate results and should be avoided.

Creation of CT Pulmo Auto Results

Automatic Results Creation

It is possible to enable automatic results creation on the arrival of relevant data to Advanced Visualization Workspace.

Once relevant data (as configured in Preferences) arrives to Advanced Visualization Workspace, AVW recognizes the data as suitable for CT Pulmo Auto Results creation. The CT Pulmo Auto Results are generated in the background and are auto-sent to the DICOM devices configured by the user. For configuration information, see section “Configuration of CT Pulmo Auto Results” on page 408.

Manual Results Creation

It is also possible to activate the CT Pulmo Auto Results creation manually, from the Patient Directory of Advanced Visualization Workspace.

Right click on the relevant series within the study and select: **Run Processing** > **Automatic Pulmonary Assessment**.

The results series is created and is stored locally on Advanced Visualization Workspace and can be viewed/copied/deleted.

Configuration of CT Pulmo Auto Results

To configure CT Pulmo Auto Results:

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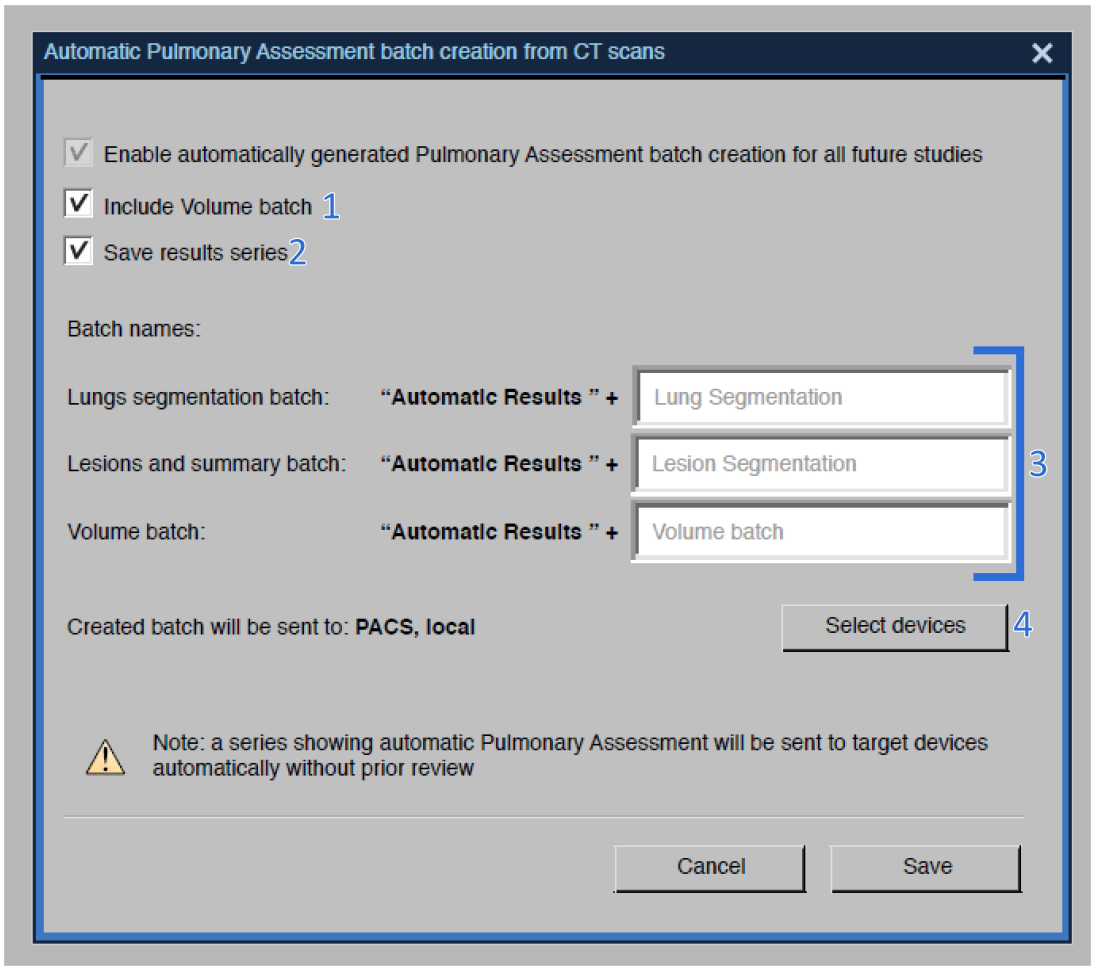
1. Go to **Preferences** and select the **Processing** page.
2. Verify that **Enable Processing** is selected.
3. Verify that **Run processing according to the following** is selected.
4. Select the **Add** button.

   A new processing rule is added to the table.
5. In the **Algorithm** column (first column), select **Automatic Pulmonary Assessment>>**

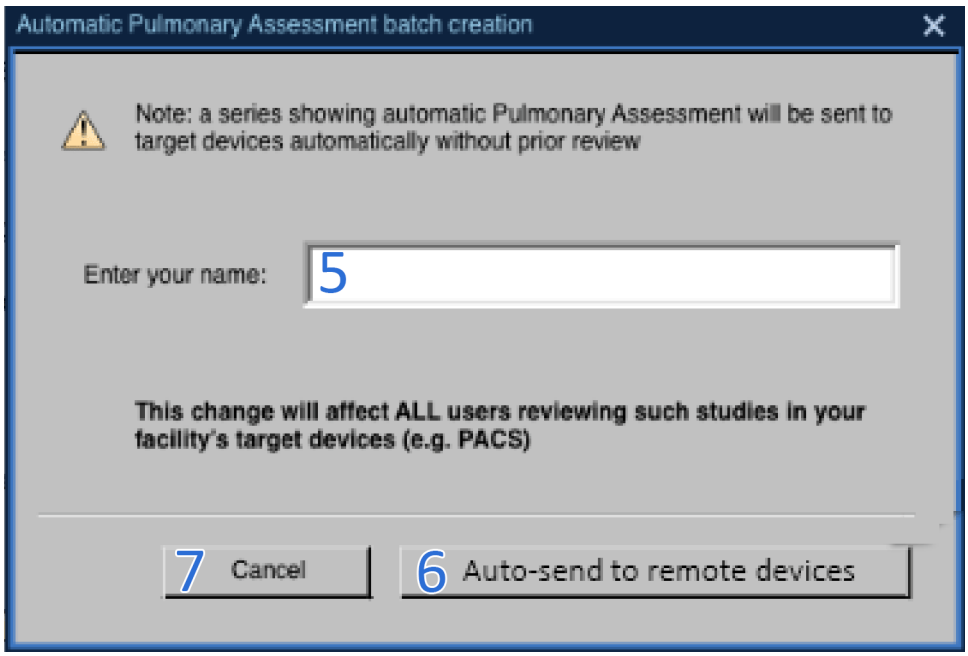
   A configuration dialog is displayed.



6. Configure the following settings:
   - Select whether to include volume batch creation (#1). Volume batch provides a 360 degree volume rendering rotation showing the lungs/lesions segmentation within the whole body volume rendering.
   - Select whether to create a results series (#2) (a non-image series, containing the lungs and lesion tissues). This series can further be used to edit the tissues in Advanced Visualization Workspace.
   - Configure the series description of each of the auto-created series (#3). The description should have the fixed prefix: **Automatic Results**.

– Select the target devices (#4) to automatically send these series to (e.g. PACS).
– Fill in the relevant DICOM attributes for identification of the suitable series - Protocol, Body Part, series description, procedure description (this is a standard setting for all preprocessing algorithms).

If a remote device was selected for saving, when **Save** is selected, another window appears asking the user to confirm sending results to PACS.



7. Type in your name (#5) and click **Auto-send to remote devices** (#6) to save the configuration.

   If the user clicks **Cancel** (#7), the remote device is removed and the window closes.

Segmentation

The application outputs a series of batch images to the PACS for users to inspect the quality of the automatic results: lung segmentation (Fig. 1) and segmentation of regions suggestive of pneumonia.

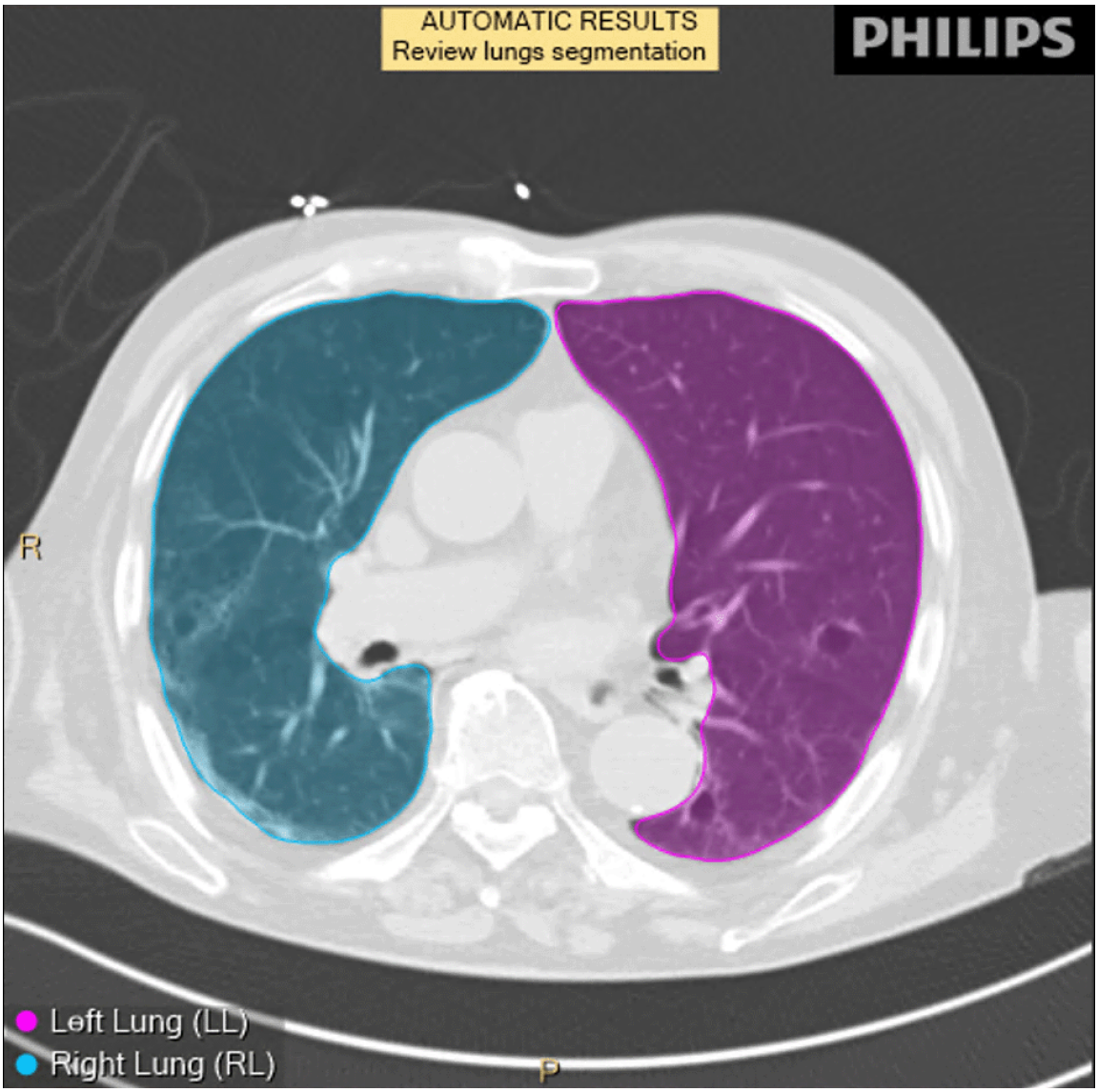


Fig. 18: Batch with segmented lungs identified as image overlays.

Regions suggestive of pneumonia are segmented and classified in two groups: ground-glass opacities (GGO) with a green contour and consolidation with a yellow contour (Fig. 2). The lungs are also marked on the images.

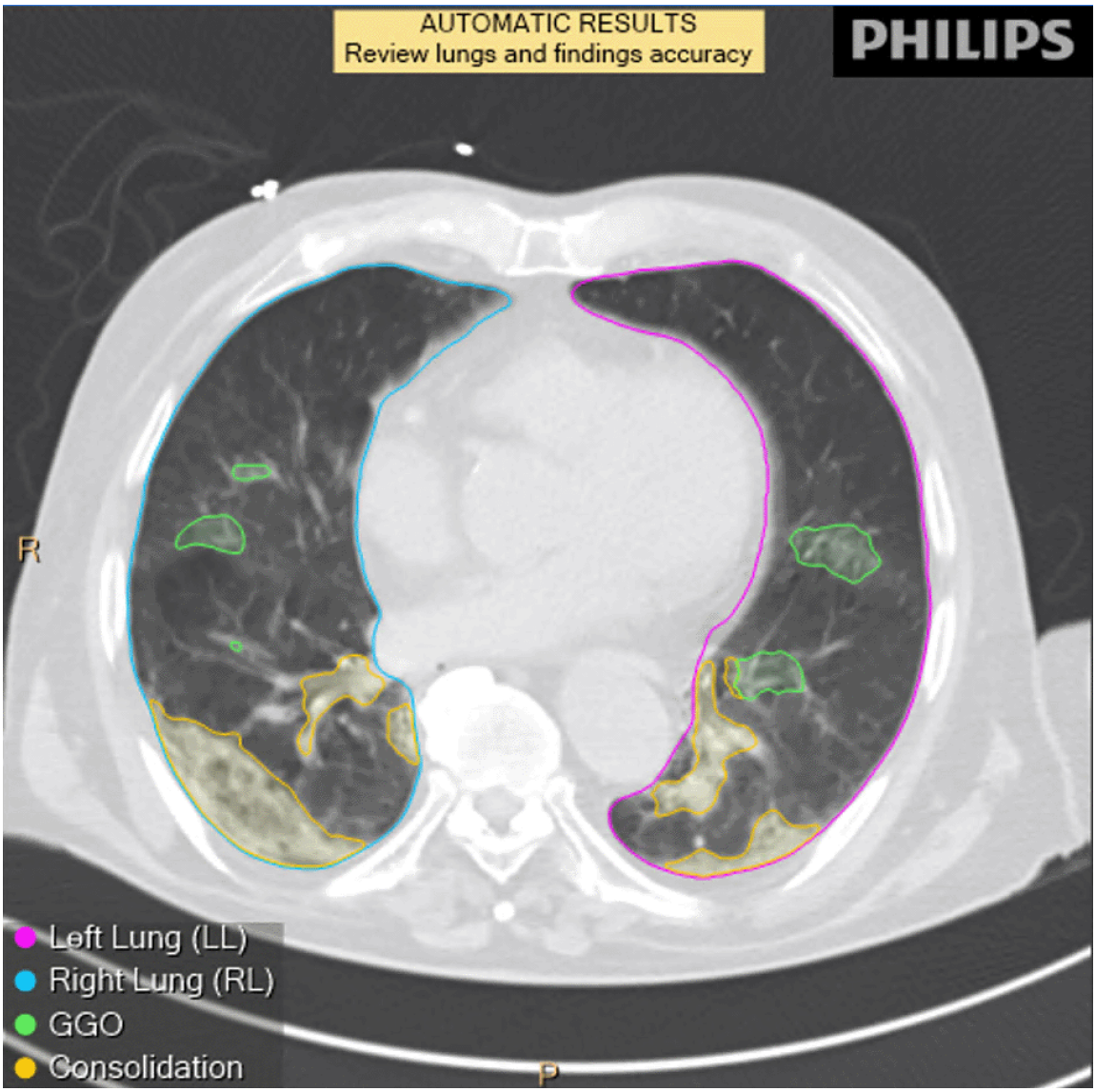


Fig. 19: Batch with areas suggestive of ground-glass opacity (GGO) and consolidation.

Segmentation results are saved in a proprietary format that can further processed in Advanced Visualization Workspace.

Viewing Segmentation Results in Advanced Visualization Workspace

The CT Pulmo Auto Results application does not provide a dedicated user interface or editing tools.

Resulting segmentation tissues are saved in an AVW proprietary format and can be launched with CT Viewer or 3D Modeling for visualization.

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Results

CAUTION

Before accepting the summary results and associated Measurements summary, verify the correctness of the lungs and lesion volume segmentation as well as the findings classification.

The CT Pulmo Auto Results application provides quantitative results (for lung volume measurements and lesion volumes per radiological classification).

Volume in ml of the following structures are provided each for: both lungs, left lung and right lung:

1. Total volume of the lungs (including lesions)
2. Lung volume after excluding lesion
3. Total lesions
4. GGO lesions
5. Consolidation lesions

The distribution between of lesion types (calculated in percentage) is per both lungs, left lung and right lung, as shown in the example below: (Fig. 3).

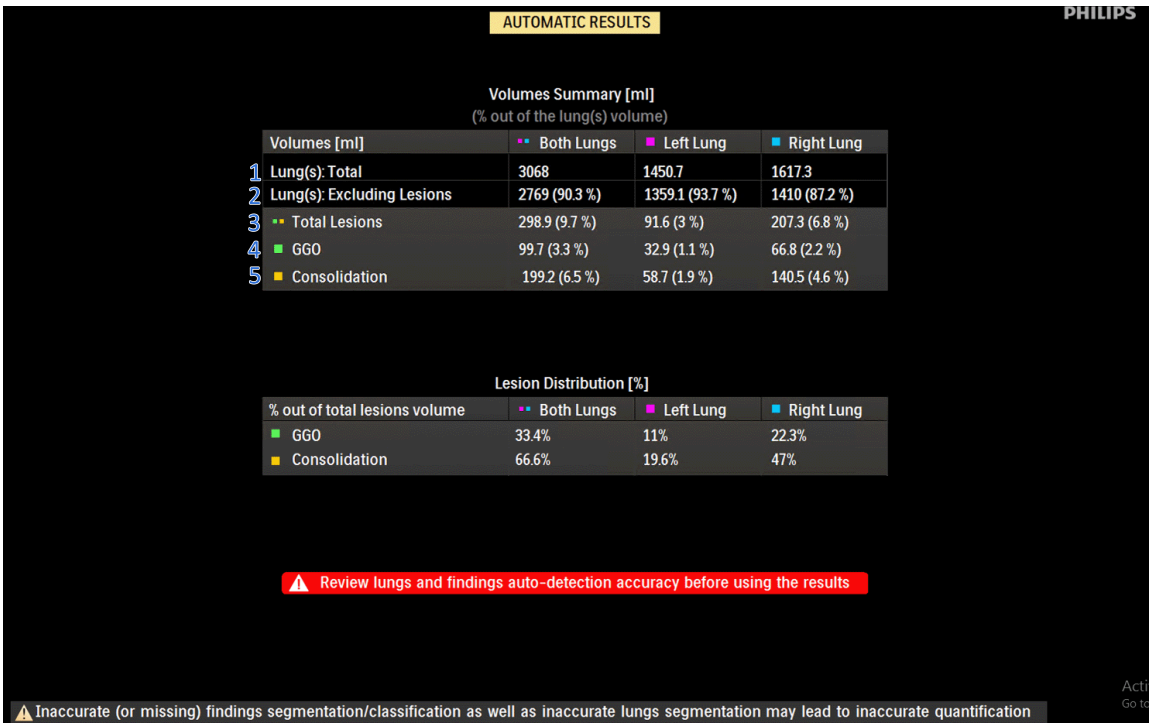

Fig. 20: Summary Results

The CT Pulmo Auto Results application also provides the results summary as a PDF.

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Measurement Accuracy

The estimated volume errors (tolerance) of lung volume, total lesion (GGO and consolidation), GGO and consolidation are 19.652 (9.060–31.989) ml, 22.281 (6.622–41.593) ml, 21.856 (12.575–118.276) ml, and 13.323 (4.341–28.693) ml, respectively.

The estimated volume ratio errors (tolerance) of the total lesion, GGO and consolidation to the lung(s) are 0.638 (0.163–1.601)%, 0.592 (0.320–2.961)%, and 0.441 (0.115–1.092)%, respectively.

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