



Document Info

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Manufacturer 

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1 Introduction

These Instructions for Use support the safe and efficient use of the medical device software **contextflow SEARCH Lung CT**. This document describes the software's most relevant safety and performance characteristics in order to support the proper use of the software in daily routine.

All efforts have been made to ensure the latest, most accurate information be included in these Instructions for Use. As part of the product's life cycle, these instructions will be updated without further notice by contextflow. Please be sure to always work with the latest version of the document to avoid any mishandling of the product. All document versions can be found on contextflow's homepage.

These instructions are available electronically either via the user interface of **contextflow SEARCH Lung CT** (see: [Instructions for Use]) or via our homepage (<https://contextflow.com/downloads/> - password: Margaretenstrasse70). Print versions are available upon request. Simply contact us by writing an email to office@contextflow.com.

contextflow ensures the proper functioning of **contextflow SEARCH Lung CT** if it is used within its intended purpose, installed according to the work instructions in **Chapter 3 "Product Installation"** and operated by trained intended users.

Sections of these Instructions for Use that indicate that the current action needs operator awareness or operator action in order to avoid undesirable consequences are marked with a caution symbol. All warnings and precautions are also listed individually in **Chapter 2 "Safety Information - Warnings and Precautions"**.

1.1 Symbols

These instructions as well as the product **contextflow SEARCH Lung CT** uses symbols according to the following standards:

- ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
- Regulation (EU) 2017/745 on medical devices (MDR)

Symbol	Description
	Caution
	Conformité Européenne This medical device complies with regulatory requirements of the regulation (EU) 2017/745 on medical devices (MDR)
	Consult Instructions for Use - electronic IFU available via contextflow.com/downloads
	Manufacturer
	Date of manufacture (YYYY-MM-DD)

1.2 Icons

The following icons are used in the Graphical User Interface (GUI) to allow a more intuitive use of the system:

Icons	Description
	<u>Create region of interest</u> - this icon is only available in the Search screen and enables a user to draw a ROI
	<u>View a slice of a region of interest</u> - this icon is only available in the Search screen and enables user to go back to a ROI
	<u>Set contrast for lung analysis</u> - this icon sets contrast settings so that the user has a better visualization of the lung
	<u>Reset to initial settings</u> - this icon resets the query image viewer to its initial settings

Icons	Description
	<u>View worklist</u> - by clicking this icon, the user will go back to the worklist
	<u>Insights</u> - only available in Search screen - this icon takes the user back to the Insights screen
	<u>Settings</u> - by clicking this icon, the user can go to settings and adjust language and time-to-logout
	<u>Support</u> - this icon takes the user to the help desk where questions to contextflow's support team can be raised
	<u>Note</u> - this symbol indicates additional information is available and is followed by a description
	<u>Error</u> - this symbol indicates an error of the software - for further questions please contact the help desk

1.3 Abbreviations

The following abbreviations are used in these Instructions for Use:

Abbreviation	Description
AI	Artificial Intelligence
API	Application Programming Interface
AUC	Area Under ROC Curve
CBIR	Content-Based Image Retrieval
CNN	Convolutional Neural Networks
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DFOV	Display Field of View
FPR	False Positive Rate
GUI	Graphical User Interface
HIS	Hospital Information System
PACS	Picture Archive and Communication Systems
RIS	Radiology Information Systems
ROC	Receiver Operating Characteristic
ROI	Region of Interest

TPR	True Positive Rate
UDI-DI	Unique Device Identification - Device Identification
UI	User Interface
VM	Virtual Machine

1.4 Incident Reporting

An “incident” means any malfunction or deterioration in the characteristics or performance of the medical device software including use errors due to ergonomic features as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effects.

It is our responsibility to assure safe and efficient products on the market. If the user feels that any malfunction of our device can be classified as an “incident” as described above, they should contact us immediately at support@contextflow.com.

2 Safety Information - Warnings and Precautions



Warning: Results provided by the system could contribute to image interpretation errors, which in turn, could contribute to an incorrect diagnosis of a patient's condition that leads to wrong treatment and ultimately causes a patient harm



Warning: The system can generate incorrect outputs (within the system's performance specifications) that are potentially misleading to users such as:

- inaccurate detection of lung anomalies
- incorrect recommendations of image patterns



Warning: Lists of possible diagnoses associated with specific image patterns provided by the system are not ranked by relevance



Warning: The system does not provide image analysis results for any anatomies other than lung tissue

3 Product Description

contextflow SEARCH Lung CT is an AI-based, Content-Based Image Retrieval (CBIR) web application for 3D medical imaging data. It provides qualitative and quantitative analysis results and corresponding reference information relevant for the identification and interpretation of lung-specific image patterns in CT (Computed Tomography) scans.

To that end, the system provides the following functionalities:

- **quantitative image analysis:**
automated detection, quantification and visualization of lung anomalies, specific image patterns and lung nodules
- **qualitative analysis:**
based on the selected image regions, both visual image retrieval from a knowledge base of expert-labeled retrospective cases and pattern classification
- **reference information for image patterns:**
links to literature, articles or guidelines, tips and pitfalls, and differential diagnosis candidates

3.1 Intended Use

3.1.1 Intended Purpose

contextflow SEARCH Lung CT provides radiologists with complementary information for the identification and interpretation of lung-specific image patterns in Computed Tomography (CT) scans.

3.1.2 Characterization of Users

The system is intended to be used by qualified radiologists whose daily work routine includes image reading and reporting tasks. Characteristics are summarized as follows:

User Group	Radiologists
Education and Training	Graduated from medical university and finished specialist training or are within specialty training for radiology
Language	At least intermediate English skills
Experiences with this or comparable products	Basic experience in working with PACS (Picture Archive and Communication Systems), HIS (Hospital Information Systems), RIS (Radiology Information Systems) and medical image viewing systems
Typical tasks in the context of this product	Interpretation of CT scans: identification and assessment of findings

3.1.3 Characterization of Context of Use

Results provided by the system are typically used by radiologists in addition to the information available from standard clinical practice for image interpretation and creation of radiology reports.

Accordingly there is no direct interaction between the system, its outputs and the patient's body nor does the system control any life-sustaining devices.

Radiologists consider image findings (assessed and evaluated based on the radiologist's personal and professional judgement), the patient's history, symptoms and other clinical tests during image interpretation. Results provided by **contextflow SEARCH Lung CT** are intended to contribute to that information.

Radiology reports are then taken into account in the context of a clinical investigation, in which a referring physician or an interdisciplinary board of healthcare professionals is diagnosing a patient's condition based on various types of information.

According to the patient's diagnosis, a treatment plan is created, and the patient is treated correspondingly.

3.1.3 Characterization of Patients

The system is intended to be used for the reporting of CT scans of clinically stable, symptomatic patients with the following characteristics:

Indication	Patients that require identification and interpretation of lung-specific imaging patterns in CT scans, DICOM (Digital Imaging and Communications in Medicine) images
Contraindication	Life-threatening state of health that requires time-critical (immediate) medical intervention
Body parts to be examined	Lungs
Demographic and physiological properties	No restrictions to demographic characteristics such as age or gender or physical properties such as weight or height; however, it is the responsibility of the healthcare professional to evaluate the relevance of results in the context of such patient characteristics

3.1.4 Indications

The system is intended to be used for qualitative and quantitative analysis of lung-specific image patterns in chest CT scans of clinically stable, symptomatic patients, with an indication that requires the identification and interpretation of those image patterns.

Quantitative information is automatically provided in the **Insights screen** for the following lung-specific imaging patterns:

- Effusion
- Emphysema
- Ground-glass opacity
- Honeycombing
- Pneumothorax
- Nodule
- Reticular pattern
- Other: lung anomalies not explicitly supported for quantitative analysis

Qualitative results are provided in the **Search screen** for the following lung-specific imaging patterns:

- Airway wall thickening
- Atelectasis
- Bronchiectasis
- Bulla
- Consolidation
- Cyst
- Effusion
- Emphysema
- Ground-glass opacity
- Honeycombing
- Mass
- Mosaic attenuation pattern
- Nodular pattern
- Nodule
- Pneumothorax
- Pulmonary cavity
- Reticular pattern
- Tree-in-bud
- Non-specific: includes patterns with no evidence of pathological changes and currently not explicitly incorporated

3.1.5 Contraindications and Exclusions

- The system is not intended to be used for images that are subject to movement artifacts.
- The system does not provide a ranking of diagnosis candidates relevant for a patient's condition.
- The system does not provide comprehensive lists of diagnoses that are relevant when specific image patterns are seen.

3.1.6 Limitations

The system provides complementary information. Results provided are intended to be taken into account in addition to the radiologist's professional judgment of the patient's imaging data, clinical history, symptoms and other clinical tests.

4 Product Installation and Client Machine Requirements

4.1 Server Installation - IT Requirements

The following requirements must be met to install contextflow's system on a local server:

- Server Specifications
 - OS: Ubuntu 20.04 or NixOS
 - CPU 16 cores, RAM 64GB, Storage >= 1TB
 - Usually provided as a virtual machine (VM)
 - Optional GPU support: NVIDIA cards based on the Pascal, Volta, Turing or Ampere architecture with at least 12GB VRAM
- Internet Access/Firewall
 - contextflow requires remote SSH access to VM (e.g. via VPN) with root privileges
 - HTTPS access is required from the VM to the following hosts
 - *.contextflow.com
 - *.amazonaws.com
 - *.nixos.org
- Local Network Configuration
 - VM connected to PACS with at least 25MB/s
 - VM reachable from radiology workstations (HTTP/HTTPS)
- If SSL (HTTPS) encryption is required:
 - A domain name assigned to the VM that is resolvable from the workstations
 - Either a valid SSL certificate for that domain name, or the signing of a CSR issued by contextflow
- Default DICOM receiver configuration (can be customized):

- Host: hostname/IP of our VM
- Port: 1104
- AET: CTXFLW

4.2 Client (Radiology Workstation) - IT Requirements

contextflow SEARCH Lung CT's user interface is designed to be accessed from machines that meet the following requirements:

- CPU > 2GHz
- RAM > 8GB
- Minimum Screen Resolution $\geq 1920 \times 1080$ px
- Network Bandwidth > 25 MBit/sec
- Supported browsers and versions:
 - Google Chrome: Version ≥ 74
 - Mozilla Firefox: Version ≥ 67
 - MS Edge ≥ 44 (Internet Explorer 11 is **NOT** supported)

4.3 Acquisition Parameters

contextflow SEARCH Lung CT takes a lung CT scan in DICOM format of a patient in a supine position as input. The scans are automatically checked as to whether or not they match the required acquisition parameters so that the system can reliably produce its intended outputs. The system does not ingest scans with acquisition parameters that do not meet the requirements as outlined in Table 1.

Table 1: Acquisition Parameters

DICOM Tag	Name	Required Value
N.A.	Slice Dimensions	512x512
(0028,0030)	Pixel Spacing Resolution	$0.5\text{mm} \leq x \leq 1\text{mm}$
(0018,0050)	Slice Thickness	$\leq 5.0\text{ mm}$

4.3.1 Recommended Acquisition Protocol

For **contextflow SEARCH Lung CT**, we recommend a 3D volumetric acquisition with slice spacing less than 2 mm and slice thickness less than 3 mm for the input inspiration scan. We also recommend that the patient lies in a supine position. A contrast enhanced acquisition does not affect the search results.

Example protocols are listed in the table below. The protocols accepted by **contextflow SEARCH Lung CT** are not limited to the protocols in the following Table 2, but the acquisition parameters should be similar.

contextflow SEARCH Lung CT has not been designed for iterative reconstruction methods. Failure to observe the recommended scan protocol could limit the software's ability to properly detect lung patterns.

Table 2: Example of Acquisition Protocol

Scan Type	Helical
kVp	120–130
mA	120–200
Convolution Kernel	B50f, B60f, B70f, Standard, YB
Thickness (mm)	0.625–1.5
Interval (mm)	0.5–1.3
DFOV (cm)	Lung

5 Product Tour

5.1 Login

In order to use **contextflow SEARCH Lung CT**, a user will need to log into the system with the username and password created during installation of the system. A screenshot of the login dialog is shown in Figure 1:

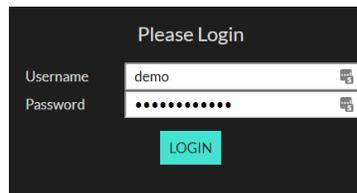


Figure 1: Login Dialog

5.2 Insights Screen

After opening a case, the **Insights screen** is shown. This screen provides an insight into the patient to be analysed and provides the user with an overview of patterns detected within the lungs without any user interaction required.

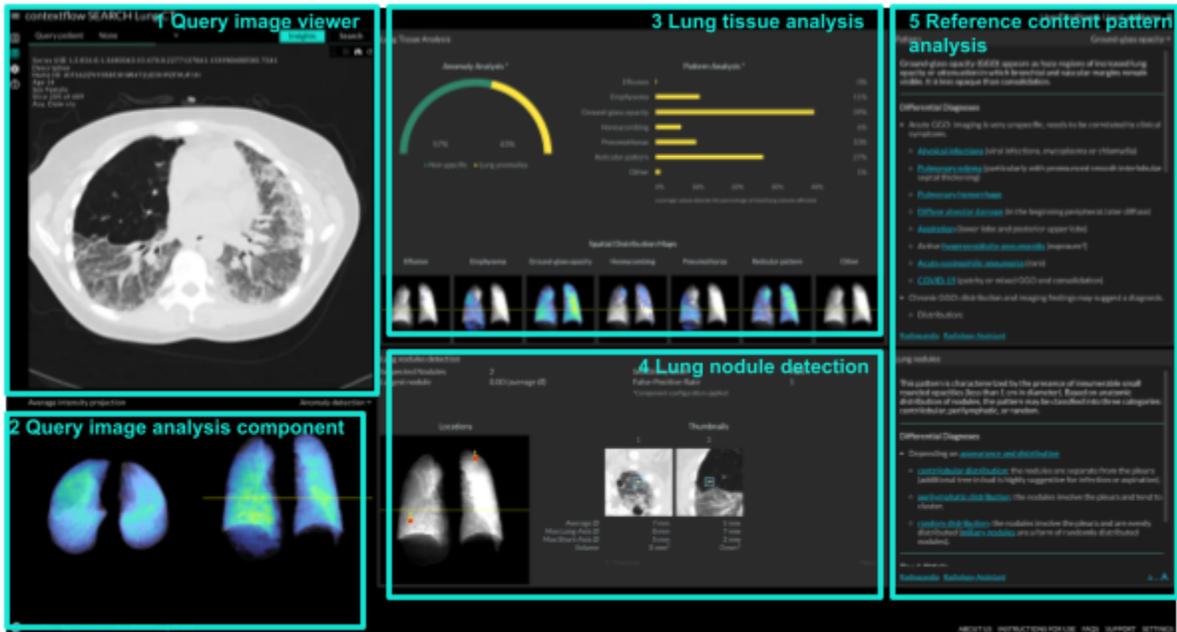


Figure 24: Insights screen

The following patterns are supported by this feature:

- Emphysema
- Effusion
- Ground-glass opacity
- Honeycombing
- Reticular pattern
- Pneumothorax
- Nodules
- Others (container of all patterns not supported by **Insights screen**, but rather supported by the **Search screen**)
- Non-specific (healthy / non-specific lung tissue)

This screen consists of the following sections:

1. **Query image viewer**
2. **Query image analysis component**
3. **Lung tissue analysis**
4. **Lung nodule detection**
5. **Reference content**

5.2.1 Query Image Viewer

The **Query Image Viewer** shows the image data of the query case and provides means for navigating through slices and basic image adjustment functionalities. It shows segmentation overlays as well as nodule overlays, if selected (Figure 3).

Icon	Description
	Create a region of interest (only in Search screen)
	View slice of selected ROI (only in Search screen)
	Set contrast for soft tissue
	Reset window to default

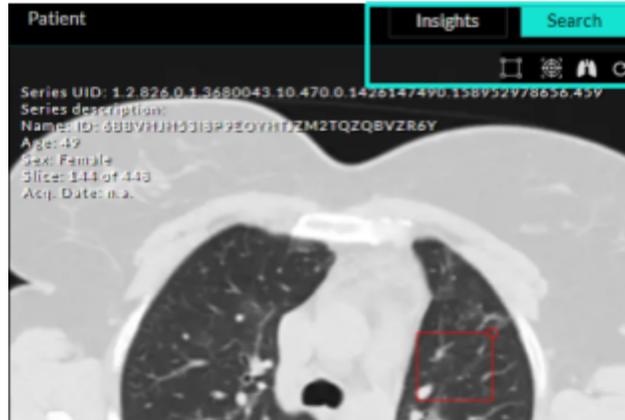


Figure 3: Query Image Viewer with Icons

The following section describes the possible adaptations of the query image case. Please note that actions described for zooming, moving the CT image, contrast adjustments and brightness adjustments are configurable for each customer site. The following functionalities are described for default settings.

Scrolling through CT images

(In both scrolling options, upwards means the user scrolls towards the head, and downwards means the user scrolls towards the feet.)

Option 1:

1. Move the mouse over the CT image.
2. Scroll up or down using the mouse wheel.

Option 2:

1. Move the mouse over the CT image.
2. Hold the left mouse button.
3. Move the mouse up or down.

Zooming (default setting)

Zooming in

1. Move the mouse over the CT.
2. Hold the control key.
3. Hold the left mouse button, and move the mouse upwards.

Zooming out

1. Move the mouse over the CT.
2. Hold the control key.
3. Hold the left mouse button, and move the mouse downwards.

Move the CT images (default setting)

1. Move the mouse over the CT.
2. Hold the [**control + shift**] keys.
3. Hold the left mouse button, and move the mouse in the direction of the spot where the picture is desired to be positioned.

Display segmentation overlays

Press [**space**] button to switch segmentation overlays on and off.

Contrast adjustments (default setting)

1. Move the mouse over the CT.
2. Hold the right mouse button.
3. Move the mouse horizontally.

Brightness adjustments (default setting)

1. Move the mouse over the CT.
2. Hold the right mouse button.
3. Move the mouse vertically.

5.2.2 Query Image Analysis Component

The **Query Image Analysis Component** shows an average intensity projection in axial and frontal plane view computed from the CT images (Figure 4).

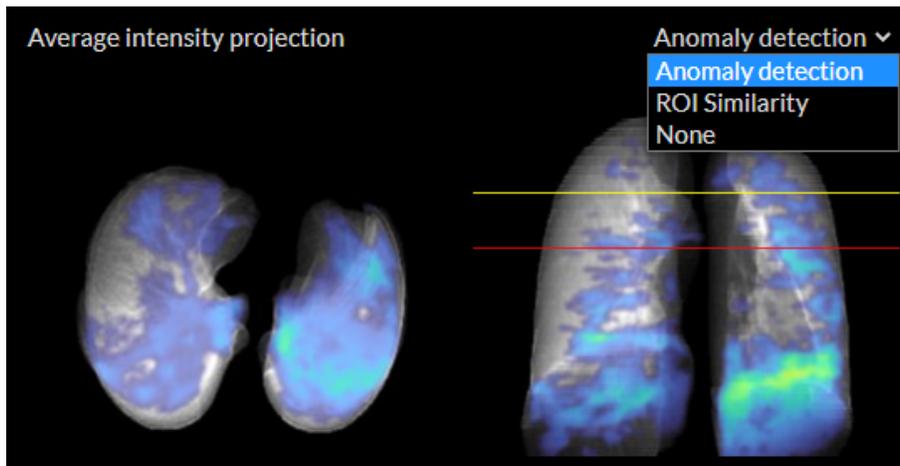


Figure 4: Query Image Analysis Component showing anomaly intensity projections

[Anomaly Detection]

Visualization of lung anomaly classification results; Indicates the likelihood of detected lung anomalies in corresponding positions of the projections. A high score means that the system has detected many lung anomalies along the indicated position of the projection.

[ROI Similarity]

(only in the **Search screen**)

Visualization of regions with similar visual appearances to the selected ROI (only available if an ROI has been selected). A high similarity score means that the system has detected visually similar regions along the indicated position of the projection.

In this view the user can either select [**Anomaly Detection**] or [**ROI Similarity**] when using the **Search screen**. Per default the user will see [**Anomaly detection**]. The heatmaps visualize anomaly or similarity scores. The following color scale is used for the intensity projections (Figure 5). These heatmaps are (semi-)transparent, allowing the user to see both the scores and the image at the same time.



Figure 5: Color scale of heatmaps

5.2.3 Lung Tissue Analysis

This component is part of the **Insights screen**. In this section the presence of the different patterns detectable by the **Insights screen** are quantified (see Figure 6).

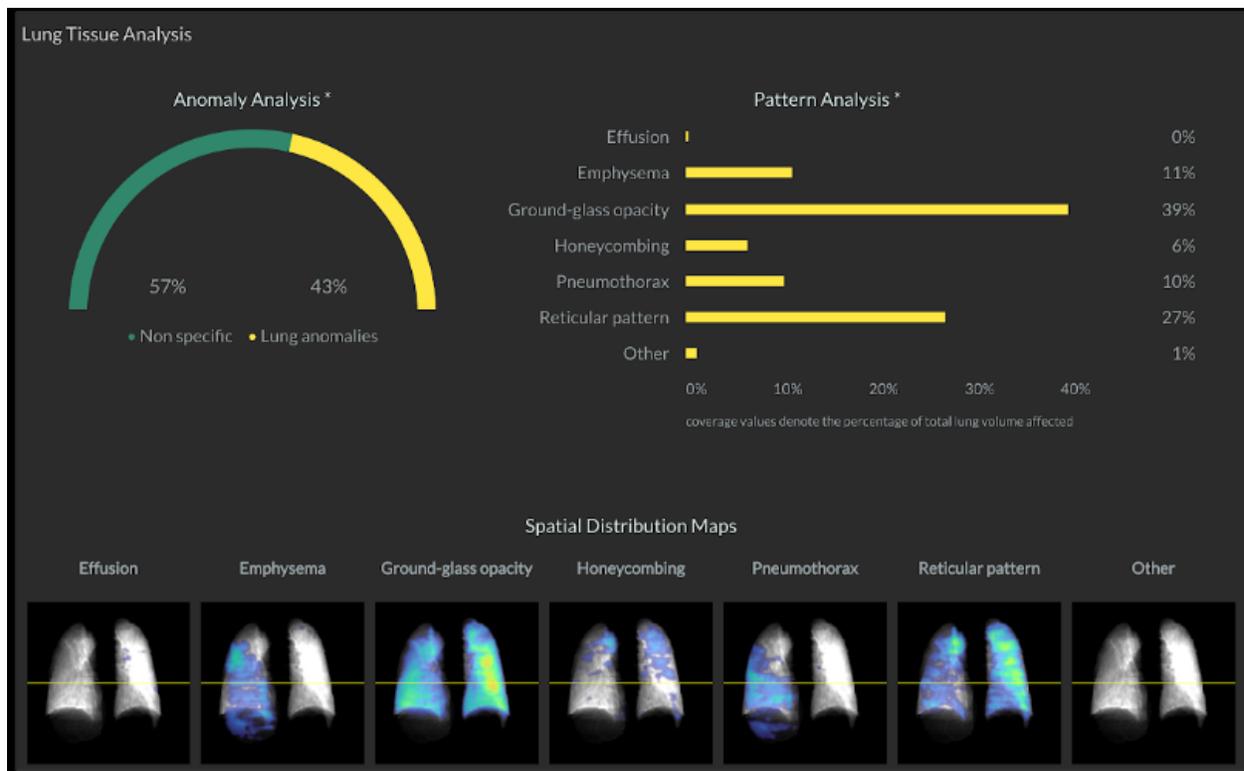


Figure 6: Lung Tissue Analysis

In an arrow plot, the distribution of lung anomalies and non-specific lung tissue is depicted. Additionally for each pattern a representative barplot with the percentage of the presence of that pattern distributed over the whole lung volume is shown.

The spatial distribution maps show the location of the specific patterns in a 3D projection of the lung.

By hovering over a pattern, the query image viewer will preview the segmentation of the specific pattern. On clicking on a specific pattern title, the segmentation pattern is selected and stays visible while scrolling through the slices in the case image viewer.

5.2.4 Lung Nodule Detection

The **Lung Nodule Detection** component provides an overview of detected nodules in the case (see Figure 7). It is visible in the lower part of the **Insights screen** and provides quantitative information next to thumbnails of detected nodules. The amount of suspected lung nodules is listed as well as the average diameter of the largest nodule. Next to the quantitative information, the system shows set sensitivity level and false positive rate for lung nodules. The following characteristics of each nodule are measured:

- Average diameter of the nodule
- Diameter along the maximal long axis of the nodule
- Diameter along the maximal short axis of the nodule
- Volume

Nodules are sorted by size with the largest listed first. The user can select or deselect a nodule either in the projection, the thumbnails or in the query image viewer. Also the user can press “previous” or “next” to slide through pages of thumbnails.

There are three sensitivity levels that can be adjusted by the user which are 90%, 92% and 94%. The impact on the system’s performance is described in **chapter 6.4**.

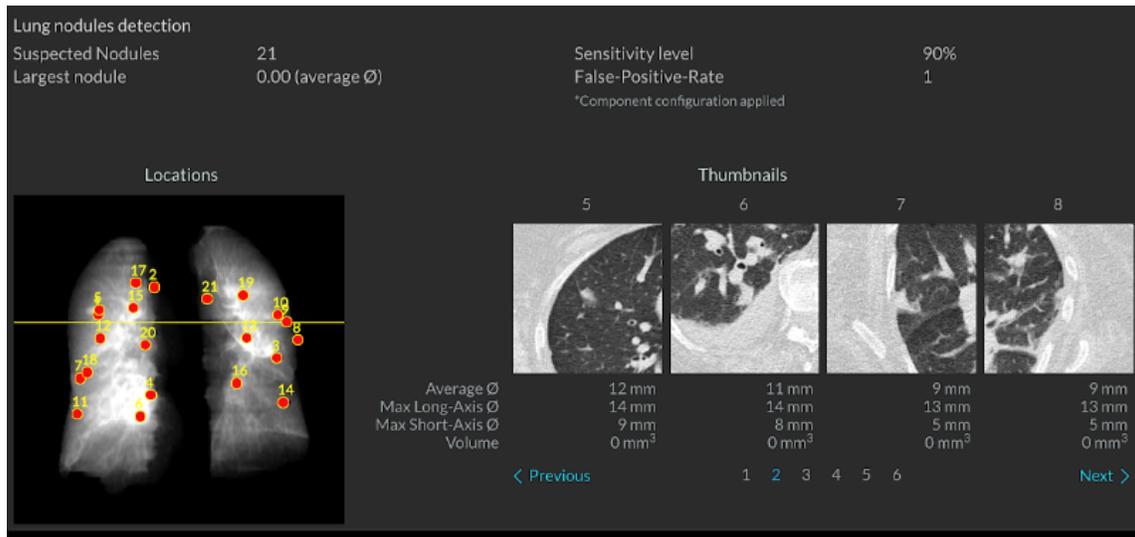


Figure 7: Lung Nodule Detection

5.2.5 Reference Content

Reference content (Figure 8) provides compact pattern-specific information for the user that may be used to support correct interpretation of image patterns. For each pattern the following information is provided:

- Short description
- List of differential diagnosis candidates with links to the corresponding [Radiopaedia.org](https://radiopaedia.org) articles.
- Tips and pitfalls
- Links to [Radiopaedia.org](https://radiopaedia.org) and [RadiologyAssistant.nl](https://radiologyassistant.nl)



Warning!

- *The content of differential diagnosis provided lists the most common diagnosis of a pattern. The completeness of these diagnoses is not assured.*
- *The list of differential diagnoses provided by the system is not ranked by relevance.*

Clicking the tabs allows the user to switch between the content relevant to each pattern detected.

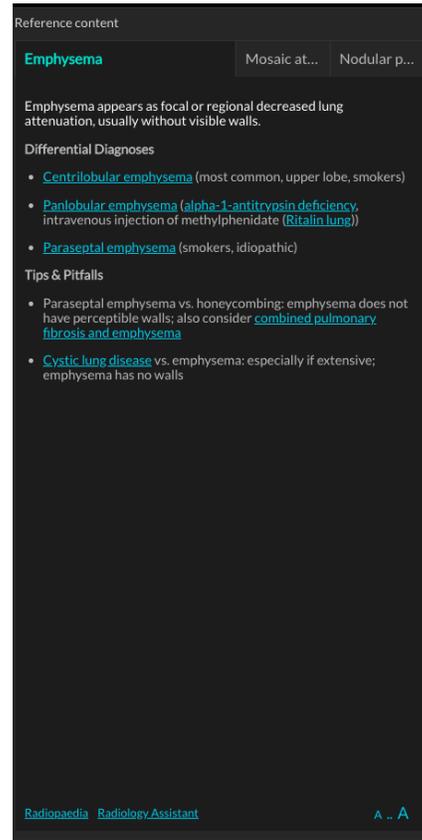


Figure 8: Reference Content

The reference content in the **Insights screen** has an additional information panel for lung nodules and provides information for the interpretation of these nodules.

5.3 Search Screen

If the user wants to take a closer look at a case and have more information about different patterns in specific regions, they can switch to the **Search screen**. Figure 9 shows the basic layout of the **Search screen** which provides image analysis results of individual image regions that can be manually selected to foster detailed assessment of specific ROIs in the query image (see Figure 9). It consists of five key elements:

1. **Query Image Viewer**
2. **Query Image Analysis Component**
3. **Search Results**
4. **Result Image Analysis Component**
5. **Reference Content**

These are described in detail in the chapters below.

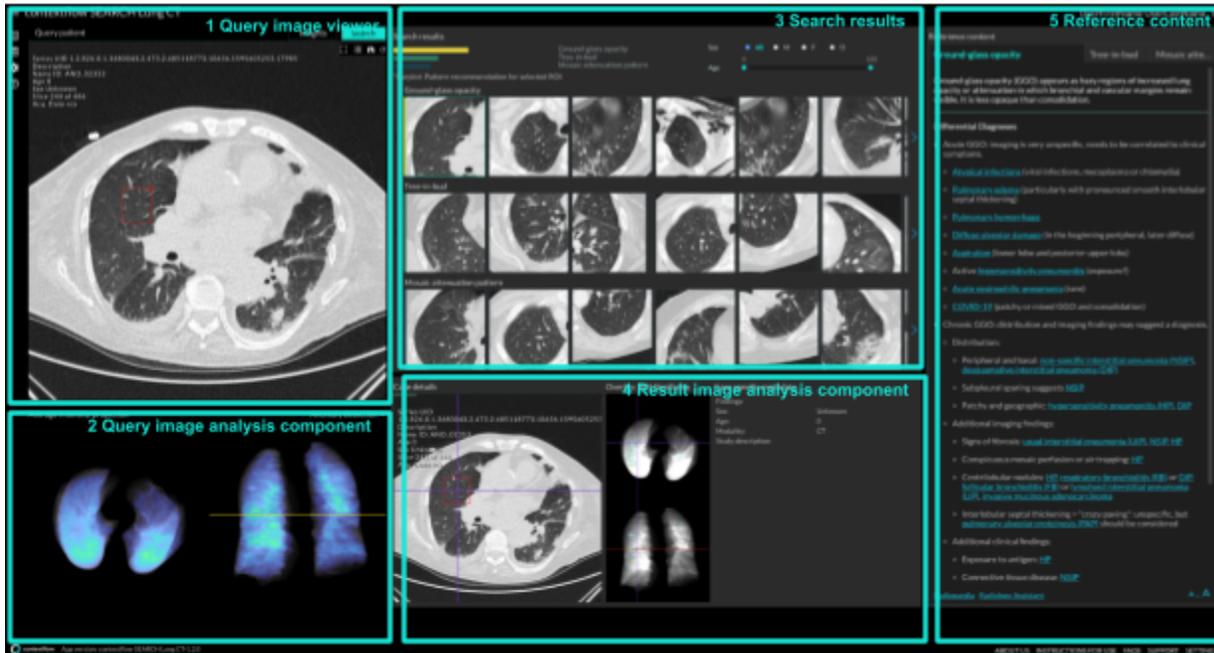


Figure 9: contextflow SEARCH Lung CT Search screen

5.3.1 Query Image Viewer

Using the **Search screen**, the query image viewer can be used in order to trigger a search. The area of interest must be marked with a ROI following the steps below:

1. Move the mouse to the spot in the CT image for which search is desired.
2. Hold the **[ALT]** key, or click on the draw ROI icon.
3. Hold the left mouse button, and start drawing a rectangle by moving the mouse.
4. Release mouse button to trigger search.

Whenever a new ROI is drawn, search results are retrieved and updated accordingly. An ROI should be centered around the region desired to be analyzed.

ROIs can be deleted by either:

- clicking the circle in the top right corner of the ROI or
- using the **[del]** key

5.3.2 Query Image Analysis Component

Please refer to chapter 4.3.2. Additionally to the anomaly heatmap available in the **Insights screen**, the **Search screen** offers a ROI similarity map.

5.3.3 Search Results

Search Results is a feature triggered by the search in the **Search screen** and derived based on the visual characteristics of a selected ROI.

First, the system provides a pattern recommendation for the selected ROI. The system then shows the top three ranked patterns obtained from a classification algorithm and indicates corresponding classification probabilities. The length of the bar represents the probability of a given pattern (Figure 10).

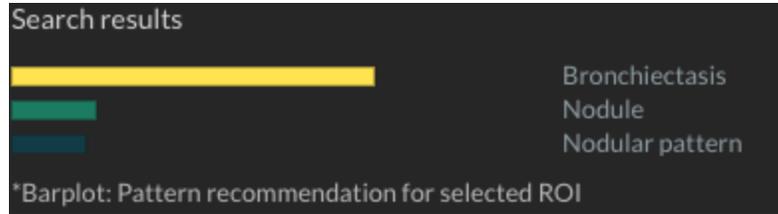


Figure 10: Pattern Recommendation bar plot

Secondly, the system retrieves result cases with similar visual appearances for each recommended pattern from a Knowledge Base of retrospective, expert-labeled cases. The system shows thumbnails of similar regions of retrieved cases grouped by patterns (Figure 11). The resultant reference cases are sorted according to their similarity to the selected ROI in the current case: the first reference case listed on the left side shows the highest similarity to the selected region. The similarity to the selected ROI decreases as the user moves to the right.

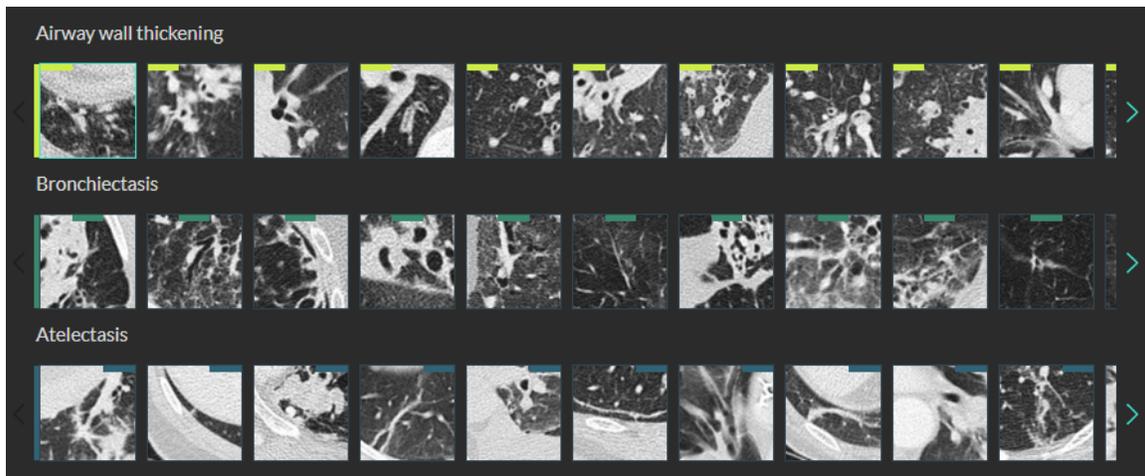


Figure 11: Search Results (cases with visual characteristics similar to those of the selected ROI)

Retrieved cases can be filtered by age and sex as shown in Figure 12.

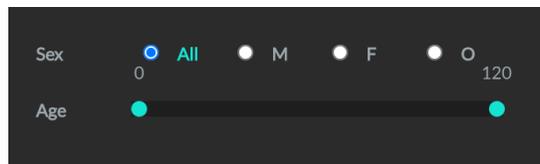


Figure 12: Result Filters

5.3.4 Result Image Analysis Component

The **Result Image Analysis Component** enables the user to navigate through the image data of a result case. It shows corresponding meta-information and visualizes regions with visual characteristics similar to the selected ROI in average intensity projections (Figure 13).



Figure 13: Result Image Analysis Component

5.3.5 Reference Content

Please refer to chapter 4.3.5.

5.4 Other Interface Functionalities

Using the navigation bar on the left side of the user interface, different actions can be performed:

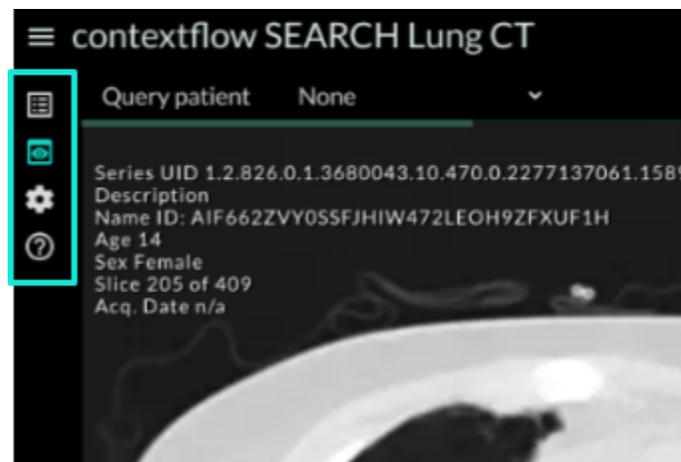


Figure 14: Navigation Bar on upper left side

Icon	Description
	<u>View worklist</u> - by clicking this icon, the user will go back to the worklist to select another case
	<u>Insights</u> - only available in the Search screen - this icon takes the user back to the Insights screen
	<u>Settings</u> - by clicking this icon, the user can go to settings and adjust language and time-to-logout
	<u>Support</u> - this icon takes the user to the help desk where questions to contextflow's support team can be raised

5.4.1 Timeout

After a certain period of inactivity, the user will be logged out (Figure 15).

The timeout can be set to different periods (min) in [**Settings**] or by clicking the icon in the upper left corner. The default value is 5 minutes.

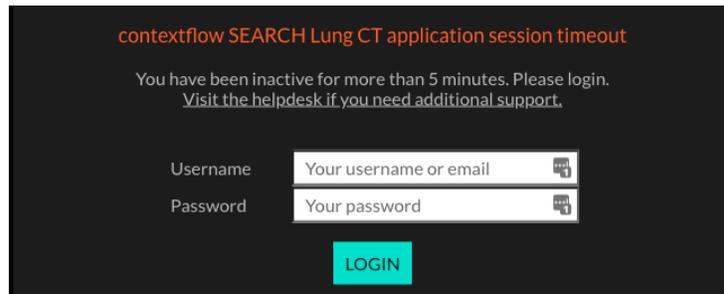


Figure 15: Timeout

5.4.2 Footer

In the lower right corner, the user will find links to subpages (Figure 16). Otherwise the user can use the following icon in the upper left corner of the **Search screen**.

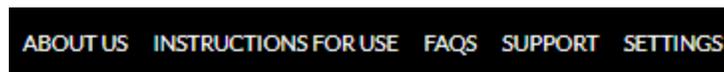


Figure 16: Footer

Section	Description
About Us	Curious about the who, why and how behind contextflow ? Here the user will find a link to our homepage with all the details as well as relevant information about contextflow SEARCH Lung CT .

Instructions for Use Here's where to click for a digital version of these Instructions for Use and the most important warnings and precautions for safe use of this medical device software.

FAQs Here we answer commonly asked questions. If additional information is still required, click on **Support**.

Support This link redirects the user to our Customer Support interface where they can ask questions, report bugs or make suggestions.

Settings Some settings are configurable within the **contextflow SEARCH** system:

1. Language
2. Color scheme: dark or monochrome
3. Time to log-out in minutes

5.5 Worklist

One configuration option of the system is the **Worklist** provided by contextflow (Figure 17), which lists DICOM series that have been sent to the system. This screen consists of:

1. **Series Table**
2. **Preview Panel**

By selecting a case in the series table, a preview of the case is shown in the **Preview Panel**. By clicking **[view]**, the case will be opened, and the **Insights screen** for that case will be shown.

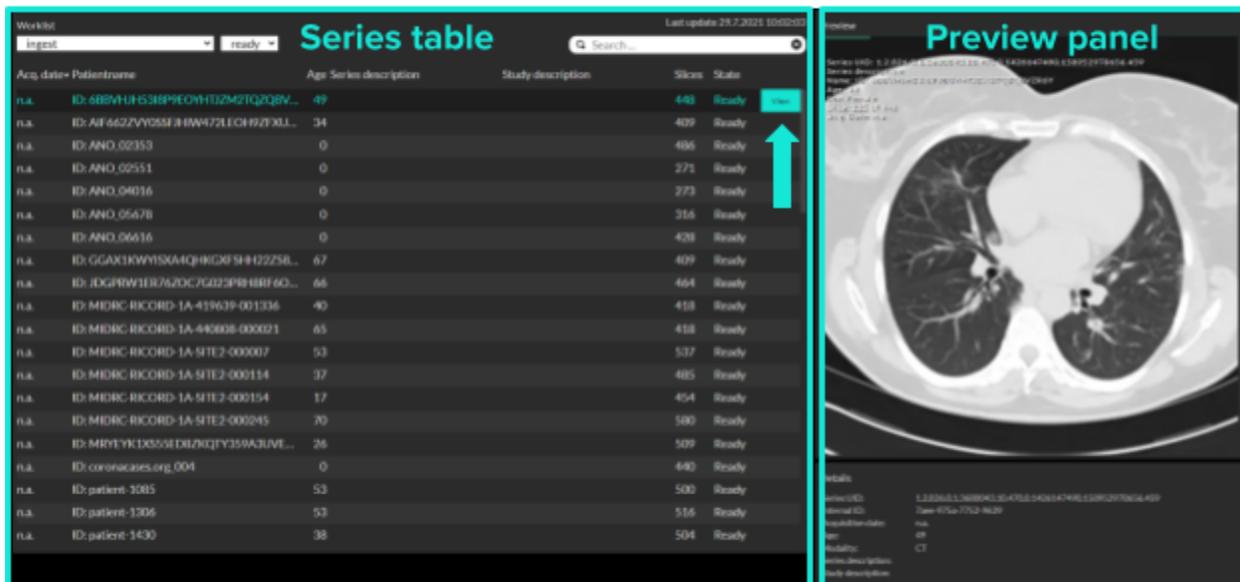
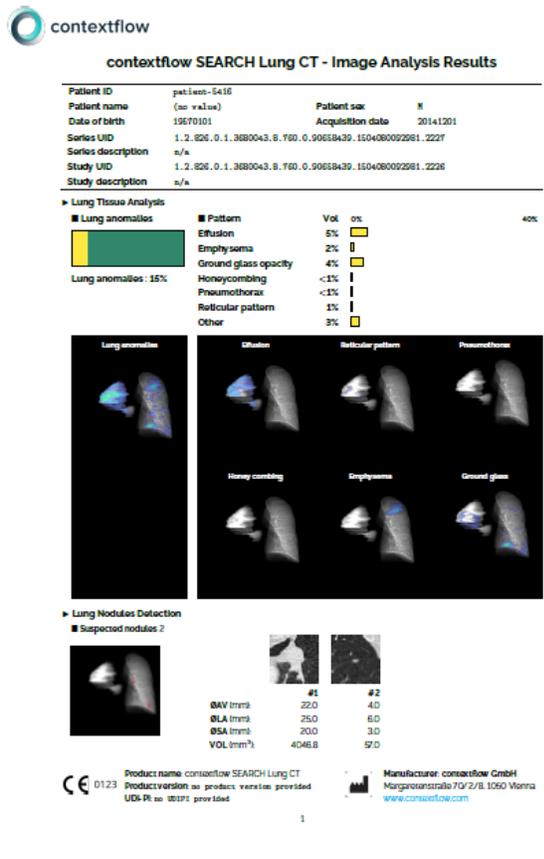


Figure 17: Worklist

5.6 PDF Report

The **Insights screen** offers the possibility to export its results either as DICOM SR objects back to the PACS or as a PDF download to be added to the radiology report. The report contains all necessary patient information as well as the results of the tissue analysis and nodule detection (see Figure 18).



contextflow SEARCH Lung CT - Image Analysis Results

Patient ID patient-5418
Patient name (no value) **Patient sex** M
Date of birth 19670101 **Acquisition date** 20141201
Series UID 1.2.826.0.1.3680043.8.760.0.90658439.1504080022981.2227
Series description n/a
Study UID 1.2.826.0.1.3680043.8.760.0.90658439.1504080022981.2226
Study description n/a

Lung Tissue Analysis

Pattern	Vol	cts
Effusion	5%	40%
Emphysema	2%	
Ground glass opacity	4%	
Honeycombing	<1%	
Pneumothorax	<1%	
Reticular pattern	3%	
Other	3%	

Lung anomalies: 15%

Lung Nodules Detection

Suspected nodules: 2

	#1	#2
ØAV (mm)	22.0	4.0
ØLA (mm)	25.0	6.0
ØSA (mm)	20.0	3.0
VOL (mm ³)	4046.8	57.0

Product name: contextflow SEARCH Lung CT
 Product version: no product version provided
 UDS-PI: no ICDIP: provided

Manufacturer: contextflow GmbH
 Margaretenstraße 70/2/8, 1050 Vienna
www.contextflow.com

Intended purpose

SEARCH Lung CT provides radiologists with complementary information for the identification and interpretation of lung-specific image patterns in Computed Tomography (CT) scans.

Lung Tissue Analysis

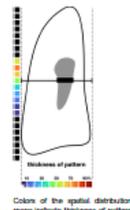
The lung tissue analysis component computes a voxel-wise labeling of lung tissue for the following image patterns: emphysema, effusion, ground-glass opacities, honeycombing, reticular pattern, pneumothorax, others (other lung anomalies) and non-specific lung tissue.

Lung coverage values

All coverage values provided denote total lung volume affected as a fraction of the overall lung volume. Bar plots visualize values up to 40% and indicate if values are above 40%.

Spatial Distribution Maps

Spatial distribution maps visualize the amount of lung tissue covered by a pattern in coronal plane projections. Colors encode coverage values along specific locations on a 7-step color map. (With finer granularity at the lower end of the thickness spectrum to differentiate thinner patterns well 100% correspond to the thickest part of the lung in the respective projection plane. Values below 5% are not visualized. See schematic drawing to the right.)



Lung nodule detection

The lung nodule detection component automatically detects, segments and provides the following measures for lung nodules:

Ø average	(ØAV)	Ø average of long and short axis diameter in mm.
Ø long-axis	(ØLA)	Ø max. measured in axial, sagittal or coronal plane in mm
Ø short-axis	(ØSA)	Ø max. perpendicular to the long axis measured in the same plane in mm
volume	(VOL)	volume in mm ³

All measurements and their derivatives are rounded to the nearest millimeter.

Configuration

Nodule detection results have been obtained by appliance of the following sensitivity configuration*:

Sensitivity: 00
 Corresponding false positive rate (FPR)**: 1.0

* Measures derived from internal performance evaluation
 ** FPR denotes expected false-positive detected nodules per case

Product name: contextflow SEARCH Lung CT
 Product version: no product version provided
 UDS-PI: no ICDIP: provided

Manufacturer: contextflow GmbH
 Margaretenstraße 70/2/8, 1050 Vienna
www.contextflow.com

Figure 18: PDF Report

6 Clinical Benefits and Performance

contextflow SEARCH Lung CT empowers its users to make more informed decisions during image interpretation, which can contribute to increased reporting accuracy.

These clinical benefits of improved quality of diagnosis and time savings in reading CT images can be achieved through the availability of the outlined components with the following performance characteristics:

6.1 Pattern Classification

Summary	The pattern classification component is trained to predict a classification of the most dominant lung-specific image pattern of a specified ROI	
Mechanism	Input Data Source	Lung CT DICOM images
	Input Data Type	Image data from a selected ROI
	Outcome	Pattern recommendations for a selected ROI
	Output	0% - 100% probabilities for each pattern
Model Application and Usage	Benefits	Automated identification of image patterns occurring within a selected ROI
	UI Component	Pattern recommendation bar plot shown on the Search screen
	Appropriate Interpretation	The component is intended to be used to create a list of pattern candidates that are likely to be relevant for the selected ROI. Results must be verified by the end user.
Validation and Performance	Test data for the pattern classification consist of manually annotated ROIs containing the patterns of interest. System performance is evaluated by its ability to return the correct most dominant pattern from a marked ROI within the top three pattern results:	
	$Sensitivity = \frac{\text{number of correct pattern recommendations in top}}{\text{total number of regions with the specific pattern}}$	
	Evaluation Data	The system's sensitivity has been evaluated on 19 lung-specific image patterns.

Pattern	Sensitivity
Airway wall thickening	0.82
Atelectasis	0.87
Bronchiectasis	0.75
Bulla	0.86
Consolidation	0.78
Cyst	0.75
Effusion	0.93
Emphysema	0.86
Ground-glass opacity	0.95
Honeycombing	0.87
Mass	0.70
Mosaic attenuation pattern	0.86
Nodular pattern	0.77
Nodule	0.73
Pneumothorax	0.97
Pulmonary cavity	0.54
Reticular pattern	0.73
Tree-in-bud	0.88
Non-specific: includes patterns	
- with no evidence of pathological changes	0.99
- not explicitly detected by the current system	
Overall Mean Sensitivity	0.82

6.2 Anomaly Detection

Summary	The anomaly detection component is used to predict the probability of anomalous lung tissue at each voxel		
Mechanism	Input Data Source	Lung CT DICOM images	
	Input Data Type	Image data	
	Outcome	Voxel-wise prediction for healthy lung tissue vs anomalous lung tissue	
	Output	Voxel-wise segmentation of lung anomaly	
Model Application and Usage	Benefits	Visualization of image regions with suspected lung anomalies	
	UI Component	<ul style="list-style-type: none"> (1) Visualisation of anomaly heatmaps on the the Search and Insights screen (2) Quantification in the lung tissue analysis panel of the Insights screen 	
	Appropriate Interpretation	The output of the model is intended to be used to obtain a visualization of image regions that are likely to contain lung anomalies. Results must be verified by the end user.	
Validation and Performance	The anomaly detection algorithm is evaluated by its ability to accurately distinguish between voxels that show normal lung tissue and voxels that show anomalous patterns. The evaluation metrics used are sensitivity, specificity, precision and F1 score in identifying anomalies on manually-annotated ROIs.		
	Sensitivity	0.82	Precision 0.97
	Specificity	0.98	F1-Score 0.89

6.3 Patch Retrieval

Summary The patch retrieval component is trained to retrieve cases with similar pattern appearance given a specified ROI of an image

Mechanism	Input Data Source	Lung CT DICOM images
	Input Data Type	Image data from a selected ROI
	Outcome	List of cases with similar visual appearances
	Output	Image regions with corresponding embedding coefficients
Model Application and Usage	Benefits	Automated retrieval of cases with similar pattern characteristics of a given ROI from a database of expert-labeled cases.
	UI Component	Search result shown in the Search screen
	Appropriate Interpretation	Results are intended to be used for efficient comparison of the selected ROI to expert-labeled cases in order to support radiologists during identification and interpretation of image patterns. Results must be verified by the end user.

Knowledge Base contextflow **SEARCH Lung CT** supports visual image retrieval from contextflow’s Knowledge Base, which consists of ~2200 anonymized and expert-labeled CT scans.

Images were taken over a period of 2.5 years from a European hospital during clinical routine without application of any disease-specific filter criteria.

Demographic Information The Knowledge Base consists of cases from **825 female and 1443 male** patients from ages 5 to 100 years. The age distribution is shown in Figure 19.

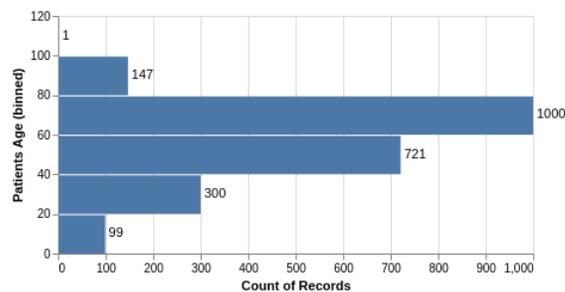


Figure 19: Age distribution of cases from contextflow’s Knowledge Base

Technical Characteristics The Knowledge Base consists of CT scans acquired by different CT scanners. Figure 20 shows a histogram of the cases’ slice thickness. Figure 21 provides

information about reconstruction kernels. Figure 22 provides information about pixel spacings from contextflow’s Knowledge Base.

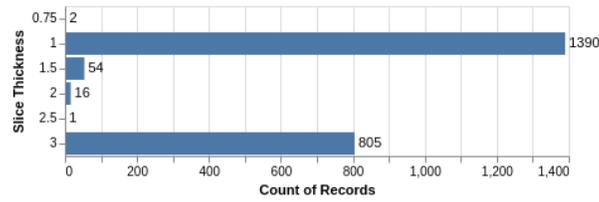


Figure 20: Histogram of slice thickness from contextflow’s Knowledge Base

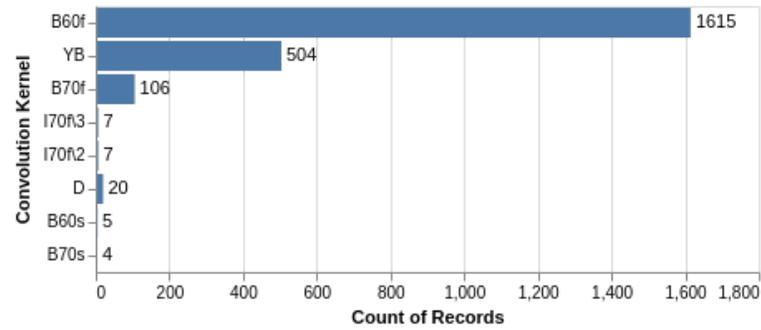


Figure 21: Summary of reconstruction kernels from contextflow’s Knowledge Base

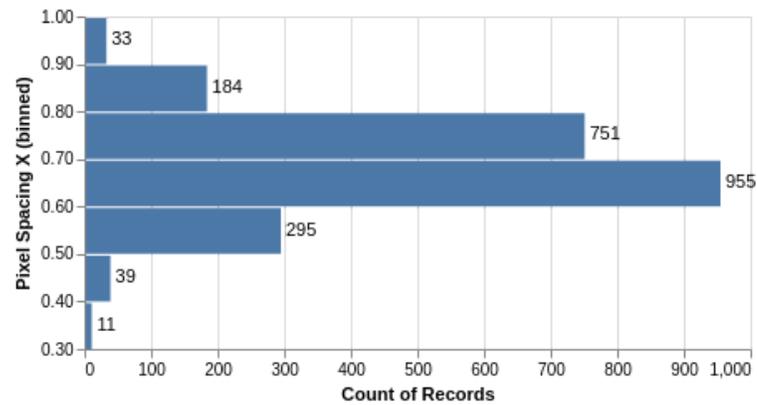


Figure 22: Distribution of pixel spacings in contextflow’s Knowledge Base

6.4 Lung Nodule Detection

Summary The nodule detection component is used to predict the location and measurements of nodule candidates. Localization of detected nodules is further used for pattern classification.

Mechanism	Input Data Source	Lung CT DICOM images
	Input Data Type	Image data
	Outcome	List of detected nodules and quantitative information for each nodule
	Output	Location and measurement of volume, short and long axis diameters of suspected lung nodules
Model Application and Usage	Benefits	Localisation and quantification of detected lung nodules
	UI Component	Detected lung nodules and nodule measurements on the lower panel of the Insights screen
	Appropriate Interpretation	Results are intended to support radiologists in locating nodules and provide nodule measurements. Results must be verified by the end user.

Validation and Performance The component performance is evaluated by defining three quality criteria: (1) sensitivity, (2) FPR (false positive rate) and (3) measurement accuracy. The component sensitivity can be adjusted for the user which has the following impact on the FPR:

Sensitivity %	FPR	Nodule axis measurement	Mean Difference
90	1.0	Manual	1.37
92	2.0	Automatic	1.47
94	3.7		

The performance of the nodule measurements is evaluated with the difference in measurement of the average nodule axis (average between long and short axis) between predicted and ground truth segmentations.

Evaluation Data The component was tested on scans containing lung nodules.

6.5 Pattern Segmentation

Summary	The pattern segmentation component is used to predict the presence of 6 supported patterns at each voxel and provide lung coverage information. Pattern presence is further used for pattern classification.		
Mechanism	Input Data Source	Lung CT DICOM images	
	Input Data Type	Image data	
	Outcome	Voxel-wise presence prediction for each of the supported patterns	
	Output	Quantitative information of the presence of the specific pattern in the total lung volume of the query case and the visual display of the segmentation overlays in the query image viewer	
Model Application and Usage	Benefits	Visualization and quantification of supported patterns	
	UI Component	<ol style="list-style-type: none"> (1) Visualisation and quantification of the patterns on the lung tissue analysis panel of the Insights screen (2) Segmentation overlays on the query image viewer, when a pattern is selected on the lung tissue analysis panel of the Insights screen 	
	Appropriate Interpretation	The output of the model is intended to be used for visualization and quantification of image regions that are likely to contain the supported patterns. Results must be verified by the end user.	
Validation and Performance	The component performance is evaluated on the segmentation overlap over a test set of 2D slices with the Dice coefficient. A subset of the test set is further annotated twice by different annotators to estimate the performance of the human rater.		

Pattern name	Manual	Automatic	
	inter-rater set	inter-rater set	full test set
Honeycombing	0.611	0.517	0.355
Reticular pattern	0.470	0.338	0.169
Ground glass	0.655	0.636	0.507
Emphysema	0.483	0.586	0.419
Effusion	0.839	0.640	0.522
Pneumothorax	0.896	0.829	0.782
Average	0.659	0.591	0.459

Evaluation Data The model was tested on a separated data set.

7 Notes and Error Messages

contextflow SEARCH Lung CT produces notifications and errors when an exception is encountered within the algorithm or in case of information that improves usability. Either individual pop-up windows will appear or a red or blue box will appear in the upper right corner of the screen. Below are possible error messages generated by the software with further descriptions and probable causes of the exceptions.

The following symbols are used to signal either an error or a note:

Symbol	Error type	Description
	Note	A note means additional information is available to the user to support proper use of the system.
	Error	An error means that the software cannot perform as specified.

contextflow should be contacted for any functionality problems.. Please refer to the error message number displayed with the corresponding error.

7.1 Error Messages

7.1.1 Image Series not Found

This error can occur if the requested patient data is not found by the system. This can happen because of the following reasons:

- Data was not sent to **contextflow SEARCH Lung CT** for processing
- Processing of data is not yet completed
- Processing of patient data was not successful

This error may lead to one of the two following conditions:

- The URL containing the data set that is searched for does not exist.
- The URL containing the data set that is searched for does not exist in that series. Here the system tries to support the user by offering a data set of another series that reflects the data originally searched for.

7.1.2 Search Out of Target

This error indicates an exception has occurred during the segmentation algorithm (Figure 23). Possible causes include:

- Input image is noisy
- Under-segmentation of the lung

Further details are described in the next chapter.

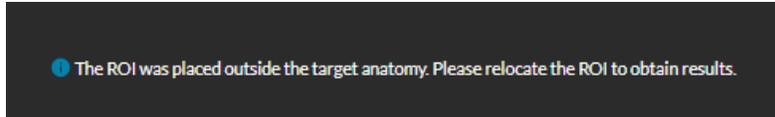


Figure 23: Error message for search out of target

7.1.3 Blue Information Box

A Blue Information Box appears as a little box on the upper right side of the Search Screen (Figure 24). These information boxes demonstrate e.g. that there is a new Application Programming Interface (API). This means that the back-end was updated, and a reload of the side is necessary. In general these boxes have informative character.

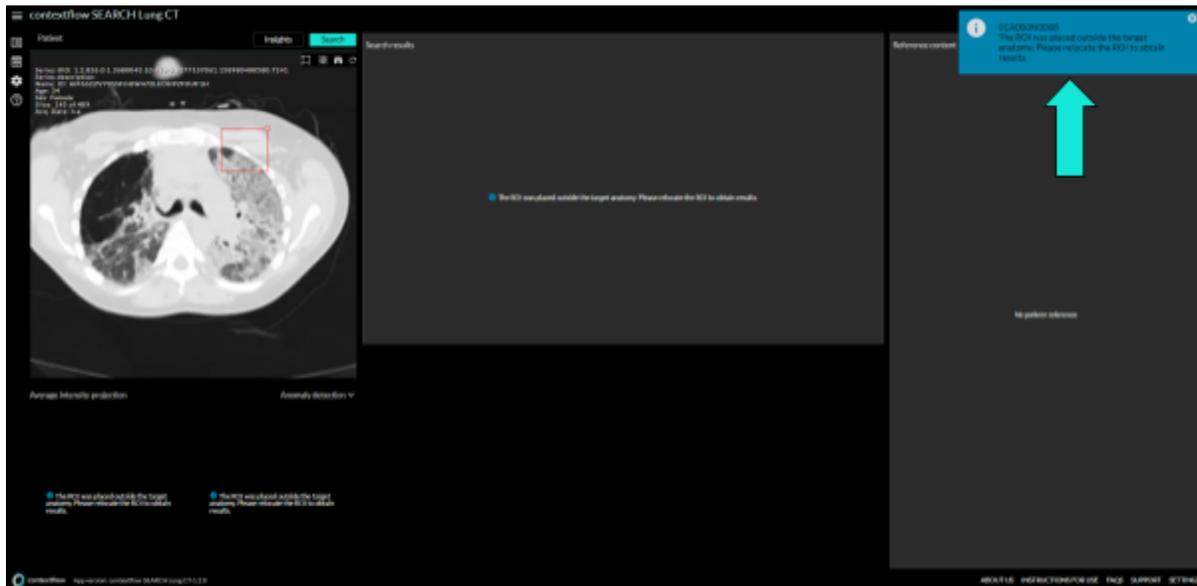


Figure 24: Blue Information Box

7.1.4 Red Error Box

A Red Error Box appears as a little box on the upper right side of the Search Screen (Figure 25). These error messages demonstrate e.g. that there is a problem with either the internet connection or the connection to the back-end server of the software. If the error message describes the necessity to reload the site, please do so.

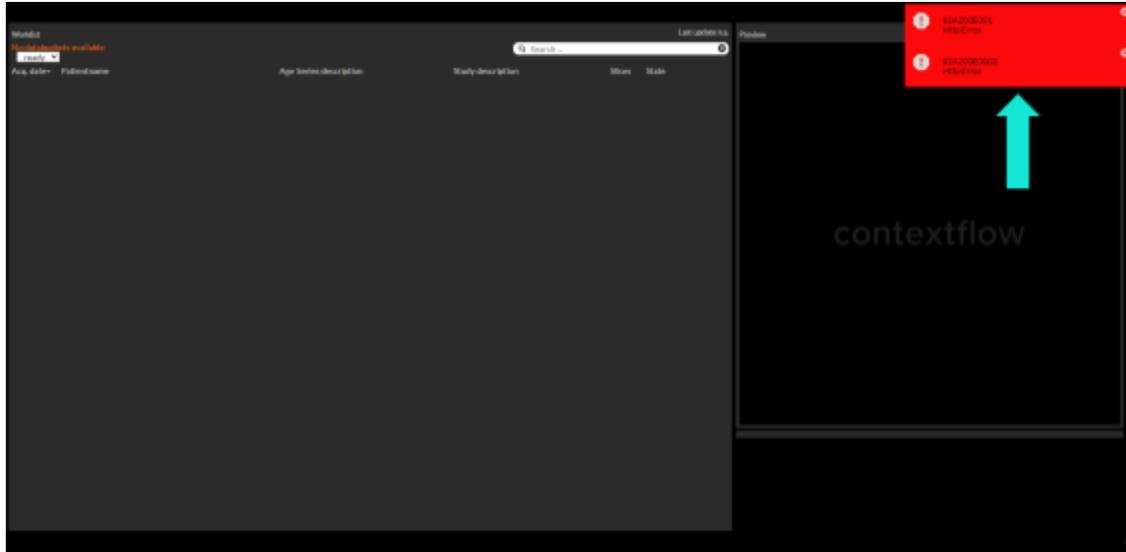


Figure 25: Red Error Box

7.2 Algorithm Errors

7.2.1 Segmentation Error

contextflow SEARCH Lung CT segments the lungs from thoracic CT images so that the system can identify whether users are selecting an area that is inside or outside of the lung. The system must only be used by intended users as specified in **Chapter 2 “Characterization of Users”**. The following segmentation errors are common:

- Over-segmentation of the lung - this includes but is not limited to the following:
 - Air outside of the body is categorized as lung
 - Air in the gut is categorized as lung
 - Peripheral non-lung tissue is categorized as lung
- Under-segmentation of the lung - this includes but is not limited to the following:
 - High-density areas of the lung parenchyma are excluded from the segmentation. This is usually caused by the presence of effusion, consolidation or mass patterns.

Below are examples of possible cases with segmentation errors. Please note that the user will not see these segmentation lines while using the software. They are only a graphical support for a better understanding of the segmentation error. Figure 26 shows under- and over-segmentation of the lung, and Figure 27 depicts over-segmentation of the lung.



Figure 26: Under-segmentation of the right lung (blue arrows); Over-segmentation of the left lung (black arrow).

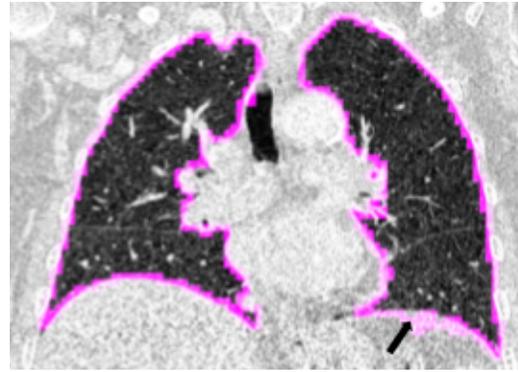


Figure 27: Over-segmentation of the left lung (black arrow)

7.3 Application Notes

In case of the following notes, the user is advised to follow described actions:

7.3.1 Interpretation of Listed Differential Diagnosis

Candidates for differential diagnosis for image patterns are listed in the section Reference Content in the **Search screen**. Please keep in mind the following:

- The content of differential diagnosis provided lists the most common diagnosis of a pattern. The completeness of these diagnoses is not assured.
- Lists of diagnoses provided by the system are not ranked by relevance.

7.3.2 Low Screen Resolution

The screen resolution of the monitor being used must be high enough (1920px by 1080px); otherwise the user may experience issues with viewing the content as a result.

7.3.3 Javascript Disabled

Javascript must be enabled or else the system does not work.

7.3.4 Access by Unsupported Browser Denied

The following browsers are supported by our system:

- Google Chrome: Version \geq 74
- Mozilla Firefox: Version \geq 67
- MS Edge \geq 44

Otherwise the system will display an error message that the software cannot be opened.

7.3.5 Access by Mobile Device Denied

contextflow's software should not be opened with a mobile device, as this functionality is not supported by the system.