CT Eye™
User Manual

Software version: 1.0
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Language: English
Revision number: 1

IMPORTANT

Refer to this guide for proper use, warnings, and cautions associated with the use of CT Eye™ medical device software. Please contact your sales representative for any questions associated with CT Eye™ software. The help and readme files included with the CT Eye™ software are provided for reference only. Please read this entire guide before using the CT Eye™ software.

INTENDED USE

CT Eye™ software is intended to support trained radiologists when reporting on computed tomography images. The final report must be approved by a trained radiologist. The software is a fully automatic computer assisted diagnosis solution. Based on collected data (deep neural network) the software analyzes a given computed tomography image. By function, CT Eye™ consists of four parts:
CT Eye™ CAD, CT Eye™ Queue, CT Eye™ Search, CT Eye™ Quality.

Depending on the configuration, the result of the analysis is:

- A preliminary list of suspected pathologies optionally with 3D overlays representing location of each finding (CT Eye™ CAD) and a reporting priority/urgency level (CT Eye™ Queue).
- List of retrospective cases with similar radiological findings (CT Eye™ Search).
- Identification of potential reporting errors made by the reporting radiologists (CT Eye™ Quality).

The software has three possible interface versions:

- Application programming interface (API) – the software may integrate with hospital systems such as picture archiving and communication system (PACS) and radiology information system (RIS) using protocols such as DICOM® and HL7®. Diagnostic images are taken directly from a hospital system and the generated report is sent directly to a hospital system. In this case the user interacts with CT Eye™ through a hospital system or systems.
- Web interface – a web application which allows uploading computed tomography images. In this case the user interacts with CT Eye™ directly.
- Analytics interface - a web-based dashboard to provide summary statistics and case-by-case information of CT Eye™ processed studies.

The software is fully configurable - each interface can be enabled or disabled independently.

The software supports radiologists in detection of following radiological findings:
Pulmonary Embolism, Lung Lesion, Lung Consolidation, Mediastinal Lymphadenopathy, Brain Aneurysm, Brain Large Vessel Occlusion, Intracerebral Haemorrhage, Brain Ischemic Lesion, Mesenteric Thrombosis, Extravasation, Liver Lesion, Abdominal Fat Stranding

Intended Patient Population: Patients undergoing computed tomography examination.
Indications: Computed tomography studies only.
Contraindications: Not computed tomography studies and other situations that are not covered by “Indications”.
Classification: CT Eye™ is classified as class IIb per Rule 11 according to Medical Device Regulation (EU) 2017/745.
Target markets: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.

Table 1. Symbol descriptions in the software label.

Symbol	Description
	**Manufacturer** Indicates the medical device manufacturer
	**Date of manufacture** Indicates the date when the medical device was manufactured
	**General warning sign** To signify a general warning
	**Consult instructions for use** Indicates the need for the user to consult instructions for use
CE 0197	**CE Marking** CE marking of conformity
MD	**Medical Device** Indicates the item is a medical device
UDI	**Unique Device Identifier** Device identification code in the GS1 system

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Chapter 1: Introduction

CT Eye™ is a suite of solutions supporting computed tomography radiological workflow. The tools in the suite increase reporting productivity by generating preliminary reports, allow more accurate differential diagnosis by image-based search and case retrieval, and prioritize cases with urgent conditions for faster reporting.

1.1. Responsibility

CT Eye™ is able to detect the supported radiological findings with high fidelity which on average results in useful information presented to the radiologist. The operation of the software has been verified based on the acquired retrospective (historical) data from radiological diagnostics, more details are available upon request. This confirmation of the effectiveness of the software makes sure that the radiologist on average receives useful information pertaining to radiological findings in the input computed tomography image. The user (radiologist) is responsible for the correctness of their report as well as for any and all diagnostic or treatment decisions.

1.2. List of abbreviations

- AI – Artificial Intelligence.
- API – Application Program Interface.
- CAD – Computer Aided Diagnosis.
- DICOM® – Digital Imaging and Communications in Medicine.
- HIS – Hospital Information System.
- HL7® – Health Level 7.
- PACS – Picture Archival and Communication System.
- RIS – Radiology Information System.
- VPN – Virtual Private Network.

1.3. General Warnings

Potentially wrong and harmful results. The report or other information presented by CT Eye™ software might be wrong, and the ultimate responsibility for the final reports lies with the user (radiologist) approving and, if necessary, amending the report.

Common false positives and false negatives. The following radiological findings are most frequently misinterpreted by the product:
Lung Consolidation, Mediastinal Lymphadenopathy, Intracerebral Hemorrhage, Brain Ischemic Lesion, Mesenteric Thrombosis, Liver Lesion, Abdominal Fat Stranding
If these findings are present in the preliminary report or suspected to be erroneously absent from the preliminary report, the preliminary report should be analyzed more carefully. It is furthermore recommended that the study be discussed with other radiologists for a more accurate final report.

Unreliable performance on images with poor technical quality. On rare occasions a computed tomography may be performed poorly due to artifacts, over or under exposure, or unique patient characteristics may be present. Such cases may be challenging for interpretation both by a radiologist and CT Eye™. It is furthermore recommended that the study be discussed with other radiologists for a more accurate final report.

Contextual limitations. The AI solution only has access to a standalone computed tomography image. It does not have access to other important information, such as clinical context, patient history, referral or prior studies. This information can be critical both in interpretation as well as the reporting part.

Interobserver subjectivity. Two different radiologists might interpret the same computed tomography image differently. There is no objective truth in medical imaging. The subjectivity factor also applies to AI on how it analyzes and reports on imaging studies.

Trade off between sensitivity and specificity. AI solutions can be made very sensitive or very specific. Yet if the product is designed to report on all of the images, sacrifices will be made in both of these areas.

1.4. Precautions

CT Eye™ does not use any clinical context while interpreting computed tomography studies - the medical device therefore will produce a significant amount of false positives and false negatives. The CT Eye™ results which raise concern may also come from the imperfections of AI models. The radiologists have to use their own judgment and always question the results provided by the CT Eye™ medical device. The radiologists have to be able to completely disregard CT Eye™ results if they see them inappropriate and harmful.

The medical device is optimized to have a reasonable sensitivity/specificity setting which assists radiologists not to miss apparent radiological findings in a stressful and heavy-workload environment or when secondary expert opinion is desired. This means that there is a high probability that subtle and less apparent findings may be undetected by CT Eye™.

Chapter 2: Description of configuration by function

CT Eye™ CAD is a fully automatic computer-aided diagnosis (CAD) computed tomography solution. It provides a preliminary list of suspected findings with location data (image in, findings and 3D overlays) which then have to be approved by a radiologist. This way it enables the user to save time, increase accuracy (e.g. decrease overlooked secondary findings), optimize screening / triage, and introduce best reporting practices. CT Eye™ CAD can be adjusted to fit a particular use case by tuning so-called thresholds, as well as providing output for either all incoming images or only a fraction of them. This solution is available both as an integral part of the hospital system (see Chapter 3) or through a web interface (see Chapter 4).

CT Eye™ Queue is a radiological queue management and patient prioritization solution, which automatically prioritizes computed tomographies of potentially unhealthy patients inviting urgent specialist attention. By doing so it reduces time-to-treatment for time sensitive conditions such as *Pulmonary Embolism, Intracranial Large Vessel Occlusion, Ischemia, Intracranial Haemorrhage, Mesenteric Thrombosis, Extravasation*. This solution is available both as an integral part of the hospital system (see Chapter 3) or through a web interface (see Chapter 4).

CT Eye™ Search is a search engine that finds similar-looking computed tomography studies in a given database. The similarity is identified by a neural network, which judges both the pathology present as well as other features in the image such as the location of the pathology, its severity etc. CT Eye™ Search empowers the user to quickly find retrospective cases with similar radiological appearance. This solution is available through a web interface (see Chapter 4).

CT Eye™ Quality is a quality assurance tool combining artificial intelligence with human radiologists. The product works in two steps. Firstly, the artificial intelligence software reads final radiologists' reports and corresponding computed tomography images. It identifies potential reporting errors made by the reporting radiologists, by comparing the radiologist's report with the internal results of CT Eye™ Quality. The software then flags the cases for reviewing radiologists to review. The second step is for the reviewing radiologist to double-check the cases, which were automatically flagged by the solution, to identify any cases with a high probability of a missed finding. Identified cases are then sent to the hospital's radiologists via email or via integration in the PACS/RIS/HIS systems. It's the hospital's radiologists' decision if any action (such as adding an addendum to/modifying the radiological report) should be taken. Using the tool prospectively enables the radiology department to identify the most common mistakes, call for extra attention, or provide additional training to mitigate the risk of missed pathologies. This solution is available through an analytics interface (see Chapter 5).

Chapter 3: Integration with hospital systems

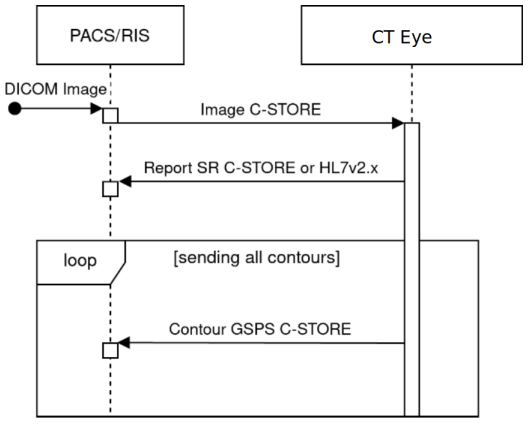
CT Eye™ is designed to act as a PACS and a reporting API (i.e. HL7®) combined. Therefore, the medical device follows all the standard PACS communication protocols for DICOM® data transmission and up-to-standard HL7® report delivery supported by most RIS/HIS vendors. This ensures that CT Eye™ is able to integrate with any PACS/RIS vendors supporting these data transmission protocols.

3.1. Configuration steps

The first step of the CT Eye™ setup consists of setting up the connection with the data source (medical institution’s PACS) given IP address, port and AET information. The medical institution is responsible for sending the DICOM® images to the CT Eye™ medical device. CT Eye™ does not actively download any information from the data source so as not to cause any issues related to the medical institution’s IT security and risk patient data protection. This means that the PACS administrator has to ensure the data delivery process to the CT Eye™ in order for the medical device to function properly.

The second step of the setup consists of setting up the connection with the data recipient via agreed-upon transfer protocol (such as DICOM®, DICOMweb™, HL7®). The report delivery process is ensured by the thorough testing of the CT Eye™ medical device. The preliminary list of findings and 3D overlay objects contain CT Eye™ metadata within.

Figure 1. Example data flow chart of the report delivery module.



Finally, the setup of CT Eye™ Quality depends on the medical institution to send their own radiology reports (if possible). The medical device is capable of processing various types of formats and protocols (such as DICOM®, DICOMweb™, HL7®, XML, YAML, JSON, etc.). If successful, the notification channels (i.e. email addresses) are set up for the delivery of CT Eye™ Quality results.

3.2. System requirements

CT Eye™ is provided as a docker container together with instructions on how to run the docker in a physical or virtual machine running Ubuntu OS (preferably the latest LTS version). The machine should allow inbound SSH access, either directly or through a VPN. The physical or virtual machine (VM) should satisfy these requirements: 32 GB of RAM, 64-bit CPU with 16 logical cores with AVX instruction support, 1 TB of disk space.
These requirements cover only minimum storage of DICOM® studies, e.g. for later viewing using CT Eye™ analytics page interface. In case of a significant study volume, the disk space figures should be reviewed. CT Eye™ is optimized to run on machines with multi-thread CPU with AI inference, taking about 15 minutes per study on latest CPU models. GPU is not required, however if it is available it is used for reducing the inference time per study to 5 minutes.

3.3. CT Eye CAD

When **CT Eye™ CAD** is integrated with the hospital systems, no special actions from the user are required, as all the software processing occurs in the background before the reporting procedure. The user may proceed reporting as before integration of CT Eye™ CAD with the following differences:

- Instead of starting to report from an empty reporting sheet, a preliminary list of suspected findings generated by CT Eye™ CAD may be available as a starting point.
- The localization of pathology (3D overlays) may be available for review as additional objects in the series of the original computed tomography image. These 3D overlays provide the approximate location of findings as detected by the software.

Processes of the original computed tomography viewing, dictating and/or typing the report, approving/submitting the report are unchanged. For more details refer to manuals of the software directly used for reporting such as DICOM® viewer and RIS/HIS.

3.4. CT Eye Queue

When **CT Eye™ Queue** is integrated with the hospital systems, no special actions from the user are required, as all the software processing occurs in the background before the reporting procedure. The user may proceed reporting as before integration of CT Eye™ Queue with the difference that an additional indicator of reporting urgency and/or detected pathologies may be available in the worklist of the user (see Figure 2).

Figure 2. Illustration of a possible radiology worklist view in the presence of CT Eye™ Queue.

SCAN DETAILS						CT QUEUE	
Exam time	**Patient Name**	**Modality**	**Description**	**Site**	**Action**	**Priority**	**Pathology**
13:50	Test patient 1	CT	Chest CE	3	View	**HIGH**	PE
13:37	Test patient 2	CT	Brain CTA	2	View	**HIGH**	Large Vessel Occlusion
13:38	Test patient 3	CT	Brain Non Contrast	2	View	**HIGH**	Ischemia
13:39	Test patient 4	CT	Abdomen CE	2	View	**HIGH**	Mesenteric Thrombosis
13:40	Test patient 5	CT	Abdomen CE	2	View	**HIGH**	Extravasation
13:41	Test patient 6	CT	Chest Non Contrast	2	View	**MEDIUM**	Lung Lesion

13:42	Test patient 7	CT	Abdomen CE	2	View	MEDIUM	Liver Lesion
13:43	Test patient 8	CT	Abdomen CE	2	View	MEDIUM	Fat Stranding
14:10	Test patient 9	CT	Brain CTA	1	View	LOW	
14:57	Test patient 10	CT	Chest CE	2	View	LOW	
15:57	Test patient 11	CT	Abdomen CE	2	View	LOW	

Processes of the original computed tomography viewing, dictating and/or typing the report, approving/submitting the report are unchanged. For more details refer to manuals of the software directly used for worklist management and reporting such as DICOM® viewer and RIS/HIS.

3.5. CT Eye Search

When **CT Eye™ Search** is integrated with the hospital systems, no special actions from the user are required, as all the software processing occurs in the background before the reporting procedure. The search database automatically updates with the incoming information from PACS/RIS/HIS. The search results can be accessed through a web interface.

3.6. CT Eye Quality

When **CT Eye™ Quality** is integrated with the hospital systems, no special actions from the user are required, as all the software processing occurs in the background after the reporting procedure. The following procedure is applied in the background while the radiologist has reported on the computed tomography study.

- computer tomography image study analysis - all computer tomography studies are automatically forwarded to CT Eye™ Quality as soon as they enter the PACS. CT Eye™ analysis is performed, the software extracts the detected pathology likelihood and location information.
- Radiologist report analysis - after a report is submitted to the reporting system (RIS or PACS) of the medical institution, it is automatically forwarded to the CT Eye™ Quality platform and matched with a corresponding computed tomography study. CT Eye™ Quality analyzes the radiologist report using Natural Language Processing algorithm, which extracts structured radiological finding data (e.g. “Pulmonary Embolism”, “Aneurysm”).
- Comparing the radiologist report with CT Eye™ Quality findings - when CT Eye™ Quality identifies a clinically significant finding, not mentioned in the radiologist report, the study is flagged as a potential Quality study. An email notification is sent to the reporting / senior radiologist about suspected missed findings. The notification includes a link to the study page with suspected missed finding areas highlighted in the image. The reporting radiologist can immediately review the study, validate the additional findings and include them in the final report.

CT Eye™ Quality can operate in a fully automated or in an assisted setting.

- **Assisted mode** – findings detected by CT Eye™ Quality are validated by a human radiologist prior to submitting them to the medical institution. In this mode, the medical institution is only notified about validated missed findings cases, requiring additional review.
- **Automated mode** – CT Eye™ Quality is solely responsible for identifying potentially missed findings. The intermediate findings are not validated by a human radiologist before they are presented to the medical institution. It might create a large volume of false positives (insignificant findings, text processing errors, etc.).

The choice between automated and assisted mode is a trade-off between time-to-response and the number of actionable notifications the medical institution would receive. The medical institutions are asked to specify the setting which they prefer before installation.

Chapter 4: Web interface

4.4. Priority

The image is assigned with a priority label based on the detected radiological findings. The priority label is determined by the significance of the findings. The priority label represents how this study would appear in the radiology worklist with CT Eye™ Queue enabled - cases with higher priority would appear at the top of the worklist. The priority is defined by checking if the following findings were detected, in the following order (until first criterion is met).

Table 2. CT Eye™ Queue priority level assignment logic.

Priority criteria	Priority level
Brain Large Vessel Occlusion	High
Brain Ischemic Lesion	High
Intracerebral Hemorrhage	High
Pulmonary Embolism	High
Mesenteric Thrombosis	High
Extravasation	High
Brain Aneurysm	Medium
Mediastinal Lymphadenopathy	Medium
Lung Lesion	Medium
Lung Consolidation	Medium
Liver Lesion	Medium
Abdominal Fat Stranding	Medium
No findings were detected from the list above	Low

4.5. Image search

Clicking on “Search for similar cases” will open the CT Eye™ Search interface. The original image is on the left side of the window. On the right side the most similar images are displayed together with their corresponding radiology reports and discussions. In the search report window the user can find:

- Ten buttons from 1 to 10. Each represents the rank of how similar the images are. All of them are clickable - each opens the associated case.
- Patient information (study number, patient number, age, sex, date)
- Projection, impression, findings, discussion, etc.
- “More images from this case” allows to toggle between images in the same case.

The purpose of CT Eye™ Search is mostly educational and if results are similar or not has to be assessed by a radiologist. The institution may choose to include open data sets and/or their own library of computed tomography studies.

4.6. Interface options

At the top right of the web interface several additional options are available to interact with the software.

- “About” - opens a page with general information about CT Eye™, contact form, software label and link to the User Manual.

- Language control - option to change the language of the interface. Only a limited number of languages are supported and may not be available in your language. A list of supported languages may change over time.
- User control - option to login or logout from the session.

4.7. Troubleshooting

Please contact your sales representative or via info@oxipit.ai for any questions associated with CT Eye™ software.

Chapter 5: Analytics interface

Analytics page serves as a dashboard to monitor the overall CT Eye™ performance by providing various summary statistics about computer tomography studies in the various time intervals. This allows a fully transparent view of how CT Eye™ operates at the institution. The data within the analytics page updates as soon as a study is finished to be processed by CT Eye™, so all the up-to-date information is available.

5.1. Login screen

The interface access may require user credentials which are provided by the CT Eye™ support team. If the credentials are required, please note that there is no user registration form - the user should request the institution's IT system administrators for assistance. The usage may be restricted.

Figure 3. User login screen to access analytics web page.

Please note that access to this interface may be available only within the institution’s network and safe connectivity tools (such as VPN) may be required to reach this interface.

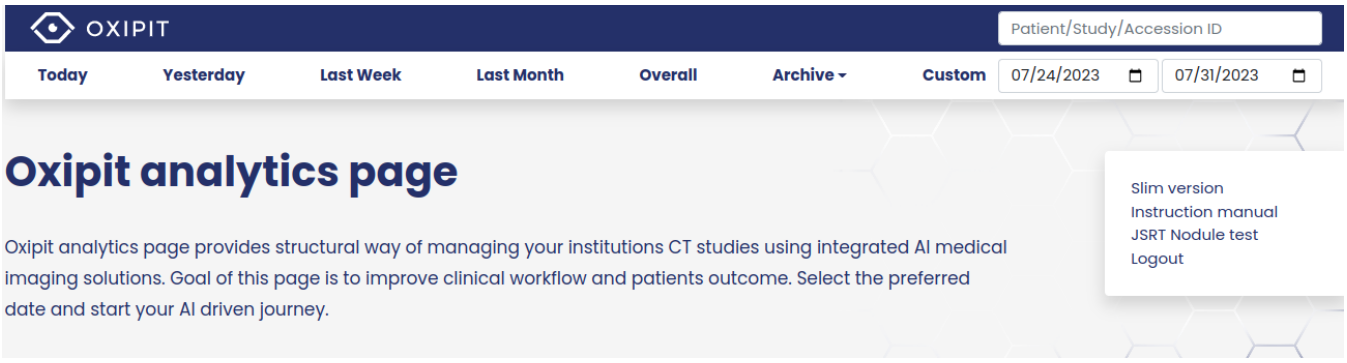
5.2. Welcome screen

After successful login, the user is redirected to the welcome screen. The contents of the welcome screen is fully customizable and may vary depending on the medical institution’s request. However, the interface has a standard option to display statistics of CT Eye™ results by various time intervals.

The menu bar contains buttons which redirect to main screen containing statistics about CT Eye™ processed computed tomography studies:

- “Today” - studies of the current day.
- “Yesterday” - studies of the previous day, excluding the current day.
- “Last week” - studies of the last 7 days, including the current day.
- “Last month” - studies of the last 30 days, including the current day.
- “Overall” - all studies in the archive.
- “Archive” - studies from a specific date.
- “Custom” - studies from a specified date range, date range values are inclusive.

Figure 4. Menu bar on the top to select a desired time interval.



The welcome screen also contains search functionality looking up computed tomography DICOM® metadata (Patient ID, StudyInstance UID, Accession Number) in the CT Eye™ processed studies database. With given input the search is applied for all these fields and multiple results can be returned. To search for multiple subjects, input strings can be comma separated (i.e. given two comma-separated IDs “1.2.3.4.5, 1.2.3.4.6”, both ID fields would be matched for records in the database). The search is done by matching ID fields exactly.
The user is also provided with links to the User Manual and the Slim version of the page. Slim version contains concise information within a simplified mobile-friendly view.

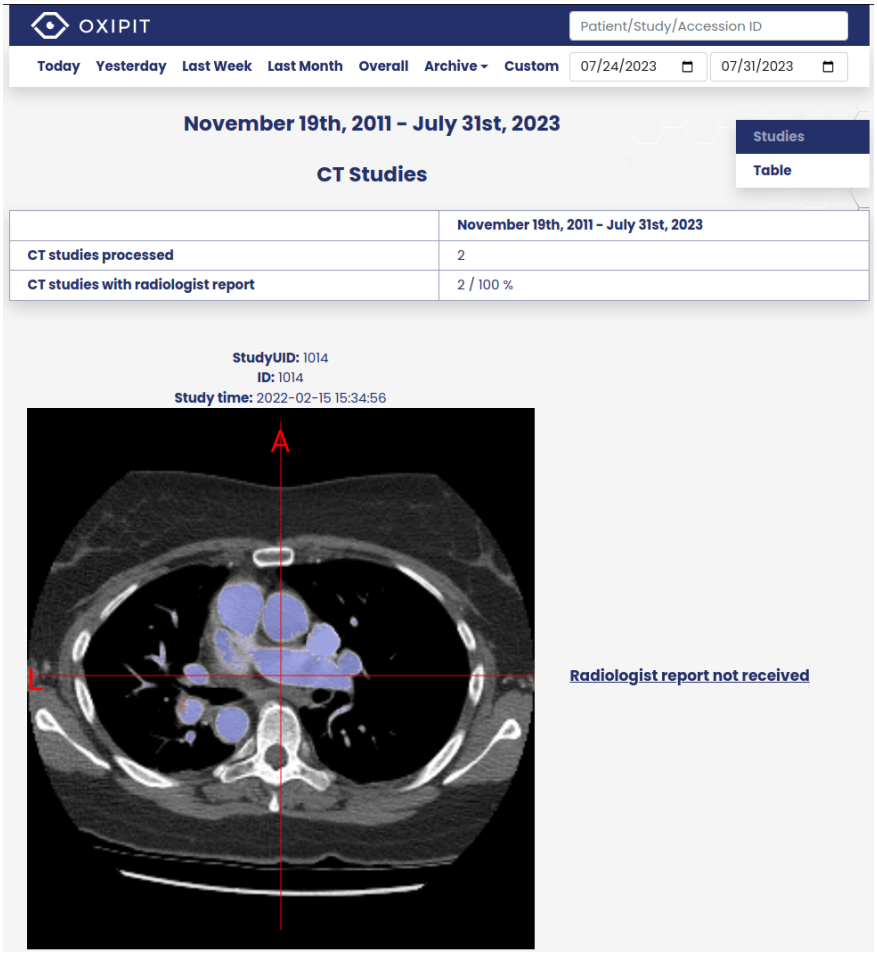
5.3. Main screen

After clicking on the desired time interval, the main screen is opened in the web browser. It consists of several key components:

- Menu bar at the top with equivalent functionality as described in 5.2. The menu bar remains constant within all pages contained throughout the pages of the main screen.
- Navigation bar on the left side with counters based on CT Eye™ results. Navigation bar is able to tell how many computed tomography studies were processed by CT Eye™ with detailed information and distribution of detected findings in the CT Eye™ CADe module, the CT Eye™ Queue module and the CT Eye™ Quality module. Each item in the navigation bar is clickable and the user is redirected to the specific subset of CT Eye™ detected findings within each module.
- computer tomography display window in the lower right part of the main screen. It contains the most recent studies within the selected time interval and filtered by the selection in the navigation bar.
    - Study DICOM® metadata - StudyInstance UID, Patient ID, Study Date, Study Time.
    - Link to the CT Eye™ results in the web interface (see Chapter 4).
    - Radiology report - Referral, Findings and Impression.
    - CT Eye™ NLP analysis of the radiology report - Impression labels.

The radiology report and the NLP analysis will be unavailable if the institution has not provided this information about the specific study to the CT Eye™ reporting module. DICOM® metadata and the computer tomography images will be shown regardless of report availability. This window can also be presented in a table spreadsheet without the actual images by pressing on the “Table” button located in the top right corner of this window.

Figure 5. The information layout in the main screen.

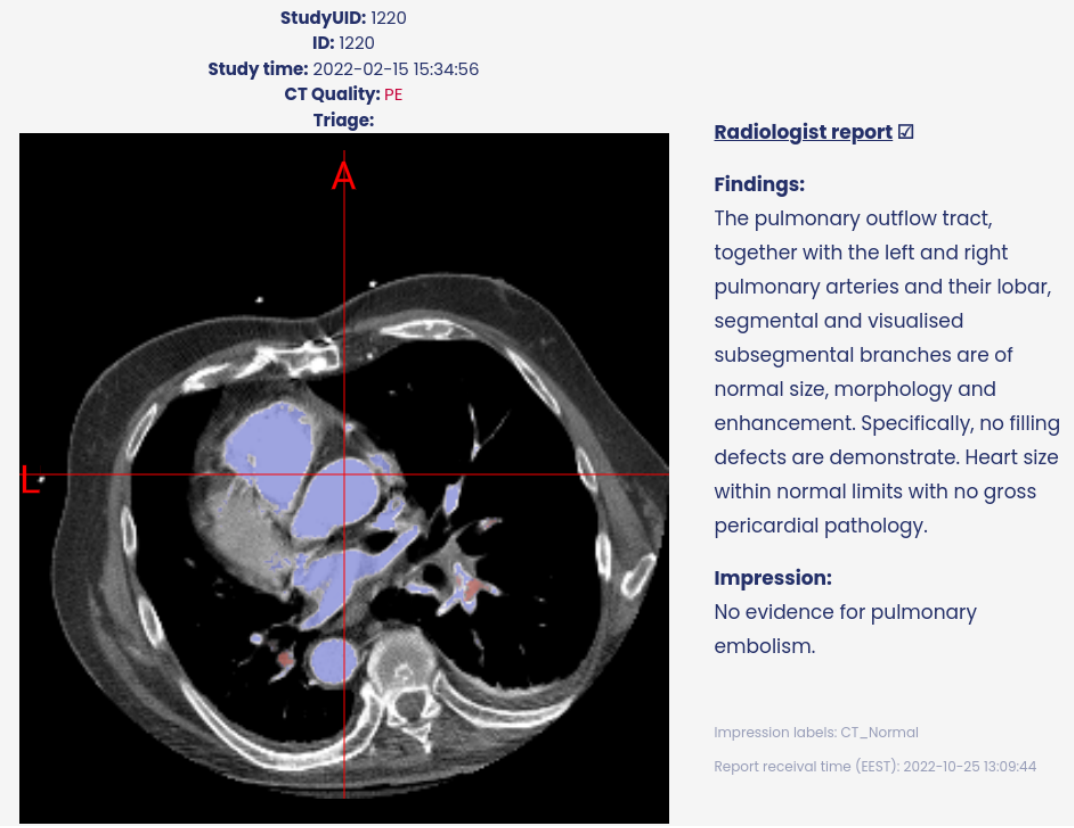


The image viewer is for CT Eye™ presentation purposes only. The computed tomography image may be displayed in a reduced resolution and 8-bit color depth. The final computed tomography interpretation should be done on a dedicated certified medical device.

5.4. Study review screen

The user may open a specific computed tomography study via search function in the menu bar or by clicking “StudyUID” above the computed tomography image. If the study is flagged by CT Eye™ Quality (there is a potential discrepancy between the CT Eye™ results and the radiology report), a study is identified as the “Quality” case with the corresponding radiological finding in question.

Figure 6. Illustrative example: computer tomography study with signs of pulmonary embolism detected by CT Eye™ (3D overlay in red). Signs of pulmonary embolism were not reported in the radiology report therefore marked as a CT Eye™ Quality case.



The image viewer is for CT Eye™ presentation purposes only. The computed tomography image may be displayed in a reduced resolution and 8-bit color depth. The final computed tomography interpretation should be done on a dedicated certified medical device.

In such a scenario, the user can manually confirm that CT Eye™ Quality indeed identified a potentially clinically significant missed finding(s). Upon clicking “Confirm Quality case” and filling in additional information the medical institution will be automatically notified about the case via email or other notification system.

Finally, the user can look for similar cases in the medical institution’s computed tomography database (limited to computed tomography studies processed by CT Eye™).

5.5. Assisted mode

The notification engine by default operates automatically without human supervision. However, medical institutions can enable the “Assisted mode” option to only get notifications when a secondary human reader has confirmed that the CT Eye™ Quality detected case has either likely or uncertain clinical significance.

The “Assisted mode” significantly reduces the number of notifications sent and the notifications would be of higher clinical relevance. This mode involves a second human reader to be involved in the computed tomography reading process. However, the second reader would not have to review all computed tomography studies - only a small fraction which were flagged by the CT Eye™ Quality.

5.6. Notification engine

As part of CT Eye™ Quality, notifications are sent to the reporting radiologist via e-mail. Notifications are highly customizable and can be adapted to a format which is preferred by the institution. Single or multiple recipients (i.e. reporting radiologist, senior radiologist, radiology supervisor) for the notifications can be configured.

Figure 7. Example of CT Eye™ Quality notification.