INSTRUCTIONS FOR USE (IFU)

Version 010
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DRAFT

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1. Version control

Cause of the revision	Date	Version
First version	11/03/2022	001
Second version • Chapter 5. Warnings and precautions has been updated.	24/03/2022	002
Third version • The table of chapter 2. General information has been updated regarding the UDI number. • Section Precautions and alerts of chapter 2.1. Alerts and warnings have been updated. • Content update on chapters 2.6. Clinical benefits, 3. Technical characteristics and specifications, and 4. How to use (adding Figures 5 and 6). • Chapter 4. How to use updated: release notes icon. • Chapter 5. Warnings and precautions have been updated.	20/10/2022	003
Fourth version • NANDO code updated. • Updated access circuit. • Updated new contact mail. • Removed reference to the 3D model. • Updated references to the warning+URL visualization method.	17/02/2023	004
Fifth version • 2.1 to 2.3 has been updated according to the planned measures in R-006-001_045.	01/09/2023	005
Sixth version • IFU SW integrated in PACS. Sycai Viewer removed • Adapted IFU to RAIM Viewer PACS • CC-42: Sens and Spec included in chapter 6. • Included new requirements defined in European Regulation 2021/2226 for the electronic IFU. • CC-50: removed reference to the need to have access to label after integration since label is included in the report of the product. Considerations mentioned in JIRA ticket are included (point 2.3) • Updated the clinical validation chapter (chapter 6) • CC-72: updated the intended use or purpose (chapter 2.4) + • CC-72: chapters 2.1, 2.3 y 3 updated to remove reference to cross-sectional imaging and referencing CT scan images.	27/11/2023	006

Seventh version
 	
• CC-89: Chapter 2.3: Updated the technical specifications and characteristics and included "Requirements for the viewer for a successful installation " synched with the installation guideline and also with REQ_INT_VIEWER requirements defined in R-008-002 Requirements. Included also the compatible viewers with SYCAI MEDICAL
• CC-98:
  ○ Chapter 6.1: included details of the nature and frequency of preventive and regular maintenance
  ○ Changed date in the cover to make it compatible with ISO 8601-1
  ○ Chapter 2.7: Include information on the use environment of the medical device synched with TF Chapter 4.2.5
  ○ Reference of mail info@sycaitechnologies.com replaced with a link to service desk platform
	24/04/2024	007

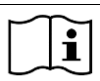
Eight version • Updated chapter 6 with new metrics from SWR2.3.0 • Chapter 2.1: warnings updated according to requirements (REQ_SAFETY_WARN category) from R-008-002. • Chapter 2.1: Alert included regarding accessory RAIM viewer (accessory) • Chapter 2.3: updated with the link of Raim viewer's IFU and with its specifications • Chapter 2.7: updated including accessory. • Chapter 3: inclussion references to accesory.	15/05/2024	008
Nineth version • Updated chapter 6 with new metrics from SWR2.4.0 • Update chapter 2.1: included warnings from CC-109	19/06/2024	009
Tenth version Updated chapter 2.6 Clinical benefits in order to align them with the last revision of TF_SYCAI MEDICAL_ANNEX_19_CER_24_007, chapter 4.9 (This change has been monitored throughout CC-109)	26/06/2024	010

Written by:	Reviewed by:	Approved by:
 COO 26/6/24	 PRRC 26/06/2024	 26/06/2024 CEO

2. General information

	Medical device manufactured in Spain
	Medical Device Software
	SYCAI Medical®

2.1. Alerts and warnings

	**Read the instructions for use before using this product**
	**Precautions and alerts** • Patient management decisions should not be based solely on test results of SYCAI Medical®. • This equipment must have connectivity with the PACS where the studies are stored. • SYCAI Medical is intended to be used with the following accessories: RAIM VIEWER 2.8 (SNXXXX2.8)(link to its Instructions for Use) In case of observing an incorrect operation of the medical device, notify the manufacturer as soon as possible: support@sycaitechnologies.com. The manufacturer will proceed accordingly. Any serious incident must be reported to SYCAI TECHNOLOGIES S.L. as well as the National Competent Authority of the country. **Undesirable side effects** No undesirable side effects specifically related to the use of the software are known or anticipated.
	Targeted patients SYCAI MEDICAL is intended to be used with adult patients (18 years old and above). SYCAI MEDICAL is intended to be used with all patients undergoing an abdominal CT imaging test. **Inclusion criteria for patients** • Patients older than 18 years old. • Patients of both sexes. • Patients who have undergone an abdominal CT scan.

	Exclusion criteria for patients • Patients younger than 18 years old. • Pregnant women. • Patients with pancreatectomy. • Abdominal CT images showing less than 40% of the pancreatic cystic lesion. • Abdominal CT images with poor image quality, blurred or defective image. • Abdominal CT images with the presence of metal/radiopaque material. • Abdominal CT images with rotated patients (>10 ˚). • Abdominal CT images with movement stripes.

The warnings that this product can offer to the user are listed below:

- In case the product detects that there is no internet network a warning to the user shall appear informing about it with the message: "Issue accessing internet or the selected study", otherwise the message should be empty
- In case the product detects an unknown configuration issue that prevents its execution a warning to the user shall appear informing about it with the message: "Technical configuration issue found. Execution is prevented"
- In case the product detects a lack of available RAM memory that prevents its execution a warning to the user shall appear informing about it with the message: "Not enough RAM memory available to execute the product".
- In case the product detects that no GPU is available a warning to the user shall appear informing that it may slow down the speed of the execution with the message: "GPU found". Otherwise, the message shall be "GPU not found. CPU used for the execution. This may make the product run slower".
- In case the product detects an unknown configuration issue that prevents its execution a warning to the user shall appear informing about it with the message: "Technical configuration issue found. Execution is prevented"
- "In case the product detects that the required DICOM metada is not available and prevents its execution a warning to the user shall appear informing about it with the message following message: "Image Orientation Found: YES" if the metada ImageOrientation is present, otherwise the message should be "Image Orientation Found: NO".
- 8_1 In case the product detects that the study is not axial and prevents its execution a warning to the user shall appear informing about it with the message "Axial: YES". If it is not axial, the message should be "Axial: NO".
- In case the product detects that the image quality of the study is low (metal artifacts were detected, e.g.) a warning to the user shall appear informing about it with the message: "Artifact: YES", otherwise the message should be "Artifact: NO".
- In case the product detects that the DICOM study has not a Series defined or the product cannot understand it a warning to the user shall appear informing that the series with a higher number of slices is selected for the execution with the message: "The SeriesDescription field is empty. The Series found with maximum number of slices and axial is selected for the execution of the product"

- In case the product cannot find the classification model and prevents its execution a warning to the user shall appear informing about it with the message: “Classification Model Found: YES“, otherwise the message should be “Classification Model Found: NO“.
- The product warns the user about the type of lesions that can be detected by the product with the message: "The product classifies pancreatic lesions into two groups: Mucinous lesions (limited to IPMN and MCN) Non-mucinous lesions (limited to SCN/SCA and pseudocysts)The product excludes classification into additional categories or subgroups of cysts.""
- The product warns about the certainty of the classification model: “The probability regarding the classification is too low. The product cannot properly classify this lesion. Please review the study manually.”
- The product warns about the final classification given by the product: “Please be aware that a classification of non-mucinous does not mean that the lesion will not become malignant. Please do not base the diagnosis of this patient solely on the outcome provided by SYCAI MEDICAL”

2.2. Contraindications

No contraindications are known or anticipated for intended users.

2.3. Previous considerations

All users must read the entire Instructions for Use before using SYCAI Medical® software. The product must be used only by qualified and trained personnel.

SYCAI Medical® is designed for the exclusive use of professional users. The software is intended to assist healthcare professionals in diagnosis and cannot fully replace their clinical judgment.

The software should only be used integrated in the PACS denominated RAIM Viewer, version 2.8 (here can be found its Instructions for Use)

Any serious incident occurred in relation to the device shall be reported to the manufacturer by sending a mail to support@sycaitechnologies.com specifying in the head of the mail the name of the Hospital, the name of the PACS and its version.

The user can always request the manufacturer a paper copy of this document by sending an email to support@sycaitechnologies.com. The receipt of this copy shall not take longer than 7 natural days.

The electronic copy of this document (eIFU) is available in the website of the manufacturer under the link provided in the installation package of the product SYCAI Medical®. All previous versions of this document are available under the same link.

The eIFU can be downloaded in pdf-format from the provided link. It can be open with any commercial or free program for visualizing pdf files, such as Adobe Reader, e.g.

The useful life of this software is set at 5 years. SYCAI Medical® meets the requirements of Regulation2016/679/EU of the European Parliament and of the Council of April 27, 2016 on the protection of individuals in relation to the processing of personal data and on the free circulation of said data.

SYCAI Medical® has a series of standard acquisition protocols that guarantee the quality of the input images and the processed data. Otherwise, SYCAI Medical® algorithms may fail if any of the following image quality indicators are not present: no signs of image blur, absence of metal/radiopaque artifacts, absence of movement stripes, and no rotation of the selected patient. Therefore, the user should use standard image acquisition protocols such as those suggested by SYCAI Medical® to obtain reliable results.

SYCAI Medical® software complies with the DICOM 3.0 standard, a format that allows the exchange of medical images. DICOM is a standard format for encoding and transmission of medical images. SYCAI Medical® is interoperable with all the systems that meet this standard. In hospitals and health center facilities, SYCAI Medical® is interoperable with most CT modality machines and PACS systems through the DICOM communications protocol.

In case an input study has several phases made by the radiographer at the moment of the image acquisition, SYCAI Medical® will process just one of those phases according to the following prioritization:

1. In the Series Description of the DICOM it is specified that the test belongs to a “Pancreas” phase test
2. In the Series Description of the DICOM it is specified that the test belongs to a “Thorax 60s” phase test
3. In the Series Description of the DICOM it is specified that the test belongs to a “Venous” phase test
4. In the Series Description of the DICOM it is specified that the test belongs to a “Portal” phase test
5. In the Series Description of the DICOM it is specified that the test belongs to a “Arterial” phase test
6. In the Series Description of the DICOM it is specified that the test belongs to a “Abdominal” phase test
7. In the Series Description of the DICOM it is specified that the test belongs to a “Thorax 31s” phase test
8. In the Series Description of the DICOM it is specified that the test belongs to a “Lung” phase test
9. In the Series Description of the DICOM it is specified that the test belongs to a “Mediastinum” phase test

The requirements and specifications listed in this chapter belong to the required conditions and capabilities of the accessories (defined in chapter 3 of this document) for a successful execution with the medical device SYCAI Medical®.

Technical specifications and requirements for SYCAI Medical®:

- The PACS where SYCAI Medical is installed shall have Internet access.

- The PACS where SYCAI Medical is installed shall have publicly/internet exposed endpoint to receive the results from the cloud.
- The PACS where SYCAI Medical is installed shall be Linux OS (Ubuntu 22.04 or higher): superuser permissions are needed.
- The PACS where SYCAI Medical is installed shall have at least 16 GB of available RAM, preferably 32 GB or higher.
- The PACS where SYCAI Medical is installed shall have 64 bits processor (i.e. i5 6500 or higher). It shall be compatible with CPU Virtualization.
- The PACS where SYCAI Medical is installed shall have preferably a 4GB NVIDIA cuda-compatible graphics card. In case GPU is not available, preferred configuration is Intel CPU from 6th. to 13th. generation.
- The PACS where SYCAI Medical is installed shall have available Hard disk (HDD) memory of 10GB
- The PACS where SYCAI Medical is installed shall be compatible with docker: docker shall be installed in the server. Docker compose functionality will be required for the installation.
- The PACS server where SYCAI Medical is installed shall have a Virtual Machine (VM) enabled for SYCAI TECHNOLOGIES SL . Regarding the remote access 8desire): VPN/AD accounts must be setup to access the customer server through VPN/Remote desktop.
- The following ports shall be opened in the VM:3000, 80, 8042.
- The PACS provider shall install the SSL/TLS/HTTPS certificates given by SYCAI TECHNOLOGIES SL
- the following DICOM metadata are necessary to exist to not prevent the execution of the product:
    - 0008,0060 (Modality)
    - 0010,0020 (PatientID)
    - 0020,0013 (InstanceNumber)
    - 0020,000e (SeriesInstanceUID)
    - 0020,0037 (ImageOrientationPatient)
    - 0008,103e (SeriesDescription)
    - 0010,0030 (PatientBirthDate)
    - 0010,1010 (PatientAge)
    - 0008,0020 (StudyDate)
    - 0018,0050 (SliceThickness)
    - 0028,0030 (PixelSpacing)

Requirements for the viewer for a successful installation:

- The viewer shall have Windows OS (version 10 or higher) or Linux OS (Ubuntu 22.04 or higher)
- The viewer shall allow the visualization of PDF or DICOM-SR (structured report) generated by SYCAI Medical.
- The viewer shall allow the visualization of PDF or Word-format documents with sufficient resolution to be readable by the user (resolution of 1024x768 or higher).
- The viewer shall have an Intel, AMD 1GHz or faster processor.
- The viewer shall be controlled by a graphic card with at least 1GB of RAM.
- The viewer shall have a network card of at least 1Gbps.

The software requirements are:

- Supported browsers:
  - Mozilla Firefox.
  - Google Chrome.
- Operating system:
  - Windows Server 2012 or higher.
  - Ubuntu 22.04 or higher

Compatible viewers with SYCAI Medical®:

SYCAI Medical® is fully compatible with RAÏM viewer. If you have questions about the compatibility of your viewer with SYCAI MEDICAL please feel free to contact us.

2.4. Intended use

SYCAI Medical® is a medical device software, based on artificial intelligence, that assists radiologists in the detection and characterization of radiological findings in the pancreas on CT scans of adult patients.

2.5. Intended users

The intended users are radiologists.

2.6. Clinical benefits

SYCAI MEDICAL assists radiologists in the detection and classification of pancreatic cystic lesions (PCLs) presented in medical images.

The software categorizes detected lesions into three groups:

1. Mucinous lesions: limited to intraductal papillary mucinous neoplasm (IPMN) and mucinous cystic neoplasm (MCN).
2. Non-mucinous lesions: limited to serous cystic neoplasm or serous cystadenoma (SCN or SCA) and pseudocyst (PCYST).
3. Indeterminate: when the software has less than 70% certainty in distinguishing between mucinous and non-mucinous PCLs.

SYCAI Medical's analysis does not extend to other categories or subtypes of cysts.

SYCAI MEDICAL offers the following clinical benefits:

- Increases the identification of incidental findings.
- Enhances classification precision.
- Reduces the number of cases classified as indeterminate.

2.7. Intended environment.

The intended environment encompasses radiodiagnosis centers, hospitals, healthcare clinics, pharmaceutical companies, and teleradiology companies that utilize the accessories required by SYCAI Medical.

3. Technical characteristics and specifications

SYCAI Medical® applies artificial intelligence and advanced computational models to radiology images to objectively measure the changes produced by a lesion, offering additional quantitative information to the qualitative approach of radiology.

SYCAI Medical® software identifies and classifies the lesions present in the input imaging tests between mucinous ones or with more malignant potential and non-mucinous ones, providing this information to the user. This product is intended to be used in combination with an existing PACS in which SYCAI Medical® is integrated.

Along with this classification, SYCAI Medical® can offer the following information:

- Size of the cystic lesion.
- Modality of the imaging test (CT scan).
- Location of the found lesion (head, body or tail of pancreas).
- Presence of calcifications
- Patient follow-up report: it tabulates the previous information regarding the cyst detected in the different successive imaging tests found for the patient. In this way, the information regarding the relative growth of the lesion is standardized throughout the follow-up performed on the patient.

All this information is intended to assist the radiologist who uses the tool in the analysis of the patient's medical image, seeking to maximize the incidental findings of these lesions and increase the detection of lesions with malignant potential.

SYCAI Medical® integrates with the customer's PACS (Picture Archiving and Communication System), which is an accessory for SYCAI Medical's proper performance (refer to chapter 4.11 Accessories).

Its execution is not conditioned to a manual trigger by the user, but it is automatic after the creation of a static cross-sectional image test performed on a patient that is coded as:

- Abdominal (or equivalent) CT
- Thoracoabdominal (or equivalent) CT
- Abdominopelvic (or equivalent) CT
- Pancreatic (or liver) CT
- Uro-CT (or equivalent)
- Abdominal (or equivalent) scanner

After the execution of SYCAI Medical® on the input medical image test a user-alert will be generated. This will be in the shape of a pop-up that contains the following information:

- Patient name
- Study date and description
- Type: type of lesion found by Sycai (NM: non-mucinous. MUC: mucinous)
- A link to the automatic generated report containing:
    - o The ID code of the patient
    - o The age of the patient
    - o The gender of the patient
    - o A table of all the studies found of that patient and the output of the product for each of them. This table summarizes:
        - the Study date
        - Modality of the study (CT)
        - Major axis (measurement of the 2D major axis of the detected lesion on its middle slice)
        - Location of the detected lesion (head, body or tail)
        - Presence of calcifications in the lesion (yes or no)
        - Final classification of the detected lesion (Non-mucinous or mucinous)

    - o An axial image of the imaging study where the detected lesion is more visible to assist the radiologist in its diagnosis.
    - o A graphic showing the evolution of the lesion size through all the patient studies found.

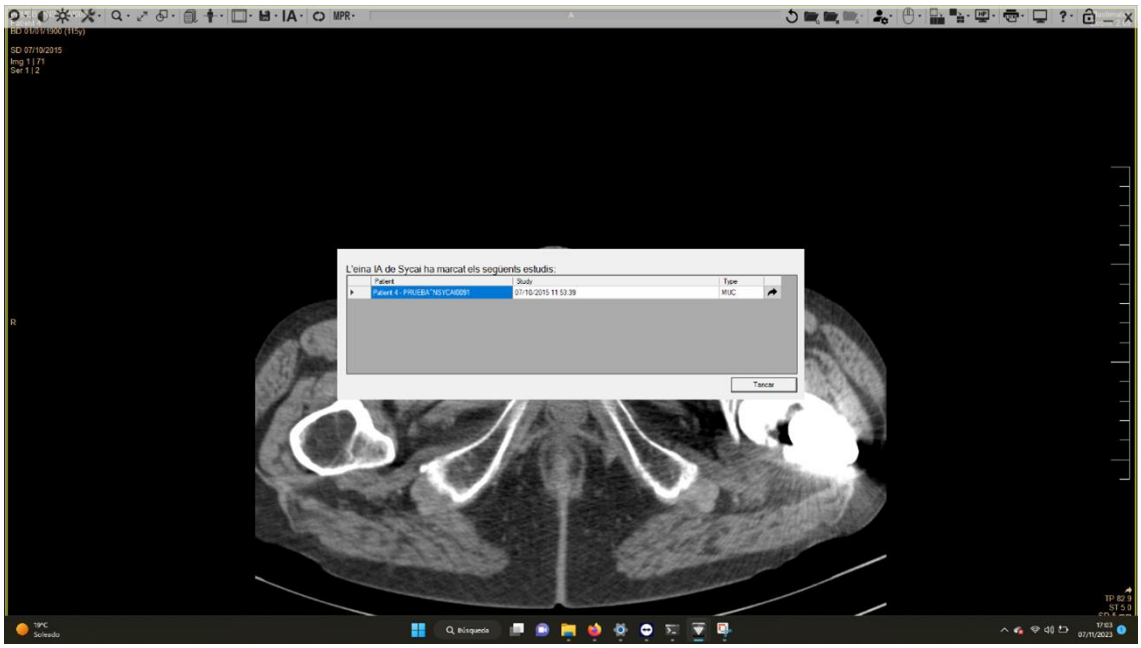


Figure 1: Example of the pop-up that appears when opening a study where SYCAI Medical® has found a lesion. The button with the arrow is the link to the automatic report.

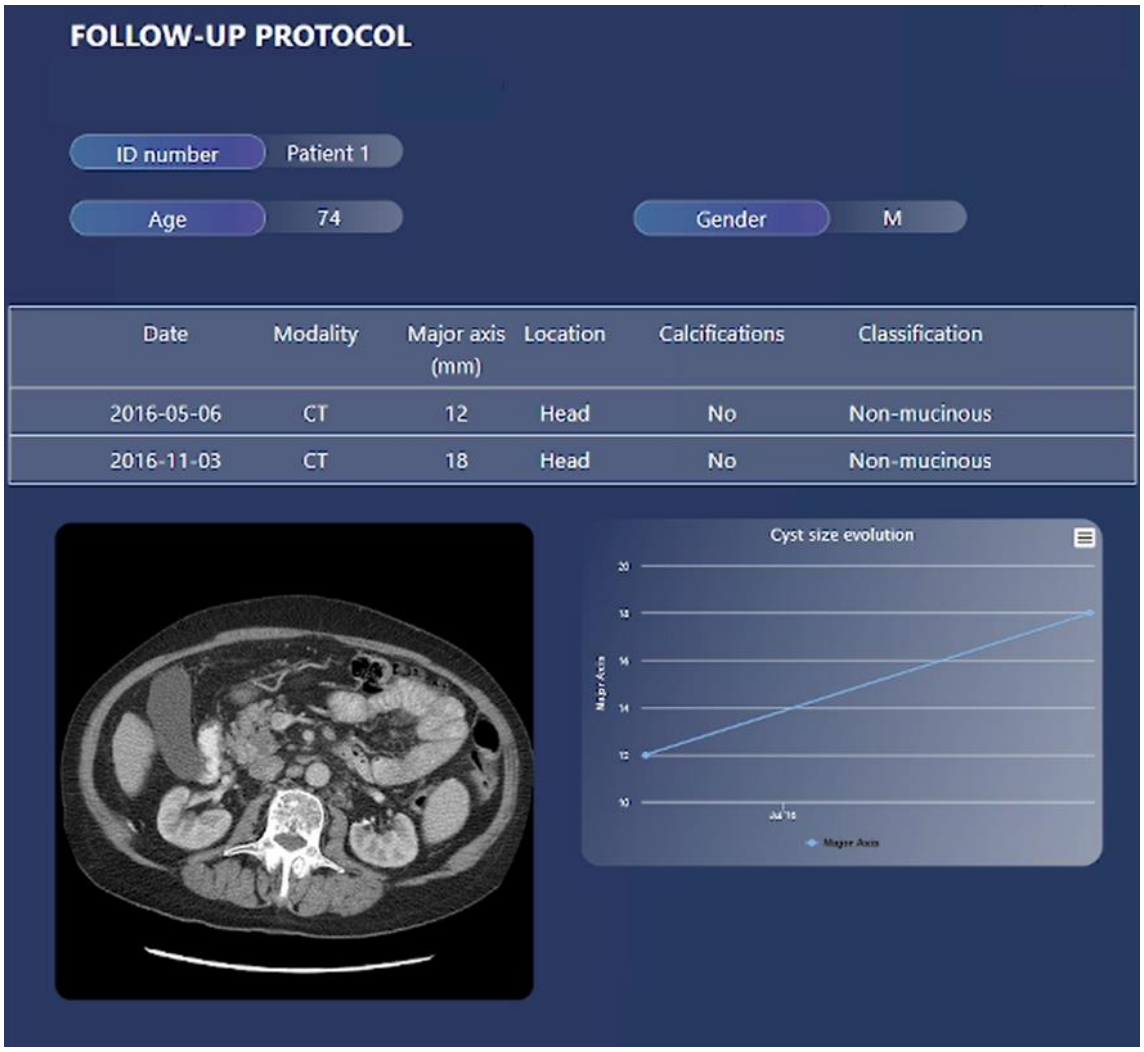


Figure 2: Example of the report that is generated and accessed through the pop-up. This report has underneath the information shown the label of the product, containing the UDI Number as well as the product version.

4. How to use

SYCAI Medical® functions as a software as a medical device, operating exclusively within the context of Picture Archiving and Communication System (PACS) integration. Access to the software is facilitated by logging into the PACS using the radiologist's regular user credentials, including the associated username and password.

The steps to review the results of SYCAI Medical® are the following:

1. Log in to the PACS
2. Click on "Selection of Studies," and you will be automatically directed to the "Consultation" sheet. Click again on "Selection of Studies," where the user can search for a patient to open an imaging study. This can be done by searching via History number, patient name, study date, patient ID, Series description, or study modality. Once you've found a study, double-click on it to open it in the PACS viewer.

3. If SYCAI Medical® has found a lesion in the selected study, a pop-up will automatically appear, similar to Figure 1. If no lesion has been found, no pop-up will appear. To open the report generated by the product, click on the button with an arrow located within the pop-up.

Alternatively, the user can manually trigger the product to display the pop-up by clicking on the button “IA” and then “Sycai Medical alerts” button on the upper menu. This will list all the lesions found for the selected study, and clicking on the available alerts will redirect the user to the generated report by SYCAI Medical®.

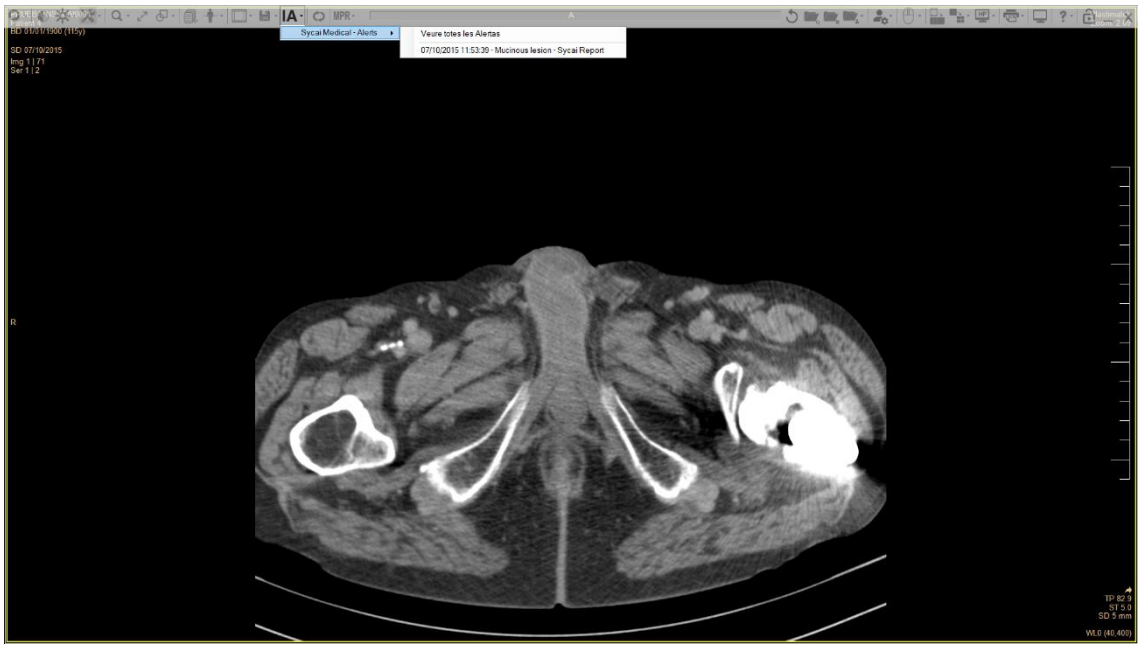


Figure 3: IA button on the upper menu to access the report/s generated by SYCAI for the selected case/s

5. Introduction

This manual is the user guide for SYCAI Medical®, software developed, marketed, and owned exclusively by SYCAI TECHNOLOGIES S.L. It provides information for a better understanding and, therefore, for a better use of the software SYCAI Medical®.

This document is intended to be a practical usage guide to help users understand and use the SYCAI Medical® software platform and workflow integrated in the PACS denominated RAIM Viewer, developed and commercialized by Hospital Parc Taulí and UDIAT (Unitat de Diagnostic per la Image).

To achieve this goal, this document contains a complete explanation of the views and features that users can use. It also includes flowcharts on how to achieve the most common uses.

5.1 Acronyms and glossary

Acronyms	
DICOM	Digital Imaging and Communications in Medicine
MR	Magnetic Resonance
HTML	Hypertext Markup Language
CSS	Cascading Style Sheets
CT	Computerized tomography
PET	Positron Emission Tomography
PACS	Picture Archiving and Communication System
ROI	Region of Interest
CSV	Comma Separated Value
XLS	Microsoft Excel spreadsheet file
PDF	Portable Document Format
DWI	Diffusion Weighted Imaging
HU	Hounsfield Unit
MSIE	Microsoft Internet Explorer
AUC	Area Under Curve

Glossary	
The user	Radiologists
The administrator	User with administrative privileges who can access (view and modify) the studies and analyzes of other users.

5.2 Way of use

ICONS	
	Button to access the generated report by SYCAI Medical® on demand. It will list all the alerts or reports generated by the product for the selected study and allow the user to click on them and open the report.
	Zoom in or zoom out.
	Rendering of the sagittal and coronal views corresponding to the axial one shown by default.
	The upper menu with this buttons shows up when approaching the mouse to the upper side of the screen. By click this button, the bar with these buttons will remain fix and always visible.
	It allows the user to save the opened DICOM serie/s as an image or as a video file
	It allows the user to print the screen

	It allows the user to change the monitor configuration (in case it is working with more than one)
	It allows the user to visualize the whole DICOM study as a movie that can be paused, moved backwards or forwards.
	Change the point of view of the viewer
	Button to apply a modification made on a single image to all images of the study or not
	Draw annotations on the DICOM study selected, create measurements between selected points, draw circles or other geometric figures to highlight a specific part.
	Draw a measurement between two points.
	Close the selected study
	Choose which actions shall be performed with each click of the left, right and central buttons of the mouse
	Selection of studies: option to open up the studies searcher and select one or more.
	Change the user's configuration to edit the default information shown when logging in.

6. PRODUCT INFORMATION

SYCAI Medical® is a medical device software designed for CT scans. It has demonstrated a sensitivity of 96.3%±1.3 and a specificity of 84.5%±2.6 in CT scan imaging tests for the detection of pancreatic cystic lesions, as well as an accuracy of 85%±3.1 in the classification of the detected lesions between mucinous and non-mucinous, with a Positive predictive value for the classification of mucinous lesions (PPV) of 92.6%±3.2 and negative predictive value (NPV) of

82.1%±4.7. The false negative rate in the detection is 3.7%, which indicates the ratio of lesions missed by the product compared to the ones found by radiologists during the clinical evaluation.

The sensitivity in the classification of mucinous lesions is 89.7%±1.2, the specificity in the classification in mucinous lesions is 86.8%±1.1.

The sensitivity in the classification of non-mucinous lesions is 75.4%±1, the specificity in the classification in non-mucinous lesions is 96.2%±1.2.

The amount of cases from the internal validation set determined as class "indeterminate" by the product is 15.7%, given "indeterminate" as a classification certainty by the model below 70%.

Moreover, the product has demonstrated the following metrics in the detection of some features of the pancreatic cystic lesions:

- Accuracy in the detection of scars on detected lesions (measured on 160 studies): 76.0%±3.0%
- Accuracy in the detection of calcifications on detected lesions (measured on 160 studies): 75.0%±3.1%
- Accuracy in the detection of the correct location of detected lesions (measured on 160 studies) separated in head, body or tail of the pancreas: 81.2%±2.8%

All confidence intervals provided with these metrics are calculated following the method "95% confidence intervals" with a standard z-score of 1.96 selected from the state-of-the-art.

These metrics were obtained during a clinical validation involving external validation from up to four different Hospitals and clinics from several cities, which included up to 414 patients and

760 studies of CT scan protocols as defined in Section 2.3 (Abdominal, thoracoabdominal, abdominopelvic, Pancreatic, uro-CT, and abdominal scanner or equivalent).

The terms of sensitivity and specificity as well as positive predictive value (PPV) and negative predictive value (NPV) are to be understood as:

$$S = \frac{TP}{TP + FN}$$

$$Sp = \frac{TN}{FP + TN}$$

$$PPV = \frac{TP}{TP + FP}$$

$$NPV = \frac{TN}{TN + FN}$$

Where:

- S: Sensitivity
- Sp: Specificity
- PPV: Positive predictive value
- NPV: Negative predictive value
- TP: true positive (the product accurately identified a lesion in a patient who did indeed have one)
- FP: False positive (the product detected a lesion in a patient who, according to the diagnosis, did not actually have one)
- TN: true negative (the product correctly identified the absence of a lesion in a healthy patient)
- FP: False positive (the product erroneously identified the absence of a lesion in a patient who had been diagnosed with one)

6.1 Preventive and regular maintenance

While there are no frequent updates scheduled, any maintenance activity or installation of newer versions will be communicated through the distributor (same distributor involved in the installation of the current version). If you want to contact the manufacturer and submit an issue or a question, you can do it through the Service Desk Platform of SYCAI TECHNOLOGIES SL:

https://sycai-technologies.atlassian.net/servicedesk/customer/portal/4

7. DATABASE INFORMATION

7.1 Training database information

The training database used for the clinical trial included a total of over 60000 images of CT scans that belong to the following proportion of diagnosed / non-diagnosed patients:

- Studies with mucinous lesions: 48%
- Studies with non-mucinous lesions: 40%
- Control studies: 12%

The distribution of studies included in the training database can be illustrated as follows:

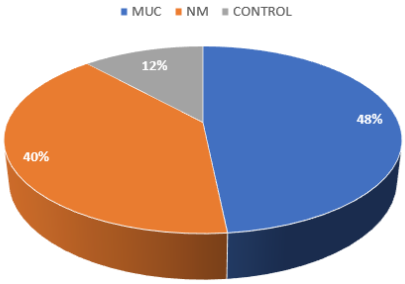


Figure 4: Distribution of studies with mucinous lesions, non-mucinous lesions and controls for the generation of the training dataset