INSTRUCTIONS FOR USE (IFU)

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CE
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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
Eleven version **SWR 2.4.1 (CC-118)** • Manufacturer´s address updated	25/09/2024	011

• CE symbol not “drafted” any longer		
Twelfth version **SWR 2.5.0 (RAQA-219)** • Updated according to latest version of SYCAI MEDICAL	13/03/2025	012

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2. 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 and workflow integrated in a PACS.

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 intended use of the product.

2.1 Acronyms and glossary

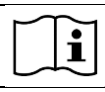
Acronyms	
DICOM	Digital Imaging and Communications in Medicine
MR	Magnetic Resonance
HTML	Hypertext Markup Language
CSS	Cascading Style Sheets
CT	Computerized tomography
PET	Positron Emission Tomography
PACS	Picture Archiving and Communication System
ROI	Region of Interest
CSV	Comma Separated Value
XLS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

Glossary	
The user	Radiologists

3. General information

	Medical device manufactured in Spain
	Medical Device Software
	SYCAI Medical®

3.1. 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. • Please note that the circled lesion is provided as a reference only • Please be aware that SYCAI MEDICAL only processes CT Scans of available studies in the PACS where it is currently installed and only that studies will be shown in the summary table presented in the report. • Please be aware that SYCAI MEDICAL's report presents a graphic diagram of a pancreas that changes in color depending if any lesion was found by the product (orange) or not (grey), regardless of its classification. • Please be aware that the cover page of the report shows the total number of lesions detected by the product on the current CT scan being analyzed. • Please note that changes in the size shown in the summary table of the report may result from the natural evolution of the findings over time, including their merging or fusion. • The product and the PACS communicate using DICOM protocol. The product SYCAI MEDICAL processes and generates DICOM compliant files • Please be aware that the circle shown in the image of the report represents the area where the finding was detected but its size and contours do not necessarily match with the detected finding. • Please be aware that the positive values shown in the "evolution vs prior" row of the generated report imply a growth in size of the finding measured in current CT scan compared to the immediate last one. 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 an unknown configuration issue that prevents its execution a warning to the user shall appear informing about it

- 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 metadata is not available and prevents its execution a warning to the user shall appear informing about it with the message following message: “Image Metadata Found: YES” if the metadata is present, otherwise the message should be “Image Metadata Found: NO”.
- 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 was not able to detect the pancreas and therefore no lesion could be detected a warning to the user shall appear informing about it
- 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 shall warn the user about the type of findings that can be detected by the product with the message:
    - The product classifies pancreatic findings 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.""
    - 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
    - The probability regarding the classification is too low. The product cannot properly classify this lesion. Please review the study manually

- When the product shall include in the summary table more than 8 findings the table shall not be shown and in substitution the following warning shall be included: “Summary table cannot be shown since more than 8 findings are present. Please review this report manually“
- When the product shall include in the summary table more than 4 columns belonging to dates, the table still be shown and the following warning shall be included: “Summary table can only show the 4 most recent CT scans belonging to the patient“
- In case the product does not detect a finding on the current and on the immediate prior CT scan, no row for that will be included in the summary table. The following warning shall always be present to alert the user about it “The summary table does not include any finding when it was not found on the current nor the immediate prior CT scan“
- In case there is a problem accessing (reading or writing) or managing the internal product’s database the following warning shall appear: “Access to internal database failed. Product execution is compromised.“
- In case the input data to the product is not DICOM compliance the following warning to the user shall be created: “The input data is not DICOM compliant. Execution is prevented.”
- In case the product’s output is not compliant with the DICOM standard and no report can be shown, the following warning shall appear: “The generated product output is not compliant with DICOM standard. Product execution is prevented“
- In case there is a problem in the communication between the product and the PACS the following warning shall appear: “Communication with the PACS failed. Product execution is prevented.“
- In case there is a problem in the report generation, the following warning to the user shall appear: “The product was executed but the report generation failed. Please contact your distributor for this medical device“
- The result of the product classification of the detected findings shall be stored in a message saying as follows: ‘Class:’ followed by the mentioned list. In case one findings is categorized as mucinous, the list should include “Finding ID: M”, if the finding is categorized as non-mucinous the list should include “Finding ID: NM”. If the category cannot be determined, the list should include “Finding ID: I“. If the classification cannot be executed due to any technical problem the message should be: “Class: NC”.
- This message shall only appear when findings were discovered in prior studies of the patient but not in current: "Please be aware that findings were detected by SYCAI MEDICAL on prior studies although not in current one. Consider reviewing this case manually".
- The following information shall be presented to the user in the IFU: “Please note that the circled lesion is provided as a reference only“

- The following information shall be presented to the user in the IFU: “Please be aware that SYCAI MEDICAL only processes CT Scans of available studies in the PACS where it is currently installed and only that studies will be shown in the summary table presented in the report.“
- The following information shall be presented to the user in the IFU: “Please be aware that SYCAI MEDICAL’s report presents a graphic diagram of a pancreas that changes in color depending if any lesion was found by the product (orange) or not (grey), regardless of its classification.”
- The following information shall be presented to the user in the IFU: “Please be aware that the cover page of the report shows the total number of lesions detected by the product on the current CT scan being analyzed.”
- The following information shall be presented to the user in the IFU and in the label: "Please note that changes in the size shown in the summary table of the report may result from the natural evolution of the findings over time, including their merging or fusion."
- The following information shall be presented to the user in the IFU and in the label: "The product and the PACS communicate using DICOM protocol. The product SYCAI MEDICAL processes and generates DICOM compliant files.".
- The following information shall be presented to the user in the IFU: “Please be aware that the circle shown in the image of the report represents the area where the finding was detected but its size and contours do not necessarily match with the detected finding”.
- The following information shall be presented to the user in the IFU: “Please be aware that the positive values shown in the “evolution vs prior” row of the generated report imply a growth in size of the finding measured in current CT scan compared to the immediate last one”.
- The following information shall be presented to the user in the IFU: “Please be aware that the cover page can contain a pancreas symbol in grey (meaning no findings in current CT) but could still have findings included in the report belonging to prior CT scans of the same patient”.
- The following information shall be presented to the user in the IFU: “Please note that when the product did not locate a finding in the current CT nor the prior (if applies), the attached report will consist on a cover page and a label”.

3.2. Contraindications

No contraindications are known or anticipated for intended users.

3.3. 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.

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 for interoperability (defined in chapter 3 of this document) for a successful execution of 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 . It is desired to access remotely to assist in the installation: 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)

To ensure interoperability between SYCAI Medical® and PACS, SYCAI Medical® undergoes rigorous internal testing, verification, and validation for DICOM compliance, guaranteeing compatibility with any system adhering to the DICOM protocol.

3.4. 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.

3.5. Intended users

The intended users are radiologists.

3.6. 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.
- Monitors changes in lesion size over time through longitudinal tracking.

3.7. Intended environment.

The intended environment encompasses radiodiagnosis centers, hospitals, healthcare clinics, pharmaceutical companies, and teleradiology companies that utilize a DICOM-compliant system where interoperability is ensure.

4. 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.

The execution of SYCAI Medical® 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)

After the execution of SYCAI Medical® on the input medical image test a two DICOM Series will be generated and attached back into the PACS. One Series is a DICOM Secondary Capture (SC) containing the product's report and the outcome of the product in a standard way. The other Series is a DICOM-SR (Structured Report) which contains warnings, execution information and other. The following information will be presented to the user within the DICOM-SC Series.

Front Page: Displays patient information and a summary of detected findings.

- Patient ID
- Study Date
- Number of findings detected within the current CT scan

- Pancreas symbol that is coloured with orange or grey depending on if at least one finding was detected

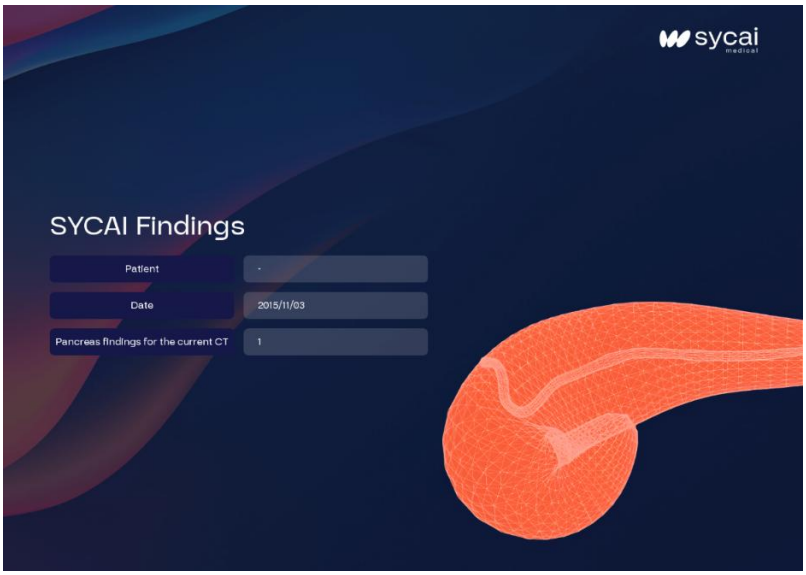


Figure 1: Example of cover page. Patient ID, Study date and number of pancreas findings are included as information to the user. Moreover, the pancreas changes color from orange (if finding is detected) to grey (if not finding is detected).

Summary Section:

- If the patient has previous CT scans, up to **four prior studies** are retrieved for comparison. A maximum of 8 findings can be found in the mentioned table.
- Information about lesion size evolution is included.

These are presented in a table with:

- Study date of the current and previous CT scans
- Measurement of the major axis (in axial in 2D) for each of the findings in each of the available CT scans
- A warning symbol if a finding changed its size over 5mm (measured in the major axis on the axial plane) in the last 2 years, a notification symbol will be presented along with the major axis measurement to alert the user about such worrisome feature.
- If any finding present in past studies is no longer available in the current one, it will be presented in the table as ND (not detected).
- If a finding was not detected by the product in the immediate prior study nor on the current, it won't be displayed in the summary table.

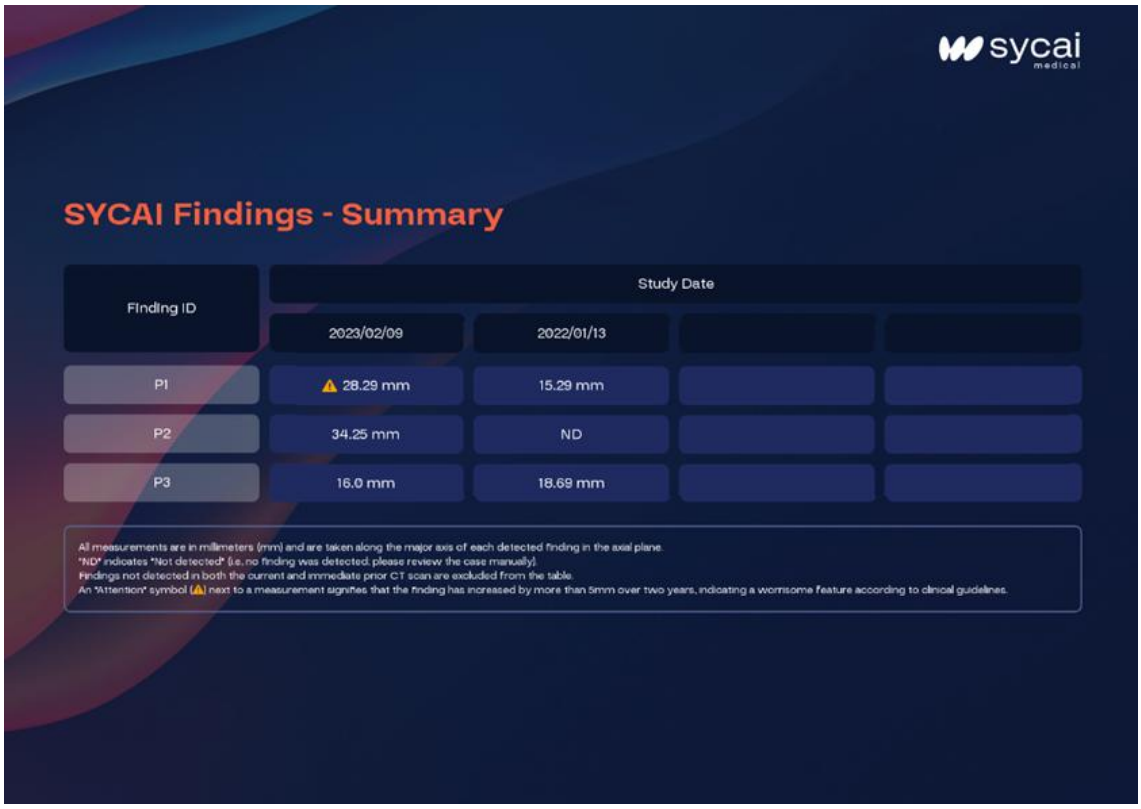


Figure 2: Example of summary table included in the second page of the report. Please note that this table covers up to the last 4 available CT scans of the same patient available in the PACS and can cover up to 8 Findings.

Findings Details Section: For each detected lesion, the following information is provided:

- **Series number / Slice number** where the lesion is located.
- **Position** (head, body, or tail of the pancreas).
- **Volume (mm^3)** and **major axis (mm)** measurements.
- **Evolution vs. prior CT** (if applicable).
- **Calcification** within the finding: yes /no
- **Classification:** mucinous, non-mucinous or indeterminate

These pages will compare prior and current study for the patient in case more than one CT scan for the patient is available in the PACS. In this case, these pages of the report will contain two images of the corresponding CT scan slices and the findings on them encircled. The table in these cases contains the same information as commented above but for the current and prior CT scan, for an easy and straightforward comparison for the user.

Figure 3: Example of the finding pages included in the report. This page can show one or two lesions depending if a prior study of the patient is found in the PACS. If a finding is appearing for the first time in the current test or is no longer detected it is shown in the report.

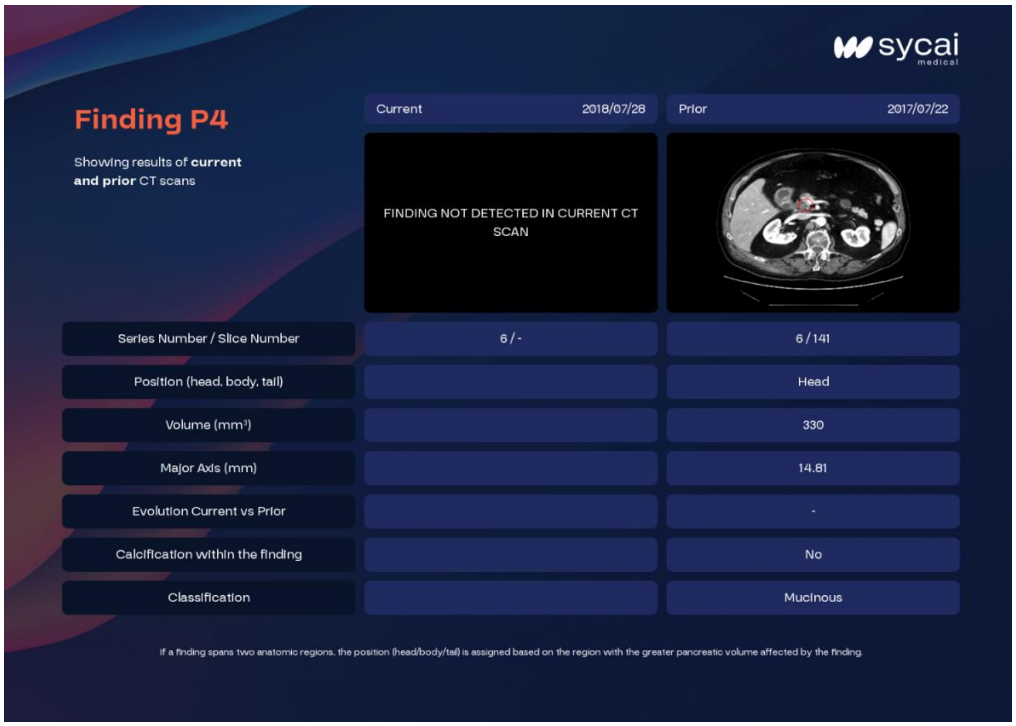


Figure 4: Example of the finding page when a finding was detected on the prior CT scan but not on current.

Final Page: Includes the label of the product.

5. 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 processed the selected study, a DICOM Series will have been attached in the PACS and will be reachable to the user by clicking on it.

Please be aware that SYCAI Medical® is triggered at the moment that the medical imaging study is stored in the PACS and does not require therefore an explicit manual triggering by the user.

6. PRODUCT INFORMATION

SYCAI Medical® is a medical device software designed for CT scans. It has demonstrated a sensitivity of 96.6%±1.1 and a specificity of 84.9%±2.2 in CT scan imaging tests for the detection of pancreatic cystic lesions, as well as an accuracy of 86%±2.2. 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 90%±0.9 and negative predictive value (NPV) of 77.3%±1.1. The false negative rate in the detection is 3.4%, 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 86%±0.9, the specificity in the classification in mucinous lesions is 88.1%±0.9.

The sensitivity in the classification of non-mucinous lesions is 77.3%±0.9, the specificity in the classification in non-mucinous lesions is 95.3%±0.9.

The amount of cases from the internal validation set determined as class “indeterminate” by the product is 15.4%, 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 calcifications on detected lesions (measured on 312 findings): 94.2%±2.5%

- Accuracy in the detection of the correct location of detected lesions (measured on 312 findings) separated in head, body or tail of the pancreas: 83.3%±4%
- Average deviation in finding size measurements: 15,8±3,9%
- Average deviation in finding volume measurements: 24,2±4,6%
- Accuracy in detecting alerts for findings that grow >5mm in less than 2 years: 86±3,7%
- Accuracy in the identification of the same finding in consecutive CT scans belonging to the same patient: 82,0±4,2%
- Average deviation in the delta percentage of size change: 16±4%

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 503 patients and 999 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 Safe disposal or 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

In the case of a product removal or update, the existing version of the software will be removed by the distributor and a new version will be then installed, if requested.

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:

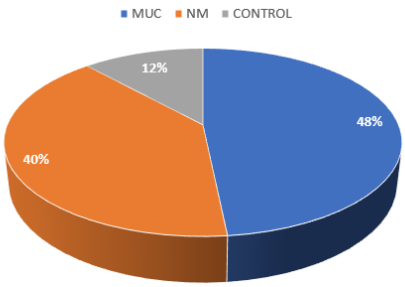


Figure 5: Distribution of studies with mucinous lesions, non-mucinous lesions and controls for the generation of the training dataset