



## INSTRUCTIONS FOR USE (IFU)

Version 013  
2025-12



2862

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## 1. Version control

Cause of the revision	Date	Version
<b>First version</b>	11/03/2022	001
<b>Second version</b> <ul style="list-style-type: none"> <li>Chapter 5. Warnings and precautions has been updated.</li> </ul>	24/03/2022	002
<b>Third version</b> <ul style="list-style-type: none"> <li>The table of chapter 2. General information has been updated regarding the UDI number.</li> <li>Section Precautions and alerts of chapter 2.1. Alerts and warnings have been updated.</li> <li>Content update on chapters 2.6. Clinical benefits, 3. Technical characteristics and specifications, and 4. How to use (adding Figures 5 and 6).</li> <li>Chapter 4. How to use updated: release notes icon.</li> <li>Chapter 5. Warnings and precautions have been updated.</li> </ul>	20/10/2022	003
<b>Fourth version</b> <ul style="list-style-type: none"> <li>NANDO code updated.</li> <li>Updated access circuit.</li> <li>Updated new contact mail.</li> <li>Removed reference to the 3D model.</li> <li>Updated references to the warning+URL visualization method.</li> </ul>	17/02/2023	004
<b>Fifth version</b> <ul style="list-style-type: none"> <li>2.1 to 2.3 has been updated according to the planned measures in R-006-001_045.</li> </ul>	01/09/2023	005
<b>Sixth version</b> <ul style="list-style-type: none"> <li>IFU SW integrated in PACS. Sycai Viewer removed</li> <li>Adapted IFU to RAIM Viewer PACS</li> <li><a href="#">CC-42</a>: Sens and Spec included in chapter 6.</li> <li>Included new requirements defined in European Regulation 2021/2226 for the electronic IFU.</li> <li><a href="#">CC-50</a>: 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)</li> <li>Updated the clinical validation chapter (chapter 6)</li> <li><a href="#">CC-72</a>: updated the intended use or purpose (chapter 2.4) +</li> <li><a href="#">CC-72</a>: chapters 2.1, 2.3 y 3 updated to remove reference to cross-sectional imaging and referencing CT scan images.</li> </ul>	27/11/2023	006

<p style="text-align: center;"><b>Seventh version</b></p> <ul style="list-style-type: none"> <li>• <a href="#">CC-89</a>: 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</li> <li>• <a href="#">CC-98</a>: <ul style="list-style-type: none"> <li>○ Chapter 6.1: included details of the nature and frequency of preventive and regular maintenance</li> <li>○ Changed date in the cover to make it compatible with ISO 8601-1</li> <li>○ Chapter 2.7: Include information on the use environment of the medical device synched with TF Chapter 4.2.5</li> <li>○ Reference of mail <a href="mailto:info@sycatechnologies.com">info@sycatechnologies.com</a> replaced with a link to service desk platform</li> </ul> </li> </ul>	24/04/2024	007
<p style="text-align: center;"><b>Eight version</b></p> <ul style="list-style-type: none"> <li>• Updated chapter 6 with new metrics from SWR2.3.0</li> <li>• Chapter 2.1: warnings updated according to requirements (REQ_SAFETY_WARN category) from R-008-002.</li> <li>• Chapter 2.1: Alert included regarding accessory RAIM viewer (accessory)</li> <li>• Chapter 2.3: updated with the link of Raim viewer’s IFU and with its specifications</li> <li>• Chapter 2.7: updated including accessory.</li> <li>• Chapter 3: inclusion references to accessory.</li> </ul>	15/05/2024	008
<p style="text-align: center;"><b>Nineth version</b></p> <ul style="list-style-type: none"> <li>• Updated chapter 6 with new metrics from SWR2.4.0</li> <li>• Update chapter 2.1: included warnings from <a href="#">CC-109</a></li> </ul>	19/06/2024	009
<p style="text-align: center;"><b>Tenth version</b></p> <p style="text-align: center;">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 <a href="#">CC-109</a>)</p>	26/06/2024	010
<p style="text-align: center;"><b>Eleven version</b> <b>SWR 2.4.1 (<a href="#">CC-118</a>)</b></p> <ul style="list-style-type: none"> <li>• Manufacturer’s address updated</li> </ul>	25/09/2024	011

<ul style="list-style-type: none"> <li>• CE symbol not “drafted” any longer</li> </ul>		
<p style="text-align: center;"><b>Twelfth version</b> <b>SWR 2.5.0 (RAQA-219)</b></p> <ul style="list-style-type: none"> <li>• Updated according to latest version of SYCAI MEDICAL</li> </ul>	13/03/2025	012
<p style="text-align: center;"><b>Thirteenth version</b> <b>SWR 2.6.0 (RAQA-316)</b></p> <ul style="list-style-type: none"> <li>• Updated according to latest version of SYCAI MEDICAL</li> <li>• <a href="#">CC-171</a>: <ul style="list-style-type: none"> <li>○ Chapter 8: Included new chapter to define the changes of current release compared to previous one</li> </ul> </li> </ul>	18/12/2025	013

<p>Written by:</p>  <p style="text-align: center;">Javier García 18/12/25</p> <p>COO</p>	<p>Reviewed by:</p> <p style="text-align: center;">Marta Parada 18/12/2025</p>  <p style="text-align: center;">PRRC</p>	<p>Approved by:</p>  <p style="text-align: center;">Javier García 18/12/25</p> <p>CEO</p>
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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 proper 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
CT	Computerized tomography
PACS	Picture Archiving and Communication System
PDF	Portable Document Format
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

	<p><b>Read the instructions for use before using this product</b></p>
	<p><b>Precautions and alerts</b></p> <ul style="list-style-type: none"> <li>• Patient management decisions should not be based solely on test results of SYCAI Medical®.</li> <li>• This equipment must have connectivity with the PACS where the studies are stored.</li> <li>• Please note that the circled lesion is provided as a reference only</li> <li>• 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.</li> <li>• 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).</li> <li>• 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.</li> <li>• 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.</li> <li>• The product and the PACS communicate using DICOM protocol. The product SYCAI MEDICAL processes and generates DICOM compliant files</li> </ul> <p>In case of observing an incorrect operation of the medical device, notify the manufacturer as soon as possible: <a href="mailto:support@sycatechnologies.com">support@sycatechnologies.com</a>. 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.</p> <p><b>Undesirable side effects</b> No undesirable side effects specifically related to the use of the software are known or anticipated.</p>
	<p><b>Targeted patients</b></p> <p>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.</p> <p><b>Inclusion criteria for patients</b></p> <ul style="list-style-type: none"> <li>• Patients older than 18 years old.</li> <li>• Patients of both sexes.</li> <li>• Patients who have undergone an abdominal CT scan.</li> </ul> <p><b>Exclusion criteria for patients</b></p> <ul style="list-style-type: none"> <li>• Patients younger than 18 years old.</li> <li>• Pregnant women.</li> <li>• Patients with pancreatectomy.</li> <li>• Abdominal CT images showing less than 40% of the pancreatic cystic lesion.</li> <li>• Abdominal CT images with poor image quality, blurred or defective image.</li> </ul>

	<ul style="list-style-type: none"> <li>• Abdominal CT images with the presence of metal/radiopaque material.</li> <li>• Abdominal CT images with rotated patients (&gt;10 °).</li> <li>• Abdominal CT images with movement stripes.</li> </ul>
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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 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
- 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 product may fail if any of the following image quality indicators are present:
  - signs of image blur
  - presence of metal/radiopaque artifacts
  - presence of movement stripes
  - rotation of the patient over 10° with respect to the machine longitudinal axis
- 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
  10. In the Series Description of the DICOM it is specified that the test belongs to a "Non-contrast" phase test
- SYCAI Medical operates integrated in the customer facilities' PACS (Picture Archiving Communication System) so that 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
  - 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".
  - 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.
  - 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 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.
  - The product automatically assigns a unique ID per finding which remains for all available CT scans of the patient.
  - The product presents the findings in the report ordered (from lower to higher) based on the unique ID assigned by the product.
  - The product can only detect findings in the pancreas with a major axis greater than 2mm measured in axial view and on the slice in which the lesion is more visible (bigger 2D area).
  - If the viewer allows it, the product has implemented a DICOM compatible synchronization method so that the user scrolls through the report pages and simultaneously the viewer displays the original CT image, at the corresponding Series and Slice number, indicated on each Follow-up page of the report.

- When compatible with the viewer, the product provides an overlay of the detected findings on the original CT scan. This feature can be hidden at the user's discretion.
- The overlay on the original CT will only appear in the CT series analyzed by the product
- The overlay on the original CT will only appear in the CT series analyzed by the product
- Dual energy image protocols shall not be processed by the product (reason: it affects dramatically the intensity distribution of the study and therefore performance. These protocols shall be excluded in a similar manner to colonographies).
- Please be aware that SYCAI MEDICAL is installed as an encrypted and compiled code to prevent potential cyberattacks or open vulnerabilities. The product utilizes safe and encrypted communication protocols to be protected against external attacks.

### **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@sycatechnologies.com](mailto:support@sycatechnologies.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@sycatechnologies.com](mailto:support@sycatechnologies.com). The receipt of this copy shall not take longer than 7 natural days.

The electronic copy of this document (eIFU) is available on 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 Regulation 2016/679/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 image quality indicators are not met. 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.

The requirements and specifications listed in this chapter belong to the required conditions for interoperability 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.
- For cloud-based installations, the client's infrastructure shall provide a publicly or internet-exposed DICOM endpoint to receive the results sent from the cloud.
- The PACS where SYCAI Medical is installed shall be Linux OS (Ubuntu 22.04 or higher): superuser permissions are needed.
- Sycai requires that the processing environment where the product is installed has at least 16 GB of available RAM when a compatible GPU is present. In cases where no GPU is available and the system relies solely on CPU processing, 32 GB of RAM or more is recommended to ensure optimal performance.
- 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.
- Sycai requires that the processing environment where the product is installed includes a CUDA-compatible NVIDIA GPU with at least 8 GB of memory, preferably 16 GB or more. If no GPU is available, the preferred configuration is an Intel CPU from 6th to 13th generation.
- SYCAI Medical requires that the processing environment where the product is installed provides at least 10 GB of available storage in the client infrastructure for cloud-based installations. For on-premise installations, 60 GB of available storage is recommended, with the use of dedicated partitions to ensure proper system operation and data management
- The PACS where SYCAI Medical is installed shall allow sending petitions from SYCAI's installation package to an external URL to activate/de-activate the license
- 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 set up to access the customer server through VPN/Remote desktop.

- The following ports shall be opened in the VM: 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

The product is designed to detect and report radiological pancreatic findings corresponding to the following categories: serous cystic neoplasms (SCN), pseudocysts, intraductal papillary mucinous neoplasms (IPMN), mucinous cystic neoplasms (MCN), solid pseudopapillary neoplasms (SPN), adenocarcinoma of the pancreas (ADC), neuroendocrine tumours (NET) and metastases. The product's analysis does not extend to other categories or subtypes of findings and it does not classify findings into the specified subtypes.

The device leverages advanced algorithms to:

- **Detect and Flag Findings:** Automates the identification of known and incidental findings, including subtle or opportunistic findings.
- **Characterize Findings:** Provides detailed finding measurements (size and volume) and precise anatomical location (head, body or tail of the pancreas).

- **Track Changes Over Time:** Performs longitudinal analysis to monitor finding evolution across multiple patient studies.

SYCAI MEDICAL is intended for use as a concurrent read tool, so that the results of SYCAI MEDICAL are available at the time of evaluation and diagnosis.

SYCAI MEDICAL offers the following clinical benefits:

- Increases the identification of pancreatic incidental findings.
- Monitors changes in finding 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 finding, offering additional quantitative information to the qualitative approach of radiology.

SYCAI Medical® software identifies pancreatic findings present in the input imaging tests. This product is intended to be used in combination with an existing PACS in which SYCAI Medical® is integrated.

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

- Size of the finding.
- Volume of the finding
- Location of the finding (head, body or tail of pancreas).
- Patient follow-up report: it summarizes information about a specific finding across multiple CT scans performed on the patient over time. In this way, the information regarding the relative growth of the finding is standardized throughout the follow-up performed on the patient.

SYCAI Medical seamlessly integrates with the customer's PACS (Picture Archiving and Communication System), ensuring smooth interoperability within the hospital's workflow.

After the execution of SYCAI Medical® on the input medical image test 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.

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

- Patient ID

- Study Date
- Number of findings detected within the current CT scan
- Symbol of the pancreas coloured orange or grey, depending on whether at least one finding has been detected or not, respectively.

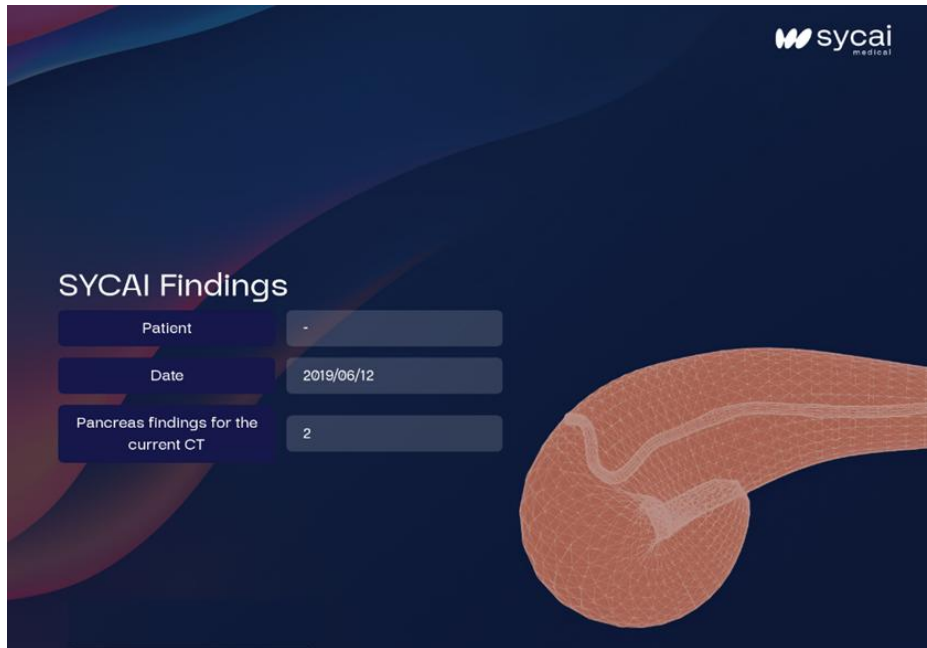


Figure 1: Example of the cover page. Patient ID, Study date and number of pancreas findings are included as information to the user. Moreover, the pancreas changes colour from orange (if any finding is detected) to grey (if not finding is detected).

### Summary Section:

- If the patient has previous CT scans, up to **three prior studies** are retrieved for comparison. A maximum of 8 findings can be found on the mentioned table.
- Information about finding 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; the notification symbol will be presented along with the major axis measurement to alert the user about such worrisome feature.
- 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.
- For any finding displayed in the summary table, if that finding is not detected in one of the displayed CT scans shown to the user, 'ND' (Not Detected) must appear in the corresponding cell for that study.

**SYCAI Findings - Summary**

Finding ID	Study Date			
	2023/02/09	2022/01/13		
P1	▲ 28.29 mm	15.29 mm		
P2	34.25 mm	ND		
P3	16.0 mm	18.69 mm		


All measurements are in millimeters (mm) and are taken along the major axis of each detected finding in the axial plane.  
 \*ND\* indicates "Not detected" (i.e. no finding was detected please review the case manually).  
 Findings not detected in both the current and immediate prior CT scan are excluded from the table.  
 An "Attention" symbol (▲) next to a measurement signifies that the finding has increased by more than 5mm over two years, indicating a worrisome feature according to clinical guidelines.

Figure 2: Example of the 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 finding, the following information is provided:


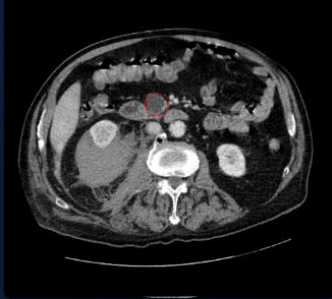
**Series number / Slice number** where the finding is located.

- **Position** (head, body or tail of the pancreas).
- **Volume (mm<sup>3</sup>)** and **major axis (mm)** measurements.
- **Comparison:** If multiple CT scans are available in the PACS, the report compares prior and current studies, showing two CT slice images with the finding circled. The table lists the same parameters for both scans for easy comparison.
- **Synchronized scrolling:** As the user scrolls through the Follow-up pages of the report, the product simultaneously displays the original CT image at the corresponding Series and Slice Number referenced on the report.
- **Graphical overlay:** In the original CT image, a graphic overlay is displayed directly on the referenced slice and series, with the option to toggle its visibility.




### Finding P1

Showing results of **current** and **prior** CT scans

	Current	2018/07/28	Prior	2014/08/02
				
Series Number / Slice Number	6 / 121		7 / 120	
Position (head, body, tail)	Head		Head	
Volume (mm <sup>3</sup> )	13054.5		7374.4	
Major Axis (mm)	35.0		26.8	


If a finding spans two anatomic regions, the position (head/body/tail) is assigned based on the region with the greater pancreatic volume affected by the finding.

Figure 3: Example of the finding page included in the report. This page can show one or two CT scans, depending on whether a prior study of the patient is found in the PACS.



### Finding P2

Showing results of **current** and **prior** CT scans

	Current	2015/04/02	Prior
			NO PREVIOUS CT SCAN AVAILABLE
Series Number / Slice Number	2 / 310		
Position (head, body, tail)	Body		
Volume (mm <sup>3</sup> )	21184.9		
Major Axis (mm)	43.6		

If a finding spans two anatomic regions, the position (head/body/tail) is assigned based on the region with the greater pancreatic volume affected by the finding.

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

**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 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 **96.2%±1.0** and a specificity of **88.3%±0.9** in CT scan imaging tests for the detection of pancreatic findings. The false negative rate in the detection is **3.8%**, which indicates the ratio of findings missed by the product compared to the ones found by radiologists during the clinical evaluation. The false positive rate in detection is **11.7%**.

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

- Accuracy in the detection of the correct location of detected findings separated in head, body or tail of the pancreas: 85.0%±1.0%
- Average deviation in finding size measurements: 12,8±4,0%
- Average deviation in finding volume measurements: 20,5±5,4%
- Accuracy in detecting alerts for findings that grow >5mm in less than 2 years: 86±1,4%
- Accuracy in the identification of the same finding in consecutive CT scans belonging to the same patient: 90,0±1,7%

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 clinical validation involving external validation from up to four different Hospitals and clinics from several cities, which included up to 399 patients and

739 studies of CT scan protocols as defined in Section 3.1 (Abdominal, thoracoabdominal, abdominopelvic, pancreatic, uro-CT, and abdominal scanner or equivalent). 80% of these studies

belong to contrast studies being the injection time and flow relative to the type of study and phase used for each sample unit.

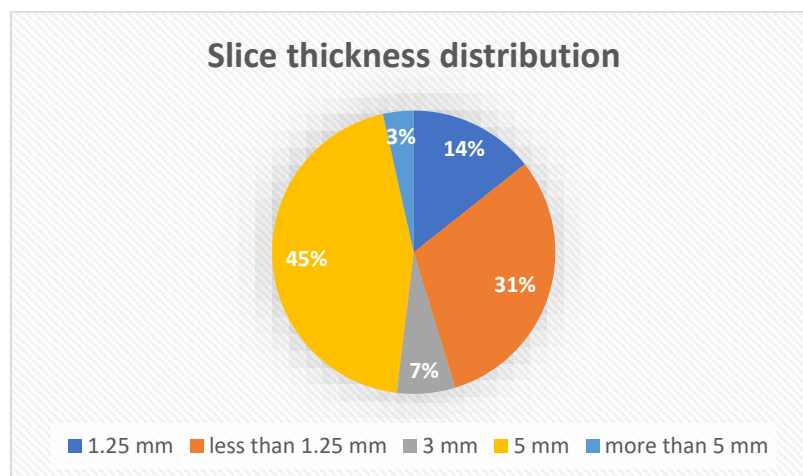
The terms of sensitivity and specificity as well as positive predictive value (PPV) and negative predictive value (NPV) are to be understood as:

$$S = \frac{TP}{TP + FN}$$
$$Sp = \frac{TN}{FP + TN}$$
$$PPV = \frac{TP}{TP + FP}$$
$$NPV = \frac{TN}{TN + FN}$$

Where:

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

Moreover, the studies included in the dataset used to validate this medical device have the following distribution in terms of slice thickness.



## 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.

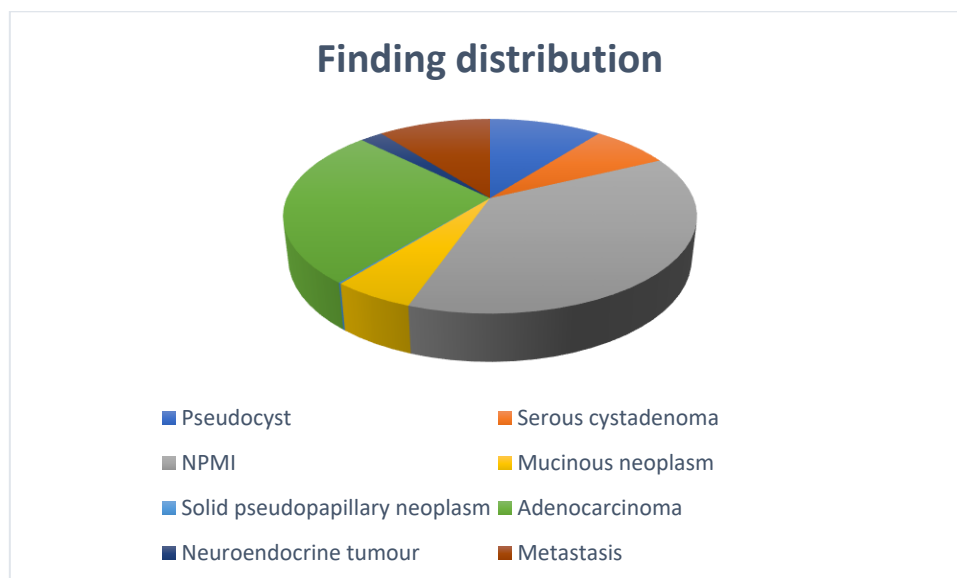
## 7. DATABASE INFORMATION

### 7.1 Training database information

The training database used for the clinical trial included a total of over 3000 CT scan studies that belong to the following proportion of diagnosed / non-diagnosed patients:

- Studies with a pancreas finding: 77%
- Control studies: 23%

All the target pancreatic findings were represented in the training dataset as the following graph shows:



## 8. Changes implemented in this version of the product

The following features have been included or changed in this product release:

<b>Feature</b>	<b>Update in SWR 2.6.0</b>
<b>Detection</b>	Included the detection of solid findings.
<b>Characterization</b>	The presence of calcifications is no longer reported. The delta in the size of the finding between the current CT scan and the previous one is no longer reported.
<b>Overlay</b>	Included a new visualization mode that shows the finding as an overlay in the original CT scan, that the user can hide as desired.
<b>Synchronized scrolling</b>	As the user scrolls through the Follow-up pages of the report, the product simultaneously displays the original CT image at the corresponding Series and Slice Number referenced on the report.