# DUOnco™ Pancreas

At your side with AI for oncology imaging

*Software Version 1.X*

# Instructions for Use

*en-UK*

intrasense
by Guerbet

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## INTELLECTUAL PROPERTY

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## SYMBOLS

The following symbols are used in this manual and labelling of DUOnco™ Pancreas:

| Symbol | Definition |
|---|---|
|  | **Important:**<br>Indicates an important information or tip. |
|  | **Caution:**<br>Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury or material damage. |
| CE<br>0459 | **CE marking:**<br>Indicates that the device complies with the general safety and performance requirements of the European Medical Device Regulation 2017/745/EU. |
| MD | **Medical device:**<br>Indicates this product is a medical device. |
| REF | **Catalogue Number:**<br>Indicates the manufacturer's catalogue number so that the medical device can be identified. |
|  | **Consult Electronic Instructions for Use:**<br>Indicates that the instructions for use should be consulted in electronic format. |
| UDI | **Unique Device Identifier (UDI):**<br>Indicates a carrier that contains Unique Device Identifier information. |

| Symbol | Definition |
|---|---|
|  | **Manufacturer:** Indicates the medical device manufacturer's name and address. |
|  | **Date of manufacture:** Indicates the release date of the software. |
|  | **Prescription only:** Indicates that the device must be dispensed with a clinician's prescription |
|  | **Swiss authorised representative:** Indicates the authorised representative in Switzerland. |

## ACRONYM TABLE

| Acronym | Definition |
|---|---|
| AI | Artificial Intelligence |
| CT | Computed Tomography |
| PACS | Picture Archiving Communication System |
| DICOM SR | DICOM Structured Report |
| DICOM Seg | DICOM Segmentation |
| DICOM GSPS | DICOM Grayscale Softcopy Presentation State |
| DICOM SC | DICOM Secondary Capture |
| DICE Score | Dice Similarity Coefficient Score |
| HU | Hounsfield Unit |

# 1 PRODUCT DESCRIPTION

DUOnco™ Pancreas is a standalone software device intended for use by healthcare professionals reading CT scans. The product employs advanced image processing and machine learning algorithms to identify and measure pancreatic lesions and the main pancreatic duct on these CT scans for further review by the qualified healthcare professional.

This software is a medical device, as defined in the European medical device regulation 2017/745.

## 1.1 INTENDED USE

DUOnco™ Pancreas is a software intended to assist the analysis and review of contrast-enhanced (portal phase) CT scan images containing the pancreas through the automatic detection and measurement of focal pancreatic lesions and main pancreatic duct

### 1.1.1 INDICATION FOR USE

DUOnco™ Pancreas is intended to be used for all indications requiring contrast-enhanced (portal phase) CT scans containing the pancreas.

### 1.1.2 CONTRAINDICATIONS AND UNDESIRABLE SIDE EFFECTS

There is no contraindication or undesirable side effect because of the use of DUOnco™ Pancreas. The solution is not in direct or undirect contact with the patient or the user

### 1.1.3 PATIENT POPULATION

DUOnco™ Pancreas is intended to process CT scans from patients over 18 years old, without specific health status nor specific diagnosis of any existing condition required.

### 1.1.4 INTENDED USER

DUOnco™ Pancreas is designed for use by healthcare professionals qualified to read CT scan studies, who are typically radiologists.

## 1.2 CLINICAL BENEFITS

Intrasense is not claiming direct clinical benefits to either patients or users associated with the use of DUOnco™ Pancreas. However, Intrasense is claiming

an indirect clinical benefit:

- Optimized clinical decision-making process leading to improved patient management

The indirect clinical benefits associated with the use of DUOnco™ Pancreas arise from the way this Medical Device Software (MDSW) influences the broader healthcare process, rather than producing direct therapeutic effects itself. Unlike direct benefits (such as an immediate change in a patient's health status following a diagnosis or intervention), indirect benefits are realized through the clinical impact of the MDSW on clinical decision-making processes.

The indirect nature of this clinical benefit is rooted in the MDSW's ability to provide valuable insights/outputs rather than directly effecting these outcomes itself.

The indirect clinical benefit associated with the use of DUOnco™ Pancreas is realized through the supportive role of the MDSW aiding specialist healthcare professionals in the analysis of medical images. DUOnco™ Pancreas is a non-autonomous tool that provides outputs intended to assist healthcare professionals in their determination of a clinical decision or action, by detecting pancreatic lesions and measuring main pancreatic duct.

This clinical benefit remains highly relevant in clinical practice for both patients and specialist healthcare professionals, as it addresses key challenges in pancreatic lesions detection while ensuring that the final responsibility for clinical decisions remains with the specialist healthcare professional.

## 1.3 PERFORMANCE CHARACTERISTICS

DUOnco™ Pancreas correctly detects pancreatic lesions, with an acquisition level specificity and sensitivity not inferior to 80%.

DUOnco Pancreas can provide a segmentation of the contours of the pancreatic lesions with an average DICE score per correspondence (detected lesion) not inferior to 50%.

DUOnco™ Pancreas can provide a measurement of the main pancreatic duct such as:

- the average relative error of the software with respect to a manual measurement is not superior to 35% .
- the measurement of the main pancreatic duct size falls into the range of a dilated* duct at least 80% of the time, when the duct is dilated .

- the measurement of the main pancreatic duct size falls into the range of non-dilated* duct at least 80% of the time, when the duct is not dilated.

**Two criteria are proposed to define the MPD dilatation:*

- *C1: The duct is dilated if its size is greater than 3mm.*
- *C2: The duct is dilated if its size in the head is larger than 3mm or its size in the body or tail is larger than 2mm.*

## 1.4 SAFETY INFORMATION

Residual risks have been identified as acceptable. The user-relevant safety information is listed in this section.

In the event of any serious incident occurring in relation to this medical device, report the details to the manufacturer and the competent authority of the country in which the user is established and/or in which the event occurred.

**⚠ CAUTION!**

DUOnco™ Pancreas provides adjunct information to assist healthcare professionals and is not intended to replace their comprehensive review of a CT scan. Diagnosis and patient management decisions should not be made solely based on analysis by DUOnco™ Pancreas.

**⚠ CAUTION!**

DUOnco™ Pancreas may produce inaccurate detection, which may ultimately lead to diagnosis delay, anxiety and morbidity due to additional diagnostic workup or user inconvenience.

**⚠ CAUTION!**

DUOnco™ Pancreas may produce inaccurate measurements and contours of the pancreas, lesions, and main pancreatic duct, which may ultimately lead to user inconvenience.

**⚠ CAUTION!**

Accurate processing of CT images by DUOnco™ Pancreas relies on the quality and correctness of the image source data. Insufficient image quality may produce inaccurate results, which may ultimately lead to diagnosis delay, anxiety and morbidity due to additional diagnostic workup or user inconvenience.

Users should always review the original images and use DUOnco™ Pancreas only for images of sufficient quality.

**⚠ CAUTION!**

When configuring the finding groups in DUOnco™ Pancreas, users should be aware that inappropriate settings may exclude certain findings from the results, which may lead to diagnosis delay or user inconvenience.

**⚠ CAUTION!**

DUOnco™ Pancreas typically takes a few minutes to process a study. In rare cases, the processing may fail or take longer than expected, which may lead to user inconvenience.

## 1.5 LIMITATIONS OF USE

The use of DUOnco™ Pancreas is not recommended for patient populations meeting the following criteria:

- Patients under 18 years old.

The use of DUOnco™ Pancreas is not recommended for CT scans meeting the following criteria:

- Multi-energy or photon-counting CT scans
- CT scans containing artifacts (such as due to noise, motion, or metallic implants) causing degradation of image quality.
- Images of patients who underwent pancreatectomy or other pancreatic surgery.
- Images with slice spacing ≥3 mm.

- Images not containing the full pancreas.
- Images without contrast injection or with a contrast bolus timing inappropriate to the intended clinical interpretation of the scan.
- Images reconstructed using bone or lung reconstruction kernels
- Images of patients with biliary stents.
- Images with slice thickness ≥ 3mm
- Images with DICOM enhanced imaging objects

The safety and effectiveness of DUOnco™ Pancreas has not been established for these patients/studies/images.

## 1.6 TRAINING REQUIRED FOR USE OF THIS DEVICE

The intended users of the software are specialists trained in the interpretation of medical images who are familiar with the use of radiological software environments. No formal training is necessary to effectively use the software. .

# 2 DEVICE OPERATING WORKFLOW

## 2.1 OPERATING ENVIRONMENT

DUOnco™ Pancreas is expected to be used in a healthcare environment (for example, hospital and radiology centers), in interface with various medical imaging systems such as visualization platforms, image archiving, and image distribution systems (see chapter 3.1). The common denominator among all these systems is the DICOM standard, which enables interoperability through network transfers or file exchanges. DUOnco™ Pancreas can be deployed on-Cloud or on-Premise.

## 2.2 PRINCIPLE OF OPERATIONS

Once installed, DUOnco™ Pancreas runs automatically in the background without requiring user interactions.

DUOnco™ Pancreas receives CT scan studies automatically transmitted from the radiology center's modalities or Picture Archiving and Communication Systems (PACS).

For each received study, its series are then filtered using DICOM headers and image processing techniques. One optimal serie meeting the input requirements (chapter 2.3) is further processed by DUOnco™ Pancreas.

If several contrast-enhanced phases are present in the study, DUOnco™ Pancreas prioritizes the portal venous phase, or the phase closest to portal venous timing. If no suitable portal venous phase is identified, the software then looks for an arterial phase. If no suitable arterial phase is identified, the software then looks for a delayed phase. If no suitable contrast-enhanced phase is detected, the study is not processed and return code 207 is generated (see Chapter 4)

Deep learning algorithms analyze the images to analyze the pancreas, pancreatic lesions and main pancreatic duct. The output resulting from processing of the device are:

- Contours of the pancreas,
- Contours of pancreatic lesions with the following information and measurements:
  - long axis (maximum axial plane diameter) coordinates and length in mm,
  - lesion volume in $cm^3$, median lesion density in Hounsfield Units (HU),
  - measurement of the maximum size of the main pancreatic duct in mm.

DUOnco™ Pancreas typically takes a few minutes to process a study. The output results are then exported as new DICOM series and returned to the PACS. Users can

access DUOnco™ Pancreas's results directly from their existing PACS workstation interface and/or from compatible viewers, using them as supporting information when reviewing the corresponding CT scan studies.

## 2.3 INPUT REQUIREMENTS FOR PROCESSING

### 2.3.1 INCLUSION CRITERIA

DUOnco™ Pancreas should process a contrast-enhanced CT imaging study containing the pancreas, usually the portal phase.

### 2.3.2 EXCLUSION CRITERIA

DUOnco™ Pancreas will reject series that meet the following exclusion criteria:

- Series with a slice spacing ≥ 3 mm
- Series without the full pancreas
- Series which do not comply with the DICOM requirements described in the DICOM conformance statement. This document is available upon user request by mail to support@intrasense.fr.

## 2.4 OUTPUT

DUOnco™ Pancreas output is forwarded to the PACS under various DICOM objects. Certain output elements are available only in certain DICOM objects:

| (see chapter 2.5 for priority group description) | DICOM SC | DICOM SR | DICOM GSPS | DICOM Seg |
|---|---|---|---|---|
| Pancreas contours | | ✓ | ✓ | ✓ |
| Lesion's contours | ✓ | ✓ | ✓ | ✓ |
| Lesion's measurements (long-axis diameter, median density) | ✓ | ✓ | ✓ | |
| Lesion's measurements (volume) | | ✓ | | |
| Main pancreatic duct measurement | ✓ | ✓ | ✓ | |
| Slice navigation bar | ✓ | | ✓ | |
| Slice info near the navigation bar | ✓ | | | |
| Finding measurements area | ✓ | | ✓ | |

DUOnco™ Pancreas result series can be identified in the PACS or compatible viewer using the DICOM Series Description. The Series Description of each generated result series follows the naming convention below:

DUO-Pa ({return code}) - #{processed series number} - {output format}

Where:

- {return code} is the processing status code generated by DUOnco™ Pancreas. Return codes are described in chapter 4.

- {processed series number} is the series number of the original CT series processed by DUOnco™ Pancreas.

-{output format} indicates the generated DICOM output format, such as SR, GSPS, SC or SEG.

For example, for a DICOM GSPS output generated after successful processing with detected findings from original series number 1234, the generated Series Description is:

DUO-Pa (201) - #1234 - GSPS

A return code, indicating the processing status of DUOnco™ Pancreas, is recorded in the DICOM SR file.

By default, only DICOM SR objects are generated. During installation, an option is provided to add the generation of DICOM GSPS, DICOM SC and/or DICOM SEG.

If DUOnco™ Pancreas does not detect any findings—including the pancreas, any lesions, or a main pancreatic duct measurement—the result series will consist only of a DICOM SR.

If DUOnco™ Pancreas fails to process a series, the output result will consist of a DICOM SR series indicating the reason why the processing failed with a return code. The return code list can be found in chapter 4.

### 2.4.1 DICOM SECONDARY CAPTURE (SC)

The DICOM SC output is composed of multiple slices:

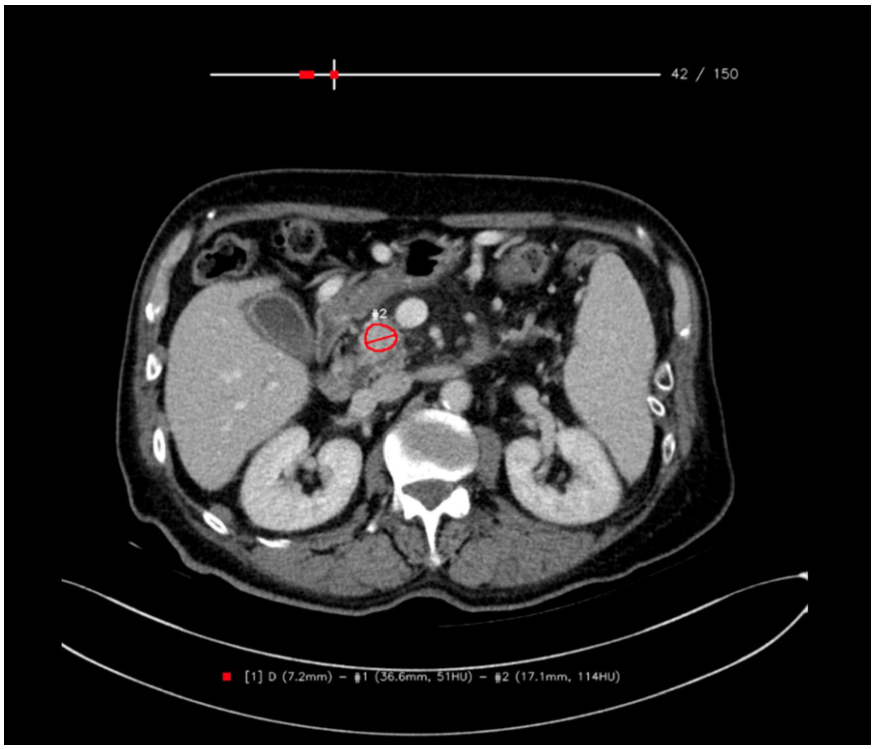
- The first slice consists of a summary table of the findings (main pancreatic duct if identifiable and lesions if any) with priority group color and priority level (see chapter 2.5 for priority group description), identification label (D symbol for main pancreatic duct and # for lesions), diameter in mm, mean density in HU, and slice over total number of slices.

| Priority group color* | Priority group index* | Finding label | Finding size | Lesion density | Slice index on which the finding was detected / Total of slices |
|---|---|---|---|---|---|
| | [1] | D | 7.2 mm | | 132 / 456 |
| | [1] | #1 | 24.6 mm6 | 1HU | 121 / 456 |
| | [1] | #2 | 18.8 mm | 81HU | 158 / 456 |

**For more information about the priority group, please refer to chapter 2.5.*

The following slices correspond to slices where the findings were detected with:

- Navigation bar at the top of the images to show position along the overall slices with colored squares, in accordance with highest group priority (see chapter 2.5 for priority group description) of findings present in slice, to indicate slices where findings can be found
- Segmentation of the lesions displayed with long maximum diameter in the corresponding slice with the corresponding identification label.
- Maximum axial diameter of the main pancreatic duct in the corresponding slice with the symbol D as identification label when the main pancreatic duct is detected. Main pancreatic duct detection might be difficult due to its limited visibility.
- Summary of the findings (including identification labels) on all slices with associated measurements (diameter in mm & density in HU) per group of priority (see chapter 2.5 for priority group description).



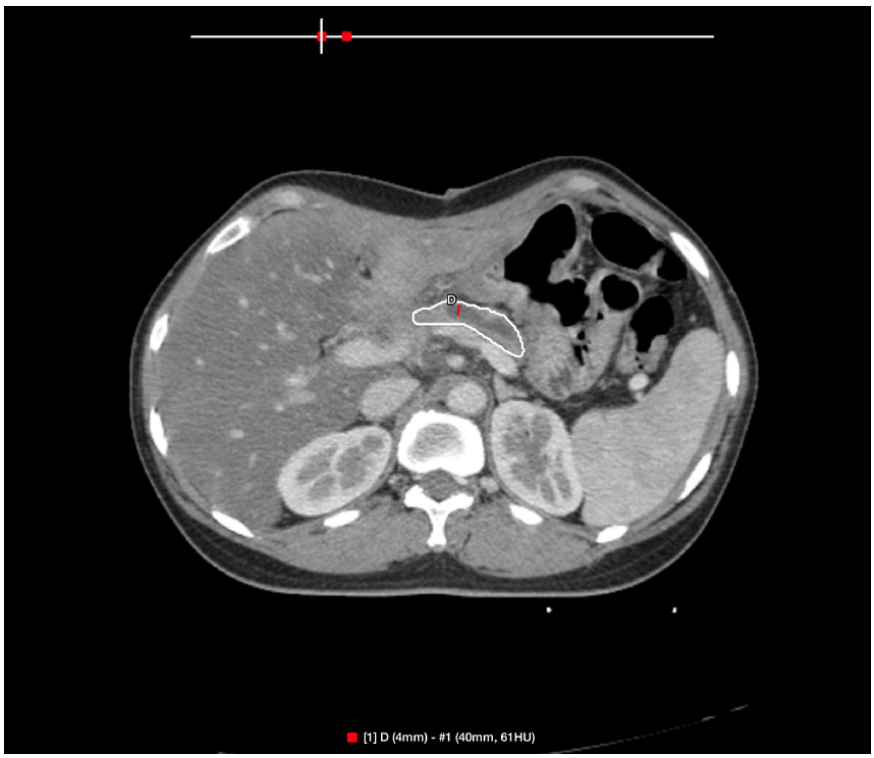

The DICOM SC object is generated only when at least one finding is detected.

### 2.4.2 DICOM GRAYSCALE SOFTCOPY PRESENTATION STATE (GSPS)

The DICOM GSPS is a DICOM object containing graphical layers including among else the findings' contours and measurements. When loaded in a compatible viewer, the DICOM GSPS can be used as an overlay on the top of the corresponding original series.

The graphical layers of the GSPS are composed of:

- Navigation bar at the top of the images to show position along the overall slices with colored squares, in accordance with highest group priority (see chapter 2.5 for priority group description) of findings present in slice, to indicate slices where findings can be found. The display of the Navigation bar can be deactivated upon request at installation.
- Contours of the pancreas displayed in all slices where the organ is present to ease the identification of the organ.
- Segmentation of the lesions displayed in all slices where the lesion is identified with long maximum diameter in the corresponding slice with the corresponding identification label.
- Maximum axial diameter of the main pancreatic duct in the corresponding slice with the symbol D as identification label when the main pancreatic duct is detected. Main pancreatic duct detection might be difficult due to its limited visibility.
- Summary of the findings (including identification labels) on all slices with associated measurements (diameter in mm & density in HU) per group of priority (see chapter 2.5 for priority group description).




The DICOM GSPS object is systematically generated, regardless of the presence of findings. In the event of a processing error, only a DICOM SR object is generated.

### 2.4.3 DICOM STRUCTURED REPORT (SR)

The DICOM SR object contains the following elements:

- Coordinates of the center of the pancreas.
- Coordinates of the center of the lesions with long max diameter position and their localization within the pancreas (head, body or queue).
- Measurement of the lesions with long-axis diameter in mm, median density in HU and volume in cm3.
- Maximum axial diameter of the main pancreatic duct in mm when the main pancreatic duct is detected. (The main pancreatic duct may not be detected on series where it is not sufficiently visible).
- Area of the maximum axial diameter of the main pancreatic duct within the pancreas (head, body or queue).
- Priority group, for each finding detected (lesions or main pancreatic duct). See chapter 2.5 , for more information.
- Priority group at a study level, which corresponds to the maximum priority group of all findings in one study.

- The return codes which represent the success or failure status after processing. Please refer to chapter 4 for more details on the return codes in the DICOM SR.

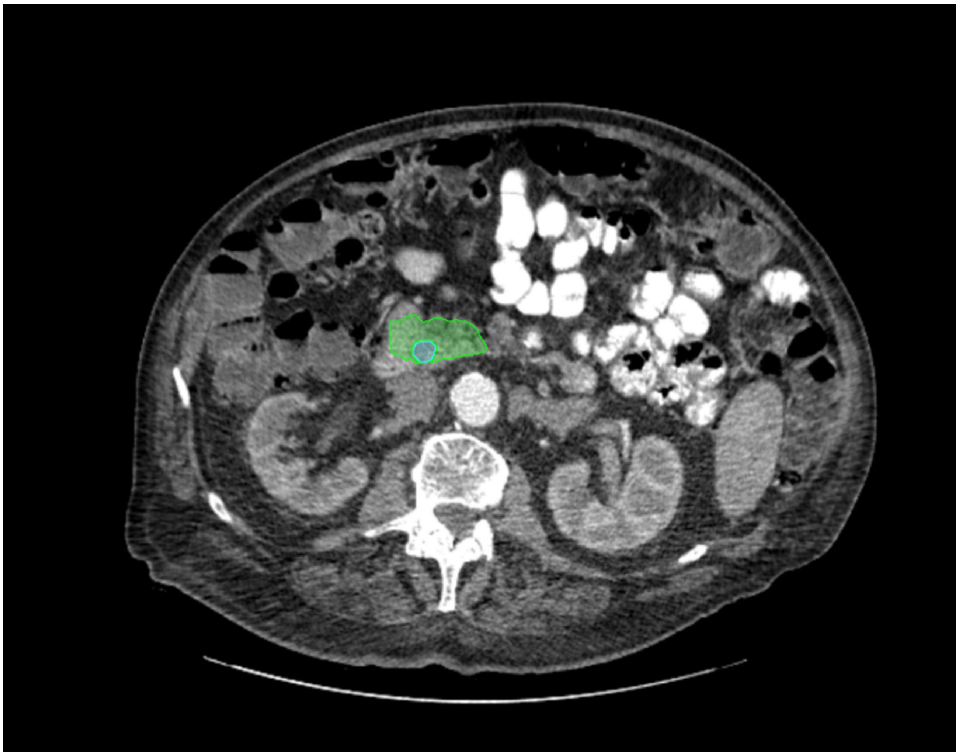
More information can be found in the DICOM conformance statement, available on request from Intrasense® customer support.

The DICOM SR object is always generated, even if there are no findings or when there is an error during processing, so it is useful for purposes.

### 2.4.4 DICOM SEG

The DICOM SEG is an object containing pancreas and lesions' regions of interest. The DICOM SEG is to be used for display of the segmentation of pancreas and lesions, if further data is needed (main pancreatic duct maximum diameter, DICOM SEG needs to be used in combination with DICOM SR.

The region of interest of the main pancreatic duct is not exported in this format.



The DICOM SEG object is systematically generated, regardless of the presence of findings. In the event of a processing error, only a DICOM SR object is generated.

## 2.5 FINDING GROUPS

DUOnco™ Pancreas can be configured to automatically organize the output findings into three priority groups [1], [2] or [3]. This grouping allows the user to set different priority levels based solely on the automatic measurement, with group [1] representing the highest priority and group [3] the lowest.


*Example of summary of the findings, visible in the DICOM GSPS and SC*

Findings are sorted by priority, allowing the user to review the images more efficiently.

The red color is associated with group [1], orange with group [2] and green with group [3].

When the DICOM viewer is compatible, colors are used to help differentiate findings from each group.

The configuration of these priority groups can only be done by Intrasense or one of its authorized distributors using the specific values requested by the user.

### 2.5.1 CONFIGURATION OF CONDITIONS FOR EACH GROUP

The following conditions can be configured independently for priority groups [1] and [2]:

- Lesions
  - Minimal density (HU)
  - Minimal size (long axis) (mm)
- Main pancreatic duct
  - Minimal size when the measurement is located in the head of the pancreas (mm)
  - Minimal size when the measurement is located in the body or tail of the pancreas (mm)

A finding is assigned to group [1] or group [2] when it meets at least one active condition configured for that group. Group [1] takes precedence over group [2]. Findings that do not meet any active condition for group [1] or group [2] are assigned to group [3].

The priority group configuration can be checked in the DICOM SR output data.

### FACTORY CONFIGURATION

In the factory configuration, the following conditions are active:

- Lesion median density ≥ 46 HU: group [1]
- Lesion long-axis diameter ≥ 7 mm: group [2]
- Main pancreatic duct measurement in the head of the pancreas ≥ 5.5 mm: group [2]
- Main pancreatic duct measurement in the body or tail of the pancreas ≥ 3.0 mm: group [2]

All other configurable conditions are disabled by default.

Please contact Intrasense or their representative if you need to modify your current finding group configuration.

The DUOnco™ Pancreas finding group configuration should be modified only on behalf of the user by an application engineer representing Intrasense or its authorized distributor

## 2.5.2 EXCLUSION OF LOWER PRIORITY GROUPS' FINDINGS

By default, findings from all three priority groups are exported in all output DICOM objects.

DUOnco™ Pancreas can be configured to exclude findings assigned to one or more lower-priority groups from the DICOM SEG, DICOM SC and DICOM GSPS outputs. This configuration is intended to control which findings are displayed in the visual output objects, to improve image review efficiency.

When a priority group is excluded from these outputs, findings assigned to this group are not exported in the DICOM SEG, DICOM SC and DICOM GSPS objects. However, these findings remain available in the DICOM SR output data, together with their assigned priority group.

At least one priority group must always be included in the DICOM SEG, DICOM SC and DICOM GSPS outputs. This configuration can only be modified by Intrasense or one of its authorized distributors.

Please contact Intrasense or their representative if you need to modify your current finding group configuration.

DUOnco™ Pancreas does not provide any indication regarding the classification or clinical significance of the output findings. Finding groups are set according to the user's preference. By configuring the exclusion of lower priority groups, the user should be aware that some of the findings will be filtered out of the outputs . Intrasense does not assume any responsibility regarding potential unexpected excluded findings. The user is expected to be trained for image reading and should understand the consequences of setting up such filter

## 2.6 ABOUT BOX AND IFU ACCESS

The About Box webpage contains all DUOnco™ Pancreas labelling information and traceability regarding the software version.

The About Box webpage is accessible at the below URL with a standard web browser:

https://intrasense.fr/en/user-documentation-duonco-pancreas-vX-Y/

Where vX-Y is the software version currently used.

An About Box page hyperlink is also available in the DICOM tag (00B1,0010) of all the DICOM objects generated by DUOnco™ Pancreas.

This Instructions for Use can be accessed and downloaded in the supported languages from either the above About Box webpage or by sending a request on the Intrasense® website: www.intrasense.fr.

## 2.7 ORDER A PAPER COPY OF THIS INSTRUCTIONS FOR USE

A paper copy of these Instructions for Use can be ordered at no additional cost by sending a request to support@intrasense.fr. In application of the EU Commission Regulation on electronic instructions for use of medical devices, in the European Union, your request should be treated within 7 calendar days. .

# 3 SYSTEM HARDWARE & SOFTWARE SPECIFICATIONS

## 3.1 COMPATIBLE IMAGING SYSTEM

DUOnco™ Pancreas can be compatible with various medical imaging solutions using DICOM protocols and accepting the output format cited in paragraph 2.4. These solutions can be modalities, archiving systems and visualization software.

## 3.2 HARDWARE SPECIFICATION

Hardware prerequisite may be asked prior integration or deployment phase for any new client.

vCPU (OpenVINO) backend:

- Container RAM requirement for 1 advisor instance: 20 GB
- CPU requirement for nominal performance: 4 cores (Xeon™ Platinum 3 GHz or equivalent)
- Disk storage for OCI images and temporary working space: 40GB

Minimum hardware configuration is the minimum required for DUOnco™ Pancreas to operate normally.

Even though DUOnco™ Pancreas may run with a configuration which does not meet the minimal requirements, Intrasense® disclaims all responsibility for these systems.

## 3.3 IT NETWORKS CHARACTERISTICS AND IT SECURITY MEASURES

DUOnco™ Pancreas is based on Kubernetes.

Environments such as Azure cloud and AWS can support cloud deployment.

The data centers hosting the data have strong physical security measures in place to shelter data from unauthorized access and from environmental threats.

The institution is responsible for the physical protection of the devices used to access DUOnco™ Pancreas. For OnPrem deployment, the hardware requirements specify the use of a hardware lock or a mechanism for securing the device. It is the institution's responsibility to prevent unauthorized physical access to the server where DUOnco™ Pancreas component is deployed.

DUOnco™ Pancreas has essential security measures to reduce network vulnerabilities by design for cloud deployment. When DUOnco™ Pancreas processes data locally (OnPrem), it is the institution's responsibility to implement network access controls and ensure system security. This includes configuring firewalls, disabling unnecessary services, ports, and users, protecting against malware, encrypting data at rest, and avoiding unnecessary software installations. DUOnco™ Pancreas is designed to use minimal network ports and protocols, with HTTPS ports required for communication with cloud services. The system has robust network controls in the cloud to prevent unauthorized access.

# 4 UNDERSTANDING RETURN CODES

A return code, indicating the processing status of DUOnco™ Pancreas, is recorded in the following locations:

1) in the Series Description (0008,103E) of each generated DUOnco™ Pancreas output series, as described in chapter 2.4.

2) in the DICOM SR output only, in the following DICOM tags:

Imaging Measurements / Algorithm Result

- (0008,0100) CodeValue
- (0008,0104) CodeMeaning (not the code itself but a short description).

The following table describes the different codes:

| Return Code | Description |
|---|---|
| 200 | DUOnco™ Pancreas successfully processed the series and no findings (main pancreatic duct measurement or lesion) were detected. |
| 201 | DUOnco™ Pancreas successfully processed the series and at least one finding (main pancreatic duct measurement or lesion) were detected. |
| 203 | DUOnco™ Pancreas was unable to process the series because the abdomen was not detected. |
| 204 | DUOnco™ Pancreas was unable to process the series because no series met the input requirements. |
| 205 | DUOnco™ Pancreas was unable to process the series due to unknown reason. |
| 206 | DUOnco™ Pancreas was unable to process the series because the pancreas was not detected. |
| 207 | DUOnco™ Pancreas was unable to process the series because no suitable contrast enhanced phase was detected. |

# 5 TECHNICAL SUPPORT

The installation and maintenance instructions of DUOnco™ Pancreas are supplied by Intrasense® in separate documentation. The installation and maintenance must be performed by appropriate personnel, authorized by Intrasense®.

When facing a system failure or problem, the user can call Intrasense® customer support to request help or assistance:

+33 (0) 4 67 130 134

support@intrasense.fr

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**Basic UDI-DI :** 37007197DUOncoPancreas3E

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