DUOnco™ Unity

At your side with AI for oncology imaging

Software Version 1.X

Instructions for Use

en-UK

intrasense
by Guerbet

MAIA-00026 v2 2026-08-10

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Intellectual property

Symbols

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

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

Acronym table

Acronym	Definition
AI	Artificial Intelligence
CT	Computed Tomography
PACS	Picture Archiving Communication System
DICOM	Digital Imaging and Communications in Medicine
DICOM SR	DICOM Structured Report
DICOM SEG	DICOM Segmentation
DICOM GSPS	DICOM Grayscale Softcopy Presentation State
DICOM SC	DICOM Secondary Capture
PDF	Portable Document Format
HU	Hounsfield Unit
SMA	Skeletal muscle area
SMD	Skeletal muscle density
VFA	Visceral fat area
SFA	Subcutaneous fat area
MdAE	Median Absolute Error
MdAPE	Median Absolute Percentage Error
L3	Third lumbar vertebra
GGO	Ground-glass opacity
RECIST	Response Evaluation Criteria in Solid Tumours
IFU	Instructions for Use
IT	Information Technology
OCI	Open Container Initiative
AWS	Amazon Web Services
RAM	Random Access Memory
CPU	Central Processing Unit
GPU	Graphics Processing Unit
URL	Uniform Resource Locator
UDI	Unique Device Identifier

1 Product description

DUOnco™ Unity is a standalone software device intended for use by healthcare professionals reading CT scans. The software uses advanced image-processing and artificial intelligence algorithms to automatically detect, segment and measure focal lesions, as well as derive body composition parameters from CT images, providing quantitative information to support further review by qualified healthcare professionals.

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

1.1 Intended use

DUOnco™ Unity is a medical device software application intended to assist healthcare professionals in the analysis and review of CT scans of the thorax, abdomen, and/or pelvis by automatically detecting and measuring focal lesions and by providing quantitative body-composition parameters. The information generated by the software is intended to support the interpretation and reporting of CT images of adult patients acquired for oncologic evaluation or follow-up.

1.1.1 Indication for use

DUOnco™ Unity is indicated for the concurrent review of CT scans of the thorax, abdomen, and/or pelvis in adult patients (≥18 years), primarily in the context of oncologic evaluation, follow-up or staging.

1.1.2 Contraindications and Undesirable Side Effects

There are no known patient-related contraindications or adverse effects associated with the use of DUOnco™ Unity. The device is not intended for use in paediatric patients (<18 years).

1.1.3 Patient population

DUOnco™ Unity is intended to process CT scans from patients over 18 years old, undergoing CT imaging of the thorax, abdomen, and/or pelvis, primarily in the context of oncologic evaluation, follow-up or staging.

1.1.4 Intended user

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

1.2 Clinical benefits

DUOnco™ Unity does not claim a direct clinical benefit for patients.

The software medical device is intended to provide an indirect patient benefit, realized through its contribution to the radiology interpretation and reporting workflow. DUOnco™ Unity automatically detects and measures focal lesions and provides quantitative body-composition parameters derived from CT images. It provides structured quantitative outputs that are intended to support specialist healthcare professionals during the review and reporting of thoraco-abdomino-pelvic CT scans.

By making lesion-level and quantitative information available in a standardized format, DUOnco™ Unity may support a more structured and comprehensive image review and reporting process. When incorporated into the radiology report by the specialist healthcare professional, these outputs may support more informed multidisciplinary discussions and patient management decisions, particularly in oncology.

All clinical interpretation and management decisions remain under the full responsibility of qualified healthcare professionals. DUOnco™ Unity does not provide diagnostic conclusions or treatment recommendations.

1.3 Performance characteristics

1.3.1 Lesion Detection Performance

DUOnco™ Unity demonstrates a lesion-level sensitivity not below 75% for the detection of:

- tumor lesions with a long-axis diameter ≥ 10 mm,
- lymph nodes with a short-axis diameter ≥ 15 mm,

on thoraco-abdomino-pelvic CT examinations, when compared against expert radiologist annotations.

1.3.2 Lesion Measurement Accuracy

DUOnco™ Unity demonstrates a lesion-level median absolute percentage error (MdAPE) not exceeding 10% for:

- long-axis measurement of tumor lesions ≥ 10 mm,
- short-axis measurement of lymph nodes ≥ 15 mm,

on thoraco-abdomino-pelvic CT examinations, when compared against expert radiologist annotations.

Other lesion measurements or computed lesion values provided by DUOnco™ Unity, such as short-axis measurement of non-lymph-node lesions, craniocaudal axis, lesion volume, lesion density, longitudinal change values, and aggregated lesion metrics, are provided as supportive quantitative information and should be reviewed by the qualified healthcare professional in conjunction with the original CT images.

1.3.3 Body-Composition Parameters Accuracy

DUOnco™ Unity demonstrates a case-level median absolute error (MdAE) not exceeding:

- 5 cm^2 for skeletal muscle area (SMA),
- 5 HU for skeletal muscle density (SMD),
- 10 cm^2 for visceral fat area (VFA),
- 10 cm^2 for subcutaneous fat area (SFA),

when compared against expert-reviewed reference annotations.

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™ Unity may produce inaccurate, incomplete, or misleading outputs, which may ultimately contribute to delayed, inappropriate, or suboptimal clinical management or may lead to unnecessary additional diagnostic workup.

DUOnco™ Unity 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™ Unity.

⚠ **CAUTION:**
When annotation filtering or display rules are configured, only lesions meeting the configured display criteria may be shown in overlays. Users should ensure that the selected configuration is appropriate for the clinical task and should consider reviewing the full CT examination.

⚠ **CAUTION:**
Accurate processing by DUOnco™ Unity relies on the quality and correctness of the input CT data. Non-diagnostic image quality or atypical acquisition / reconstruction characteristics may lead to reduced accuracy. Users should always review the original images and use DUOnco™ Unity outputs only as supporting information.

⚠ **CAUTION:**
RECIST documentation support is optional and intended to assist documentation only. DUOnco™ Unity may provide incomplete or inaccurate RECIST support outputs, including target lesion lists, measurements, calculated values, or automatically generated text, or may be used inappropriately by the user.

Target lesion selection, confirmation of RECIST applicability, verification of selected lesion measurements, and final response assessment remain the responsibility of the qualified healthcare professional. Any automatically generated text should be reviewed before inclusion in the radiology report. If RECIST documentation support is unavailable, incomplete, or not configured, RECIST assessment and documentation shall be performed manually according to local clinical practice.

⚠ **CAUTION:**
The quantitative body-composition parameters are provided as contextual quantitative information. They are not established as standalone decision biomarkers and should not be used in isolation to guide diagnosis or treatment decisions.

⚠ **CAUTION:**
Absence of DUOnco™ Unity outputs does not indicate absence of lesions or absence of findings. If outputs are missing, delayed, corrupted, or not visible, users should review the original CT images and verify processing status or contact technical support.

⚠ **CAUTION:**
DUOnco™ Unity typically takes a few minutes to process a study (10 minutes max.). In rare cases, the processing may fail or take longer than expected, which may lead to user inconvenience.

⚠ **CAUTION:**
Use of DUOnco™ Unity outputs in the wrong patient, examination, or longitudinal comparison context may contribute to delayed, inappropriate, or suboptimal clinical management.
Users should verify patient identity, study date, processed series information, and, when applicable, longitudinal comparison context in the PACS/viewer and generated summary before relying on DUOnco™ Unity outputs.

1.5 Limitations of use

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

- Patients under 18 years old

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

- Multi-energy or photon-counting or low-dose CT scans
- CT scans containing artifacts (such as due to noise, motion, or metallic implants) causing degradation of image quality
- CT scans covering anatomical regions other than the thorax, abdomen or pelvis

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

Quantitative outputs provided by DUOnco™ Unity are intended to support image review and reporting. The validated accuracy limits and the scope of validated quantitative performance are described in Section 1.3 Performance Characteristics. Measurements and computed quantitative values shall be reviewed by the qualified healthcare professional in conjunction with the original CT images and the clinical context.

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™ Unity 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. The common denominator among all these systems is the DICOM standard, which enables interoperability through network transfers or file exchanges.

2.2 Principle of operations

Introduction
DUOnco™ Unity is a software-only medical device intended to operate within healthcare IT environments. Once deployed, it automatically receives CT examinations transmitted by CT scanners and/or PACS systems, analyzes eligible examinations using artificial intelligence algorithms, and returns the generated results as standard DICOM objects that can be reviewed within the user's existing PACS or compatible viewing software.

The software operates automatically in the background and does not require any user interaction during image processing.

Input acquisition and study selection
DUOnco™ Unity automatically receives CT examinations in DICOM format from the clinical imaging environment.

For each received examination, the software evaluates all eligible CT series and automatically selects the series, or combination of series, that best covers the anatomical regions intended for analysis: thorax, abdomen and/or pelvis.

When several eligible CT series are available:

- for thoracic analysis, series reconstructed with sharp kernels are prioritised.
- for abdominal and pelvic analysis, series reconstructed with smooth or intermediate kernels are prioritised.
- when several contrast phases are available, portal venous phase series are prioritised, followed by arterial phase series, then delayed phase series.

Non-contrast-enhanced CT series may also be processed when they meet the processing requirements. However, when suitable contrast-enhanced series are available for the same anatomical region, contrast-enhanced series are prioritised for processing.

When necessary, more than one CT series from the same examination may be processed to maximize anatomical coverage. Results originating from multiple processed series are automatically reconciled to provide a coherent set of findings for the examination.

Image analysis and lesion processing
Once the appropriate CT series have been selected, DUOnco™ Unity automatically analyzes the images using artificial intelligence algorithms.

For each detected focal lesion, the software automatically generates:

- a unique lesion identifier
- a three-dimensional lesion segmentation

- long-axis annotation indicating the measurement location, together with the corresponding length in mm
- short-axis annotation indicating the measurement location, together with the corresponding length in mm
- craniocaudal-axis length in mm
- lesion volume in cm^3 or mm^3
- median lesion density in Hounsfield Units (HU)
- anatomical location
- lesion semiology (e.g. lymph node, cystic lesion, solid lesion, ground-glass opacity (GGO), lytic or sclerotic bone lesion)

When a suitable prior CT examination is available, DUOnco™ Unity also performs longitudinal lesion matching to identify corresponding lesions between examinations and provides information regarding lesion evolution, including:

- new lesions
- disappeared lesions
- changes in lesion measurements

Body composition analysis
In addition to lesion analysis, DUOnco™ Unity automatically performs body composition analysis at the level of the third lumbar vertebra (L3).

The software generates the following quantitative parameters:

- Skeletal Muscle Area (SMA)
- Skeletal Muscle Density (SMD)
- Visceral Fat Area (VFA)
- Subcutaneous Fat Area (SFA)

Associated tissue segmentations are also generated to support visual verification of the measurements.

Output generation
Processing results are exported as new DICOM objects and transmitted back to the configured clinical imaging environment.

Depending on the system configuration, DUOnco™ Unity may generate:

- DICOM Grayscale Softcopy Presentation State (GSPS)
- DICOM Structured Report (SR)
- DICOM Segmentation (SEG)
- DICOM Secondary Capture (SC) or Encapsulated PDF optional summary document

The generated outputs are intended to be reviewed alongside the original CT examination using the user's existing PACS or compatible image-viewing software.

Management of prior studies
When a new exam is received for processing, the software automatically checks whether a result associated with a previous exam exists for the patient in question, in order to automatically calculate lesion evolution.

To do this, SRs are stored directly by the software so that they can be reused when processing subsequent exams, and the search is performed based on the exam date. The software selects the first available result whose Study Date is earlier than that of the exam currently being processed.
As a result, only a single SR corresponding to an already-processed exam can be used as a prior.

Example:

- N-2: exam already processed, with a result SR available.
- N-1: exam not processed, without result SR available.
- N: new exam to be processed.
- When processing exam N, the software searches for a prior SR. Since no SR is available for N-1, the software uses the SR corresponding to N-2 as the prior.

Optional RECIST documentation support
When enabled, DUOnco™ Unity may generate an optional interactive documentation page intended to assist healthcare professionals in preparing RECIST documentation.

Users may select target lesions, review automatically generated measurements, modify measurements when appropriate, and obtain automatically updated RECIST calculations and report-ready text.

The selection of target lesions, confirmation of RECIST applicability, and all clinical interpretation remain under the responsibility of the qualified healthcare professional.

The RECIST summary included in the PDF document contains interactive form fields. To ensure that these interactive elements are displayed and function correctly, open the document using one of the PDF viewers integrated into your Chromium-based browser. If the interactive fields do not appear or do not respond as expected, make sure that your browser is up to date.

2.3 Processing requirements

DUOnco™ Unity analyses CT examinations that contain at least one CT image series meeting the technical and anatomical requirements described below. If no eligible CT image series is identified, the examination is not processed, and an appropriate processing status is returned (see Section 4).

2.3.1 Required examination characteristics

For successful processing, the submitted examination must contain at least one CT image series meeting the following conditions:

- the series is a CT image series
- the series is provided in DICOM CT Image Storage format
- the series is axial
- the series includes the thorax, abdomen and/or pelvis
- the series has a slice spacing not exceeding 5 mm
- the series has a pixel spacing not exceeding 1.1 mm
- the series contains at least 30 slices

Additional DICOM compatibility requirements are described in the DICOM Conformance Statement. This document is available upon user request by email to support@intrasense.fr.

2.3.2 Examinations not processed

DUOnco™ Unity does not process examinations when no eligible CT image series is available for analysis. This includes:

- non-CT examinations
- examinations that do not include the thorax, abdomen or pelvis
- examinations that do not contain any CT image series meeting the supported processing requirements

When no eligible CT series is available for analysis, no lesion or body-composition result is generated and DUOnco™ Unity returns an appropriate processing status (see Section 4).

2.4 Output

DUOnco™ Unity generates DICOM output objects that are returned to the configured clinical imaging environment and are intended to be reviewed together with the original CT images.

The table below summarizes the main result elements available in each output format.

Result element	DICOM SR	DICOM GSPS	DICOM SEG	DICOM SC summary	DICOM Encapsulated PDF summary
Return code in Series Description	✓	✓	✓	✓	✓
Processing status details / failure reason	✓				
Lesion identifier	✓	✓		✓	✓
Lesion contour / segmentation	✓	✓	✓	✓	✓
Long-axis annotation position	✓	✓		✓*	✓*
Short-axis annotation position	✓	✓		✓*	✓*
Long-axis measurement	✓	✓		✓	✓
Short-axis measurement	✓	✓		✓	✓
Craniocaudal-axis measurement		✓		✓	✓
Lesion volume	✓	✓		✓	✓
Lesion median density	✓	✓		✓	✓
Anatomical descriptor	✓	✓		✓	✓
Semiology descriptor	✓	✓		✓	✓
Lesion load summary				✓	✓
Longitudinal comparison information, when available		✓		✓	✓
Body-composition measurements	✓			✓	✓
Optional RECIST documentation support					✓

* In the GSPS, long-axis and short-axis annotation positions are displayed as graphical measurement lines. In the summary document, the key image displays the measurement location of the principal axial diameter: the long axis for non-lymph-node lesions and the short axis for lymph nodes. The summary display may use marker points rather than the full measurement line.

2.4.1 Dicom output identification

DUOnco™ Unity 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-Un ({return code}) - #{processed series number(s)} - {output format}

Where:

- **{return code}** is the processing status code generated by DUOnco™ Unity. Return codes are described in Section 4.
- **{processed series number(s)}** identifies the original CT series processed by DUOnco™ Unity.
- **{output format}** indicates the generated DICOM output format, such as SR, GSPS, SEG, SC or PDF.

For GSPS and SEG outputs, the Series Description identifies the source CT series on which the annotations, contours or segmentations are intended to be displayed.

For SR, SC and PDF outputs, the Series Description may include several processed series numbers when several CT series were processed within the same study.

2.4.2 DICOM Grayscale Softcopy Presentation State (GSPS)

The DICOM Grayscale Softcopy Presentation State (GSPS) is a DICOM object that contains graphical annotations and presentation information. When loaded into a compatible DICOM viewer, the GSPS is displayed as an overlay on the corresponding original image series. The GSPS allows users to review DUOnco™ Unity findings without modifying the original CT images.

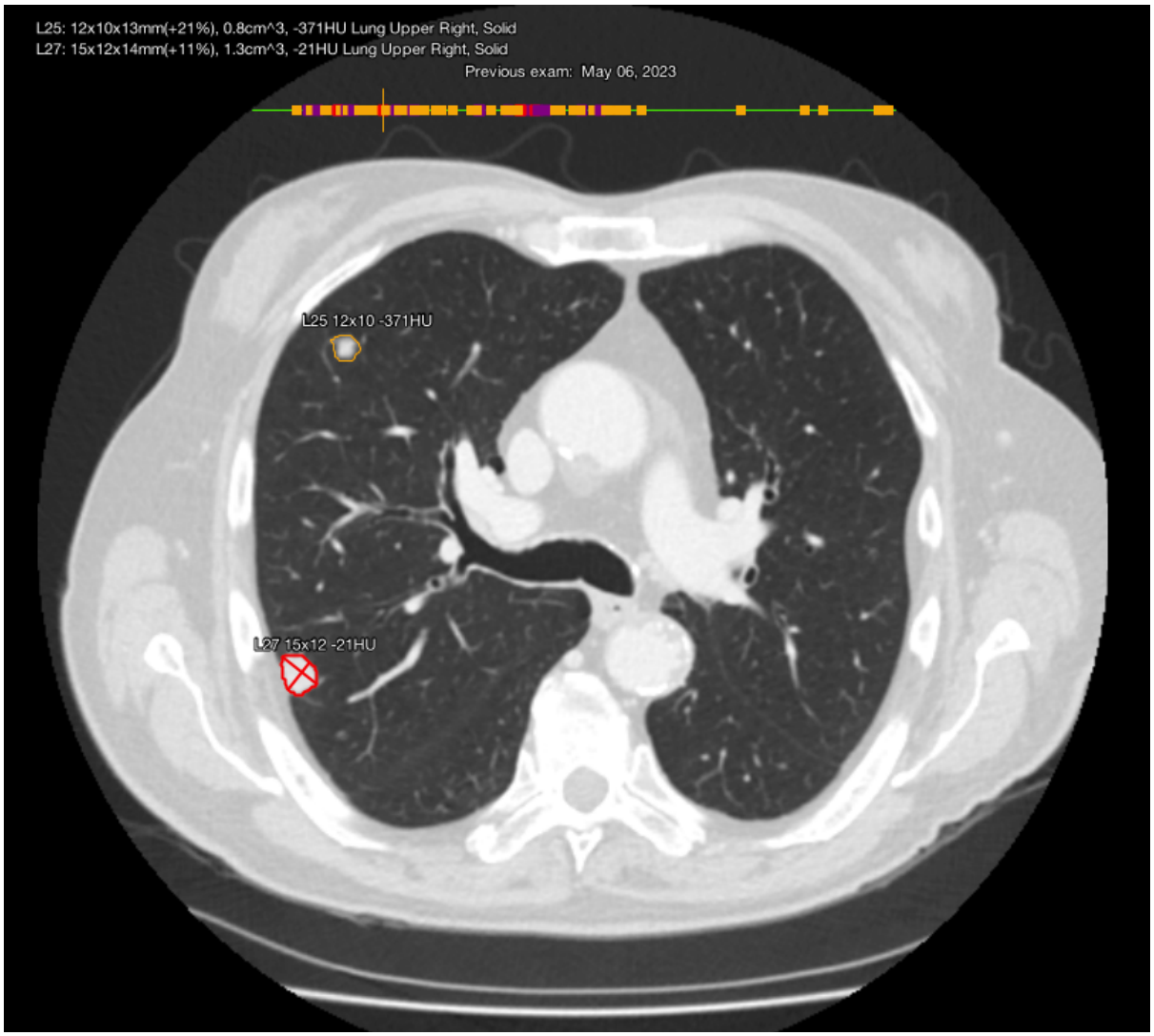
The GSPS results from DUOnco™ Unity are provided as an additional series alongside the original CT series. This series can be identified using the rule provided previously. However, if this series is not visible in the expected location, refer to the header of your summary document, which identifies the original CT series or series that were processed.

Depending on the processed findings and the configured presentation profile, the GSPS graphical overlay may include:

- a slice navigation bar indicating the relative position within the image series
- markers identifying slices containing detected findings
- lesion contours
- long-axis and short-axis annotations indicating the measurements location
- lesion short description displayed close to the lesion contour
- lesion detailed description displayed in the finding information area
- longitudinal comparison information, when available

The lesion short description provides a concise label intended to identify the lesion directly on the image. It includes the lesion identifier, axial measurements and median density, for example:
L10 15×13 79HU

The lesion detailed description provides additional information for review and reporting, including the lesion identifier, measurements, anatomical descriptor and semiology descriptor.



If no lesion is displayed in a successfully processed series, a “No lesion found in this series” message is displayed.

The visibility, color and display style of lesions may depend on the configured lesion presentation groups described in Section 2.5.

Multi-series case
When several CT series are processed within the same study, DUOnco™ Unity reconciles corresponding lesions across the processed series to provide a coherent lesion identification across the study.

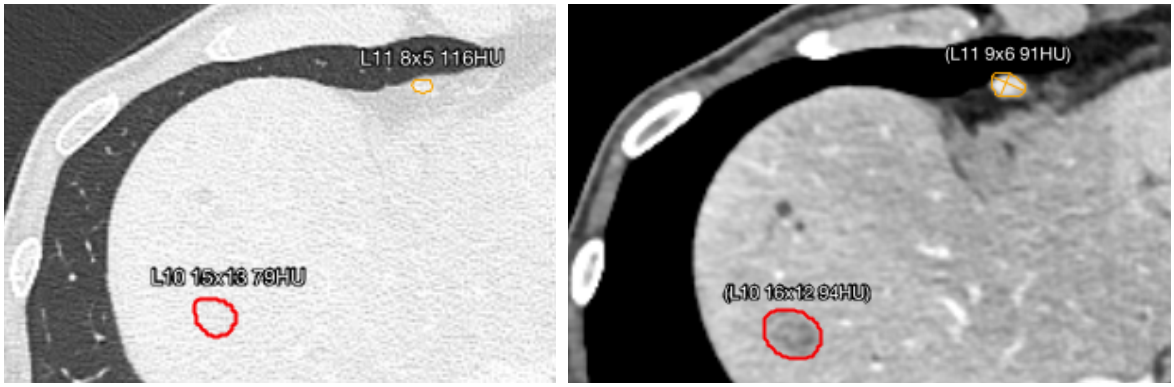
A lesion identified as corresponding across several processed series keeps the same lesion identifier. One serie is selected as the reference serie for that lesion.

On the reference serie, the lesion short description is displayed without parentheses, for example:
L10 15×13 79HU

On another processed series where the same reconciled lesion is displayed, the lesion short description is displayed between parentheses, for example:
(L10 16×12 94HU)

Parentheses indicate that the displayed lesion corresponds to the same reconciled lesion but is not shown on its reference serie.

The measurements and density displayed in the GSPS correspond to the values calculated on the CT series on which the lesion is displayed. Therefore, values may differ between processed series for the same reconciled lesion.



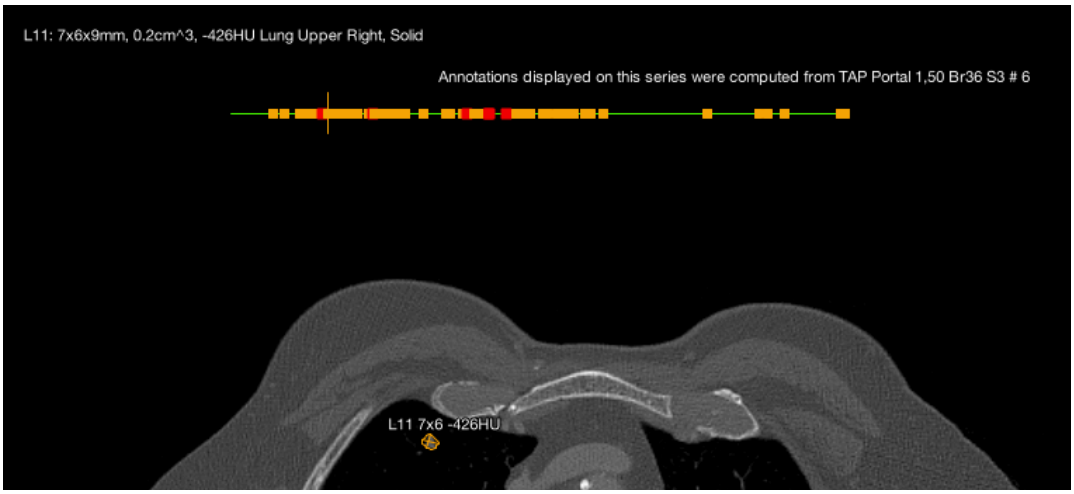
In the DICOM SR and summary document, lesion characteristics are reported from the reference serie for each reconciled lesion.

GSPS display on related series from the same acquisition

In addition to the GSPS generated for the CT series directly processed by DUOnco™ Unity, GSPS overlays may also be generated for related CT series from the same study that originate from the same CT acquisition event. This may include the original acquisition series and reconstructed series generated from the same raw acquisition data, for example lung-kernel or bone-kernel reconstruction series.

This allows lesion contours and annotations to be displayed on series commonly used during radiological review, even when these series were not directly processed by DUOnco™ Unity. GSPS overlays are generated on such related series only when their image geometry is compatible with the processed series, including the same image matrix and field of view. If a related series is zoomed, cropped, or has a different field of view or image matrix, the corresponding GSPS overlay is not generated.

When results are displayed on a related series that was not directly processed by DUOnco™ Unity, an information message is displayed to indicate that the results were generated from another series.



2.4.3 DICOM Structured Report (SR)

DUOnco™ Unity generates one DICOM Structured Report (SR) per processed study.

The DICOM SR contains the structured analysis results generated by DUOnco™ Unity, including:

- processing status and return codes
- processed series information
- lesion identifiers
- lesion contours or coordinates
- quantitative lesion measurements, including:
  - long-axis measurement
  - short-axis measurement
  - lesion volume
  - median lesion density
- lesion descriptors, including:
  - anatomical descriptor
  - semiology descriptor
- body-composition measurements, when available
- configuration information relevant to the generated outputs

The DICOM SR is intended for structured data exchange, traceability and archival. It is also the reference output for checking the complete set of generated results, including information that may not be displayed in all visual output formats. More information can be found in the DICOM Conformance Statement, available upon user request by email to support@intrasense.fr.

The DICOM SR is always generated, including when no lesion is detected or when processing is unsuccessful. In case of processing failure, the DICOM SR contains the corresponding processing status code.

2.4.4 DICOM SEG

The DICOM SEG object contains voxel-based lesion segmentations generated by DUOnco™ Unity.

The DICOM SEG is intended to support visualization of lesion segmentation masks in compatible DICOM viewers. It does not contain quantitative measurements or descriptive lesion information. Such information is provided in the DICOM SR and, where configured, in the summary output.

A DICOM SEG object is generated only when this output format is configured and when at least one applicable lesion segmentation is available.

2.4.5 Summary document: DICOM Secondary Capture (SC) or PDF

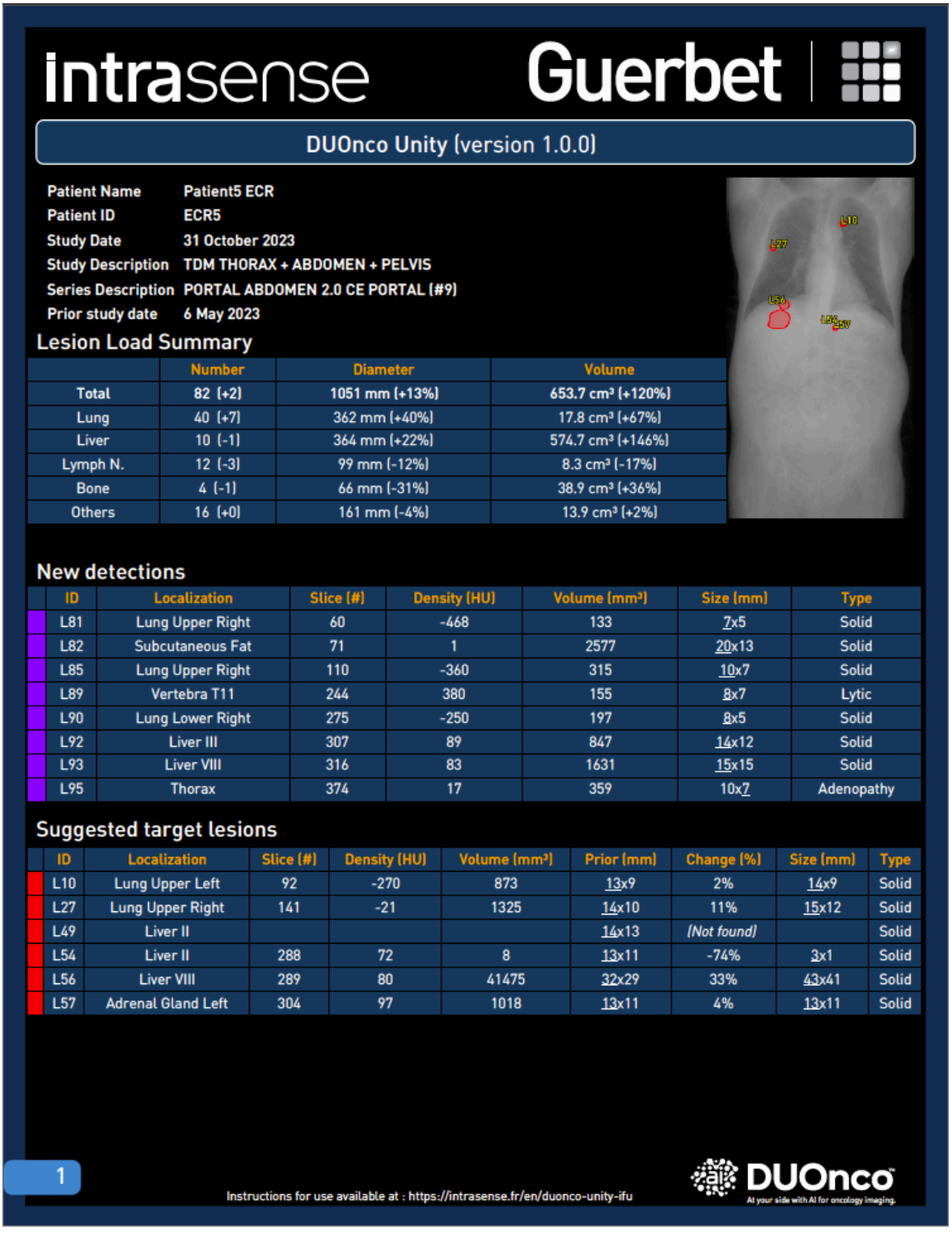
When configured, DUOnco™ Unity generates one summary document per processed study, either in DICOM Secondary Capture (SC) format or in DICOM Encapsulated PDF format.

The summary document provides an overview of the analysis results for the processed study. Depending on the processed findings, available prior examination and system configuration, it may include:

- patient and study identification information
- processed series information
- lesion load summary
- lesion list
- lesion measurements and descriptors

- longitudinal comparison information, when available
- body-composition analysis, when available
- lesion key images
- optional RECIST documentation support, when configured

The summary document is intended to facilitate review and documentation of DUOnco™ Unity results. It does not replace review of the original CT images and associated DICOM outputs.



intrasense Guerbet

DUOnco Unity (version 1.0.0)

Patient Name	Patient5 ECR
Patient ID	ECR5
Study Date	31 October 2023
Study Description	TDM THORAX + ABDOMEN + PELVIS
Series Description	PORTAL ABDOMEN 2.0 CE PORTAL (#9)
Prior study date	6 May 2023

Lesion Load Summary

	Number	Diameter	Volume
Total	82 (+2)	1051 mm (+13%)	653.7 cm³ (+120%)
Lung	40 (+7)	362 mm (+40%)	17.8 cm³ (+67%)
Liver	10 (-1)	364 mm (+22%)	574.7 cm³ (+146%)
Lymph N.	12 (-3)	99 mm (-12%)	8.3 cm³ (-17%)
Bone	4 (-1)	66 mm (-31%)	38.9 cm³ (+36%)
Others	16 (+0)	161 mm (-4%)	13.9 cm³ (+2%)

New detections

ID	Localization	Slice (#)	Density (HU)	Volume (mm³)	Size (mm)	Type
L81	Lung Upper Right	60	-468	133	7x5	Solid
L82	Subcutaneous Fat	71	1	2577	20x13	Solid
L85	Lung Upper Right	110	-360	315	10x7	Solid
L89	Vertebra T11	244	380	155	8x7	Lytic
L90	Lung Lower Right	275	-250	197	8x5	Solid
L92	Liver III	307	89	847	14x12	Solid
L93	Liver VIII	316	83	1631	15x15	Solid
L95	Thorax	374	17	359	10x7	Adenopathy

Suggested target lesions

ID	Localization	Slice (#)	Density (HU)	Volume (mm³)	Prior (mm)	Change (%)	Size (mm)	Type
L10	Lung Upper Left	92	-270	873	13x9	2%	14x9	Solid
L27	Lung Upper Right	141	-21	1325	14x10	11%	15x12	Solid
L49	Liver II				14x13	*(Not found)*		Solid
L54	Liver II	288	72	8	13x11	-74%	3x1	Solid
L56	Liver VIII	289	80	41475	32x29	33%	43x41	Solid
L57	Adrenal Gland Left	304	97	1018	13x11	4%	13x11	Solid

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Instructions for use available at : https://intrasense.fr/en/duonco-unity-ifu

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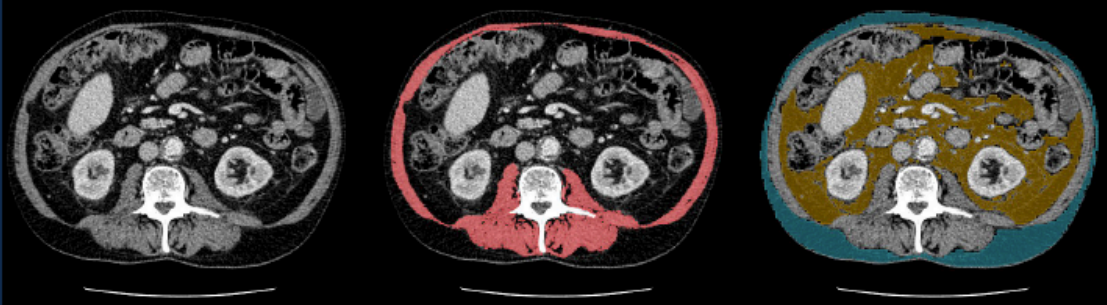
Body composition



PORTAL ABDOMEN 2.0 CE PORTAL (#9)
Slice 392

Abdominal muscles

Subcutaneous fat
Visceral fat

Parameter	Value	Evaluation (percentiles)
Muscle surface L3	137 cm² (-12%)	
Muscle surface L3 normalized	45 cm²/m²	11
Visceral fat surface L3	207 cm² (-33%)	61
Subcutaneous fat surface L3	107 cm² (-16%)	30
Muscle L3 density	34 HU (-7)	83

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List of all observed elements

ID	Localization	Slice (#)	Density (HU)	Volume (mm³)	Prior (mm)	Change (%)	Size (mm)	Type
L81	Lung Upper Right	60	-468	133			7x5	Solid
L82	Subcutaneous Fat	71	1	2577			20x13	Solid
L83	Thorax	92	69	324			11x5	Adenopathy
L84	Lung Upper Right	102	-572	78			5x4	GGO
L85	Lung Upper Right	110	-360	315			10x7	Solid
L86	Lung Upper Right	155	-538	104			5x4	Solid
L87	Lung Upper Left	174	-674	31			3x3	Solid
L88	Lung Lower Right	245	-463	148			6x5	Solid
L89	Vertebra T11	244	380	155			8x7	Lytic
L90	Lung Lower Right	275	-250	197			8x5	Solid
L91	Liver IV	295	37	10			3x2	Cystic
L92	Liver III	307	89	847			14x12	Solid
L93	Liver VIII	316	83	1631			15x15	Solid
L94	Kidney Left	354	27	26			3x3	Cystic
L95	Thorax	374	17	359			10x7	Adenopathy
L10	Lung Upper Left	92	-270	873	13x9	2%	14x9	Solid
L27	Lung Upper Right	141	-21	1325	14x10	11%	15x12	Solid
L49	Liver II				14x13	*(Not found)*		Solid
L54	Liver II	288	72	8	13x11	-74%	3x1	Solid
L56	Liver VIII	289	80	41475	32x29	33%	43x41	Solid
L57	Adrenal Gland Left	304	97	1018	13x11	4%	13x11	Solid
L1	Subcutaneous Fat				18x11	*(Not found)*		Solid
L2	Lung Upper Right	48	-226	115	5x4	21%	6x5	Solid
L3	Lung Upper Left	64	-558	75	3x3	33%	5x4	GGO
L4	Lung Upper Right	63	-271	909	11x9	8%	12x11	Solid
L5	Thorax				11x8	*(Not found)*		Adenopathy
L6	Lung Upper Right	73	-89	218	6x5	6%	7x6	Solid
L7	Thorax				9x8	*(Not found)*		Adenopathy
L8	Thorax	83	54	1168	13x9	-7%	13x9	Adenopathy
L9	Lung Upper Right	79	-28	799	9x7	24%	11x9	Solid
L11	Lung Upper Right	95	-407	426	7x6	33%	9x6	Solid
L12	Lung Upper Right	103	-110	1037	10x8	32%	14x12	Solid
L13	Thorax	100	27	262	8x6	17%	8x7	Adenopathy
L14	Lung Upper Right	104	-220	287	7x6	16%	8x6	Solid
L15	Lung Upper Left	115	-353	993	11x9	19%	13x11	Solid
L16	Thorax				9x5	*(Not found)*		Adenopathy
L17	Lung Upper Right	116	-216	316	7x5	31%	9x7	Solid
L18	Lung Upper Right	129	-122	770	9x9	17%	11x10	Solid
L19	Lung Upper Left	122	-463	155	5x4	18%	6x5	Solid
L20	Vertebra T6				5x4	*(Not found)*		Lytic
L21	Lung Upper Right	116	-315	341	6x5	32%	8x7	Solid
L22	Thorax	134	83	700	13x9	3%	14x9	Adenopathy
L23	Thorax	136	44	287	7x6	3%	7x6	Adenopathy
L24	Thorax	131	1262	482	10x9	-14%	10x9	Sclerotic

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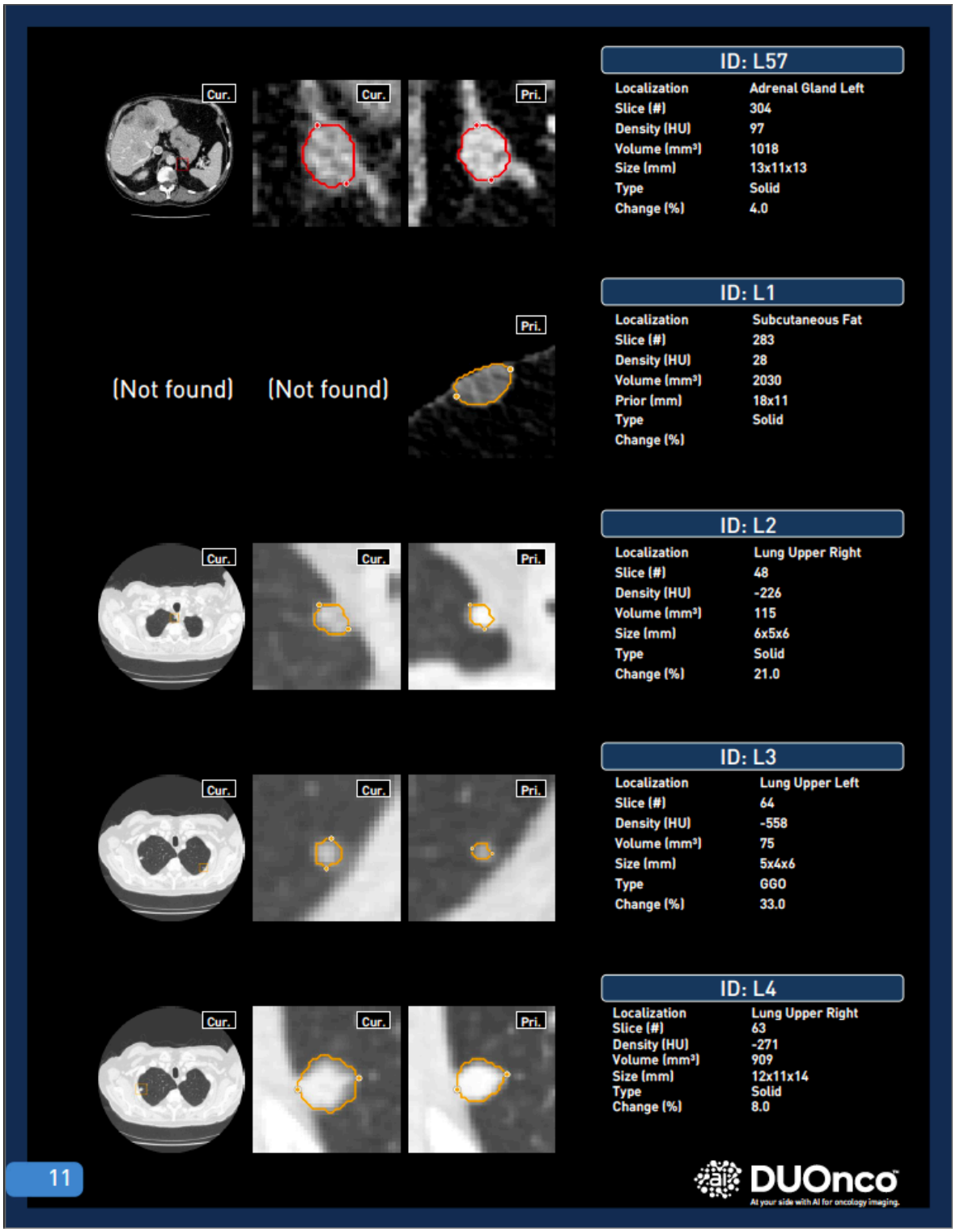
Cur.
Cur.
Pri.
ID: L57
Localization Adrenal Gland Left
Slice (#) 304
Density (HU) 97
Volume (mm³) 1018
Size (mm) 13x11x13
Type Solid
Change (%) 4.0
(Not found)
(Not found)
Pri.
ID: L1
Localization Subcutaneous Fat
Slice (#) 283
Density (HU) 28
Volume (mm³) 2030
Prior (mm) 18x11
Type Solid
Change (%)
Cur.
Cur.
Pri.
ID: L2
Localization Lung Upper Right
Slice (#) 48
Density (HU) -226
Volume (mm³) 115
Size (mm) 6x5x6
Type Solid
Change (%) 21.0
Cur.
Cur.
Pri.
ID: L3
Localization Lung Upper Left
Slice (#) 64
Density (HU) -558
Volume (mm³) 75
Size (mm) 5x4x6
Type GGO
Change (%) 33.0
Cur.
Cur.
Pri.
ID: L4
Localization Lung Upper Right
Slice (#) 63
Density (HU) -271
Volume (mm³) 909
Size (mm) 12x11x14
Type Solid
Change (%) 8.0
11
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RECIST documentation page

When the summary document is generated in DICOM Encapsulated PDF format and RECIST documentation support is configured, the summary may include an interactive RECIST documentation page.

This page is intended to support documentation of RECIST-based assessment. It does not determine RECIST applicability and does not replace the user's clinical judgement.

The RECIST documentation page allows the user to:

- select target lesions using checkboxes
- review and edit target lesion measurements in editable text fields
- enter the baseline sum of diameters and nadir sum of diameters, when applicable
- indicate whether new lesions are present
- document non-target lesion status, including unequivocal progression or disappearance of all lesions
- obtain automatically updated RECIST 1.1 calculations based on the entered information
- obtain dynamically generated report-ready text that can be copied into the radiology report

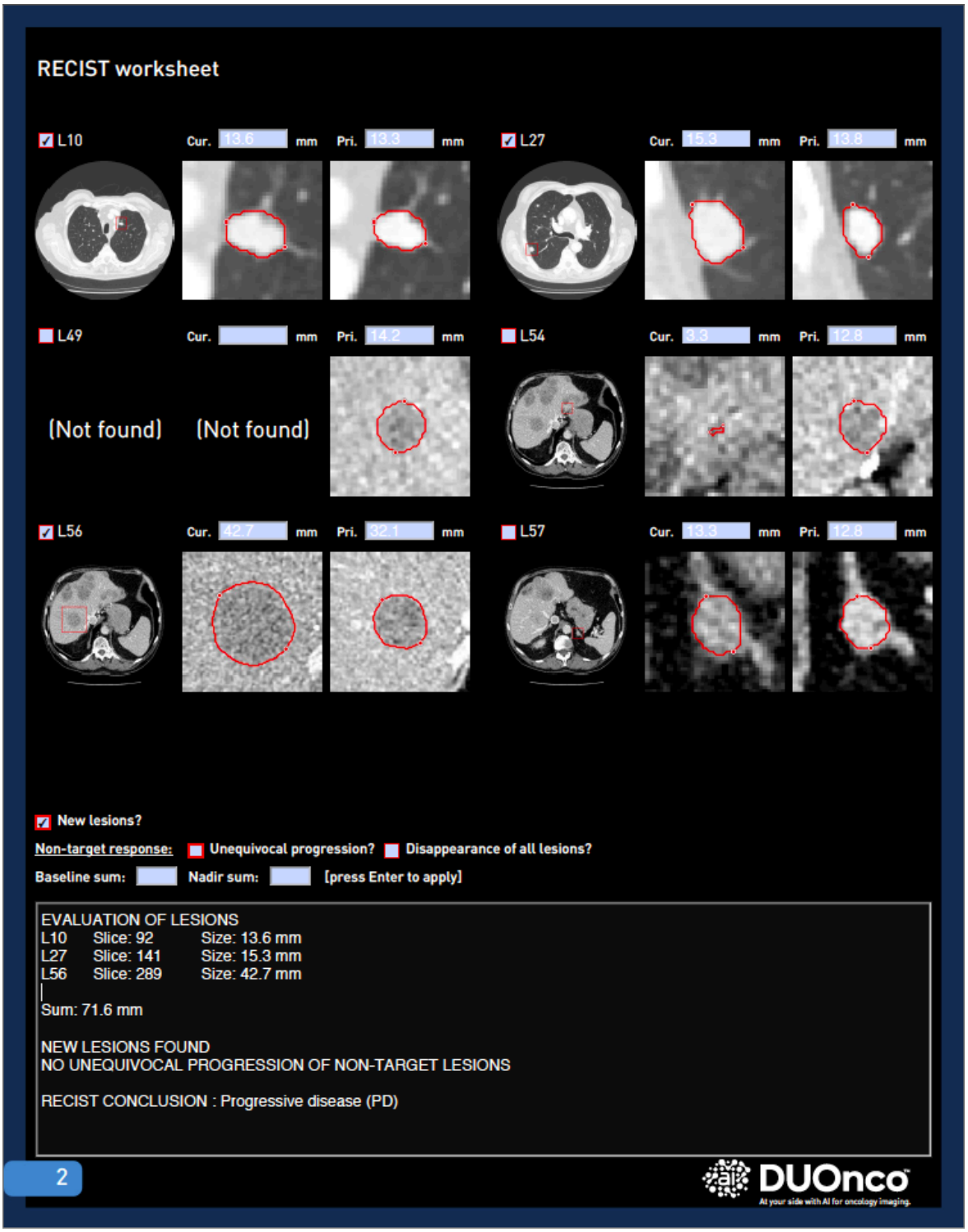
For each target lesion, the software provides a long-axis measurement (or short-axis measurement for lymph nodes) used to perform the RECIST calculation. If this value is incorrect or imprecise, it is possible to remeasure the lesion using a standard measurement tool and modify the value in the interactive PDF to correct the calculation. Press **Enter** to trigger the text update.

The software does not retain the information entered by the user regarding target lesions. Therefore, the user must manually enter the value of the sum of the long-axis measurements of the target lesions in the corresponding **"Baseline Sum"** or **"Nadir Sum"** field of the interactive calculator. When performing this action, press **Enter** to initiate the RECIST calculation and update the associated text intended for the report.

In addition, in some configurations, the automatically generated text intended for the report may not be updated immediately after selecting or deselecting a checkbox corresponding to a target lesion. If this occurs, place the cursor in the **"Baseline Sum"** or **"Nadir Sum"** field, then press **Enter** to trigger the update of the displayed text and sum.

The DICOM SC summary does not provide interactive RECIST documentation support.

RECIST applicability, target lesion selection, verification of lesion measurements, baseline and nadir values, assessment of new lesions, assessment of non-target lesions, validation of calculated values and review of any generated text remain under the responsibility of the qualified healthcare professional.



2.5 Lesion presentation groups

DUOnco™ Unity can organize detected lesions into presentation groups to support image review in the PACS or compatible DICOM viewer.

Presentation groups determine how lesions are visually displayed in the graphical outputs, including their color, contour style and display priority. They are intended to help users navigate the detected lesions and identify findings that may require particular attention.

Presentation groups do not modify the underlying detection, segmentation, measurement, descriptor or longitudinal comparison results generated by DUOnco™ Unity.

2.5.1 Default lesion presentation

By default, DUOnco™ Unity visually distinguishes detected lesions using the following presentation groups.

Suggested target lesions
Suggested target lesions are displayed in **red**, with a thicker contour to make them more visible during image review.

If the PACS or viewer does not support the configured color display, suggested target lesions may be displayed with an additional bounding box around the lesion contour.

Suggested target lesions are lesions that meet predefined image-based criteria intended to identify lesions that may be suitable for RECIST 1.1 target lesion selection. These criteria include lesion size, lesion semiology, anatomical location and other image-based characteristics intended to favour lesions that are measurable and suitable for longitudinal follow-up.

The suggested target lesion group is provided as a support for review and documentation. It does not automatically determine RECIST target lesions. Target lesion selection remains under the responsibility of the qualified healthcare professional.

By default, DUOnco™ Unity may suggest up to 3 lesions per organ and 8 lesions in total.

The user may select other lesions as target lesions when clinically appropriate.
Other lesions
Other displayed lesions are displayed in **orange**, with a thinner contour than suggested target lesions.

This group includes detected lesions that do not meet the configured criteria for suggested target lesions, but remain displayed for review.

Depending on the site configuration, other lesions may be hidden from GSPS overlays to reduce visual overload during image review. When hidden from the GSPS, these lesions remain available in the summary document and in the DICOM Structured Report.

New lesions
When longitudinal comparison is available, lesions identified as new compared with the prior examination are displayed in **purple**.

If the PACS or viewer does not support the configured color display, new lesions may be displayed with a double contour.

New lesion identification is intended to support follow-up review. The user remains responsible for confirming lesion correspondence, clinical relevance and interpretation.

2.5.2 Configurable display options

The lesion presentation configuration can be adjusted at site level according to clinical workflow, PACS/viewer capabilities and customer preferences.

The following display options may be configured:

- display or hide “other lesions” in GSPS overlays
- display cystic lesions as a distinct visual group, in **green**
- exclude cystic lesions from the “other lesions” visual group
- modify the criteria used to identify suggested target lesions, including the maximum number of suggested lesions per organ and the maximum total number of suggested lesions
- disable the suggested target lesion group by setting the maximum number of suggested target lesions to zero

These settings affect the visual presentation of lesions in the outputs. They do not modify the underlying algorithm results.

2.5.3 Detection display thresholds

In addition to presentation group settings, minimum size thresholds can be configured to determine which detections are included in the generated outputs.

The configurable size thresholds may include:

- minimum long-axis diameter
- minimum short-axis diameter
- minimum craniocaudal-axis diameter
- minimum short-axis diameter for lymph nodes

By default:

- the minimum size threshold for non-lymph-node lesion detections is **1 mm**.
- the minimum short-axis threshold for lymph-node detections is **5 mm**.

Detections below the configured size thresholds are not included in the generated lesion results.

2.5.4 Interpretation of presentation groups

The presentation groups are intended to support efficient image review and documentation. They should not be interpreted as diagnostic categories.

In particular:

- a suggested target lesion is not automatically a RECIST target lesion
- an “other lesion” may still be clinically relevant
- a cystic lesion display group, when configured, does not determine benignity or malignancy
- a new lesion indication should be reviewed and confirmed by the qualified healthcare professional

All lesion review, target lesion selection, assessment of disease progression and clinical interpretation remain under the responsibility of the qualified healthcare professional.

2.6 About Box and IFU access

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

The About Box webpage can be accessed with a standard web browser using the following URL:
https://intrasense.fr/en/duonco-unity-ifu

The About Box URL is included as text in DICOM tag (0081,1010) of the DICOM objects generated by DUOnco™ Unity.

When a summary document is generated, the About Box URL is also displayed at the bottom of the first page of the DICOM Secondary Capture or DICOM Encapsulated PDF summary.

The electronic Instructions for Use can be accessed and downloaded in the supported languages from the About Box webpage or from the Intrasense® website: www.intrasense.fr.

2.7 Order a paper copy of the 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 and software specifications

3.1 Compatible Imaging system

DUOnco™ Unity is intended to be used within a clinical imaging environment capable of producing DICOM CT examinations and reading the DICOM objects generated by DUOnco™ Unity.

The compatible imaging environment may include, depending on the customer configuration:

- CT scanners
- PACS
- DICOM routers or image distribution systems
- DICOM-compatible viewers
- other clinical imaging systems able to exchange DICOM objects

The review of DUOnco™ Unity outputs requires a PACS or DICOM viewer compatible with the generated output formats configured for the installation, such as DICOM SR, DICOM GSPS, DICOM SEG, DICOM SC or DICOM Encapsulated PDF.

The display and usability of each output format may depend on the capabilities and configuration of the customer's PACS or DICOM viewer. The compatible output formats and integration configuration are defined during deployment.

3.2 Hardware specification

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

vCPU (OpenVINO) backend:

- RAM requirement for 1 instance: 32 GB
- CPU requirement for nominal performance: 16 cores (Xeon™ Platinum 3 GHz or equivalent)
- Disk storage for OCI images and temporary working space: 40GB

GPU (CUDA) backend:

- vCPU requirement: 4
- RAM requirement for 1 instance: 16 GB
- GPU requirement for nominal performance: Nvidia® Ampere, Cuda 12+, with 16 GB VRAM
- Disk storage for OCI images and temporary working space: 40 GB

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

ⓘ Even though DUOnco™ Unity 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™ Unity is container-based and can be deployed through Kubernetes or other container orchestration platforms.
Cloud environments such as Microsoft Azure and Amazon Web Services (AWS) can support cloud deployment.

The data centres 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™ Unity. 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™ Unity component is deployed.

DUOnco™ Unity has essential security measures to reduce network vulnerabilities by design for cloud deployment. When DUOnco™ Unity 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™ Unity 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 is generated by DUOnco™ Unity to indicate whether processing was successful and whether results were generated.

The return code can be found in the following locations:

1. In the DICOM tag **Series Description** (0008,103E) of each generated DUOnco™ Unity output series, as described in Section 2.4.1.
2. In the **DICOM Structured Report (SR)**, in the following DICOM tags, under **Imaging Measurements / Algorithm Result**:
    - **(0008,0100) Code Value**: return code
    - **(0008,0104) Code Meaning**: short description of the processing status

The following table describes the possible return codes:

Return code	Description	Interpretation
200	Assessment available, 0 finding detected	Processing was successful. No lesion was included in the generated lesion results according to the applied configuration.
201	Assessment available, at least 1 finding detected	Processing was successful. At least one lesion was included in the generated lesion results.
204	Not able to evaluate, no series meeting input requirements	Processing failed because the submitted examination did not contain any eligible CT image series for analysis. See Section 2.3 for processing requirements.
205	Not able to evaluate, unknown reason	Processing failed for an unspecified reason. Contact Intrasense® customer support if the issue persists.

Codes 200 and 201 indicate successful processing.
Codes 204 and 205 indicate processing failure. In case of processing failure, no lesion or body-composition result is generated.

ⓘ The absence of DUOnco™ Unity results for a study should in no way be interpreted as indicating that no lesions were detected.

5 Technical support

The installation and maintenance instructions of DUOnco™ Unity 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

1231 Avenue du Mondial 98
34000 Montpellier
France
Tel: +33 4 67 130 130
Fax: +33 4 67 130 132
Contact: support@intrasense.fr
Website: www.intrasense.fr

Basic UDI-DI: 37007197DUOncoUnityYG

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REF DUOnco Unity 1.X