DUOnco™ liver

At your side with AI for oncology imaging

Software Version 1.X

Instructions for Use

en-UK

intrasense
by Guerbet

LAIA-00030 v2 **2024-07-16**

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INTELLECTUAL PROPERTY

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SYMBOLS

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

Symbol	Definition
	**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.
	**Consult Instructions for Use:** Indicates that the user shall read the Instructions for Use.
	**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 SR	DICOM Structural Reporting
DICOM Seg	DIOM Segmentation
DICOM GSPS	DICOM Grayscale Softcopy Presentation State

1 PRODUCT DESCRIPTION

DUOnco™ Liver is a standalone software intended to aid healthcare professionals trained to read CT scans for the detection and segmentation of liver focal lesions. The product employs advanced image processing and machine learning algorithms to identify and measure potential liver focal lesions on portal phase images of a CT scan study containing the liver 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™ Liver is a software intended to assist the analysis and review of contrast-enhanced (portal phase) CT scan images containing the liver through the automatic detection and measurement of liver lesions.

1.1.1 INDICATION FOR USE

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

1.1.2 CONTRAINDICATIONS AND UNDESIRABLE SIDE EFFECTS

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

1.1.3 PATIENT POPULATION

DUOnco™ Liver is intended for use only on patients over 18 years old who are scanned with contrast-enhanced (portal phase) CT scan sequences containing at least a significant portion of the liver.

1.1.4 INTENDED USER

DUOnco™ Liver is intended to be used by healthcare professionals qualified to read CT scan studies, who are typically radiologists.

1.2 CLINICAL BENEFITS

DUOnco™ Liver assists healthcare professionals in the analysis of medical images by detecting, segmenting, and measuring liver lesions.

1.3 PERFORMANCE CHARACTERISTICS

DUOnco™ Liver can provide accurate automatic detection, segmentation and measurement information on liver focal lesions based on contrast-enhanced (portal phase) liver CT images containing the liver.

- Sensitivity for target liver lesions of size > 10mm not inferior to 75%
- An average number of False Positive (FP) lesions per study not superior to 1, for lesions ≥ 5mm
- An average dice segmentation per correspondence (detected lesion) not inferior to 0.65, for lesions ≥ 10mm.

1.4 SAFETY INFORMATION

Residual risks have been judged 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 which the event occurred.

⚠ CAUTION!

DUOnco™ Liver may produce inaccurate lesions detections and measurements, which may lead to inaccurate diagnosis or inadequate treatment.

DUOnco™ Liver 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™ Liver.

⚠ CAUTION!

Accurate processing of CT images by DUOnco™ Liver relies on the quality and correctness of the image source data. Insufficient image quality may produce inaccurate results, which may lead to inaccurate diagnosis or inadequate treatment.

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

⚠ CAUTION!

The accuracy of measurements performed by DUOnco™ Liver depends on the resolution and quality of the original images.

1.5 LIMITATIONS OF USE

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

- Patients under 18 years old,
- Patients who have undergone prior liver surgery or received other local treatment for liver lesions,
- Patients with right-sided heart failure, constrictive pericarditis, or other vascular or congenital conditions likely to cause diagnostic ambiguity for focal liver lesions.

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

- Slice spacing > 5 mm,
- Images containing artifacts (such as due to noise, motion or metallic implants) within the region covered by the liver,
- Images reconstructed using bone or lung reconstruction kernels,
- Contrast media: barium.

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

1.5 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™ Liver is expected to be used in a healthcare environment (for example, hospital and radiology center), 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™ Liver can be deployed on-Cloud or on-Premises.

2.2 PRINCIPLE OF OPERATIONS

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

DUOncoTM Liver receives CT scan studies automatically transmitted from the radiology center's modalities or Picture Archiving and Communication Systems (PACS). Then, the studies are filtered based on DICOM headers and image processing techniques. Studies meeting the input requirements (chapter 2.3) are further processed by DUOnco™ Liver.

Deep learning-based algorithms analyze the images to identify, segment and measure potential focal liver lesions. The output resulting from processing of the device are:

- contour placed around all identified focal liver lesions
- with the following information and measurements:
  - long axis (maximum axial plane diameter) coordinates and length in mm,
  - short axis (diameter orthogonal to the long axis) coordinates and length in mm,
  - lesion volume in cm^3,
  - average lesion density in Hounsfield Units (HU) (for lesion ≥10mm) as well as HU standard deviation.

DUOnco™ Liver 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™ Liver'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™ Liver will process portal venous phase, from a single or multiphase contrast-enhanced CT imaging study, containing at least a significant portion of the liver.

2.3.2 EXCLUSION CRITERIA

DUOnco™ Liver will reject (not process) series that meet the following exclusion criteria:

- Series with less than 1/3 liver coverage
- Series which are not portal venous phase
- 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™ Liver results are forwarded to the PACS under various DICOM objects:

- DICOM SR (Structured Reports) containing lesions contour, and measurements
- DICOM Seg (Segmentation) containing lesions contour

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

By default, all DICOM objects can be generated. However, during installation, you have the option to exclude the generation of DICOM Seg

If DUOnco™ Liver does not detect any focal liver lesions, the result series will consist in a DICOM Structural Reporting (SR) series indicating that no focal liver lesions were identified.

If DUOnco™ Liver fails to process a series, the output result will consist in 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.

2.5 ABOUT BOX AND IFU ACCESS

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

The About Box can be accessed through a web browser using this URL pattern:

URL pattern	Purpose
* /advisors/app/about	Access to the About box
* /advisors/app/ifu	Access to the IFU

Here the symbol "*" represents the side-based web address where DUOnco™ Liver is accessible.

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

2.6 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™ Liver 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.

In particular, DUOnco™ Liver can be integrated with Liflow ® starting from software version 2 and higher.

3.2 HARDWARE SPECIFICATION

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

CPU (OpenVINO) backend:

- Container RAM requirement for 1 advisor instance: 18 GB
- CPU requirement for nominal performance: 16 cores (x86 64 bits, Intel® AVX-512 instruction set, ≥ 2.24GHz)
- Disk storage for OCI images and temporary working space: 34GB

GPU (CUDA) backend:

- Container RAM requirement for 1 advisor instance: 10 GB
- GPU requirement for nominal performance: Nvidia® Ampere, Cuda 11+, with 12GB VRAM
- Disk storage for OCI images and temporary working space: 34GB

ⓘ Minimum hardware configuration is the minimum required for DUOnco™ Liver to operate as specified.

ⓘ Even though DUOnco™ Liver 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™ Liver is based on Kubernetes.

Environment 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™ Liver. For DUOnco™ Liver 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™ Liver component is deployed.

DUOnco™ Liver has essential security measures to reduce network vulnerabilities by design for cloud deployment. When DUOnco™ Liver 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™ Liver 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™ Liver, is recorded in the DICOM SR output file.

The following table describes the different codes:

Return Code	Description
200	DUOnco™ Liver successfully processed the series and no focal lesions were detected.
201	DUOnco™ Liver successfully processed the series and at least 1 focal lesion was detected.
202	DUOnco™ Liver was unable to process the series because less than 1/3 of the liver was detected.
203	DUOnco™ Liver was unable to process the series because no portal venous phase was detected.
205	DUOnco™ Liver was unable to process the series due to unknown reason
207	DUOnco™ Liver was unable to process the series because the liver was not detected.
208	DUOnco™ Liver was unable to process the series due to DICOM filtering rejection.

5 TECHNICAL SUPPORT

The installation and maintenance instructions of DUOnco™ Liver 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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