User Manual

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Product	Innersight3D	
Model No	Innersight3D	
Process Owner		Signature:
Prepared By - Name: Lorenz Berger	Designation: Head - Design	
Reviewed By - Name: Eoin Hyde	Designation: CEO	
Approved By - Name: Lorenz Berger	Designation: Head - Design	

Reviewed On	24 Sep 2024	Changes Made	☒ Yes ☐ No
Reviewed By Name	Eoin Hyde	Next Review Date	24 Sep 2026

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Document Revision History

Rev No.	Details of Revision	Date	Starting Software Version No.
1.0	Initial Release.	30 Jul 2019	1.0
1.0.1	Updated product version number to 1.1.	2 Apr 2020	1.1
1.1.1	Updated Warning Icon.	10 Mar 2023	1.2
1.1.2	Updated product version number to 1.2.	14 Mar 2023	1.2
2.0	Updated product version number to 1.5.	04 Aug 2023	1.5
3.0	Updated User Manual revision number to product number range mapping to this table.	23 Oct 2023	1.6
4.0	Updated manufacturer address	15 Feb 2024	1.9
5.0	Updated residual risk	20 Jun 2024	1.9
6.0	Updated selected images	24 Sep 2024	1.9

innersight3D

USER MANUAL

Doc No. : I3D0032	Doc Name: User Manual	Ver No: 6.0

User Manual

Contents

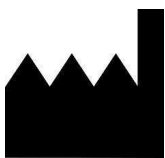# User Manual

User Manual

Document purpose

This document explains the form and function of the Innersight3D Web Platform, outlining all safety information, descriptions, operation, risks, warranty and contact details.

Upon request, we will send the print version of the manual to your clinic/office.

Innersight manufacturer responsibility:

Innersight Labs Ltd, referred here as ISL, the manufacturer of the product Innersight3D, considers itself responsible for the safety, reliability and performance of the product, provided:

- All device modifications are carried out by authorised personnel of ISL

- The device is used in accordance with the instructions presented in this 'ISL -User Manual'

- The device is used in the intended environment and to specifications for which it was designed.

<table>
<tr>
<td rowspan="2"></td>
<td>Company name:
Innersight Labs Ltd

Company address:
415 Perth Avenue, Slough, Berkshire, England, SL1 4TQ</td>
</tr>
<tr>
<td>CE Class 1 Medical device</td>
</tr>
<tr>
<td colspan="1">Company number:</td>
<td>09586858</td>
</tr>
<tr>
<td>MHRA Registration number:</td>
<td>8770</td>
</tr>
<tr>
<td>ICO Registration number:</td>
<td>ZA637258</td>
</tr>
<tr>
<td>DSPT Organisation code:</td>
<td>8KH06</td>
</tr>
</table>

Safety information

a. General Safety information

    i.   Device use and patient safety

The 3D model from Innersight3D is for use by trained physicians only.

There are no adverse events detailed as Innersight3D is not directly associated with patient treatment and low accuracy segmentations and their derived 3D models are not linked to diagnosis as Innersight3D is not a diagnostic tool, but is only used for visual assessment of the patient's anatomy, which assists with surgical planning.

    ii.   In case of device not functioning

Contact the Innersight support team at support@innersightlabs.com

b. Precautions and warnings

- Innersight3D is not for use on neonates.
- Innersight3D 3D models are only supposed to be used alongside the original CT/MRI of surgical planning decision making.
- Ensure that the device used for viewing the Innersight3D web-platform is connected to the internet.
- Do not refresh the 3D Viewer page when using the model during a time or place of no internet connectivity.
- Innersight3D is designed to work with CT/MRI scans with a slice thickness up to a maximum of 3.0mm
- Scans with slice thickness greater than 3.0mm will be rejected by the system as unsuitable.
- The 3D model from Innersight3D must be interpreted with consideration of the underlying segmentation and scan quality.
- The accuracy of the 3D model can be degraded by imaging artefacts which can affect the technical quality of the CT/MRI scans and therefore the underlying quality of the 3D model.
- It is advised that the user run periodic health-checks on their device to ensure correct function and interaction with the Innersight3D platform.
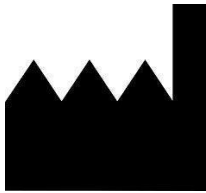
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c. Device Identification
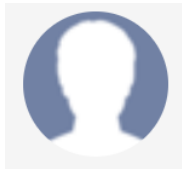
Name: Innersight3D
UDI-DI: (01)5070002625308-(11)190706

d. Symbols used

CE marked medical device		Legal manufacturer details	
Date of manufacture		Medical device	
Caution		Warning	

e. User Interface buttons
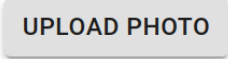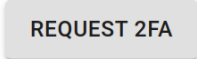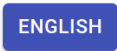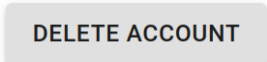
i. Profile

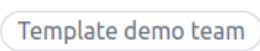| Go home to diary page		View profile and log out	
Add new case			
Reply to message left by Innersight team		Notification check box	Email SMS
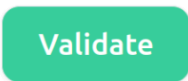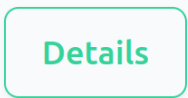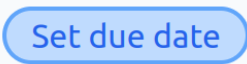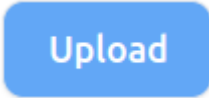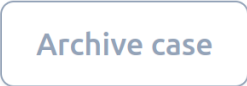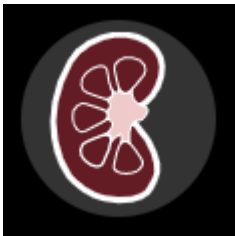
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Upload profile picture file	UPLOAD PHOTO	Request multi factor authentication activation	REQUEST 2FA
Select preferred language	DEUTSCH ENGLISH	Delete account including all related profile information	DELETE ACCOUNT

ii. Diary
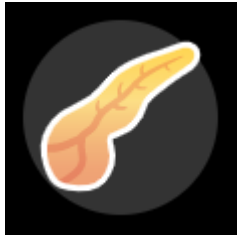
View 3D model	View 3D	Validate 3D model	Validate
Select team	Template demo team	Case details	Details
Set case due date	Set due date	Upload scans	Upload
Archive case	Archive case		

iii. Organs

Kidney		Prostate	
Bladder		Stomach	

Colon		Pancreas	
Gallbladder		Uterus	
		Ovaries	

iv. Bones

Pelvis		Sacrum	
Right pelvis		Left pelvis	
Bone			

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v. Organ anatomy

Collection system			
Seminal vessels		Neurovascular bundle	
Rectum		Mesorectum	
External sphincter		Internal sphincter	
Bronchi		Bronchi detail	
Urethra		Sinus fat	

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Adrenal gland		Lymph node	
Biliary duct			

vi. Implants

Stent	

vii. Vessels

Artery		Vein	
Portal vein			

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viii. Vessel detail

Artery detail		Vein detail	

ix. Vessel names

Middle colic artery		Middle colic vein	
Right colic artery		Right colic vein	
Ileocolic artery		Ileocolic vein	
Gastroduodenal artery		Gastrocolic trunk of Henle	
Superior mesenteric artery		Right gastroepiploic vein	

Sigmoid artery	SA	Inferior mesenteric vein	IMV
Inferior msenteric artery	IMA	Superior mesenteric vein	SMV
Left colic artery	LCA	Inferior pancreaticoduodenal vein	IPDV
Upper rectal artery	URA		

x. Vessel uncetain

Uncertain artery	Y	Uncertain vein	Y

xi. Lobes

Lung - Right upper lobe (superior)	RU	Liver - Right lobe	RL
Lung - Right middle lobe (Medial)	RM	Liver - Left lobe	LL
Lung - Right lower lobe (inferior)	RL	Lung - Left upper lobe (superior)	LL
		Lung - Left lower lobe (inferior)	LU

xii. Lobe segments

Lung lobe Segment S1	S1	Lung lobe Sub-segment Sa	S a
Lung lobe Segment S2	S2	Lung lobe Sub-segment Sb	S b

Lung lobe Segment S3		Lung lobe Sub-segment Sc	

xiii. Lobe segment vessels

Lung lobe Segment S1 - artery A1		Lung lobe Sub-segment Sa - artery Aa	
Lung lobe Segment S2 - artery A2		Lung lobe Sub-segment Sb - artery Ab	
Lung lobe Segment S3 - artery A3		Lung lobe Sub-segment Sc - artery Ac	

xiv. Minerals

Calcification		Stone	
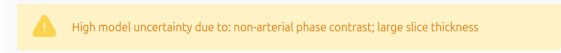
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xv. Unknown

Unknown object	

xvi. Warning

View warning message	
Warning message	High model uncertainty due to: non-arterial phase contrast; large slice thickness

xvii. Lesions

Tumour		Cyst	
Uncertain lesion			

Product description

b. Short description or overview

Innersight3D is a software-only device that allows surgeons to request a patient specific 3D model to be created from a patient's scan. After having received the scan and prescription, Innersight will label the scan according to different tissue types, and then create an interactive 3D model representation of the scan. The 3D model can then be accessed and interacted with via a web link which is sent to the clinician.

The 3D images generated using Innersight3D are intended to be used in connection with surgical operations in which CT or MR images are used for preoperative planning and/or reviewed intraoperatively.

The manner in which the 3D images are viewed and used does not vary between surgery types. The 3D images are viewed solely from the clinicians' compatible mobile devices, and are not viewed through or otherwise integrated with surgical navigation systems.

c. Intended use

Innersight3D is intended for the re-visualization of any anatomical region of a patient's body in three Dimensional views by the clinician to aid the clinician to plan the treatment of the patient as decided by the clinician, through segmentational and/or surface mesh visualisation of different components of the anatomy. It is intended to be used in addition and alongside the original CT/MRI scan images of the patient.

Innersight3D aids the re-visualization of existing CT or MRI data which is uploaded via the users PACS system to the Innersight3D platform, into an interactive 3D model of anatomical structures to facilitate improved surgical planning.

d. Intended Users

It is intended to be used by [trained] healthcare professionals such as surgeons or radiologists in a clinical setting to better inform their clinical judgement on assessment of the patient's anatomy for the purpose of assisting with their pre and intraoperative surgical planning.

e. Indications of use

There are no specific indications of use for Innersight3D, the use of the device is left to the discretion of the clinician.

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f. Contraindications for use

Innersight3D must not be used if:

The segmentation of the 3D model has not been verified/checked for correctness by a clinician using the validator page.

Innersight3D is not:

Supposed to be used to solely guide surgical decision making. It should always be used alongside the original CT/MRI scan.

g. Product features

Diary
- enables the user to view all upcoming and previous cases

- enables the user to edit notes of cases

- enables the user to upload and create new cases.

Validator
- enables the user to review the segmentation against the CT.

3D Viewer
- enables the user to view and interact with the 3D model.

h. Product specifications

The web-app will work in the following browsers:

- Chrome v.70 and above

- Firefox v.67 and above

- Safari v.16 and above

- Edge v.108 and above

Minimum screen requirements: 375 x 667 pixels

It is recommended but not required to use Innersight3D with a touch screen device.

User Manual
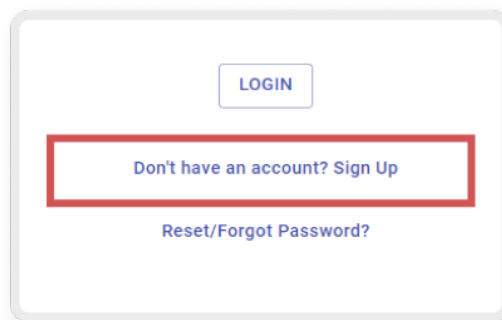
Operation

a. Principles of Operation

Innersight3D is operated on an internet connected device and accessed through the domain https://diary.innersightlabs.com/login on a web browser using the most stable release. Innersight3D works on the principle that all services and features are provided and operated via this web platform.
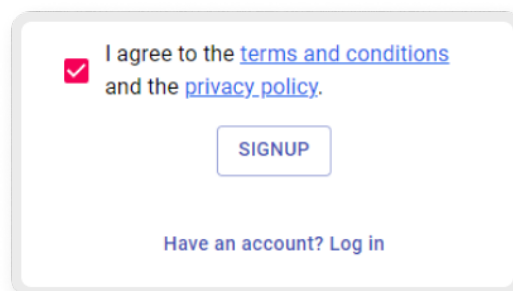
b. Step by step of operation from Log in to end

i. Signup and login Innersight3D Web Platform

All users of the innersight platform will be required to create an account at
https://diary.innersightlabs.com/login
Click on 'Don't have an account? Sign up'

Enter a user name with an email address and create a unique password.

Password must contain at least 8 characters, including: - an uppercase character, - a lowercase character, - a number

Read and agree to the terms and conditions and the privacy policy then click 'Sign up'

ii. Update personal details

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Login in at https://diary.innersightlabs.com/login go to profile (top right icon) and select 'Profile'
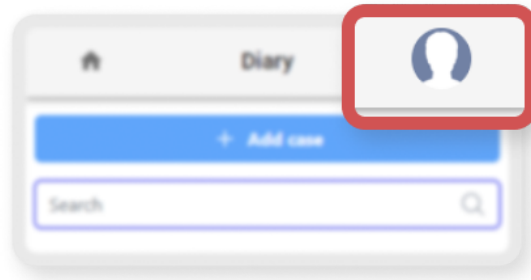
Personal details can be edited on the profile page.
- First name
- Last name
- Phone number

Language options available by clicking on the relevant button.
- German
- English
- Spanish
- French
- Italian
- Portuguese

Clicking the 'Home' icon will return you to the home page with all diary cases.

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iii. Profile features and buttons

Click 'UPLOAD PHOTO' to change the profile picture on the account.

[UPLOAD PHOTO]

Click 'REQUEST 2FA' to activate two factor authentication on the account.
Note: must have a recognised phone number on the account profile

[REQUEST 2FA]

Accounts can be deleted by clicking on the 'DELETE ACCOUNT' button.

[DELETE ACCOUNT]

Notification preferences can be changed by ticking the relevant 'Email' or 'SMS' box

Notification preferences

Notify me when...	Email	SMS
a model is ready	☑	☐
I have an operation due today	☑	☐

iv. Team information

At the bottom of the profile page, team information can be viewed in 'My Team'

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My Team

eoinhyde+regularuser@gmail.com

Eoin Reg
eoinhyde+regularuser@gmail.com

-
eoinhyde+segmenter@gmail.com

Pending invitations:

eoinhyde+test2@gmail.com

Invite a colleague

Team case history

Total number of cases in last year: 4
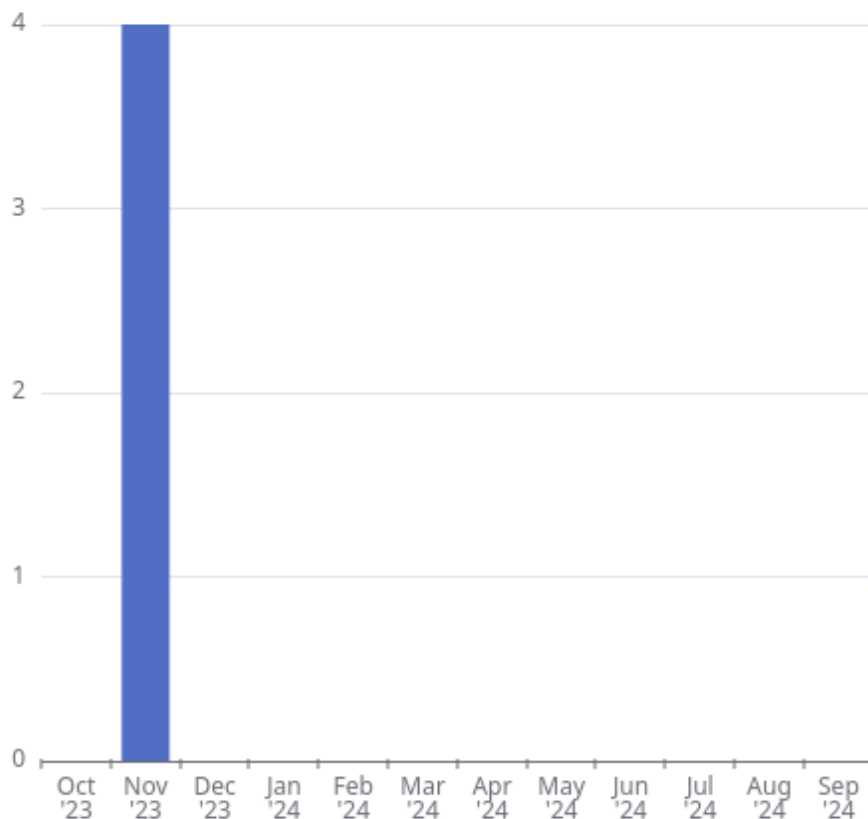
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The email address and profile name of team members is displayed.

Team case history can be viewed to track the number of 3D cases published each month.

v. Invite a colleague

Login in at https://diary.innersightlabs.com/login go to profile (top right icon) and select 'Profile'
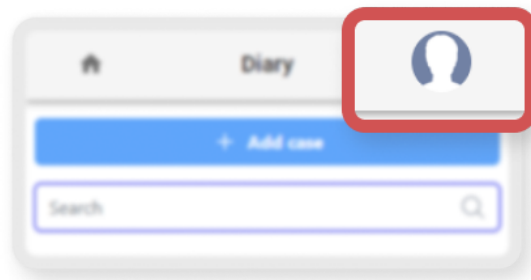
Go to 'My Teams' and enter the email address of those you want to add to the team. An email invitation will then be sent to that address.

PLEASE NOTE: If you would like to be added to a 'Team' you are not already part of, email someone on that team and ask them to invite you using the above steps.

Alternatively email us at support@innersightlabs.com

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vi. Add case using 'Via Image Exchange Portal' method

To request a 3D model from Innersight, sign in to your account or create a new account at
https://diary.innersightlabs.com/login

Click 'Add case' at the top of the page
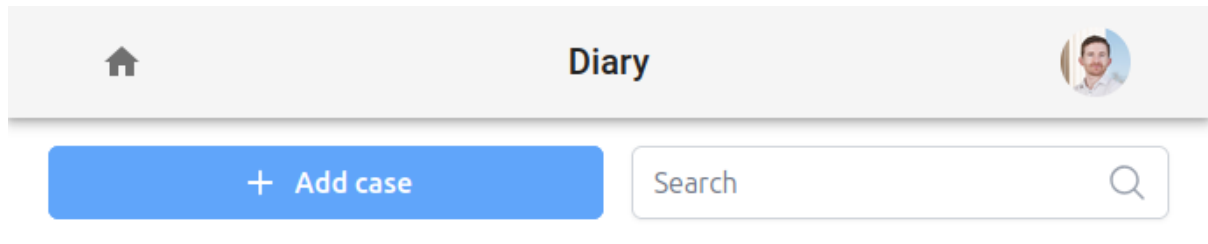
Select the relevant clinical 'Team' and complete the request form
with the correct information in all essential fields, marked *

Select the 'Model Type' you require

Ensure that Upload method is set to 'Via Image Exchange Portal'

Select the location of the patient scans in 'Where were the scans taken?'

Enter the required patient details in the essential fields, marked *

Once the request form is complete click 'REQUEST SCANS VIA IEP'

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REQUEST SCANS VIA IEP

The following status will show on you're newly created case and the Innersight team will request the scans through SECTRA IEP https://www.iepservice.co.uk/ to begin constructing you're 3D model.

iepRequestSubmitted

vii. Add case using 'Upload' method

To request a 3D model from Innersight, sign in at https://diary.innersightlabs.com/login
Click 'Add case'
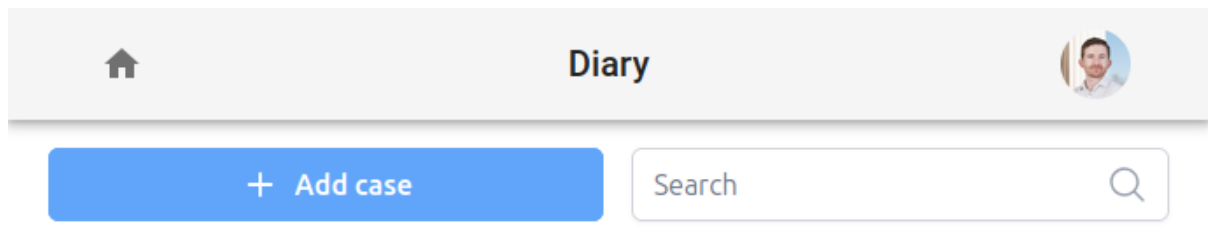
Complete the form:
- Select your clinical team
- Choose Model type
- Create a unique patient reference
- Add case notes to help guide the 3D team
- Select a due date for the 3D model

Click 'Upload Scans'

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Diary

Add a new case

Model type *

Kidney ▾

Required

ⓘ   Expected scan modality: CT (Contrast enhanced) - Recommended

Local file upload. Use this method when you have access to the DICOM files in a folder on the computer that you are using.

Patient reference number *

E.g. JB-17-05-1948

Enter an anonymous reference id. E.g. patient intials and date of birth.

Case notes *

E.g. Left side, 4cm lower pole tumour.

Add notes about the region of interest and tumour anatomy.

Side *

▾

Required

Due by

mm / dd / yyyy 📅

When the 3D model is needed by

UPLOAD DATA

'Drag and drop' the correct DICOM folder in to the upload box
or
click 'add from your computer' and select the correct DICOM folder

Drag and drop here or
add from your computer
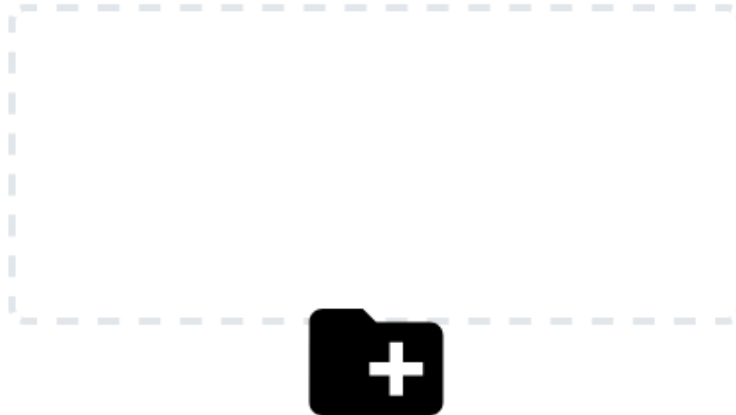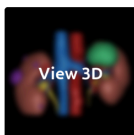
viii. Case status

Once you have created a case you can track the progress on you diary by following the status updates and checking the thumbnail images

Status	Example
'Case created' You successfully created a case and the scans are yet to be uploaded	Reference / Referenz / Referencia / Référ...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Case created Details Upload

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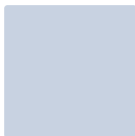|	
'Requesting scans' (if via IEP) iep request has been raised with SECTRA iep and the scans will be uploaded shortly	Reference / Referenz / Referencia / Référ...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Requesting scans [Details]
'Scans received' Scans have been uploaded successfully	Reference / Referenz / Referencia / Référ...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Scans received [Details]
'Building model' The process for building a 3D model has started	Reference / Referenz / Referencia / Référ...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Building model [Details]
'Reviewing model' The 3D model is built and undergoing reviews before publication	Reference / Referenz / Referencia / Référ...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Reviewing model [Details]
'Case published' Your 3D model is approved and published and is ready to view on your team Diary	View 3D Reference / Referenz / Referencia / Réfé...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Case published [Details] [Validate]

ix. Case status (Troubleshooting)

If there are any issues with a case, you may see one of the following status: closed, withUploader, noSuitableVolumes, which can be followed up with a response via email to support@innersightlabs.com or the feedback box in the case details by clicking the 'Reply' button

Status	**Example**
'Case closed' Cases can be closed for various reasons, for example: The clinician no longer requires a 3D model, suitable scans for 3D were unavailable, the planned procedure was cancelled.	Reference / Referenz / Referencia / Référ...Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Case closed [Details]

'Scans not suitable' The scans received are not suitable for building a 3D model. You can reply to the message via the email notification or by clicking 'Reply' to leave your response in the feedback section, or simply use the 'Reupload' button.	**Reference / Referenz / Referencia / Référ...** Sep 24 Case notes / Fallnotizen / Notas del caso / Notes de cas side: left Scans not suitable Reply Reupload
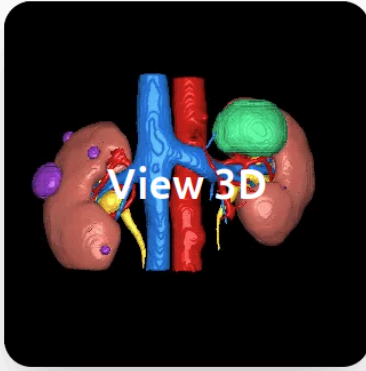
x. Case details

Case details will display case specific information and features.

Diary

Reference / Referenz / Referencia / Référence

Case reference	Created by	Team
Reference / Referenz / Referencia / Référence	eoinhyde+regularuser@gmail.com	created team

Model type	Created	Due by
Kidney	Sep 24	Sep 24

Status 3D model is available.

Case notes Case notes / Fallnotizen / Notas del caso / Notes de cas

Unique model identifer (01)5070002625308-(11)190706-(21)1727212499102

Feedback

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Click on the 'Details' button to view case details.
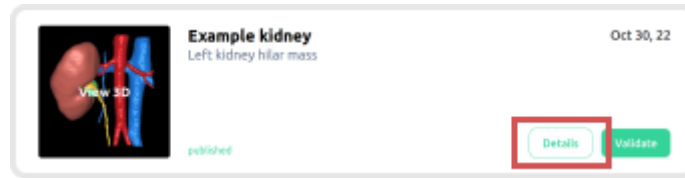
Fields with a blue pencil adjacent can be edited, once the information is correct click the green tick to update the field.

Fields that can be edited are:
- Case notes
- Due by
- Feedback

Volume information is also displayed in 'Details' along with 'Validate' and 'Upload more volumes'
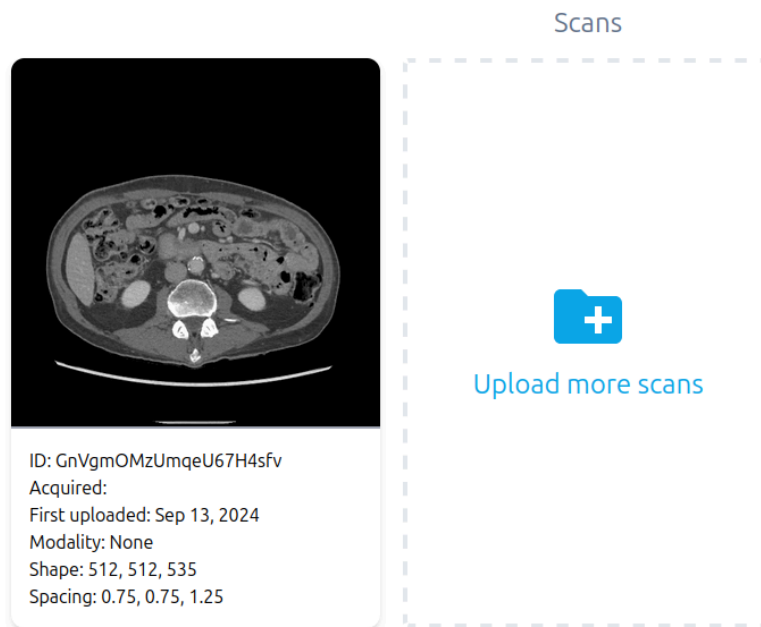
xi. Validate the labelled scan

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To validate the CT scan and the labels used to generate the 3D model, first sign in at https://diary.innersightlabs.com/ Find the relevant case and then click the 'Validate' button
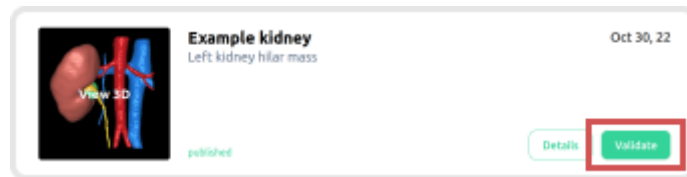
The validate button will also be found in 'Details' shown in green
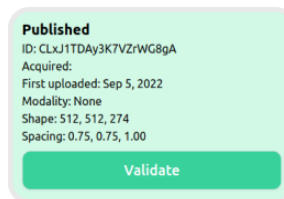
You can now view the scan and validate the image using the tools on right side of the browser window
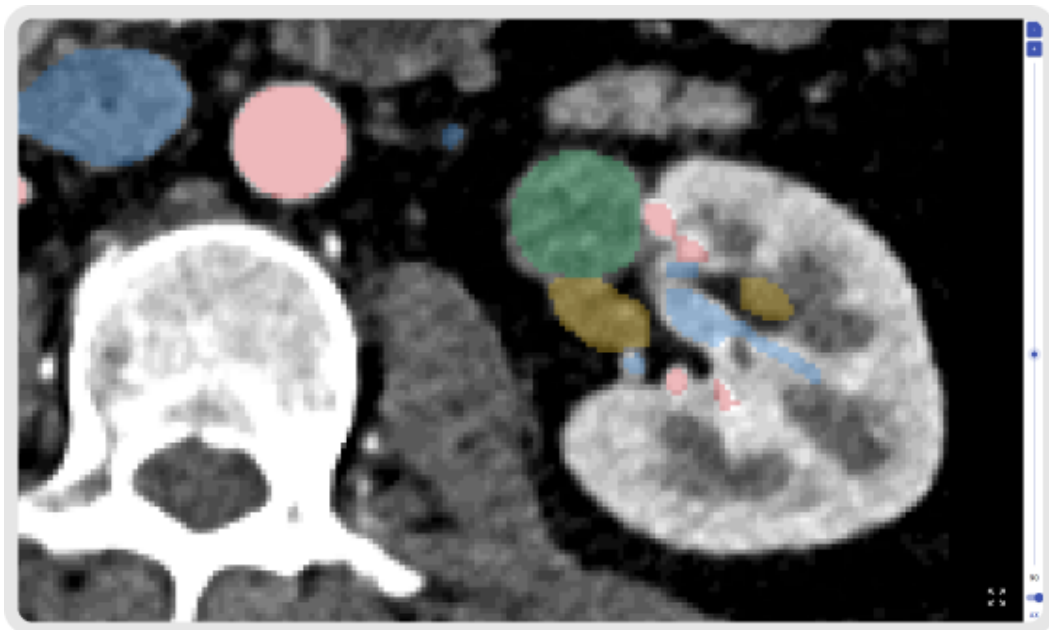
xii. View 3D model

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To view your 3D model sign in at https://diary.innersightlabs.com/login
All cases for your clinical team will be displayed here, along with the case details and the current status of each case
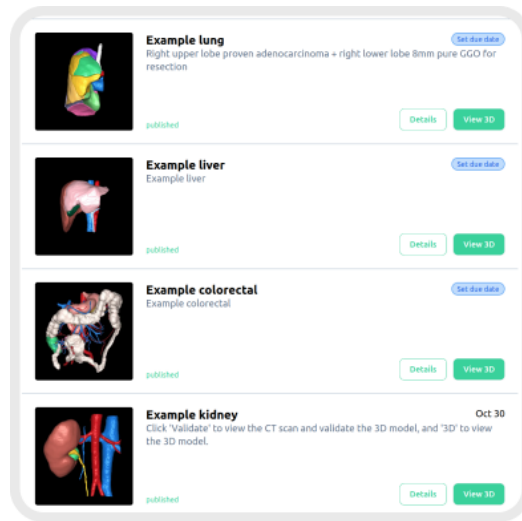
To interact with the 3D model click the thumbnail image of the 3D model where is says 'View 3D'
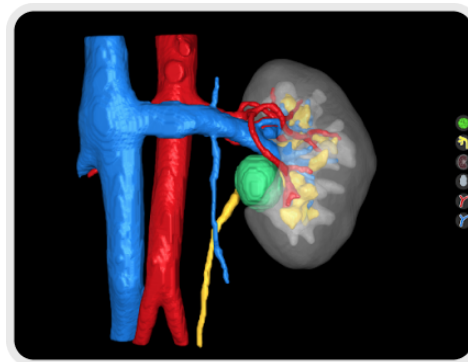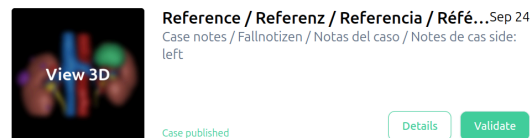
xiii. 3D model controls and functions

'3D viewer' mouse controls

Doc No. : I3D0032	Doc Name: User Manual	Ver No: 6.0

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Mouse button	Action	Function
Left mouse	Click and hold	Rotates the 3D model on its axis
Right mouse	Click and hold	Drags the 3D model across the plane of view
Mouse wheel	Click and hold or scroll	Zoom in and out of the 3D model

| '3D viewer' touch screen controls		
Fingers	**Action**	**Function**
One finger	Tap and hold	Rotates the 3D model on its axis
Two fingers	Tap and hold	Drags the 3D model across the plane of view
Two fingers	Pinch	Zoom in and out of the 3D model

Each 3D model has its own set of buttons for each anatomical object set out on the right hand side of the 3D viewer. Each button functions the same regardless of the object it represents.
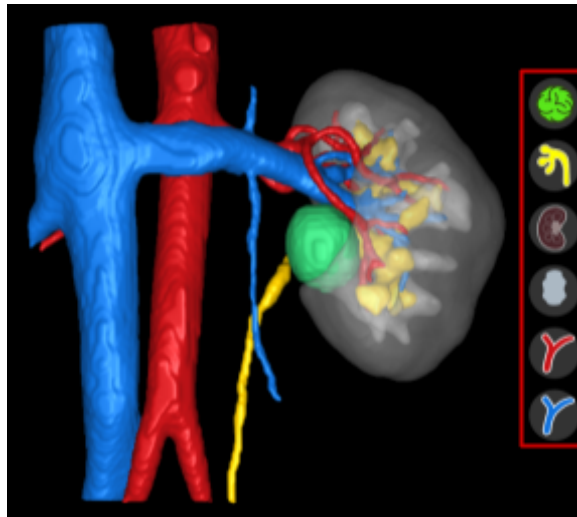
User Manual

Action	Object button	Object appearance
First left mouse click - Translucent		
Second left mouse click - Transparent		
Third left mouse click - Opaque		

xiv. Log out

To log out of https://diary.innersightlabs.com/login go to profile (top right icon)
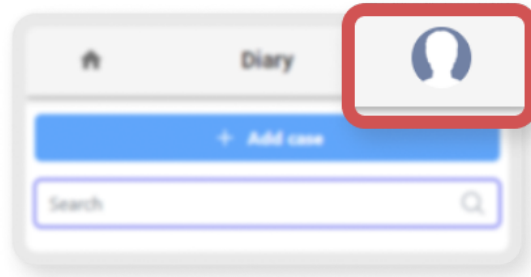
Select 'Logout'
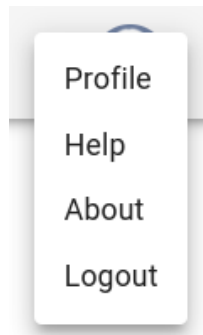
You will now be lagged out of your Innersight account.

Next time you open https://diary.innersightlabs.com/login in your browser you will need to log in with your correct username and password, to access 3D cases on the Innersight3D Web Platform.

Residual Risks

Using Innersight3D might lead to the following remaining risks:
- Surgeon could use an inaccurate 3D model that is not 100% representing the patient's anatomy for treatment planning due to bad quality input data.

Product Warranty statement

Other than the seller CE marked product, all other software and services are provided on an 'as is' basis without a warranty of any kind being provided by the seller. The seller expressly disclaims all warranties, either expressed or implied, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose.

User Manual

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