




User Manual

Product / Specific Document Details:

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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	Signature: 	
Approved By - Name: Lorenz Berger	Designation: Head - Design	Signature: 	
Reviewed On	07 March 2025	Changes Made	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Reviewed By Name	Eoin Hyde	Next Review Date	07 March 2027

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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
7	Updated selected images	07 Mar 2025	1.11

innersight3D

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Document purpose

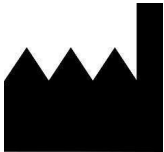

This document explains the form and function of the Innersight3D Web Platform, outlining all safety information, descriptions, operation, risks, warranty and contact details.

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.

	Company name: Innersight Labs Ltd Company address: 415 Perth Avenue, Slough, Berkshire, England, SL1 4TQ
	CE Class 1 Medical device
Company number:	09586858
MHRA Registration number:	8770
ICO Registration number:	ZA637258
DSPT Organisation code:	8KH06

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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.


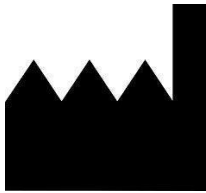




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c. Device Identification

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	






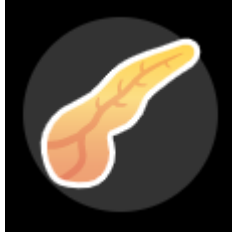



e. User Interface buttons

i. Profile



Go home to diary page		View profile and log out	
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ii. Organs

Kidney		Prostate	
Bladder		Stomach	
Colon		Pancreas	
Gallbladder		Uterus	
		Ovaries	








iii. Bones

Pelvis		Sacrum	
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Right pelvis		Left pelvis	
Bone			


iv. Organ anatomy

Collection system			
Seminal vessels		Neurovascular bundle	
Rectum		Mesorectum	
External sphincter		Internal sphincter	

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Bronchi		Bronchi detail	
Urethra		Sinus fat	
Adrenal gland		Lymph node	
Biliary duct			

v. Implants



Stent	
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vi. Vessels

Artery		Vein	
Portal vein			













vii. Vessel detail

Artery detail		Vein detail	
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viii. Vessel names

Middle colic artery		Middle colic vein	
Right colic artery		Right colic vein	



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Ileocolic artery		Ileocolic vein	
Gastroduodenal artery		Gastrocolic trunk of Henle	
Superior mesenteric artery		Right gastroepiploic vein	
Sigmoid artery		Inferior mesenteric vein	
Inferior mesenteric artery		Superior mesenteric vein	
Left colic artery		Inferior pancreaticoduodenal vein	







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Upper rectal artery			
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ix. Vessel uncertain

Uncertain artery		Uncertain vein	
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x. Lobes

Lung - Right upper lobe (superior)		Liver - Right lobe	
Lung - Right middle lobe (Medial)		Liver - Left lobe	
Lung - Right lower lobe (inferior)		Lung - Left upper lobe (superior)	





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	Lung - Left lower lobe (inferior)	
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xi. Lobe segments

Lung lobe Segment S1		Lung lobe Sub-segment Sa	
Lung lobe Segment S2		Lung lobe Sub-segment Sb	
Lung lobe Segment S3		Lung lobe Sub-segment Sc	


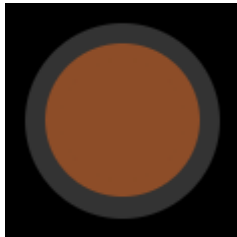
xii. Lobe segment vessels

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	


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Lung lobe Segment S3 - artery A3		Lung lobe Sub-segment Sc - artery Ac	
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xiii. Minerals

Calcification		Stone	
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xiv. Unknown




Unknown object	
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xv. Warning

View warning message	
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xvi. 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.

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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.

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.

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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.

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>

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Innersight3D

Enter email

Enter password



LOGIN

[Don't have an account? Sign Up](#)

[Reset/Forgot Password?](#)

Click on 'Don't have an account? Sign up'

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Innersight3D

Enter name

Enter hospital

Enter surgical speciality

Enter email

Enter password

Enter password confirmation

☐ I agree to the [terms and conditions](#) and the [privacy policy](#).

[Have an account? Log in](#)

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

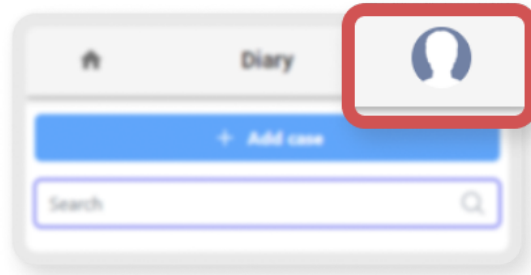
Read and agree to the terms and conditions and the privacy policy then click 'Sign up'

ii. Update personal details

Login in at <https://diary.innersightlabs.com/login> go to profile (top right icon) and select 'Profile'

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A desktop web application interface for 'Innersight3D'. The top navigation bar includes a home icon, the text 'Innersight3D', and a user profile icon. The main content area is titled 'Profile'. Below the title, there's a red pill-shaped button that says 'Email not verified'. Underneath, the section 'Personal details' contains several input fields: an 'email' field with the value 'top.surgeon@leadinghospital.com', a 'First name' field with the value 'Top', a 'Last name' field with the value 'Surgeon', and a 'Phone number' field. Below these fields, there's a 'LANGUAGE' section with a grid of buttons for different languages: БЪЛГАРСКИ, ČEŠTINA, DANSK, DEUTSCH, ENGLISH (highlighted in blue), ESPAÑOL, FRANÇAIS, ITALIANO, 日本語, NORSK, PORTUGUÊS, and SVENSKA.

Personal details can be edited on the profile page.

- First name
- Last name
- Phone number


Language options available by clicking on the relevant button.

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

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iii. Profile features and buttons

PHOTO



Upload photo

Available actions

REQUEST EMAIL VERIFICATION LINK

Enable 2FA

DELETE ACCOUNT

Notification preferences

Notify me when...	Email	SMS
a model is ready	<input checked="" type="checkbox"/>	<input type="checkbox"/>
I have an operation due today	<input checked="" type="checkbox"/>	<input type="checkbox"/>

My Team

top.surgeon@leadinghospital.com


TS

Top Surgeon
top.surgeon@leadinghospital.com

Invite a colleague

Team case history

Total number of cases in last year ...



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

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Click 'REQUEST 2FA' to activate two factor authentication on the account.

Note: must have a recognised phone number on the account profile

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

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

iv. Team information

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

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

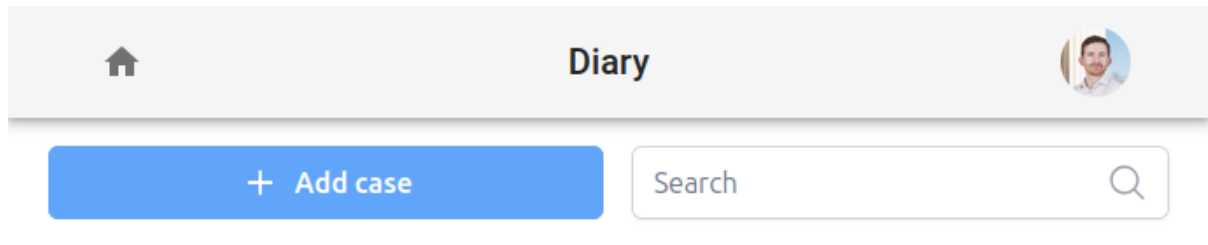
vi. Add case using 'Via Image Exchange Portal' method

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.

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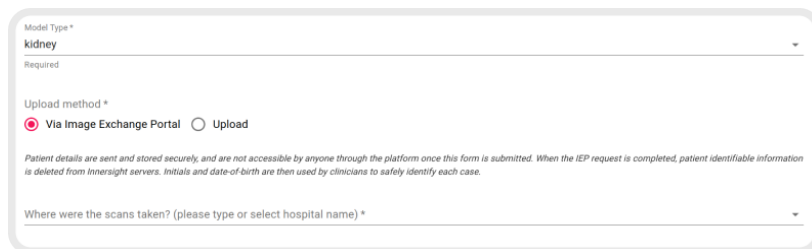


Select the relevant clinical 'Team' and complete the request form with the correct information in all essential fields, marked *


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'

REQUEST SCANS VIA IEP

The following status will show on you're newly created case and the Innersight team will request the scans through SPECTRA 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>

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Click 'Add case'.



Add a new case

Team *


top.surgeon@leadinghospital.com

Required

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 *

Ref 2025-03-07 15:48:46.357756

Enter an anonymous reference ID e.g. patient initials and date of birth.

Case notes *

My case notes...

Add notes about the region of interest and tumour anatomy.

Side *

Both

Required

Due by

01/31/2025

When the 3D model is needed by

UPLOAD DATA

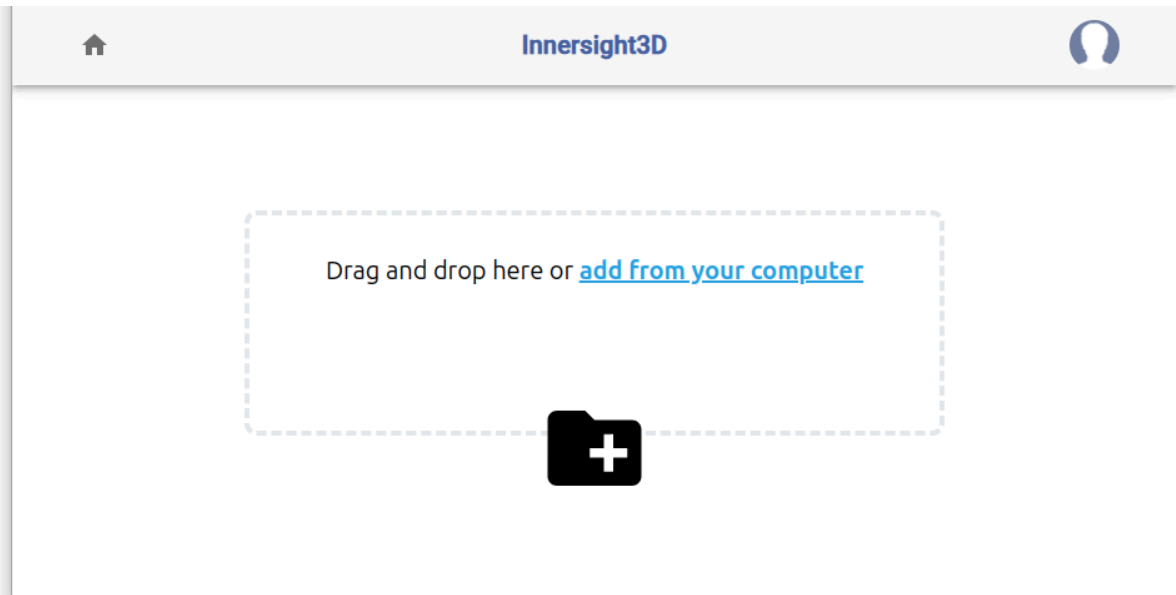
Complete the form:

- Select your clinical team
- Choose Model type
- Create a unique patient reference

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- Add case notes to help guide the 3D team
- Select a due date for the 3D model

Click '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.


Great!

6 files are ready for upload.


NEXT - ANONYMISE & UPLOAD

Then you will be able to see the upload progress.


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STORZ
KARL STORZ ENDOSKOP

Innersight3D




+ Add case

Search 

Top Surgeon's Other Team

top.surgeon@leadinghospital.com



Ref 2025-03-07 15:48:46.357756

Jan 31

Anonymising

3MB/3MB — 6/6 files

100%

Compressing

3MB/3MB — 6/6 files

100%

Uploading

3MB/3MB — 6/6 files

100%

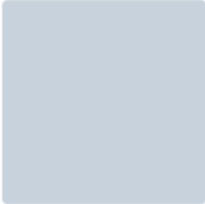
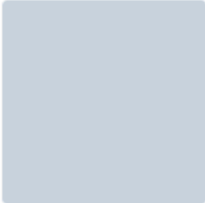



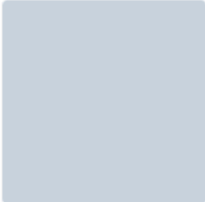
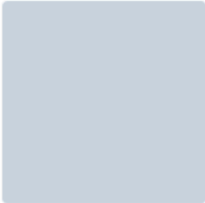
Uploading

Details

viii. Case status

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

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	Ref 2025-03-07 16:51:42.080649 My case notes... side: both	Jan 31
Case created	Details	Upload
	Ref 2025-03-07 16:31:19.882978 My case notes... side: both	Jan 31
Scans received	Details	
	Ref 2025-03-07 16:00:27.313429 My case notes... side: both	Jan 31
Building model	Details	
	Ref 2025-03-07 16:00:11.178635 My case notes... side: both	Jan 31
Reviewing model	Details	
	Ref 2025-03-07 15:59:55.138228 My case notes... side: both	Jan 31
Case published	Details	Validate
	Ref 2025-03-07 15:59:39.058859 My case notes... side: both	Jan 31
Case closed	Details	
	Ref 2025-03-07 15:59:22.507832 My case notes... side: both	Jan 31
Scans not suitable	Reply	Reupload

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Status
'Case created' You successfully created a case and the scans are yet to be uploaded
'Requesting scans' (if via IEP) iep request has been raised with SECTRA iep and the scans will be uploaded shortly
'Scans received' Scans have been uploaded successfully
'Building model' The process for building a 3D model has started
'Reviewing model' The 3D model is built and undergoing reviews before publication
'Case published' Your 3D model is approved and published and is ready to view on your team Diary

ix. Case status (Troubleshooting)

If there are any issues with a case, you may see one of the following status 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
'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.
'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.

x. Case details


Case details will display case specific information and features.

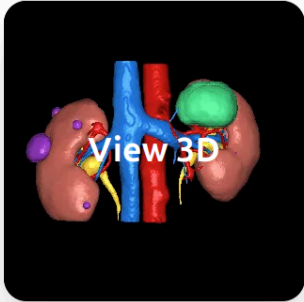
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Innersight3D







Ref 2025-03-07 15:59:55.138228

Case reference Ref 2025-03-07 15:59:55.138228	Created by top.surgeon@leadinghospital.com	Team top.surgeon@leadinghospital.com
Model type Kidney	Created Mar 7	Due by Jan 31 
Status	3D model is available.	
Case notes	My case notes... side: both 	
Unique model identifier	(01)5070002625308-(11)190706-(21)1741369441928 	


Messages



Add your comment...



Scans



Published

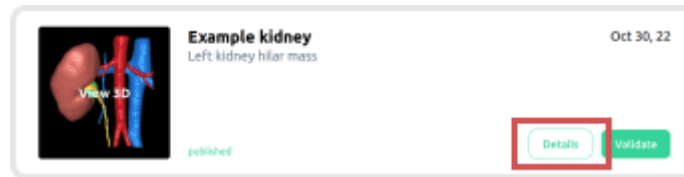
Acquired:
Modality: CT
Shape: 512, 512, 114
Spacing: 0.74, 0.74, 1.50
First uploaded: Mar 7, 2025
ID: NDjZYZqlpygJey2t9sBS

Validate

Archive case

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Click on the 'Details' button to view case details.



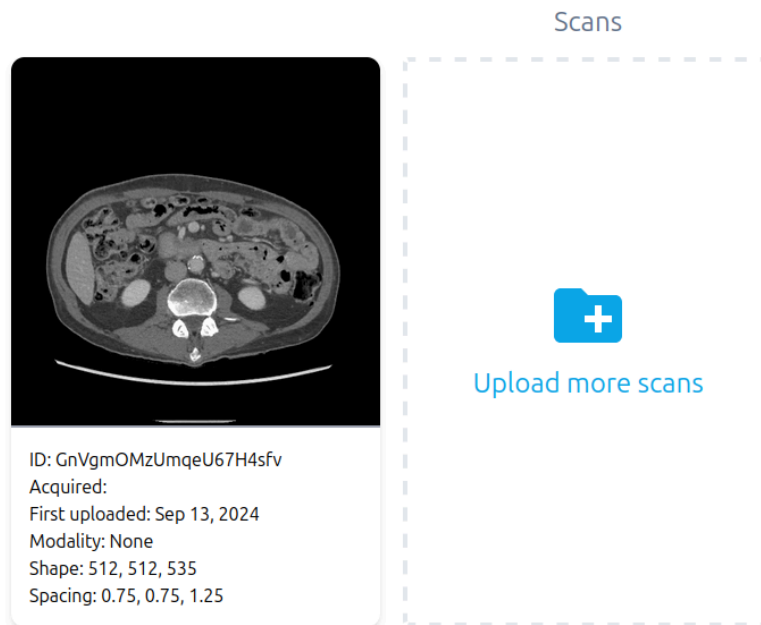
Fields with a blue pencil adjacent can be edited, once the information is correct click the green tick to update the field.



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'

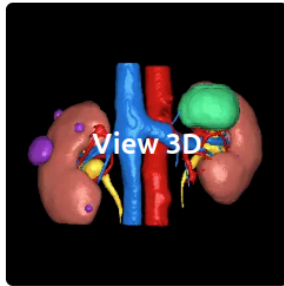


xi. Validate the labelled scan

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

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Ref 2025-03-07 15:59:55.138228

Jan 31

My case notes... side: both

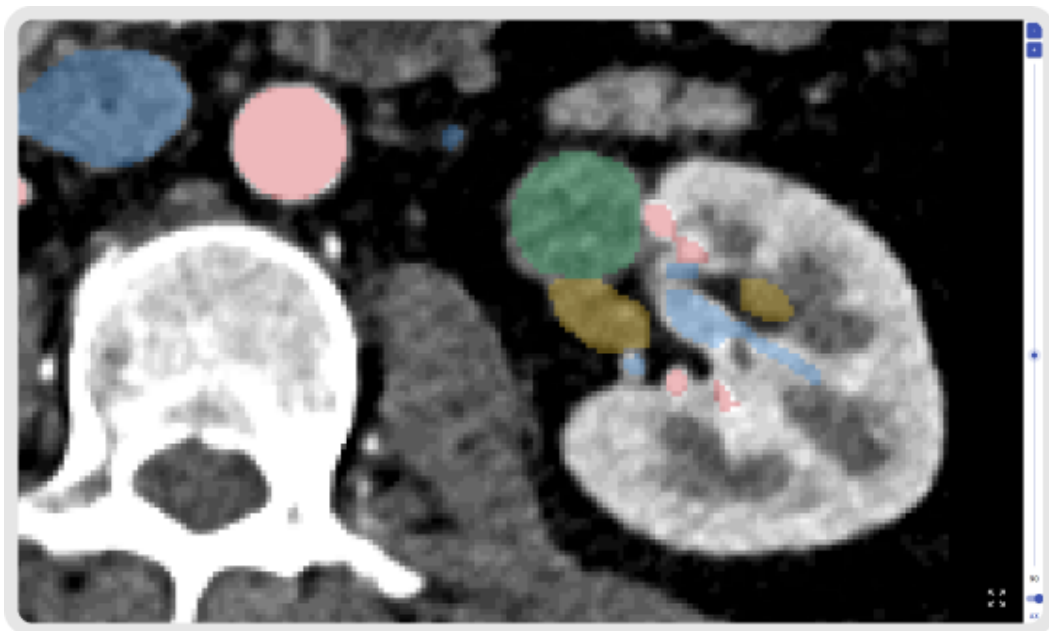
Case published

Details

Validate

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



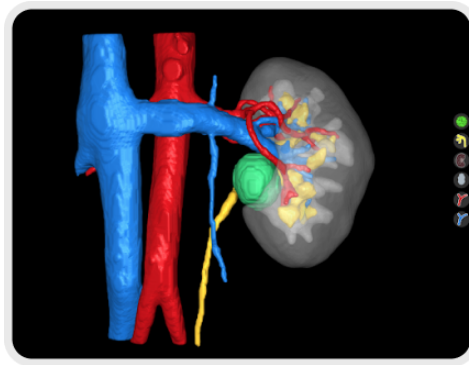
xii. View 3D model

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 it says 'View 3D'.

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xiii. 3D model controls and functions

'3D viewer' mouse controls		
		
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

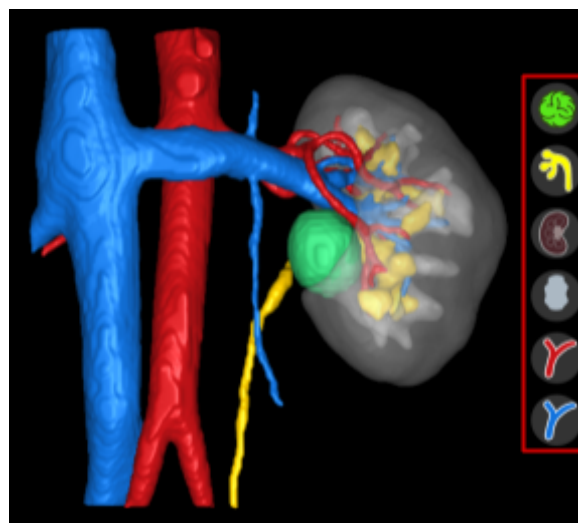
'3D viewer' touch screen controls		
		
Fingers	Action	Function
One finger	Tap and hold	Rotates the 3D model on its axis

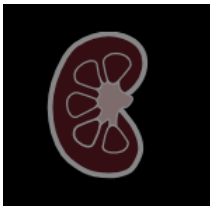
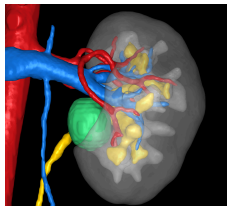
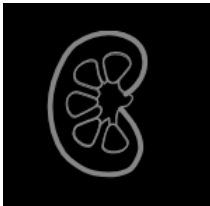
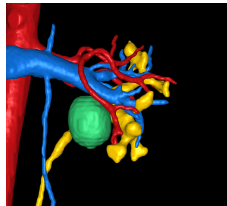
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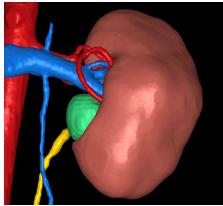
Two fingers	Tap and hold	Drags the 3D model across the plane of view
Two fingers	Pinch	Zoom in and out of the 3D model

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.



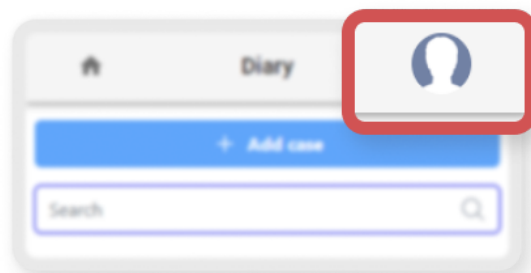
Action	Object button	Object appearance
First left mouse click - Translucent		
Second left mouse click - Transparent		

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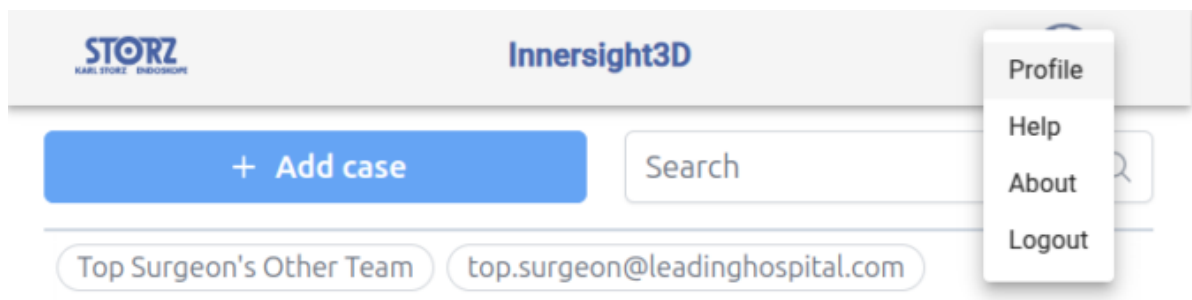
Third left mouse click - Opaque		
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xiv. Log out

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.

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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.

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