
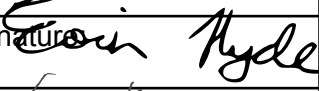

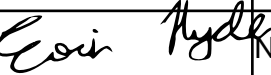


User Manual

Product / Specific Document Details:

| | | | |
|---------------------------|---|---|--|
| Document Name | User Manual | | |
| Document No | I3D0032 | | |
| Effective date | 23 Oct 2023 | | |
| Version | 3.0 | | |
| Project | Innersight3D - Image segmentation application software | | |
| Product | Innersight3D | | |
| Model No | Innersight3D | | |
| Process Owner | | Signature: | |
| Prepared By - Name: | Designation: | Signature: | |
| Lorenz Berger | Head - Design |  | |
| Reviewed By - Name: | Designation: | Signature: | |
| Eoin Hyde | CEO |  | |
| Approved By - Name: | Designation: | Signature: | |
| Lorenz Berger | Head - Design |  | |
| Reviewed On | 23 Oct 2023 | Changes Made | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No |
| Reviewed By Name and Sign | Eoin Hyde  | Next Review Date | 23 Oct 2025 |

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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 |

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innersight3D

USER MANUAL



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6. Product Warranty statement

7. Contact Details

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Document purpose

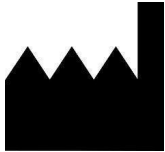

This document explains the form and function of the Innersight3D Web Platform, outlining all safety information, descriptions, operation, risks, warranty and contact details.

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: 7 Astbury House, Lambeth Road, London SE11 6LZ | |
|  | 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.


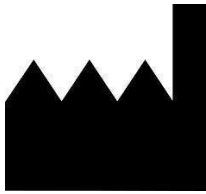




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c. Device Identification






Innersight3D 1.5

d. Symbols used

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

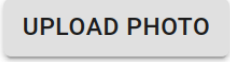
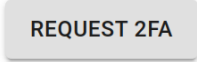


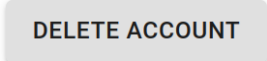
e. User Interface buttons

i. Profile




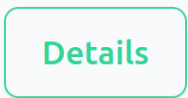
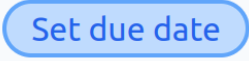
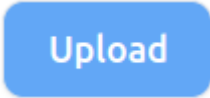
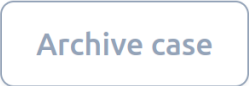
| | | | |
|--|---|----------------------------|--|
| Go home to diary page |  | View profile and log out |  |
| Add new case |  | View uploaded DICOM volume |  |
| Reply to message left by Innersight team |  | Notification check box | <div> <div>Email</div> <div><input checked="" type="checkbox"/></div> </div> <div> <div>SMS</div> <div><input type="checkbox"/></div> </div> <div> <div><input checked="" type="checkbox"/></div> <div><input type="checkbox"/></div> </div> |

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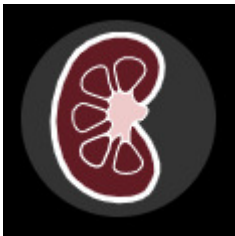



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| | | | |
|-----------------------------|---|--|---|
| Upload profile picture file |  | Request multi factor authentication activation |  |
| Select preferred language |   | Delete account including all related profile information |  |

ii. Diary


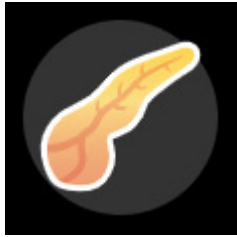



| | | | |
|-------------------|---|-------------------|--|
| View 3D model |  | Validate 3D model |  |
| Select team |  | Case details |  |
| Set case due date |  | Upload scans |  |
| Archive case |  | | |

iii. Organs


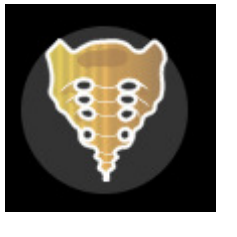



| | | | |
|---------|---|----------|---|
| Kidney |  | Prostate |  |
| Bladder |  | Stomach |  |

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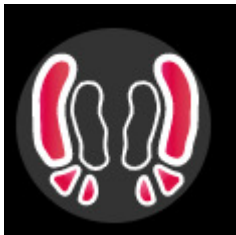





| | | | |
|-------------|---|----------|---|
| Colon |  | Pancreas |  |
| Gallbladder |  | Uterus |  |
| | | Ovaries |  |

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 |  |

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| | | | |
|---------------------------|--|-----------------------------------|---|
| Sigmoid artery |  | Inferior mesenteric vein |  |
| Inferior msenteric artery |  | Superior mesenteric vein |  |
| Left colic artery |  | Inferior pancreaticoduodenal vein |  |
| Upper rectal artery |  | | |

x. Vessel uncetain





| | | | |
|------------------|---|----------------|---|
| Uncertain artery |  | Uncertain vein |  |
|------------------|---|----------------|---|

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xi. 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) |  |
| | | Lung - Left lower lobe (inferior) |  |







xii. Lobe segments

| | | | |
|-------------------------|---|-----------------------------|---|
| Lung lobe Segment S1 |  | Lung lobe Sub-segment Sa |  |
| Lung lobe Segment S2 |  | Lung lobe Sub-segment Sb |  |



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| | | | |
|-------------------------|---|-----------------------------|---|
| 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 | <div> High model uncertainty due to: non-arterial phase contrast; large slice thickness.</div> <div>OK</div> |

xvii. Lesions

| | | | |
|------------------|---|------|---|
| Tumour |  | Cyst |  |
| Uncertain lesion |  | | |

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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.

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Operation

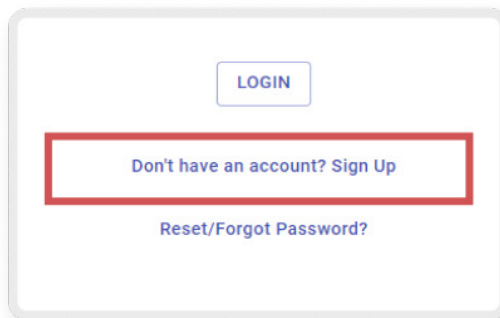
a. Principles of Operation

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.

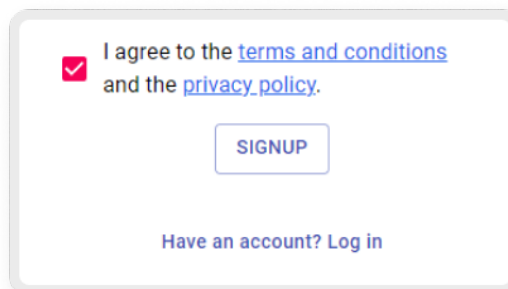
b. Step by step of operation from Log in to end

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

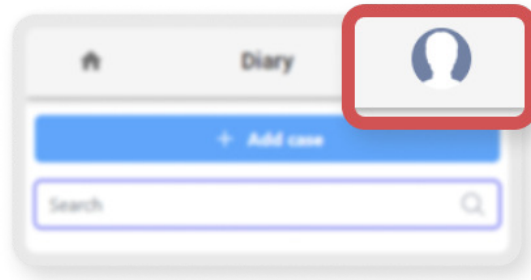
Read and agree to the terms and conditions and the privacy policy then click 'Sign up'

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
- French
- Italian
- Portuguese



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



iii. Profile features and buttons

| | | |
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PHOTO

UPLOAD PHOTO

Available actions

REQUEST 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"/> |

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 | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| I have an operation due today | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

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iv. Team information

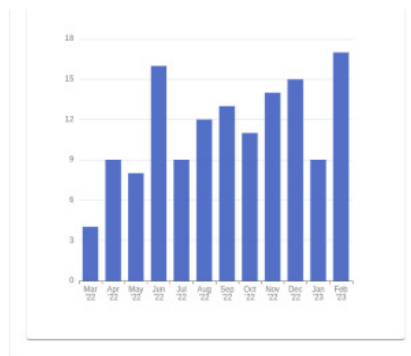
At the bottom of the profile page, team information can be viewed in 'My Team'



The email address and profile name of team members is displayed.



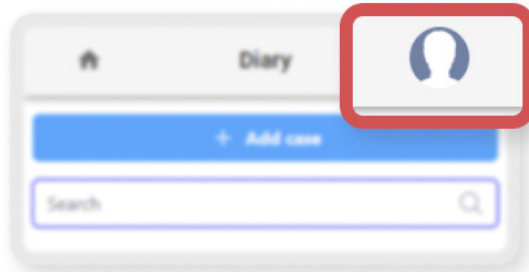
Team case history can be viewed to track the number of 3D cases published each month.



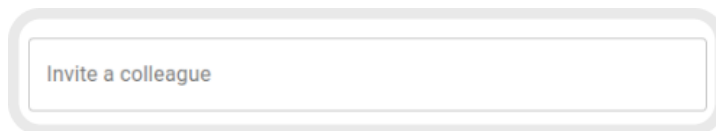
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v. Invite a colleague

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

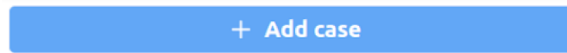
| | | |
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vi. Add case using 'Via Image Exchange Portal' method

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?'

Model Type *

kidney

Required

Upload method *

☒ Via Image Exchange Portal ☐ Upload

Patient details are sent and stored securely, and are not accessible by anyone through the platform once this form is submitted. When the IEP request is completed, patient identifiable information is deleted from Innersight servers. Initials and date-of-birth are then used by clinicians to safely identify each case.

Where were the scans taken? (please type or select hospital name) *

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

Patient first name *

Patient last name *

Gender *

Required

Date of birth *

dd/mm/yyyy

Case notes *

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

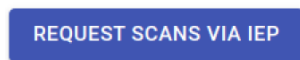
Add notes about the region of interest and tumour anatomy.

Due date

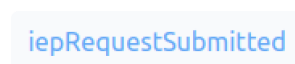
dd/mm/yyyy

When the 3D model is needed by.

Once the request form is complete click '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.

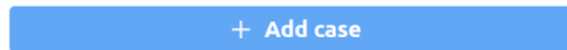


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vii. Add case using 'Upload' method

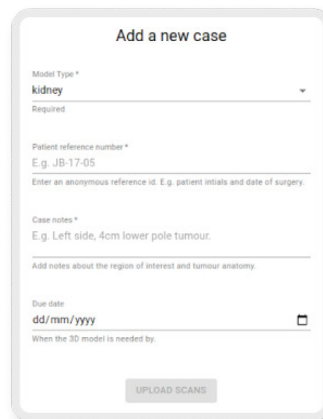
To request a 3D model from Innersight, sign in at <https://diary.innersightlabs.com/login>
Click 'Add case'



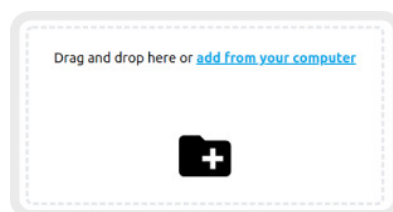
Complete the form:

- 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'



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

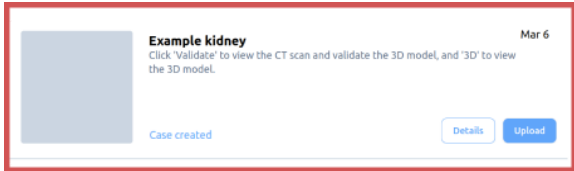
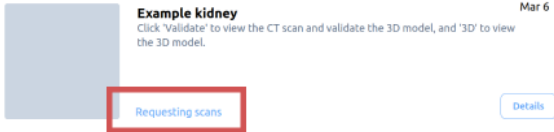
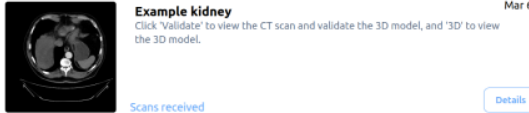
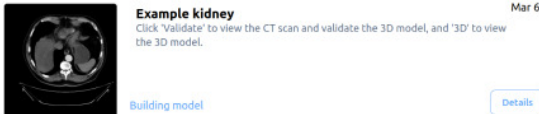
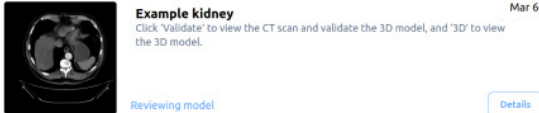
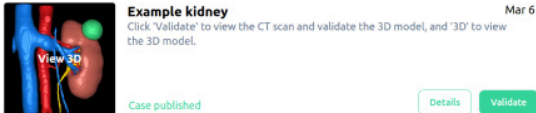


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viii. Case status 'Via Image Exchange Portal' method

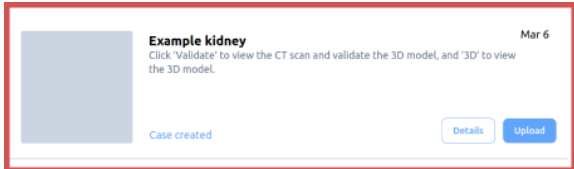
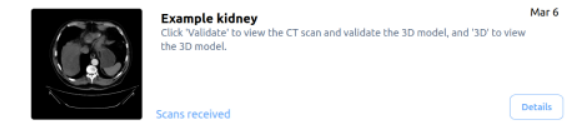
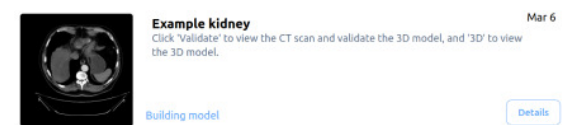
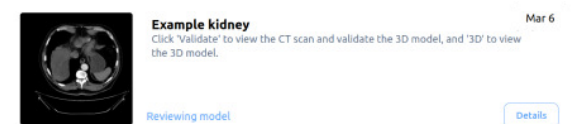
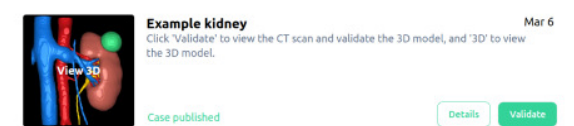
Once you have created a case you can track the progress on your diary by following the status updates and checking the thumbnail images

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

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ix. Case status 'Upload' method



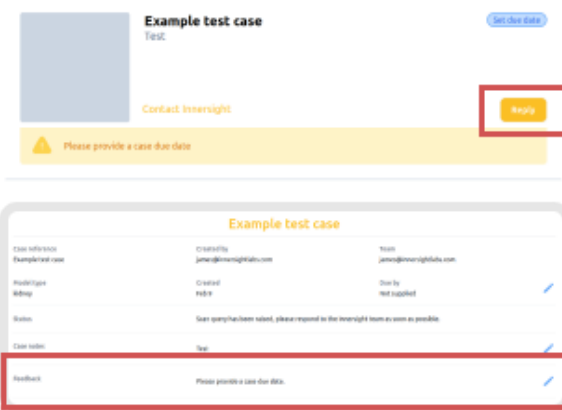
Once you have created a case you can track the progress on you diary by following the status updates and checking the thumbnail images

| Status | Example |
|--|--|
| <p>'Case created'</p> <p>You successfully created a case and the scans are yet to be uploaded</p> |  |
| <p>'Scans received'</p> <p>Scans have been uploaded successfully</p> |  |
| <p>'Building model'</p> <p>The process for building a 3D model has started</p> |  |
| <p>'Reviewing model'</p> <p>The 3D model is built and undergoing reviews before publication</p> |  |
| <p>'Case published'</p> <p>Your 3D model is approved and published and is ready to view on your team Diary</p> |  |

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x. Case status (Troubleshooting)

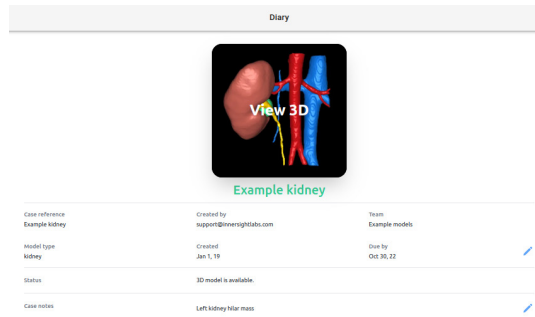
If there are any issues with a case, you may see one of the following status: closed, withUploader, noSuitableVolumes, which can be followed up with a response via email to support@innersightlabs.com or the feedback box in the case details by clicking the 'Reply' button

| Status | Example |
|---|--|
| <p>'Case closed'</p> <p>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.</p> |  |
| <p>'Contact Innersight'</p> <p>There has been a request by the Innersight team for more information to help process the case. You can reply to the message via the email notification or by clicking 'Reply' to leave your response in the feedback section.</p> |  |
| <p>'Scans not suitable'</p> <p>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.</p> |  |

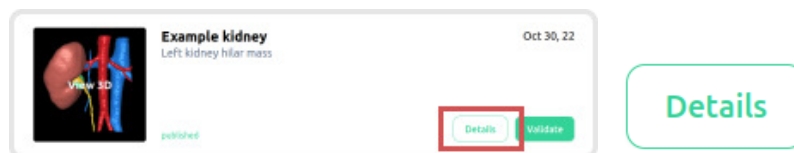
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xi. Case details

Case details will display case specific information and features.



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



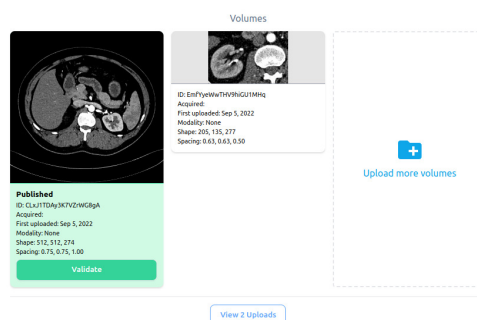
Fields with a blue pencil adjacent can be edited, once the information is correct click the green tick to update the field.



Fields that can be edited are:

- Case notes
- Due by
- Feedback

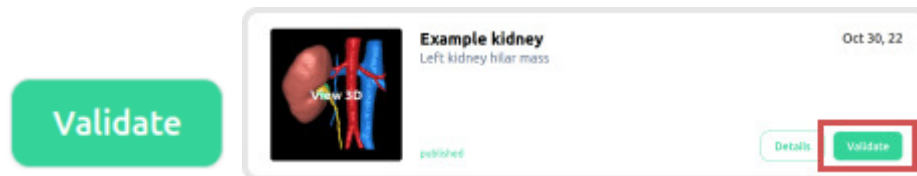
Volume information is also displayed in 'Details' along with 'Validate' and 'Upload more volumes'



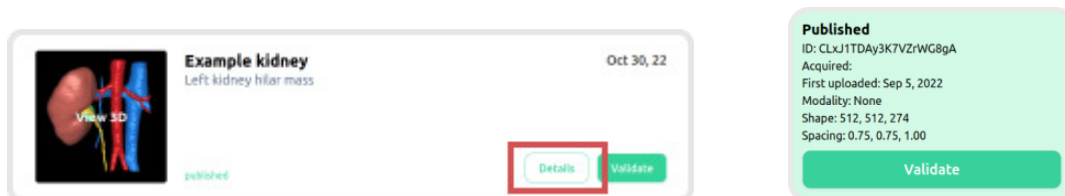
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xii. Validate the labelled scan

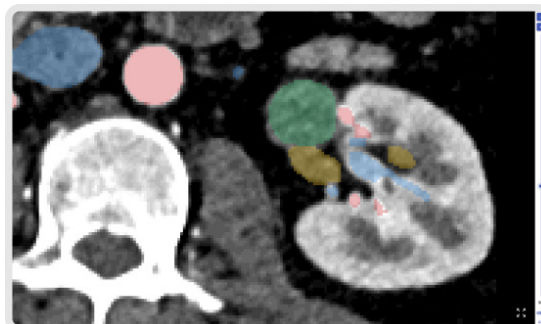
To validate the CT scan and the labels used to generate the 3D model, first sign in at <https://diary.innersightlabs.com/> Find the relevant case and then click the 'Validate' button



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



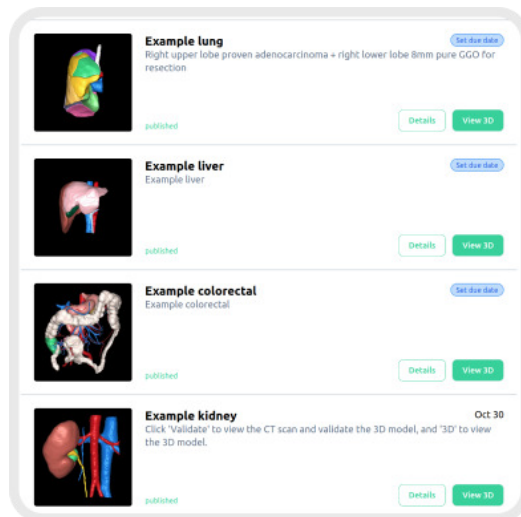
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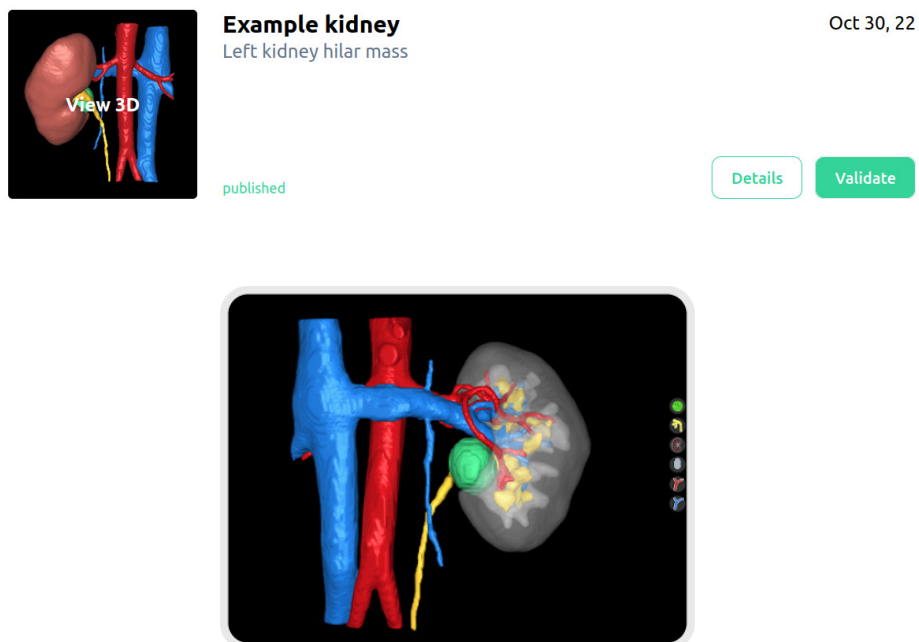
xiii. View 3D model

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'




xiv. 3D model controls and functions

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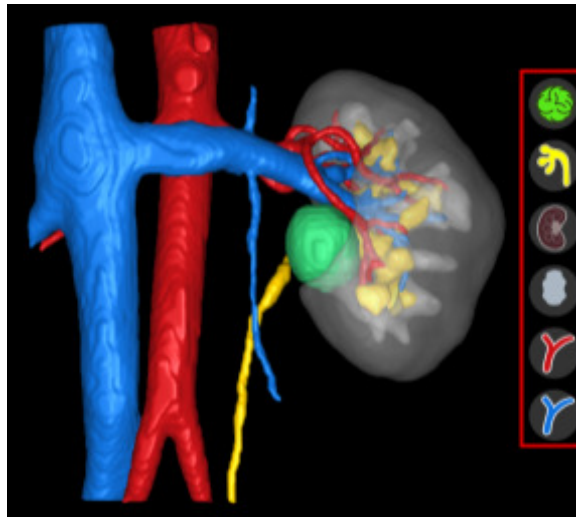
| '3D viewer' mouse controls | | |
|---|--------------------------|---|
|  | | |
| Mouse button | Action | Function |
| Left mouse | Click and hold | Rotates the 3D model on its axis |
| Right mouse | Click and hold | Drags the 3D model across the plane of view |
| Mouse wheel | Click and hold or scroll | 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 |
| 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.

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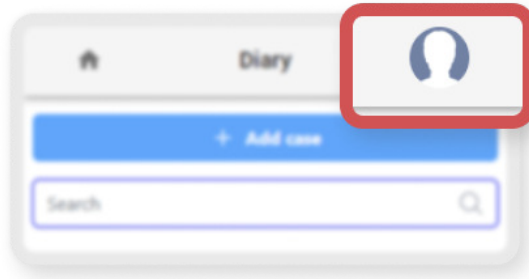
| Action | Object button | Object appearance |
|--|---------------|-------------------|
| First left mouse click - Translucent | | |
| Second left mouse click - Transparent | | |
| Third left mouse click - Opaque | | |

xv. Log out

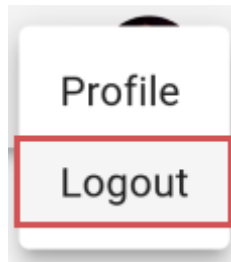
To log out of <https://diary.innersightlabs.com/login> go to profile (top right icon)

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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.

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Residual Risks

a. Residual risk statements as per Risk Management file

Innersight Labs Ltd have undertaken a formal and structured clinical risk assessment of Innersight3D v.1.5 pursuant to compliance with EN ISO 14971:2012 and the England and Wales Safety Standard DCB 0129 ("the Standard").

A rigorous and methodical analysis of the product has identified a number of potential hazards. These have been characterised and documented in the associated Risk Analysis / Hazard Log.

The Residual Risk associated with each hazard has been evaluated and the risk profile established - with no unacceptable risks post mitigation. The evaluated clinical risk has been tested against Innersight's Risk Acceptability Criteria.

| | Hazard | Harm | Severity | Probability | Level |
|---|---|---|----------|-------------|------------|
| 1 | Operational Hazard: Poor 3D model accuracy. The 3D model is missing a key artery/vessel. | Inconvenience to the surgeon. For main and critical vessels, the surgeon would always rely on the original vessel count based on the original scan, and therefore not miss any. | 2 | 2 | Acceptable |
| 2 | Operational Hazard: Poor 3D model accuracy. Mislabelling of secondary vessels. Incorrectly labelling a vein as an artery or vice versa. | Inconvenience to the surgeon as in this case they might be looking for an artery only to find a vein, or vice versa, or no vessel at all. Since this is only a secondary/minor vessel - this as a minimal impact on the surgery. | 3 | 1 | Acceptable |
| 3 | Operational Hazard: Very poor 3D model accuracy. Mislabelling of tumour, vessels and other critical structures, by a large amount. | The patient might be selected for a more complex partial nephrectomy rather than simpler radical nephrectomy. This would result in the surgeon initially attempting a more complex procedure but then, inter-operatively the surgeon finds the anatomy too complex (different from the 3D model), they would continue with their updated surgical plan, e.g. reverting back to a radical nephrectomy. | 1 | 3 | Acceptable |

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| | | | | | |
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| | | Thus this could extend the operation by 30-60 minutes. | | | |
| 4 | Operational Hazard: Failure to view 3D model. | Inconvenience to the surgeon as in this case they would not be able to use the 3D model and only use the original CT scan. | 1 | 2 | Acceptable |
| 5 | Operational Hazard: imaging data cannot be processed. | 3D model generation is delayed. Causing an inconvenience to the surgeon. | 4 | 1 | Low |
| 6 | Human factors: Mismatch between 3D model and the patient. | The surgeon would use a 3D model of another patient's anatomy during the operation. In this case they might take longer to find the correct vessels or look for the tumour in a different place, or make incorrect assumptions about the position of the tumour. | 1 | 3 | Acceptable |
| 7 | Information hazard: Inadequate description of intended use and inadequate disclosure of limitations | May contribute to incorrect surgical decision making. | 2 | 4 | Low |
| 8 | Human factors: Clinician is confused by user interface and can not properly operate the 3D model viewer during the surgery. | Clinician may not get the required 3D anatomical information from the 3D model. This would result in inconvenience to the surgeon as in this case they would not be able to use the 3D model and only use the original CT/MRI scan. | 2 | 2 | Acceptable |

In conclusion, the level of clinical risk associated with Innersight3D v.1.5 has been found, at this time, to be Tolerable.

b. Statement on Benefit vs Residual risks

The Risk Analysis does not take into account the use of Innersight3D outside the intended use.

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Further, Innersight3D is a software device which is intended to provide additional information to clinicians and does not provide a diagnosis; the clinician remains responsible for any clinical diagnosis.

The risk controls utilise control measures that are in line with those commonly used and accepted within the medical device industry for these hazards, it is considered that the overall residual risk presented by Innersight3D is outweighed by the benefit of the device.

Although the risk level of all risks is already acceptable before the implementation of the risk mitigations, the risk mitigations were effective to make Innersight3D safer because the probability of some risks was further reduced. After the implemented risk mitigations the probability of all but three risks were reduced to low.

As a result, all identified risks for the use of Innersight3D, according to the intended use and the contraindication, have the risk level acceptable. Considering the proven benefit of the intended prevention purpose of Innersight3D, the remaining risks are justifiable. After the risk mitigations the use of Innersight3D accords to high standards of health protection and security for the patients and third parties.

We can conclude that Innersight3D is safe to use and the benefit outweighs the remaining risks.

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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