Cydar EV Maps
Instructions for Use

Contents

Intended Use

Cydar EV Maps provides tools to:

- Import and visualise CT data
- Segment and annotate vascular anatomy from CT data
- Place and edit virtual guidewires and measure lengths on them
- Make measurements of anatomical structures on planar sections of the CT data
- Produce an operative plan from measurements and segmentation of preoperative vessel anatomy
- Overlay planning information such as preoperative vessel anatomy onto live fluoroscopic images, aligned based on the position of anatomical features present in both
- Non-rigidly transform the visualisation of anatomy when intra-operative vessel deformation is observed
- Post-operatively review data relating to procedures where the system was used

Indications for Use

Cydar EV Maps is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen and pelvis by presenting the operative plan in the context of intraoperative fluoroscopy.

Cydar EV Maps is intended to be used for patients undergoing a fluoroscopic X-ray guided endovascular surgery in the chest abdomen and pelvis, and who have had a pre-operative CT-scan.

The performance of the *Cydar EV Maps* software in the presence of immature vertebral anatomy is unknown. The Instructions for Use explicitly state this uncertainty and that the software is therefore not recommended for use in patients under the age of 18.

IMPORTANT: Pre-Operative Maps show static anatomy derived from the pre-operative CT. Real-time anatomy moves with the cardiorespiratory cycle; progressive disease may cause the anatomy to change over time; and stiff wires, stents, or other surgical instruments, may straighten and displace blood vessels from the pre-operative position

It is therefore mandatory to check the real-time anatomy with a suitable imaging technique, such as contrast angiography, before deploying any invasive medical device.

Intended Users

The target clinical users for the *Cydar EV Maps* software are experienced medical practitioners specialising in endovascular surgery (such as vascular surgeons and interventional radiologists) radiographers, and specialist nurses. Other users of the planning functions may include medical device company representatives and product specialists.


Caution: U.S Federal law restricts this device to sale by or on the order of a Physician


All users must complete the *Cydar EV Maps* training programme prior to use. Access it via this link Cydar EV Maps training or using this QR code.


These Instructions for Use must be studied before use.

Intended patient population and medical condition

The *Cydar EV Maps* software device is intended for use on patients with mature vertebral anatomy (over the age of 18) undergoing a planned X-ray guided endovascular procedure in the chest, abdomen, or pelvis. Patients must have had a pre-operative CT scan.

Patient Selection and Contra-indication

Cydar EV Maps is intended to assist fluoroscopic X-ray guided endovascular procedures in the chest, abdomen, and pelvis by presenting the operative plan in the context of intraoperative fluoroscopy.

Cydar EV Maps is intended to be used for patients undergoing a fluoroscopic X-ray guided endovascular surgery in the chest, abdomen, and pelvis, and who have had a pre-operative CT-scan.

The performance of the *Cydar EV Maps* software in the presence of immature vertebral anatomy is unknown. The Instructions for Use explicitly state this uncertainty and that the software is therefore not recommended for use in patients under the age of 18.

Pre-Operative Maps show static anatomy derived from the pre-operative CT. Real-time anatomy moves with the cardiorespiratory cycle; progressive disease may cause the anatomy to change over time; and stiff wires, stents, or other surgical instruments, may straighten and displace blood vessels from the pre-operative position. **It is therefore mandatory for users to check the real-time anatomy with a suitable imaging technique, such as contrast angiography, before deploying any invasive medical device.**

Clinical Benefits

Cydar EV Maps improves the visualisation of the surgical plan in relation to the real-time anatomy during X-ray fluoroscopic guided endovascular procedures in the chest, abdomen, and pelvis. Clinical users are able to view a CT scan, segment the relevant anatomy and make accurate (to the same level of accuracy as the CT scan) measurements relevant to the planned procedure on that CT scan. The resulting operative plan (Pre-operative Map) is accurately (better than minimum human-detectable error, 3mm) and reliably (better than 99.8% positive predictive value) overlaid on the live X-ray fluoroscopy during surgery.

The improved visualisation provided by the overlays during surgery can help reduce procedure time, reduce X-ray exposure, and reduce the use of nephrotoxic contrast.

Hospital Vaults and making maps

1. Your Hospital Vault

Your Hospital vault is cloud repository that has been approved by the Hospital's Information Security and Data Protection or Privacy Officers. The Hospital controls access to its Vault and sets the rules on retention of the patient data.

When using Cydar EV Maps, the correct map must be used to assist surgery on the correct patient. The Cydar EV Maps software assures this 'correct map: correct patient' match by using three patient identifiers (patients name, date of birth and unique identifier number) derived from the patient's CT scan to identify all maps. Therefore, anonymised CT scans should not be used with Cydar EV Maps. All patient data is stored in your Hospital Vault.

2. How to access your Hospital Vault

Enter your Hospital Vault URL into your web browser. New users must register and a designated user administrator in the Hospital needs to approve your application.

Access controls are set by your Hospital. This may be a Single Sign On system which means you use your usual username and password, or it may require a unique strong password or Two Factor Authentication (2FA). When using 2FA, you will need to confirm your identity using an authentication code generated in a smartphone. The simplest way to get authentication codes is with the Cydar smartphone app (available on iOS and Android phones). Cydar's Online Support team can assist with the initial setup.

3. Navigating your Hospital Vault

Successful login to a Hospital Vault opens it on the Home Page. You can log out at any stage by clicking on the Log Out button top right. If there is a prolonged period of inactivity, you will be automatically logged out to protect patient data.

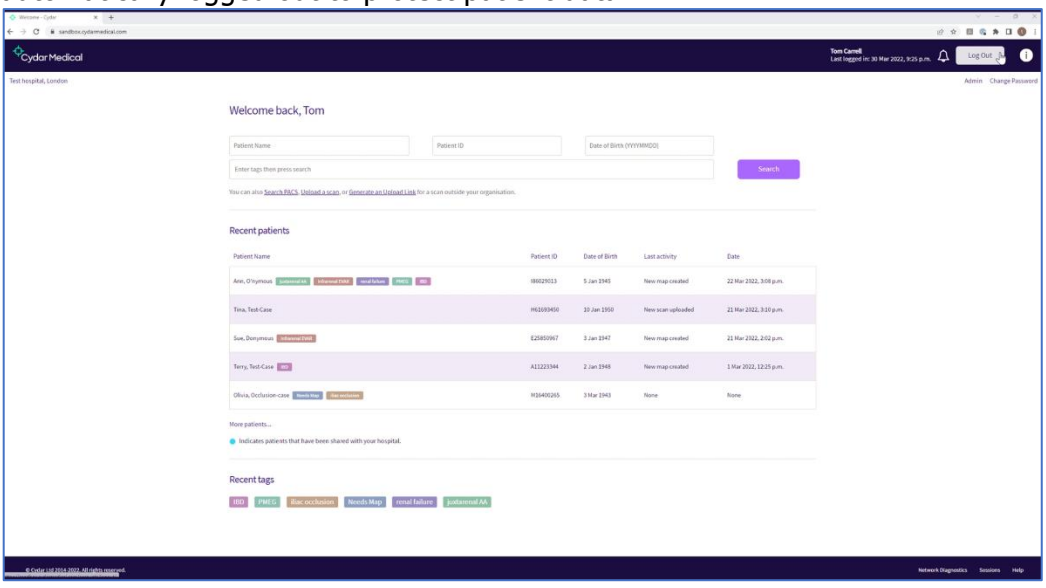


Figure: *A Hospital Vault Home Page*

The Home Page offers you several options for searching for patients in your Vault and for importing new CT scans.

1. At the top of the Home Page, entering partial or full patient identifiers into the search box starts a search for that patient first in your Hospital Vault and then in your Hospital PACS.
2. Clicking on the Cydar logo, the breadcrumb ('*Hospital name> Patients>…*') top left or using the back button in your browser returns to the Home Page

3. Below the search boxes is a list of recent patient activities that shows what maps have been made recently, what patients have had surgery, and what patients have recently had scans imported.

4. The Patient Page

Clicking on a patient name in a Hospital Vault opens their corresponding Patient Page. The first import of a CT scan for new patient automatically creates a new Patient Page. As with the Home Page, there are navigation shortcuts in the logo and breadcrumbs top left and the notifications, log out and support buttons top right.

The Patient Page shows a chronological display of activity with the patient. The timeline runs from left to right and there is a vertical hierarchy to indicate the relationship between scans, maps, and X-ray guided surgical procedures. In the figure below, there is one CT study and one map that has been made from it and used twice in surgery. Clicking on the CT study icon reveals how many usable scans were in that original CT study import. Clicking on the map icon displays a preview of the map and offers the option of opening that Map for full review and editing. Clicking on the surgery icon opens a review mode to see the use of maps in surgery. In the review mode, there are options to select and download still and video images.

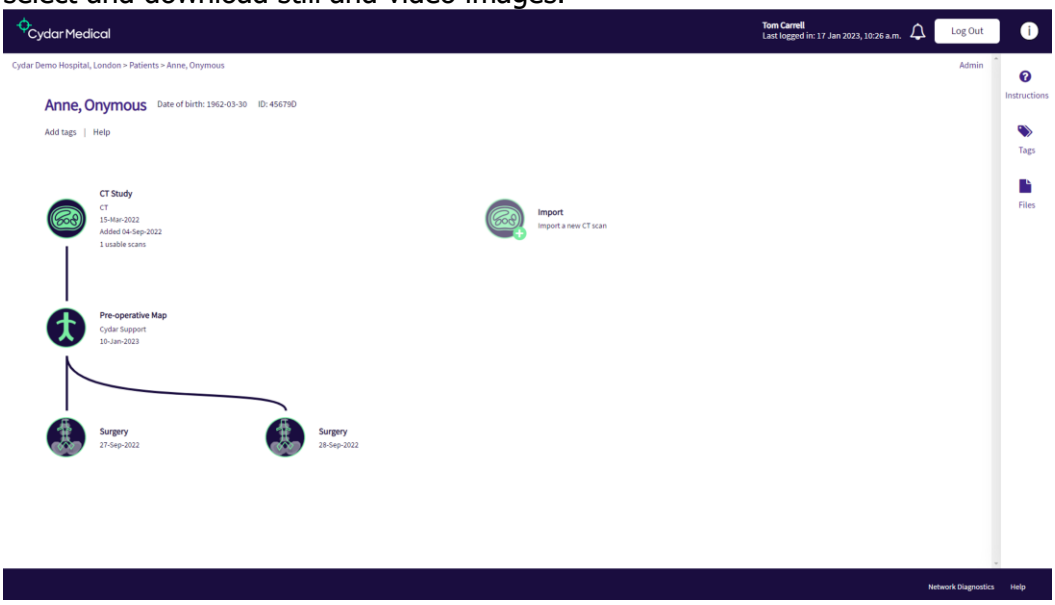


Figure: *The standard layout of a Patient Page*

In the right-hand sidebar, there are several options:

1. '*About*' provides reminders about what each of the icons on the Patient Page does.
2. '*Tags*' allows users to label the patient with either an existing tag or create a new tag.
3. '*Files*' allows users to attach other files.

5. Importing a CT scan

Making a map starts with importing a CT scan. For a map to be overlaid in surgery, the CT scan must contain axial slices without any discontinuities, contain the pelvis, and include the vertebral spinous processes. See the inset box below for the full CT scan criteria for a map to be overlaid in surgery.

During surgery, the Cydar computer vision ('Image Tracking') will compare 2D Image Data generated from the live Xray images with 3D Image Data generated from the CT scan. When the computer vision is confident it has found a match between the 2D and 3D Image Data to locate the patient's position in 3D space with high accuracy and confidence, it will generate an overlay. Good quality

Xray imaging leads to higher resolution 2D Image Data and will improve overlay performance during surgery. Similarly, a high-quality CT scan with slices that are 1mm or thinner will give higher resolution 3D Image Data and will also improve overlay performance during surgery. Scans with a slice thickness greater than 3mm are too low resolution and are automatically labelled as unusable.

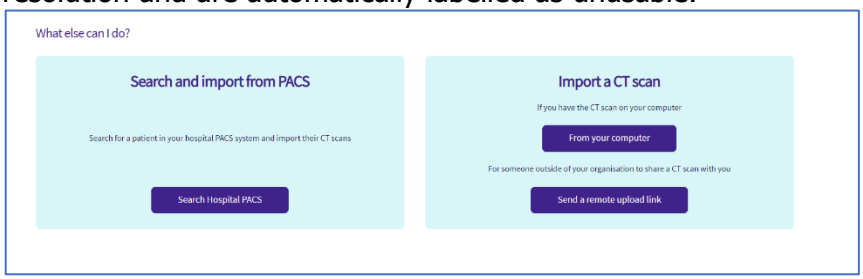


Figure: *CT scan import option buttons in a Hospital Vault*

There are three ways to import scans into a Hospital Vault:

1. From your Hospital PACS
2. From your computer desktop, or
3. Via a remote upload link.

You can import CT scans directly from your Hospital PACS into your Hospital Vault either by searching in the Home Page, searching in the PACS Search Page, or by clicking on the Import CT icon in an existing Patient Page.

When Hospital PACS finds a matching patient, it displays a list of CT studies available for import. The '*List Scans*' link allows you to select individual scans from a series of scans in a CT study.

CT scan requirements for overlays

CT scans should be at the same slice thickness and intervals as the original scan acquisition.

Optimal overlay performance is seen with CT slice thickness 1.0mm or thinner.

CT scans **must** include the pelvis and whole vertebrae including the spinous processes

CT scans **must not** have any missing slices or discontinuities, or use gantry tilt

Why? Compression of CT scans to thicker slices than the original acquisition loses data and can significantly impair the overlay performance if slice thickness is greater than 1mm. Cydar Maps will automatically reject any scans with greater than 3mm slice thickness.

To import a CT scan directly from your computer desktop, click the '*From your computer*' button (see figure above) and follow the instructions to compress and import the CT scan.

To get a third party at a remote site to upload a CT study to your Hospital Vault, click the '*Send remote upload link*' button (see figure above) and enter the third party's email address. This sends them an email with a one-time weblink and instructions on how to upload the scan.

Importing a single usable scan starts the Automated Pre-operative Processing that generates 3D Image Data for a new map. When an imported CT study includes multiple usable scans, you will receive a notification by email, in the Cydar smartphone app, and in the Vault that you need to select the preferred scan where indicated in the Patient Page. Selecting a single scan starts the Automated Pre-operative Processing.

If you have any difficulties with importing, selecting, or processing scans, contact Cydar Online Support using the (i) help button in the top right corner of all Vault pages or via the Cydar smartphone app.

6. Making maps

There are two types of maps:

1. A Preoperative map, always shown in green, which contains pre-operative 3D Image Data, with annotations such as virtual wires, markers, labels, and measurements.
2. An Updated map, always shown in blue, which represents a Pre-operative map that has been non-rigidly (i.e., 3D plasticine-like) transformed during surgery to reflect observed changes in soft tissue anatomy.

7. Making a map

Maps open on the 'Your Map' page which shows a simulated digital radiograph (X-ray) of the Pre-operative map. This represents what an overlay of the current map would look like during surgery. You can drag the map around to view the 3D anatomy from various virtual C-arm positions. The virtual C-arm angulation is shown in the top left corner as LAO/ RAO and Cranial/ Caudal angles in degrees. The actual C-arm angles needed during surgery are likely to differ because the patient may lie in a different position on the operating table than on the CT table, and soft tissue anatomy is likely to deform.

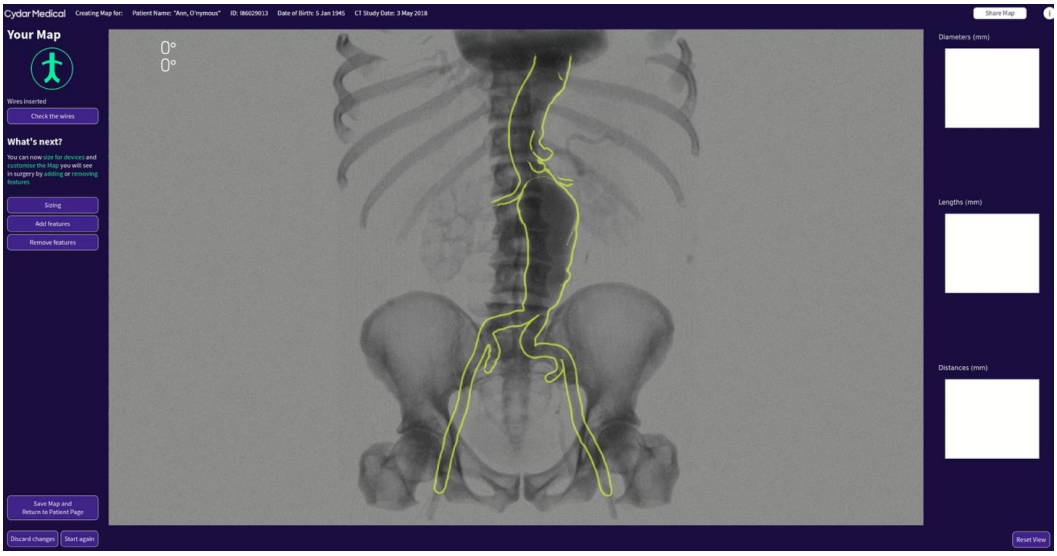


Figure: '*Your Map'* page

The '*View scan'* button allows users to review the 3D Image Data in the map using conventional Multiplanar Reconstruction (MPR) views. Clicking in an MPR window jumps the cross hairs to that position in all MPR windows. You can zoom in and out and orientate the viewing plane by dragging the cross hairs. Click and drag measures a straight-line distance in millimetres. Measurements in the '*View scan'* mode are not saved.

Figure: MPR views in the '*View scan'* mode

8. Sharing a map

Authorised Clinical Users can collaborate on maps by sharing online access to a map using the '*Share Map*' button top right. Examples of use cases include asking a colleague or a medical device

company expert to assist with device sizing. You can also use '*Share Map* ' to request technical assistance from Cydar Online Support.

When an authorised Clinical User clicks on '*Share Map* ', you are asked to enter the email address of the person that you want assistance from. Two Factor Authentication ensures that only the person specified can access the Map. The first part of the authentication is the email address, the second is a verification code number that is generated on-screen. It is a one-time code which is specific for the person whose email address was entered. Because first part of the authentication is sent by email, the verification code number must not be sent by email. Cydar recommends users either use verbal phone messaging, SMS, or an encrypted messaging service.

The email recipient will receive an email link to access a Map. The link opens a page that asks for the verification code. Entering the correct verification code opens the Map and allows the recipient to interact with the Map. The access authorisation remains valid for 14 days.

9. Virtual wires

To start making a map, click on '*Get started* '

Inserting wires

The first step is to insert virtual guide wires. These virtual guide wires will enable the anatomy to deform during surgery, so they should be positioned where the clinical user expects the real guidewire(s) will go. To insert a virtual wire, position the crosshair in either a 3D view or 2D MPR view on the expected access point(s), for example on both femoral arteries for bilateral transfemoral surgery in the figure below. If using the 3D view, check the position on the 2D MPR view. When satisfied, click the '*Confirm* ' button or press the Return key. Then mark where you expect the distal end of the wire(s) to go; for the transfemoral example this might be in the aortic arch using the same process. Confirm in the same way as before.

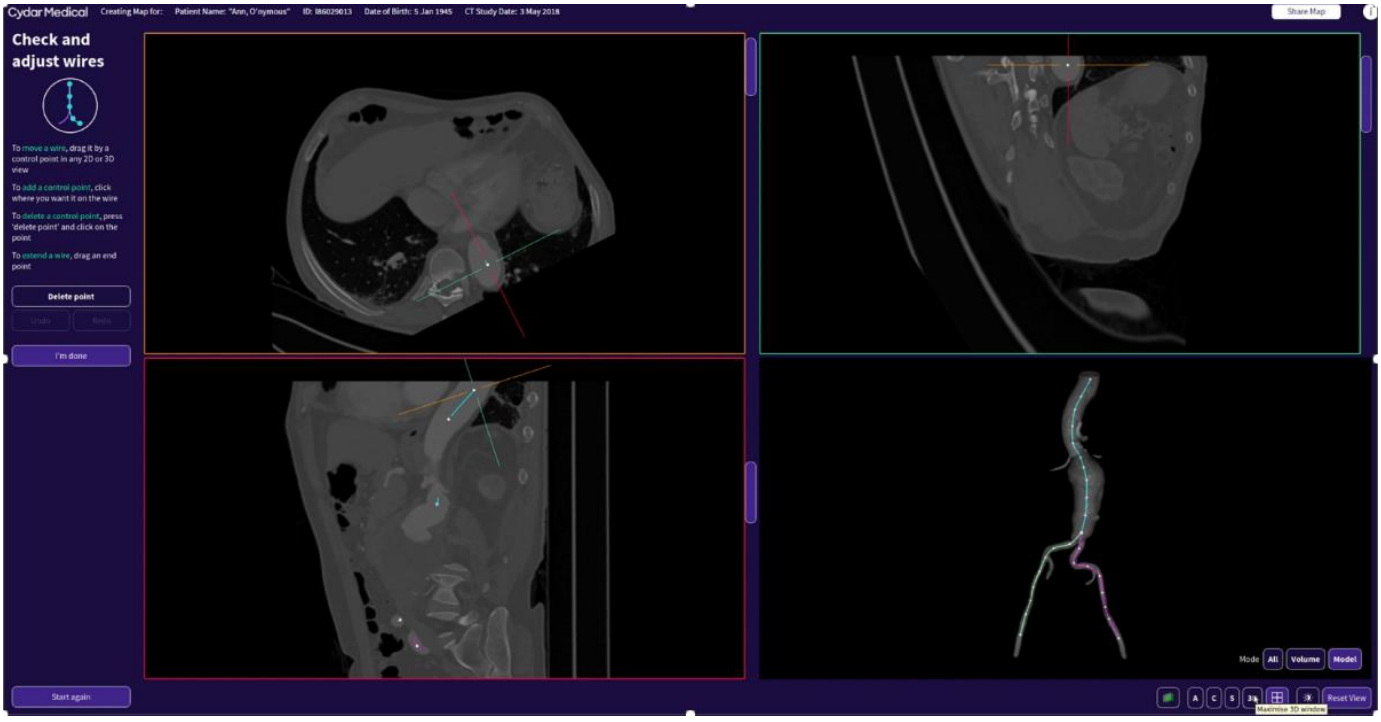


Figure: Checking and adjusting virtual wire positions

Checking wires

The software will first try to find an intravascular path between the access point(s) and the marked distal end of the wire. The clinical user **must** always check the wire path and manually edit it if necessary to match the expected path. To edit the wires, drag on the control points on the wires in either the 2D MPR or 3D views. Add additional control points along the wires by clicking on the guidewires. Delete them by clicking on '*Delete point*' and then on the control point. Once satisfied with the position of the wires, clicking on '*I'm done*' will return you to the '*Your Map*' page

If the software cannot find an intravascular path between the access point(s) and the intended distal end of the wire, then the clinical user must manually position the wires. The controls are as detailed in the paragraph above. The online training has some video tips on how to do this efficiently using the axial and 3D views.

Virtual wires are what enables the map to update when real guide wires deform blood vessels during surgery

Always check the position of the virtual wires and adjust them manually if necessary

Your Map

The Your Map page offers the choice of '*Sizing*', '*Add features*' and '*Remove features*'.

Sizing

The left-hand panel of '*Sizing*' offers the choice of '*Wire view*' and '*MPR view*' modes. The default is the '*Wire view*' mode.

'*Wire view*' consists of three panes:

1. The left-hand pane displays a **straightened** view ('straightened CurviPlanar Reconstruction') along the guidewire. Dragging on the scroll bar at the bottom of the straightened view rotates the view around the wire.
2. The top right pane is a slice **orthogonal** to the guidewire corresponding to the horizontal line on the wire view and to the plane shown on the 3D view.
3. The lower right pane shows the **3D** positions of the wires and the orthogonal slice.

The guidewires are coloured to help orientation. If there is more than one virtual wire, clicking on a different wire in the 3D view jumps the straightened and orthogonal views to that wire. Alternatively, click the '*Use other wire*' button in the left-hand sidebar.

To move the orthogonal slice along the wires, either click on the wire in the straightened view, click on the wire in the 3D view, or scroll up and down in the orthogonal slice pane using a mouse wheel.

To make a diameter measurement, first position the orthogonal slice along the guidewire to the desired position and then zoom the view as necessary. Click and drag in the orthogonal slice to measure a diameter distance in millimetres. A prompt appears in the right-hand sidebar for you to label that measurement. You can enter a free text label or use a pre-set label from a device sizing template. Clicking on '*Save*' or pressing the return key saves the measurement. A diameter measurement is visually displayed on the '*Your Map*' digital radiograph with the diameter in millimetres. The visibility of the rings in the map can be toggled on and off in the '*Your Map*' page by clicking on the diameter measurements in the table view.

To measure a length along a wire, click and drag alongside the wire in the straightened wire view. Do not click on the wire itself as that will jump the orthogonal view to that position. Label and save the measurement as for diameters. To measure multiple lengths, click and drag in parallel lines

beside the wire. Note that length measurements along straightened CurviPlanar Reconstructions do not vary with distance away from the wire, so multiple lengths can be measured parallel to each other.

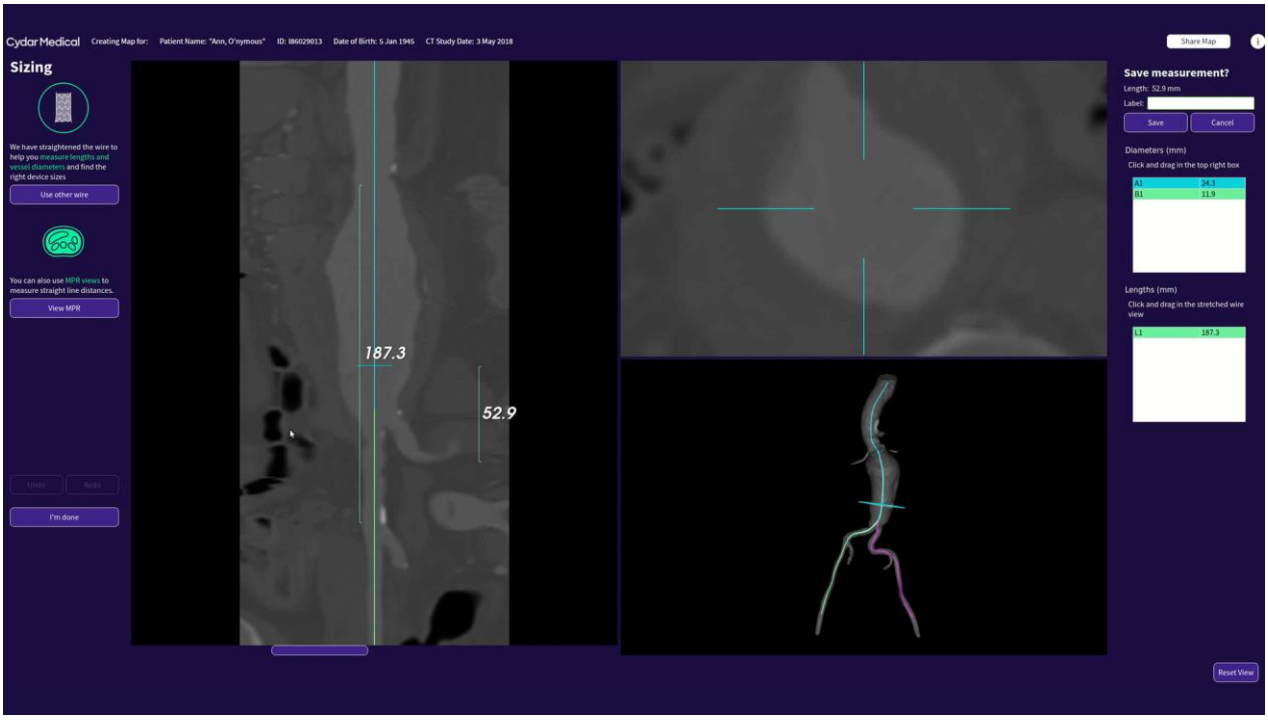


Figure: Two parallel length measurements (187.3 and 52.9 mm) along a straightened wire view.

'*MPR view'* shows conventional three-axis MultiPlanar Reconstruction views.
To measure straight line distances in 3D space, orientate and zoom the view in the MPR windows and then click and drag. Label and save the measurement as with diameter and length measurements.

To delete any measurement, go to the relevant '*Wire view'* or *'MPR view'* page, click on the measurement and press the Delete or 'D' key.

Derived measurements If using a planning template for a specific surgical procedure or medical device, the template may contain pre-set algorithms to derive certain measurements such as lengths along wires between two reference points, or curvatures along a wire in a set direction from a reference point. The reference points are defined when the user labels a diameter measurement with a specific, algorithmically linked pre-set label. The derived measurements are not editable as they are algorithmically defined from the virtual wires, reference points and segmented anatomy.

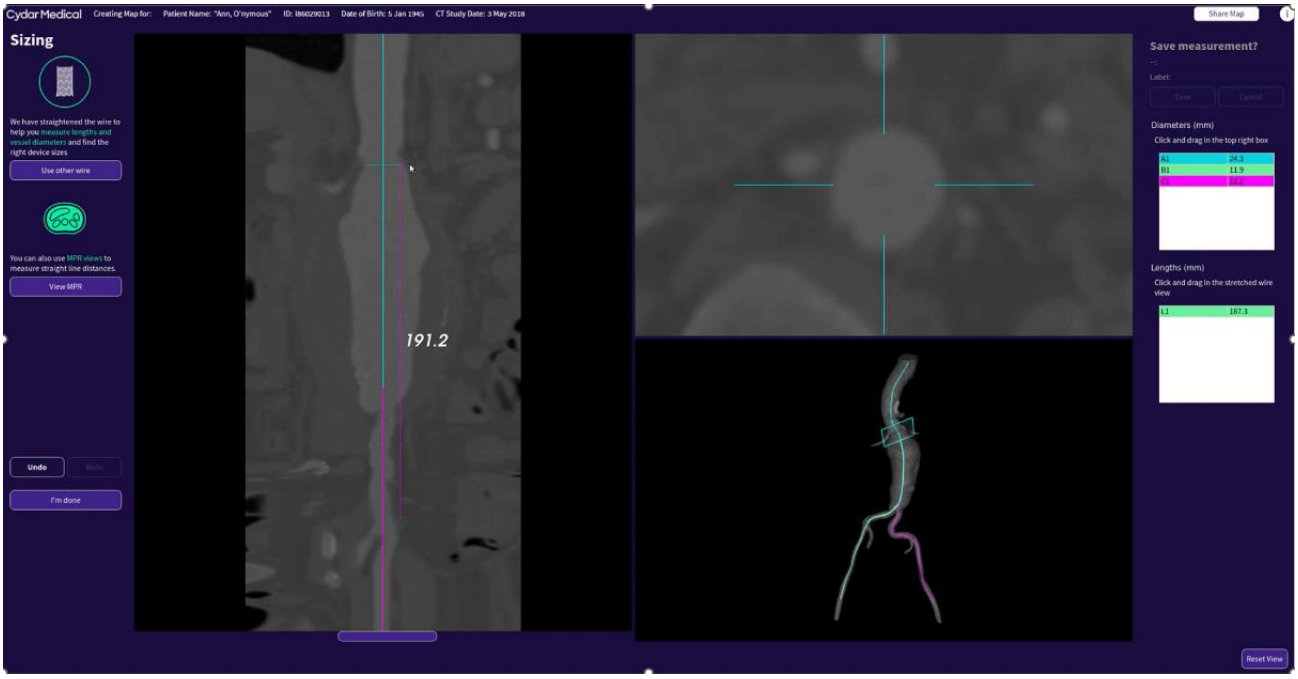


Figure: Wire view mode

Clicking *'I'm done'* returns to the '*Your Map'* page.

Add features

The '*Add features*' button on '*Your Map'* allows clinical users to edit the segmented 3D anatomy in the map. By default, the pre-operative processing uses a deep learning algorithm to try to segment aortoiliac arterial anatomy with main side branches. Users have the options to delete anatomic segmentations (see '*Remove* features"), extend anatomic segmentations or manually segment anatomy. Segmented anatomy can be visualised in the 3D view '*Volume'* or '*Model'* view options. Toggling on the green icon in the view control panel highlights all segmented regions in the MPR views in green.

To semi-automatically extend a vessel segmentation, click '*Add features*' then '*Add anatomy',* click on the intended contrast-enhanced vessel in a 3D or 2D MPR view, and then click '*Extend vessel'*. A region-growing algorithm will try to grow the vessel segmentation to that point from the nearest existing segmentation.

To manually segment anatomy, go to '*Add anatomy*' and use the '*Add marker point'* option. Click on a desired segmentation point in a 2D MPR view and click '*Add marker point'*. The point appears as a small sphere. Repeat as needed.

'*Add marker rings*' is used to place ring markers in positions away from the virtual wires. This can be useful for highlighting branch vessels. This function uses an automated deep-learning algorithm that will try to assist you with orientation and sizing of the ring. The ring is then manually editable.

Click either on a segmented vessel in the 3D view or on a point in a 2D MPR view then click '*Add ring'*. If the algorithm detects a contrast-enhanced vessel, it automatically positions and sizes the ring in the orientation that it considers optimal. To edit the diameter of the ring, either toggle the up and down arrows on the ring diameter in the left-hand sidebar, or type in the diameter in the same place. To edit the orientation of the ring, first 'pin it' to one of the 2D MPR view panes using this ring icon button in the bottom right corner of the pane. Once a ring is pinned to a plane, the plane can be dragged with the crosshairs in the other two MPR view panes. The colour around the

frame of the pinned window, corresponds to a crosshair colour in the other panes to help you orientate the plane. The ring can also be panned in pinned pane. Click '*Confirm this ring*' if happy, or '*Delete this ring*' if not.

To edit or delete an existing ring, click on the ring in either the 3D or 2D panes in the '*Add marker rings*' page.

All actions in '*Add features*' have an Undo and Redo option in the left-hand sidebar. '*I'm done*' returns to the '*Your Map*' page

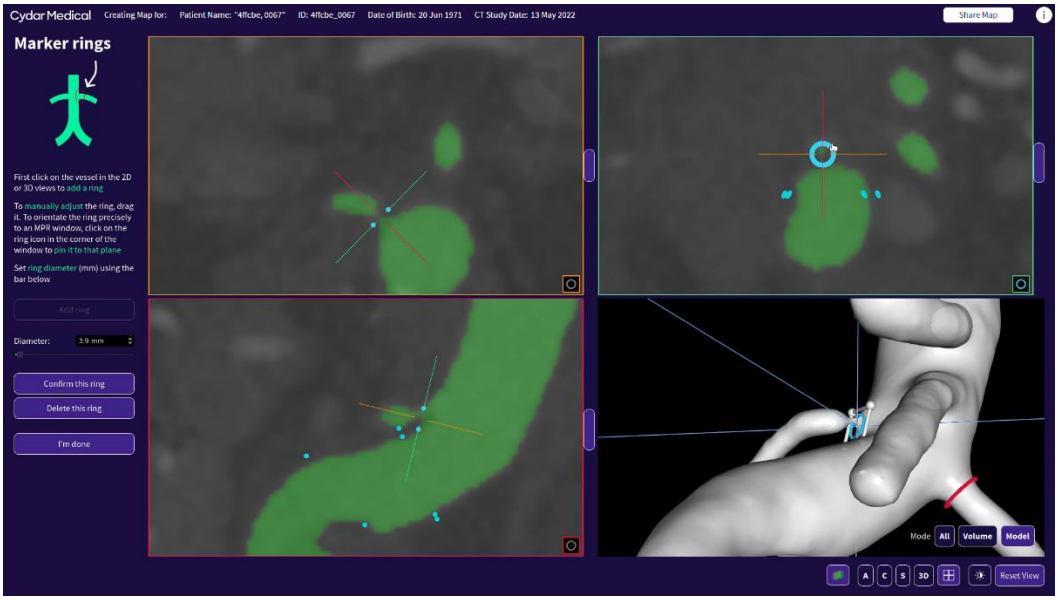


Figure: Manual editing of marker rings. The ring has been pinned to the top right MPR pane with a green border. The blue ring can be dragged in that plane. Dragging the crosshairs in the other MPR panes changes orientation. The ring diameter controls are in the left sidebar.

Remove features

The '*Remove features*' button in '*Your Map*' is used to delete regions of segmented anatomy in the map. The edit is done in the 3D view (i.e., not in the 2D MPR view). Click on '*Cut out*' and draw around the region to remove it from the Map.

There are '*Undo*' and '*Redo*' options. '*I'm done*' returns to the '*Your Map*' page.

C-arm angles

The digital radiograph view on the '*Your Map*' page indicates what C-arm position and angles can be expected to give certain views. Remember that the actual angles during surgery are likely to differ because the patient is likely to be lying in a different position on the operating table than on the CT table, and changes in soft tissue anatomy may have occurred.

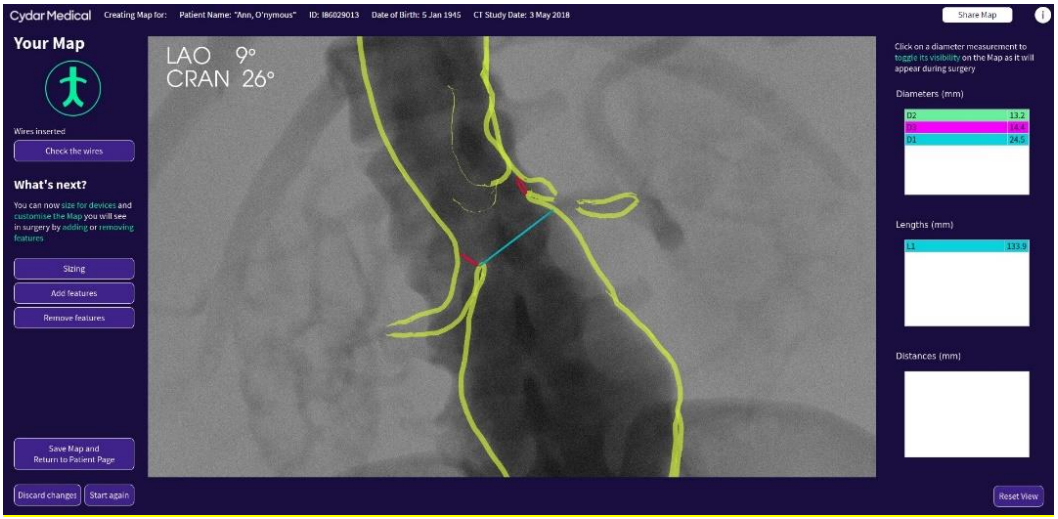


Figure: Using the digital radiograph on the '*Your Map*' page to view expected optimal C-arm viewing angles, in this instance by aligning an infrarenal diameter ring. It indicates LAO (Left Anterior Oblique) 9 degrees and Cranial 26 degrees angulation.

Saving the map

It is possible to exit a map at any stage from the '*Your Map*' page and return to the Vault. Changes to the map are autosaved but the best option if the map edits are satisfactory is to '*Save and return to the Patient Page*'. The map will remain editable until it is selected for use on the Cydar Appliance in the operating room. Alternatively, '*Discard changes*' erases all edits made in the current session. Selecting '*Start again*' discards everything including all measurements, anatomy segmentation edits and virtual wires.

Reviewing your Map before surgery

In the Hospital Vault, go to the relevant Patient Page and click on the 'Preoperative Map' icon to preview the map. To view the map in more detail, or to edit or share it, click '*Open Map*'.

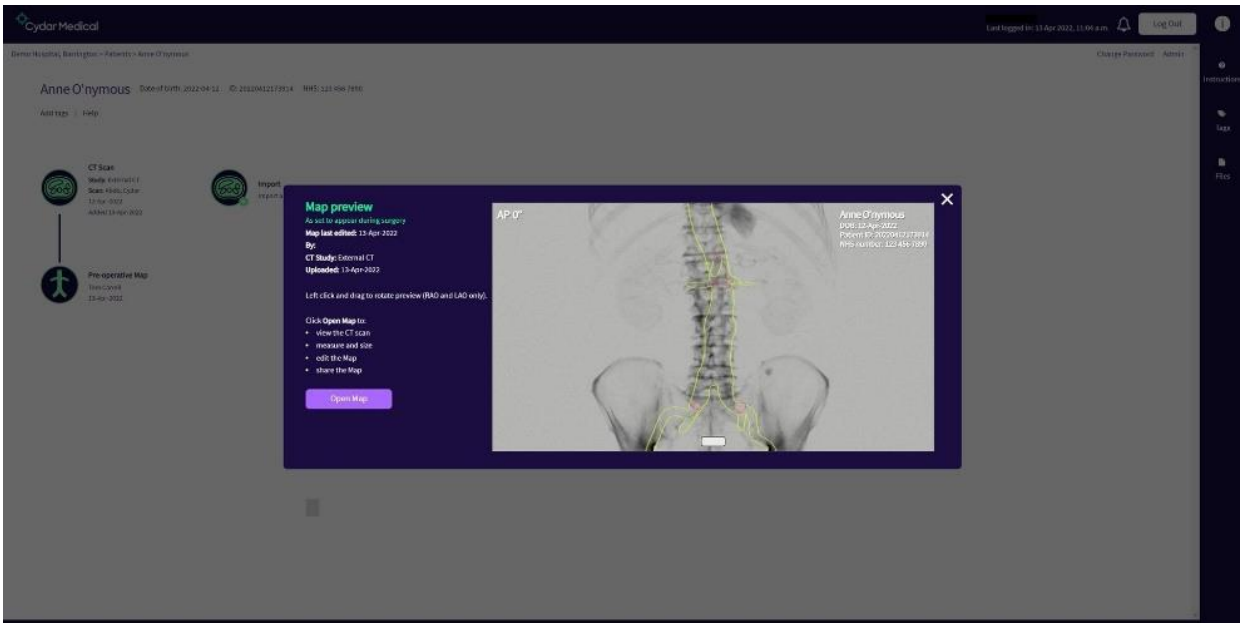


Figure: Map preview as seen in a Hospital Vault

Using maps in surgery

1. Check setup

Cydar EV Maps software is connected in the operating room through the Cydar Appliance and is designed to be used with a Cydar remote control. In some setups, there is also the option of using a touchscreen.

Figure: A Cydar remote control (right) and receiver

Before starting surgery:

If using a mobile C-arm, check the Cydar Appliance All-in-One is connected correctly:

1. The mains power lead is connected and switched on at the wall.
2. The Video (DVI) cable is connected correctly from the X-ray set to the Cydar Appliance
3. The Ethernet cable is connected to the correct network point.

Ensure that the Cydar Appliance and the Cydar EV Maps software is working:

1. If the Cydar EV Splash screen is visible (see figure below), it indicates that the Cydar Appliance is powered on and the monitor display is working. If this screen is not visible, check that the Cydar Appliance is powered on and check the display monitor settings in the operating room.
2. Select a map to check that the Cydar Appliance is receiving a video signal from the X-ray set. If not, then:
    - check the Xray set is powered on
    - check the DVI cable connection and that any signal convertors and optical isolators are powered on
    - consider powering the Xray set off then on again to re-establish a connection.

Figure: Cydar EV Splash screen indicating that the Cydar Appliance is powered on and the display monitor is functioning.

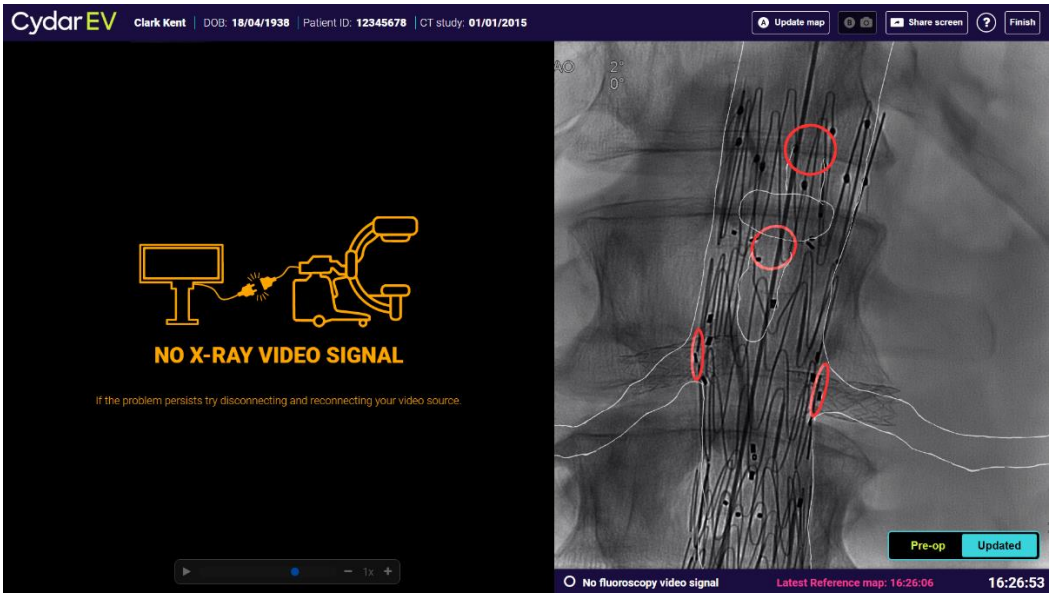


Figure: The message on the left indicates that the Cydar Appliance is not receiving a video signal from the X-ray set. Check the Xray set is powered on, the DVI cable is connected, and any signal converters are powered on. If problem persists, contact Cydar Online Support.

If any problem persists, contact Cydar Online Support as soon as possible either via the constantly monitored support@cydarmedical.com or via the Cydar smartphone app. Cydar Online Support can perform remote diagnostics and resolve most problems.

2. Select the patient, check, and confirm

The Map selection screen displays a list of the patient identifiers in the maps. The default list shows the most recent maps. You can also search by patient names alphabetically using the letters on the right. When you select a map, the user is asked to check that the three patient identifiers in the map match those of the patient on the operating table.

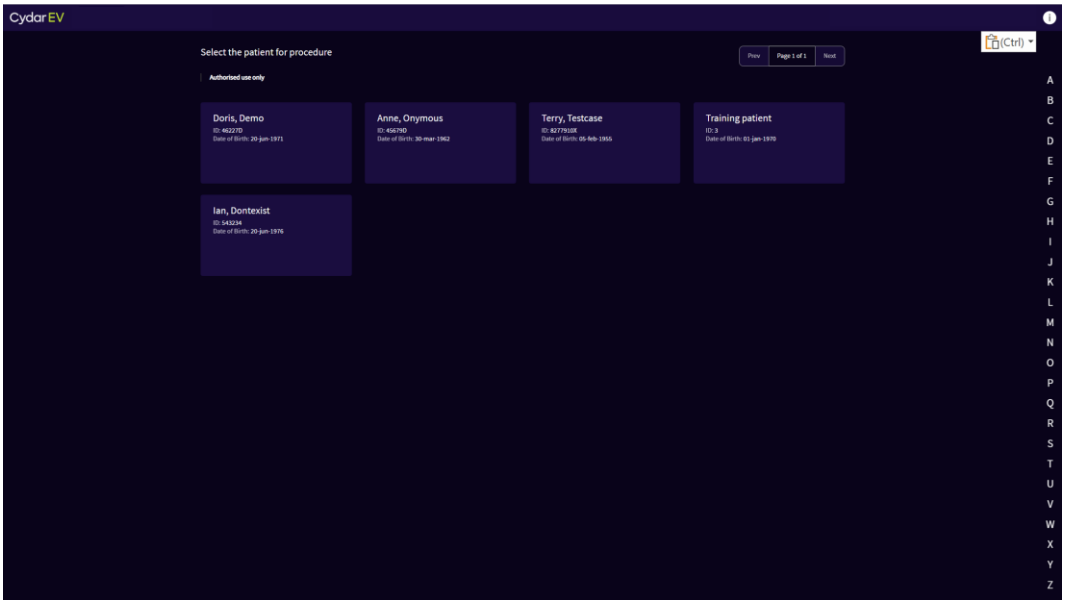


Figure: Map selection screen

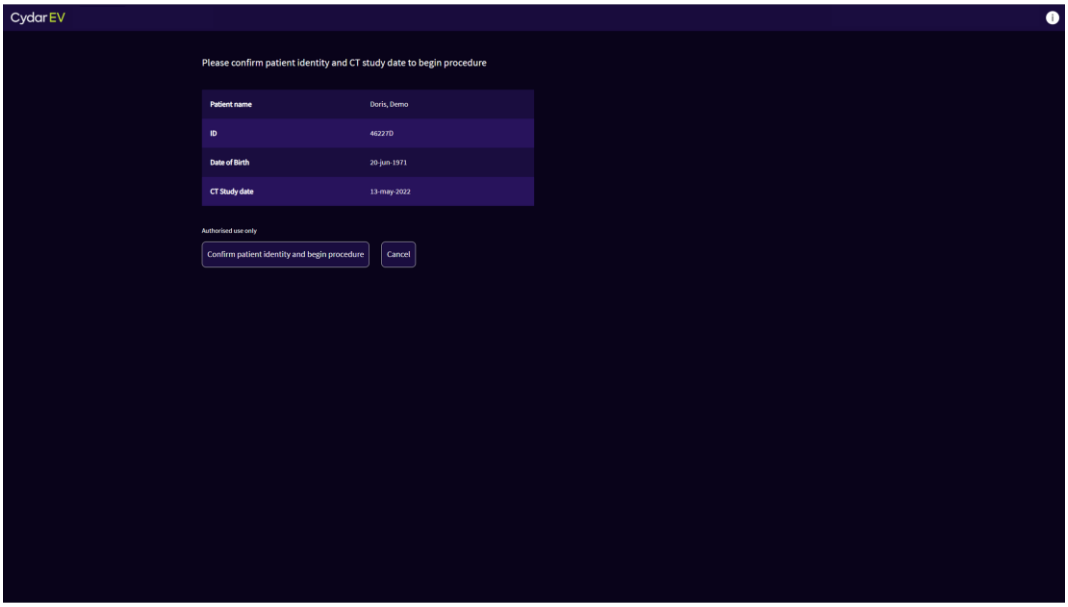


Figure: Patient identifier confirmation screen

Always ensure that the identifiers on the Map match the patient on the operating table. Always check all three patient identifiers: patient name, date of birth, and unique identification number.

3. The screen and controls during surgery

The *Cydar EV Maps* User Interface consists of two display panels with the following information and controls:

Figure: Standard screen layout with the Overlay Panel on the left and Map panel on the right

The Overlay panel (left). Always shows the 2D Image Data generated from the live video X-ray set. If the software is confident of the patient position, it overlays either a Pre-operative Map in green, as seen here, or an Updated Map in blue. In the Update map mode, the video on the left is paused.

The Map Panel (right). Displays a 3D render of the overlaid map. If the software cannot confidently overlay a map, the Map Panel displays the most recently overlaid 'Reference map' with a timestamp to show when it was last valid.

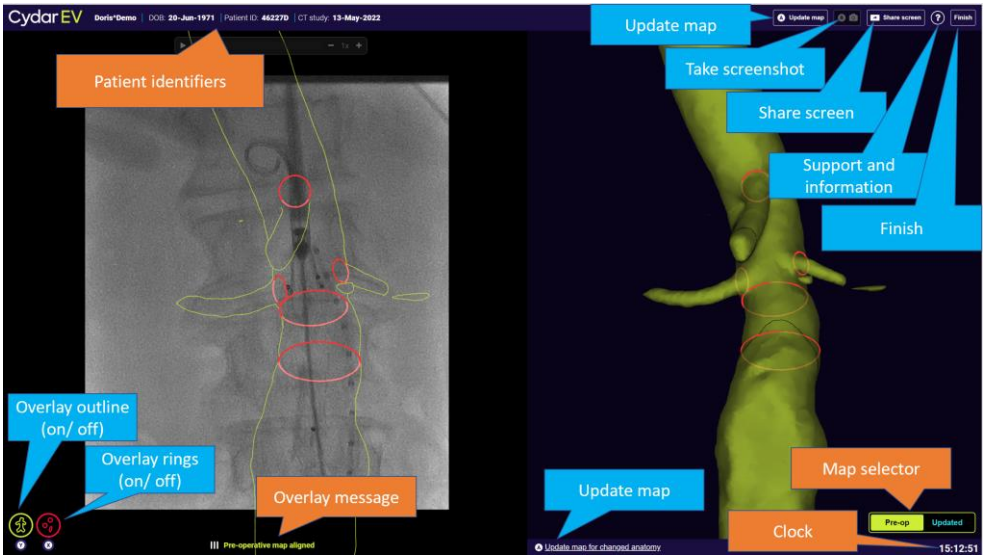


Figure: Standard layout of Information and Controls with remote control shortcuts

Information (orange callouts):

- Patient Identifiers for the map
- Overlay message bar shows overlay status
- Clock

Controls (blue callouts):

- Update map (two buttons, one top and one bottom, same function) with remote control shortcut: displays virtual wires and the control points used to Update the map for soft tissue deformation.

- Overlay view selectors (bottom right) with remote control shortcuts: Overlay outline on/ off; Overlay rings on/ off
- Share screen
- Take screenshot, with remote control shortcut
- Support and technical information
- Finish

Figure: Overlay view selector, showing (left to right): Outline off, rings on; Rings off, outline on; Outline and rings off. The icons are coloured when turned on. Remote control shortcuts are indicated ('Y' and 'X').

If no overlays are visible, check that the overlay selectors for rings and outline are both turned on.

4. Image Tracking

Image Tracking is name given to the computer vision software that watches the skeletal anatomy in the live 2D Image Data to locate the patient's position in 3D space (translation in 3 axes, rotation in 3 axes and magnification). Image Tracking starts automatically when the first X-ray fluoroscopy images are acquired and processed and continues until turned off by 'Finish'.

Whenever the computer vision sees enough vertebral skeletal anatomy to be highly confident (>99.8%) of the patient position, it will automatically overlay the selected map (i.e., Pre-operative or Updated map) in the Overlay Panel.

When the view changes, for example when the C-arm or patient moves, the map is automatically removed while the computer vision searches for a new solution. It takes 3- 5 seconds for the Image Tracking software to search, verify and confirm a solution before displaying a new map.

Image Tracking will not overlay a map if the C-arm angle relative to the patient's original CT scan is greater than 70 degrees lateral (LAO or RAO).

If Image Tracking is not highly confident (>99.8%) of the patient's position, it will not overlay a map, and will instead display the most recently overlaid map image in the right-hand Map panel as a '**Reference map**'. A Reference map is labelled with a timestamp to indicate how recently that overlay was valid.

Tips to improve the intra-operative performance of Cydar EV Maps

Always use CT scans with 1mm or thinner slices

- Use good quality fluoroscopy imaging
- Magnify the fluoroscopy image by changing field-of-view not digital zoom.
- Ensure parts of two or more vertebrae from T6 to L5 are visible. More vertebral anatomy visible on screen improves performance
- Avoid steep lateral X-ray views beyond 70 degrees LAO/ RAO

5. Pre-operative and Updated maps

The Pre-operative Map (green)

The Hospital Vault sends the Pre-operative map to the Cydar Appliance when a patient map is selected at the start of surgery. Pre-operative Maps are always shown in green, both in the overlays and in the 3D renders.

The soft tissue anatomy in the Pre-operative map is very likely to change as stiff wires and delivery systems are introduced through blood vessels. **It is therefore mandatory for users to check the real-time anatomy with a suitable imaging technique, such as contrast angiography, and update the map before deploying any invasive medical device.**

The Updated Map (blue)

Updated maps-previously referred to as Adjusted maps. The 'Update' terminology has been introduced to convey that the non-rigid transformations to the Pre-operative map are intended to reflect how the soft tissues have deformed. The feature **should not** be used to correct or adjust for any perceived alignment (2D-3D registration) error.

The Update map feature should only be used to update the Pre-operative map anatomy for observed soft tissue deformation.

'*Update map* ' can be found both in the top right bar and in the lower right bar of the Map panel. There is a remote-control shortcut (e.g., 'A'). '*Update map* ' will not function if there has not yet been an overlay displayed. Clicking '*Update map* ' reveals control points along the virtual wires inside the map. Arrow and rotate buttons in the map panel enable the user to move (pan and rotate) these control points on the virtual wires to non-rigidly deform (i.e., like plasticine) the soft tissues in the map to match on-screen deformed anatomy.

An Updated map is always shown in blue, both in the overlays and in the 3D renders. An Updated map can be repeatedly updated either if the state of the soft tissue deformation changes or if more information becomes available, for example when a new C-arm position shows a new perspective. Changes to the Updated map can be discarded and reset to the original Pre-operative map using the '*Reset to original*' button in the '*Update map* ' mode.

Figure: Updated maps are shown in blue

The original Pre-operative map remains available throughout the procedure. To switch between Pre-operative and Updated maps, toggle the Map selector between '*Pre-op* ' (green), which always remains unchanged, and '*Updated* ' (blue).

Figure: The Pre-operative Map remains available throughout by toggling the Map selector (indicated on this image with the orange callout) between 'Pre-op' to 'Updated'.

How to use a Digital Subtraction Angiogram (DSA) to Update a map

First, both the contrast angiogram and the Map need to be on the screen at the same time:

1. Before taking the DSA, ensure that there is an overlay displayed in the Overlay Panel on the left.
2. Without moving the C-arm or changing the Field of View (FOV, magnification), perform a Digital Subtraction Angiogram (DSA). If the subtraction is effective, no bony anatomy will be visible and therefore the computer vision will remove the overlay. A new Reference map will appear in the Map Panel on the right, with a fresh timestamp.
3. Click '*Update map* '
4. You are asked to ensure that the Reference map position and Field of View (FOV, magnification) matches the position and Field of View in the Overlay Panel view. If so, click '**Yes, continue to update the map'** (or remote shortcut A). If in any doubt, click '**Cancel'** (or remote shortcut B).
5. Select a control point on the virtual wires and use the arrow keys to pan and rotate that segment of the Map. When a segment has been updated by changing its shape, that segment is then '**pinned**'. This means that updates in neighbouring segments along the virtual wire will not move the pinned segment. **You should therefore update key segments such as the renal and visceral branches first.**

The Reference map must not be used to Update the map if the patient or C-arm has moved, or if the Field of View has changed. If any of these have changed, then errors will be introduced into the map.

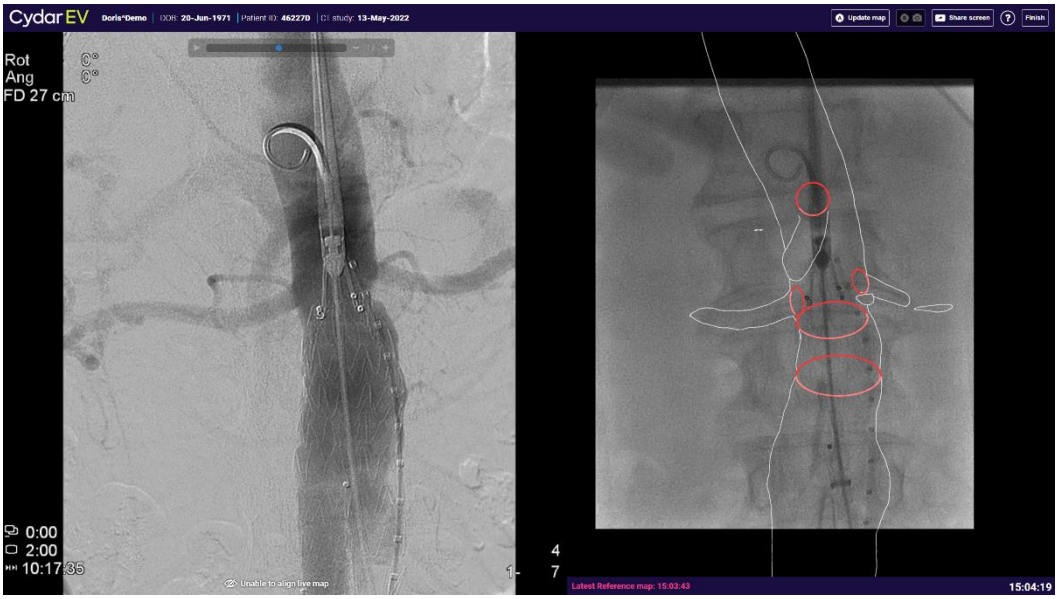


Figure: Checking real-time anatomy using DSA. No overlay is displayed on the Overlay Panel on the left because the vertebral anatomy is subtracted. The most recent Reference map is shown in the Map Panel on the right with its timestamp in yellow.

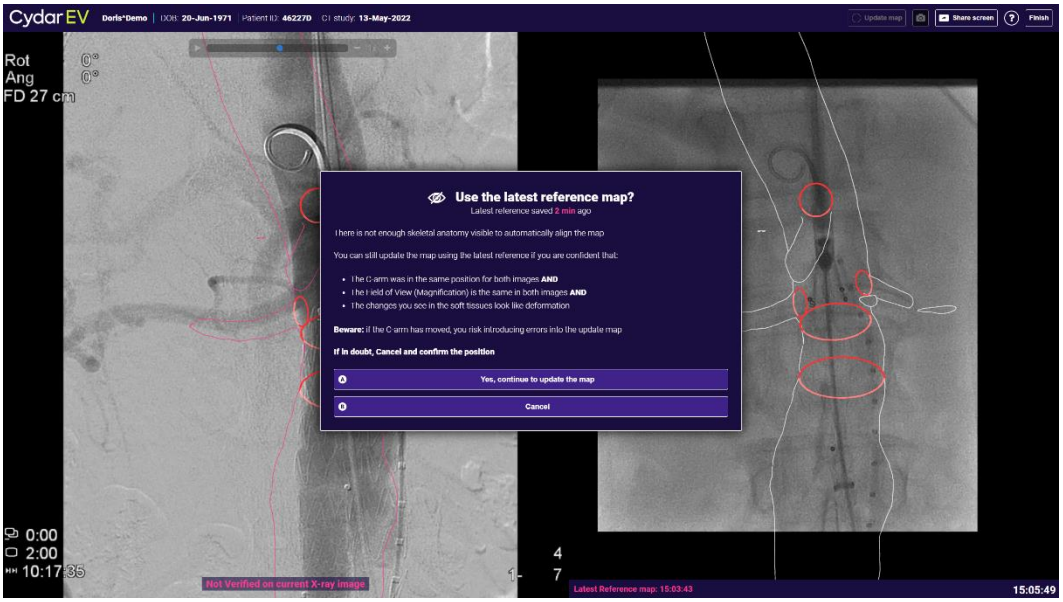


Figure: Clicking '*Update Map*' has paused the Overlay Panel video on the left and overlaid the last Reference map over the paused image in same position as in the Map Panel (right). The user is confident that the C-arm is in the same position and FOV on both images and checks that the changes are consistent with soft tissue deformation. It is typical for stiff wires to displace the renal arteries in a cranial direction as seen here.

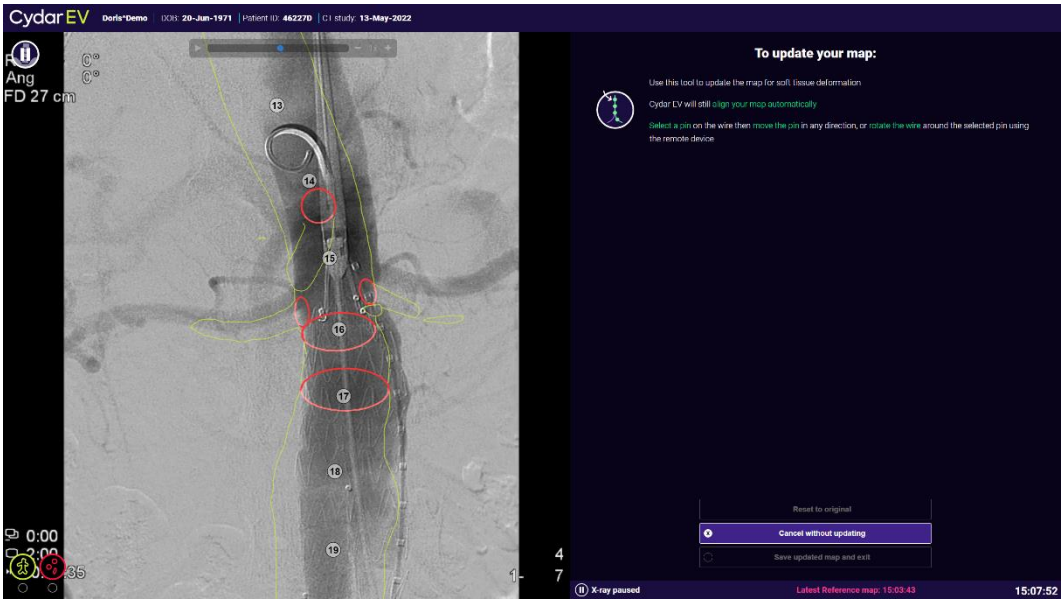


Figure: Ensure the overlay outline and rings are both turned on. This is because the 'silhouette' view of a DSA may not show anterior vessel origins clearly and could lead to the renal artery origins appearing to be lower than they actually are.

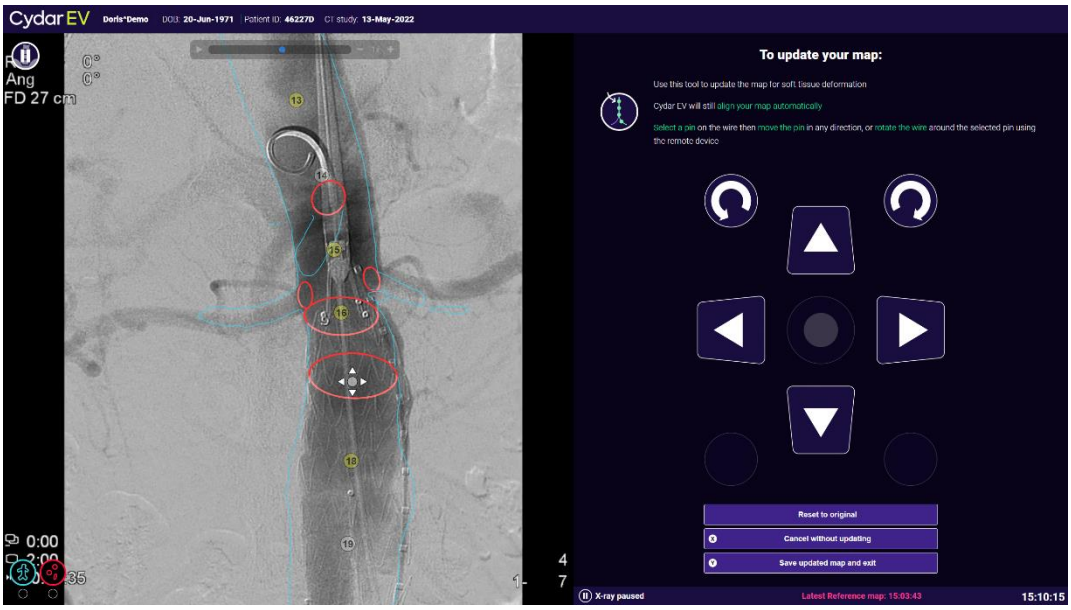


Figure: Select a control point along a virtual wire. Use the remote-control (or touchscreen) arrow keys to pan and rotate vessel segments along the virtual wires. Once a segment is updated, it is '**pinned**' and will not move when other segments are adjusted. Update the clinically most important segments first as here with the aortic segment at the level of the renal branches

When satisfied with the match between the Updated map and the current anatomy, click Save updated map and exit' to return to the live fluoroscopy. Image Tracking will overlay the Updated map when it is next confident of the patient's position.

6. Sharing the screen

For intraoperative clinical support, you can share the live screen online with a remote individual, for example a colleague or a medical device company expert. Screen sharing requires Two factor Authentication. Instructions are displayed on screen. The steps are:

1. Contact the external individual by phone, SMS, or encrypted messaging app. Check that they are available for support and have access to a web browser either on a desktop, laptop, tablet, or smartphone.
2. Then click the '*Share Screen'* button. This generates a one-time web address on the screen along with instructions (First factor).
3. Convey that web address to the external individual by phone, SMS, or encrypted messaging app.
4. The external individual enters the web address into their web browser. **They must not close the window or browser once it is open until the screen sharing is finished as it is a one-time weblink**.
5. The external individual will be asked to enter their name and email address (Second factor) then wait.
6. Their name and email address will appear on the Map Panel in the operating room with options to '*Accept*' or '*Decline*' the request. Clicking '*Accept*' starts the live screen share.
7. An alert saying '*Screen is being shared*' is displayed along with an '*Stop sharing*' button that ends the screen sharing session.

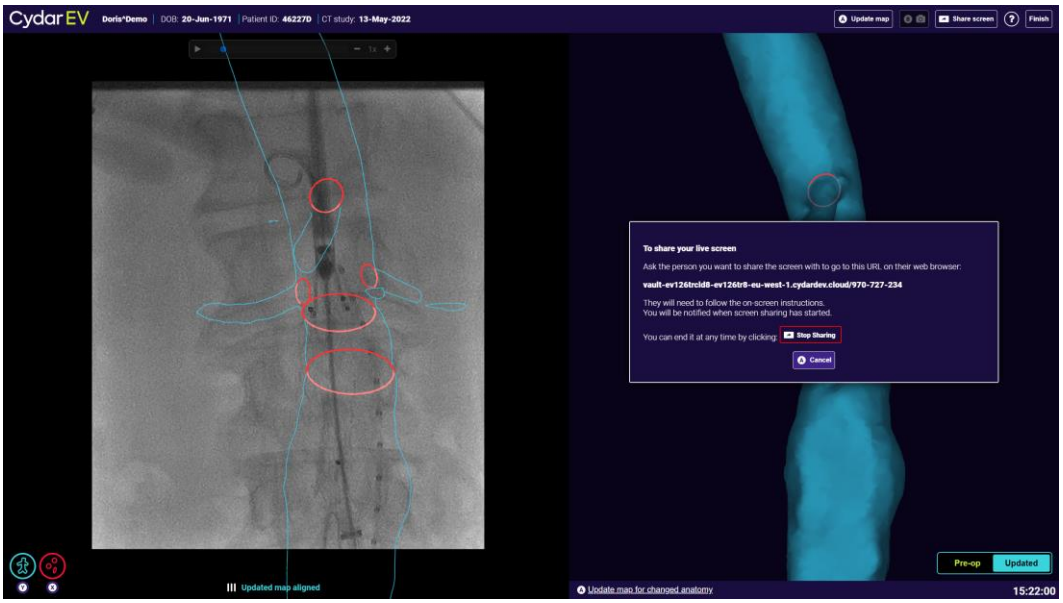
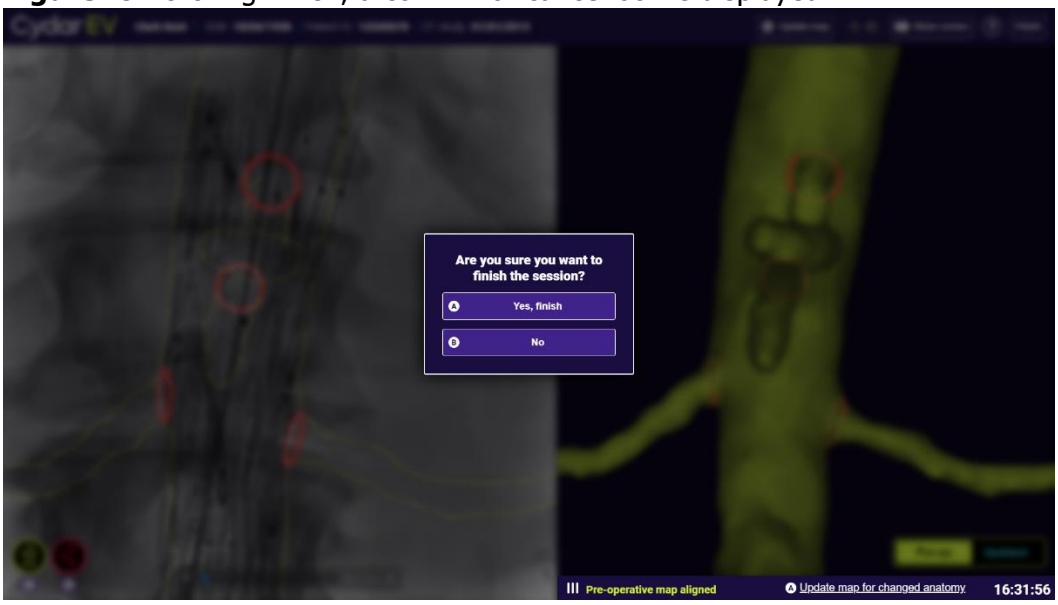


Figure: Share screen instructions

7. Finish

When finished, click '*Finish*' in the top bar. If no user activity or new imaging is detected for a prolonged period, *Cydar EV Maps* will enter an automatic standby sequence.

Figure: On clicking Finish, a confirm or cancel box is displayed.



8. Getting help

Technical support and Information are accessed via the '?' button in the top bar. A box appears with tabs on:

1. How to contact Cydar Online Support. Once activated, Cydar Online Support can view the screen and monitor consoles. Cydar Online Support can place pop-up messages on the Map panel with button options, for example to acknowledge the message.
2. Cydar EV Maps information including how to access the online training. There is a shortcut to the Maps in surgery training module. This feature is intended for familiarisation of ancillary operating room personnel with Cydar EV Maps.

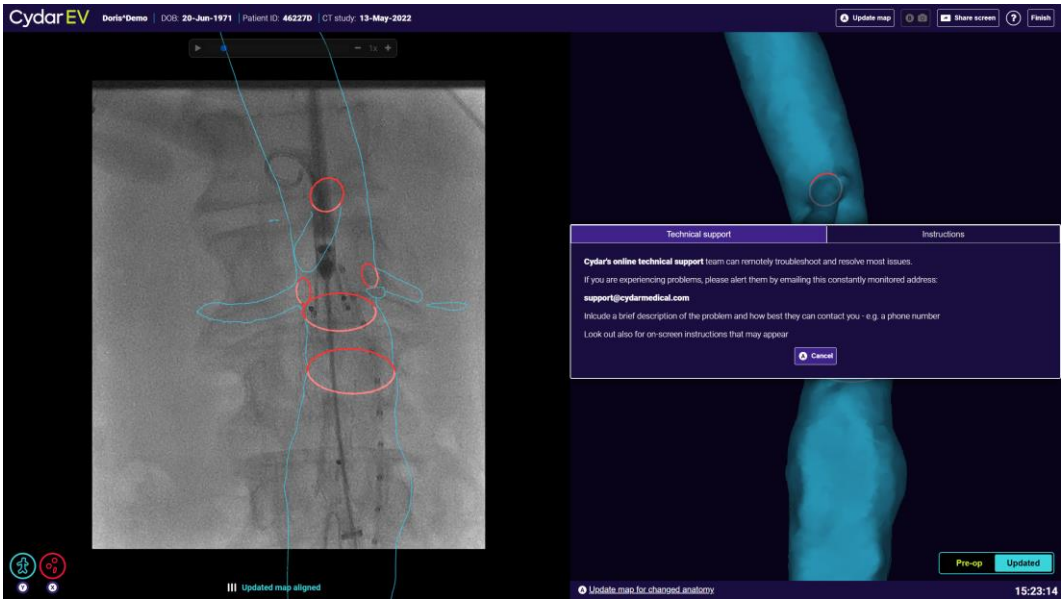


Figure: Technical support instructions

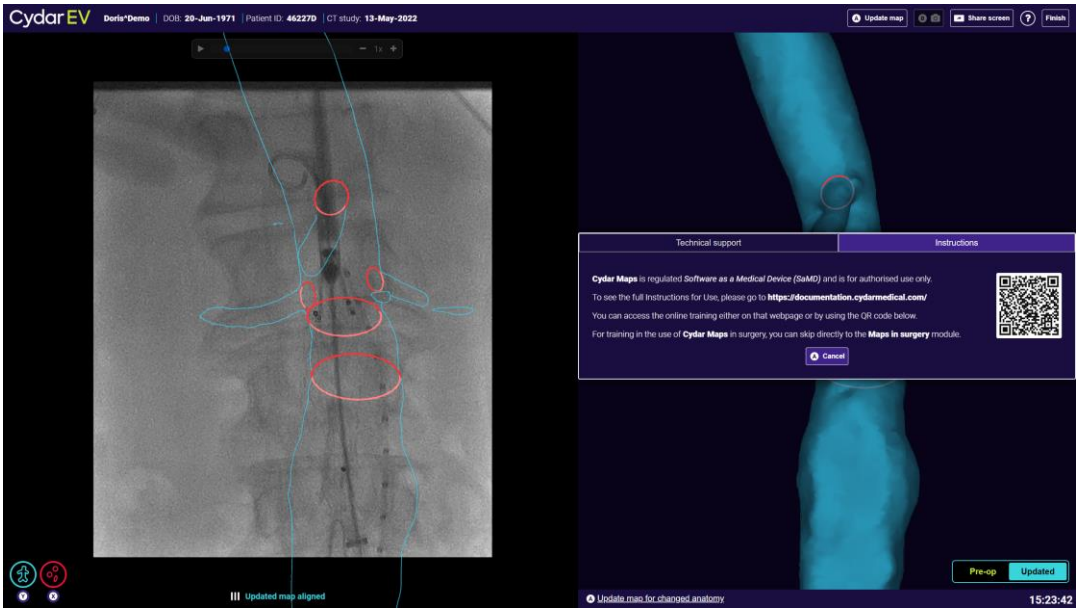


Figure: Instructions and links to further device information

Post-operative review

1. Reviewing surgery

After surgery, a '*Surgery*' icon will appear in the Patient page of the Hospital Vault, showing the relationship between the original CT study, the Pre-operative map and the use of that map in surgery. Clicking on the icon will give details and access the 2D Image Data generated during surgery, including the map overlays. There is an option to save and download still and video images.

Any screenshots taken during surgery can be viewed and downloaded in the Files tab.

2. Post-operative scan analysis

When a post-operative CT scan is imported, it is processed to 3D Image Data in the same format as a pre-operative CT scan. Deep learning segmentation helps the clinical users to compare changes in anatomy.

There is an option to set an automated check and import post-operative CT scans after a map has been used in surgery. Alternatively, click on the Import icon in the Patient Page to check for a new CT scan with the same patient identifiers.

If the patient identifiers on an imported CT scan matches the existing Patient Page, it is displayed to the right (i.e., chronologically later) of the surgery icon.

Post-operative maps can be opened, measured, and labelled in the same way as a Pre-operative map.

Figure: A Patient Page indicating that a single map has been used twice in surgery and a new post-operative CT scan has been imported (flashing blue indicator).

3. Abdominal Aortoiliac Volume Estimation

This feature displays the volume, in millilitres, of a 3D Deep Learning segmentation of the lumen and thrombus in the abdominal aorta and common iliac arteries. The feature is intended to assist an expert clinical user to calculate the volume of an aortic aneurysm to help track disease progression. It is an adjunct to assist, and not a replacement for, expert clinical judgement.

The feature is active in patients who have been tagged as having, or suspected of having, an abdominal aortic aneurysm ('AAA'). These tags may be applied either:

1. Automatically by a suspected AAA detector algorithm. Tag 'Cydar AI: Suspected Abdominal Aortic Aneurysm", or
2. Automatically if an AAA planning template has been used. Tag 'AAA Map', or
3. Manually by applying the tag 'Abdominal Aortic Aneurysm'.

Clicking on the Map icon in a Patient Page with the feature active, shows the segmented volume highlighted in both a 3D render and a 2D axial slice viewer in the Map Preview window (see figure). False positives (i.e., segmentation of volumes that are not AAA) and/ or false negatives (i.e., failure to segment AAA volumes) may occur. The 3D render can be rotated to inspect for any outlying false positives and the axial slice viewer scrolled to inspect accuracy of the segmentation ie false positives and false negatives. The volume calculation is an accurate calculation of the volume of the orange segmentation.

A toggle switch turns the feature on and off. The axial slice viewer can be enlarged to help detailed inspection.

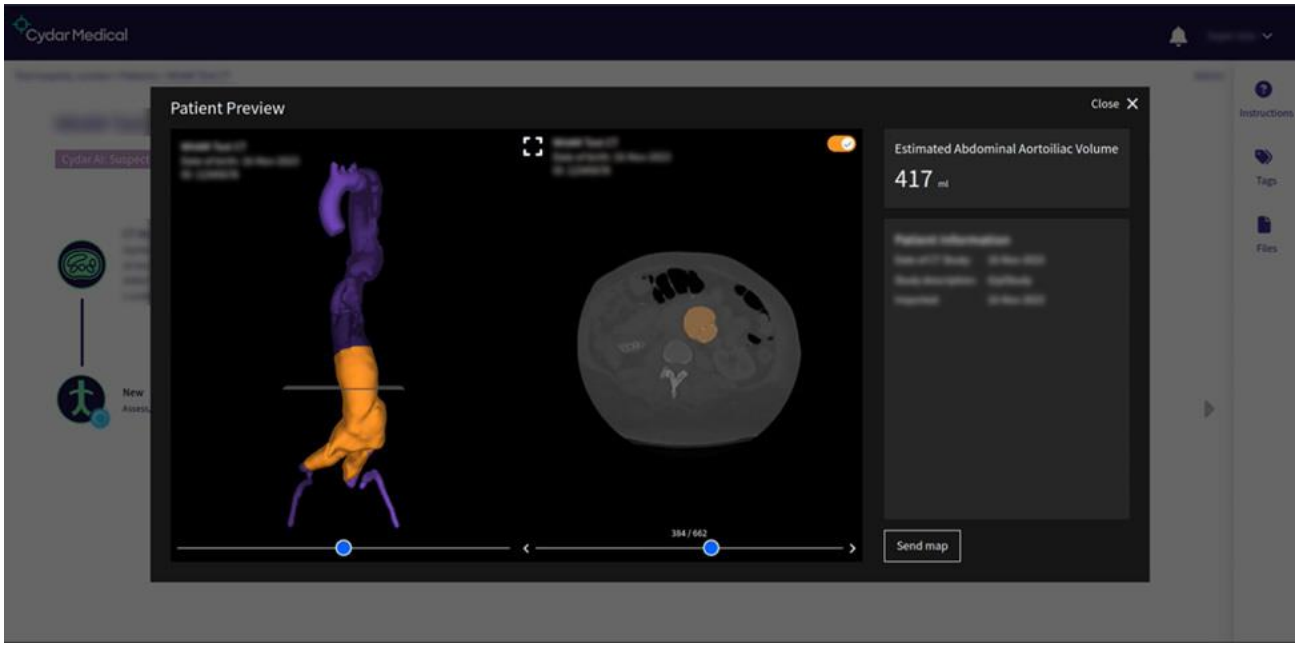


Figure: A Patient Preview on showing the Abdominal Aortoiliac Volume Estimation feature. The volume of the AAA (orange) segmentation is displayed top right: 417ml. The 3D render on the left can be rotated to check for discontinuities and outlying false positives. The axial slice viewer on the right can be scrolled to inspect the correlation of the AAA (orange shading) segmentation to the underlying CT scan data (false positives and false negatives). The orange toggle flips the segmentation on and off to assist this inspection. The full-screen view icon, top centre, enlarges the axial slice viewer.

When comparing serial volumes, clinical users should pay particular attention to the vertical extent of the segmentations as well as the integrity of the segmentation at the various levels. For example, the Deep Learning may struggle to identify the renals in non-contrast scans and the cut-off level for the volume calculation may therefore vary from a scan with good contrast enhancement.

Appendix A: Reducing radiation exposure

Recommended use of Cydar EV Maps to reduce radiation exposure and iodinated contrast use in Endovascular Aneurysm Repair (EVAR)

1. Use the Pre-operative Map (green) without digital subtraction angiography (DSA) to guide the introduction of initial wires and catheters and to approximately position the device delivery system.

2. Use the Pre-operative Map (green) to position the C-arm to the preferred angulation and FOV magnification.

Tip: Image Tracking conveys the actual perspective of the C-arm relative to the patient. Use the appearance of the map rings to fine tune the C-arm angle.
Note: Because the patient posture has likely changed on the operating table, the real-time C-arm angles may differ from angles predicted from the CT, which are measured relative to the CT table.

3. Always use contrast angiography to check for deformation and Update the map accordingly before deploying the main body. Then use the Updated Map (blue) to guide deployment of the EVAR main body.

Tip: Stiff wires generally displace the renal artery origins superiorly. Use the outline view to Update the Map to the DSA.

Tip: Think of Updating the map in much the same way as you would with marking the screen; with the advantage over marking the screen that the overlay is more accurate if the patient or C-arm moves

4. For fenestrated and branched EVAR, use the Updated map (blue) to guide graft alignment and branch vessel cannulation.

5. For iliac limbs, use the map to position the C-arm to the preferred angulation and magnification. Check for deformation using contrast angiography. Update the map to act as a marker for iliac limb deployment.

Tip: When updating iliac anatomy in the map, toggle off the Outline on the View Selector and only use the iliac Vessel Rings

Appendix B: System Requirements

To access your Hospital Vault, you need:

1. A modern web browser, such as:
- Internet Explorer 11 or later
- Microsoft Edge (any version)
- Firefox 60 or later
- Chrome 48 or later

2. An internet connection that supports:
- 10Mbps bandwidth or greater both directions
- Outbound connections using HTTPS to your Hospital Vault

Glossary

Cydar Appliance	The Cydar Appliance is a PC suited to operating room use that displays Patient Identifiers, Map Data and 2D Image Data during surgery.
Hospital Vault	The Hospital Vault is a Customer-specific cloud repository where all Customer data is stored
Compute Cloud	The Cydar Compute Cloud is a specialised high-performance cloud GPU compute resource
Cydar Gateway	A Hospital PACS node hosted inside the Hospital Network which enables. authorized Clinical Users on the Hospital Vault to query and retrieve CT scans and prevents third party access to the PACS
X-ray set	The X-ray fluoroscopy set (either fixed or mobile)
X-ray image	The X-ray fluoroscopy image
3D Image Data	Cydar 3D Image Data is a Cydar-specific 3D data format with associated metrics processed by the Automated Pre-operative Processing, computer vison and machine learning.
2D Image Data	Cydar 2D Image Data is a Cydar-specific 2D data format with associated metrics processed by the computer vison and machine learning.
Image Tracking	Cydar computer vision during surgery that locates the patient's position in 3D space based on the 2D Image Data and 3D Image Data.
Maps	3D models of the surgical plan, consisting of 3D anatomical Image Data generated originally from a patient's own CT scan, along with measurements, labels, and medical device details.
Pre-operative Map	Patient-specific 3D model of the plan before surgery. Always shown in green when overlaid or 3D rendered.
Updated Map	A non-rigidly (plasticine-like) transformed map representing the clinical user's updates to the Pre-operative Map based on their observations of soft tissue deformation. Always shown in blue when overlaid or 3D rendered
Virtual Wires	Imaginary 3D lines in the 3D Image Data that simulate guidewires. Used to Update Maps and as reference for diameter, length and curvature measurements.
Marker Rings	Ring-shaped markers in a map. Used as reference points to mark intended positions and to highlight key features.

Regulatory Information

CE 2797

This software product is a Medical Device as defined by 2017/745

MD

This symbol denotes Cydar EV Maps is a medical device.

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Caution: US Federal law restrict this device to sale by or on the order of a Physician. Notice to user should any serious incident including patient death, patient injury or additional surgical intervention that has occurs in relation to Cydar EV Maps device the incident must be reported to Cydar Ltd and the national Competent Authority in the country the incident occurred.