Cydar Medical

Cydar EV Maps Instructions for Use

Cydar EV Maps **gives you a dynamic 3D model of your plan for surgery, updated during surgery as anatomy changes**

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

All users must complete a *Cydar EV Maps* training programme prior to use.

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 (95% confidence that 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.

Pre-operative workflow

There are two pre-operative steps:

1. Select a patient with a compatible CT scan

In your Cydar Vault account, search for the relevant patient, go to that patient's page and select the CT scan relevant for your planned surgery. If the patient is not already in the Cydar Vault, then upload a CT scan from PACS, your desktop or via a guest link to create a new patient in the Vault, and then select the CT scan. Please allow 20 minutes between CT scan upload and surgery for the full automated pre-op *Cydar EV Maps* processing to complete.

Please note the essential CT scan requirements in the box on the right.

CT scan requirements

CT scans should be at the same slice thickness and intervals as the original scan acquisition. **Optimal Cydar EV Maps 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

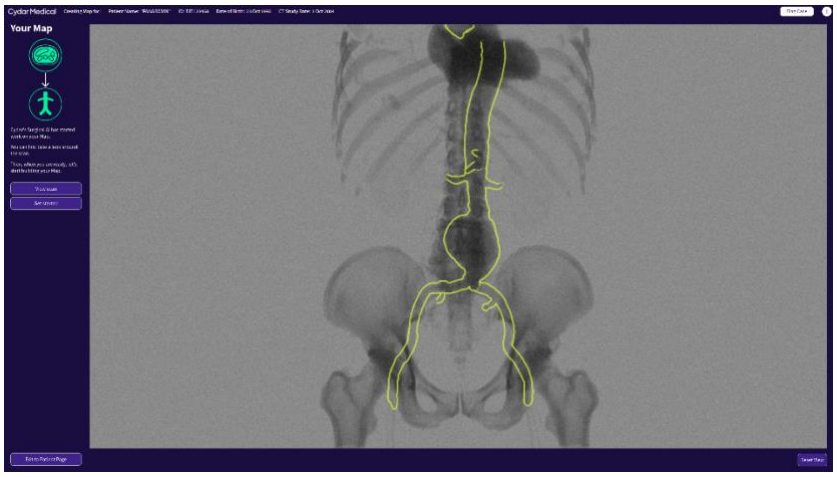
Why? Compression of CT scans to thicker slices than the original acquisition loses data and can significantly impair the intra-operative performance of Cydar EV Maps if slice thickness is greater than 1mm. Cydar EV Maps will automatically reject any scans with more than 3mm slice thickness.

2. Create a Map

Maps are dynamic, patient-specific, virtual 3D models of the plan before surgery, updated by the events during surgery. Each Map contains the following virtual elements:

- Blood vessels
- Guide wires
- Measurements (optional)
- Markers (optional)

Having selected the preferred CT scan from the patient page in The Cydar Vault, click '**Create Map**' or '**Redo Map**'. This opens an interactive planning session. Throughout a session, *Cydar EV Maps* continuously autosaves progress so that if for any reason a session is terminated prematurely, you can resume it later.

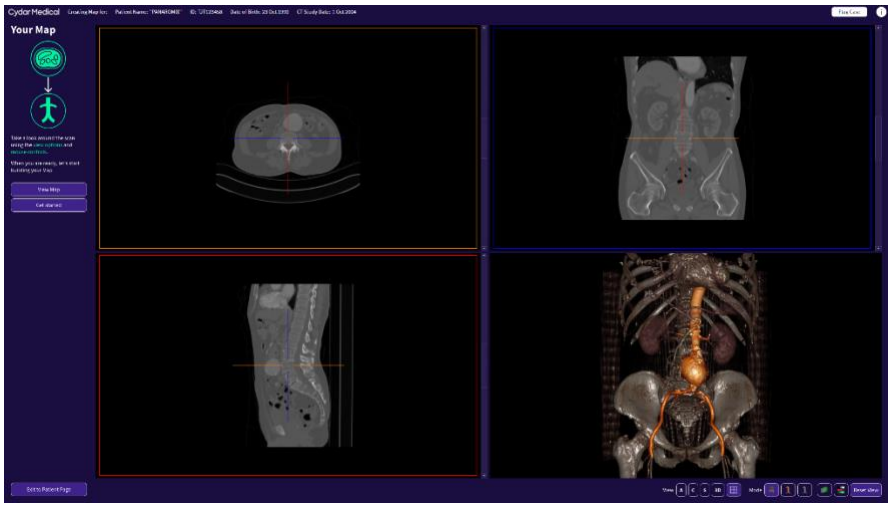


In the first 10-15 minutes after first upload of a CT scan, the Augmented Intelligence identifies the blood vessels that its neural net has learned most likely to be relevant to surgery.

On first starting a session, you will see this initial state of the Map. Your options are to take a look around the scan with '**View scan**' or to '**Get started**' building the Map by inserting virtual guide wires.

View scan

This display is a conventional four-panel view with three planes along orthogonal axes (Multi-Planar Reconstruction, MPR). The fourth panel is a 3D view with a choice of view modes in the bottom bar. The axes can be altered by dragging the cross hairs in the orthogonal view panels. Away from the crosshairs, clicking and dragging the mouse measures distance in millimetres (mm).

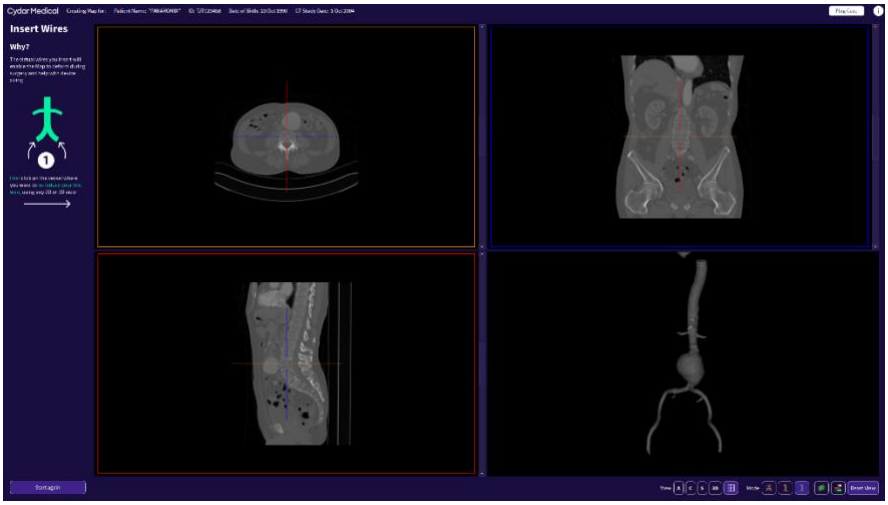


Measurements are not saved in 'View scan'

Insert wires

The virtual wires you insert define which blood vessels in the Map will be able to deform during surgery and will also help with device sizing. The wires are introduced in a similar way as during surgery.

Blood vessels in the Map must have wires inserted inside them to be deformable during surgery.

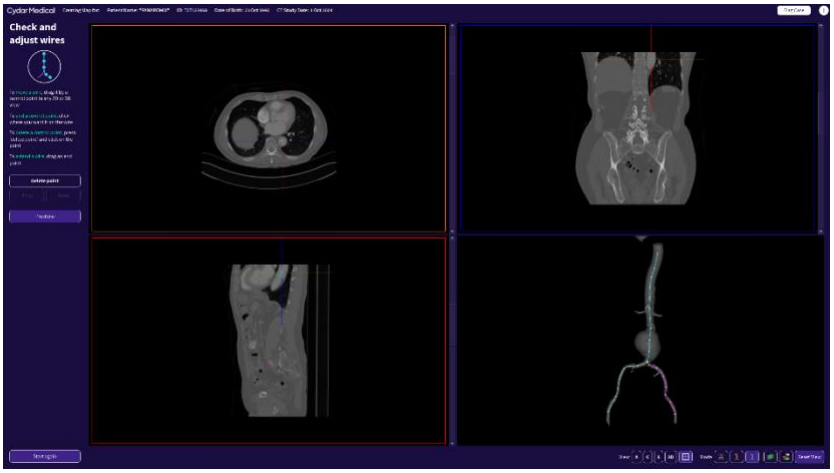


The steps to insert wires are as follows:

1. First click on the vessel where you want to introduce your first wire, for example a common femoral artery for EVAR, using any 2D or 3D view. Then click '**Confirm**' when it appears in the left-hand bar.
2. You will then be offered the option to click on another vessel if you want to introduce a second wire, for example a contralateral femoral artery for EVAR, and '**Confirm**', or to '**Skip**' if you are just using one wire and unilateral access.
3. Finally click high up on the vessel where you want the top end of the wires to go, for example in the proximal descending thoracic aorta for EVAR and click '**Confirm**'.

Check and adjust wires

The virtual guide wires have neon colours to help visualise them: the first wire is green, second pink, and any shared wire path, for example in the aorta, is coloured blue.



The position of the wires must be checked and may need to be adjusted manually.

Manually positioning the wires is essential in certain circumstances, for example if there was insufficient contrast visible inside the vessels for the automatic algorithms.

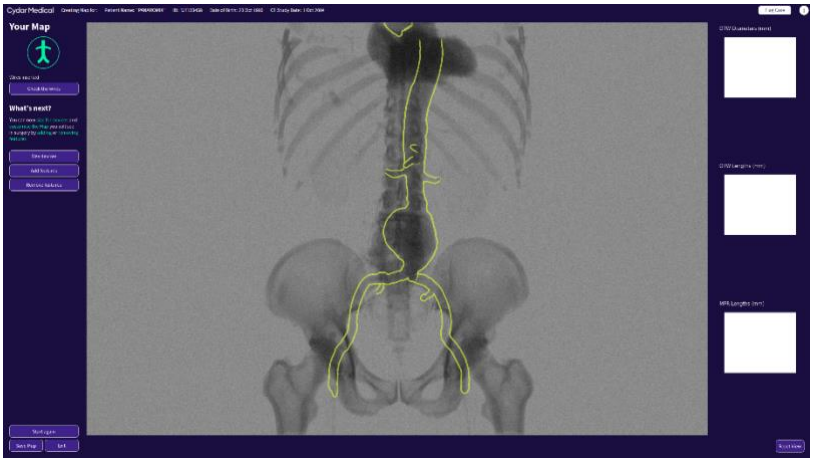
The controls are:

1. To move a wire, drag it by a control point on the wire in any 2D or 3D view.
2. To add a control point, click where you want it on the wire
3. To delete a control point, click on it then press '**Delete point**'

When satisfied with the position of the wires, click '**I'm done**' to proceed to the 'Your Map' page.

Your Map

Having inserted and checked the wires, you now have a basic Map that can be used in surgery. '**Save Map**' exits the planning session and makes the Map available in the operating room.

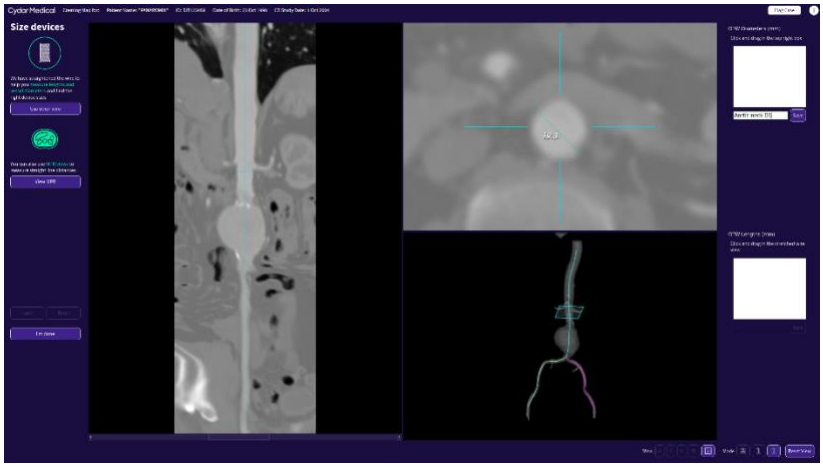


More commonly, you will want to measure the blood vessels for implanting devices (click '**Size devices**') and customise the Map you will see in surgery by adding or removing features (click '**Add features**' or '**Remove features**'). When measurements have been made, they are displayed in the table on the right-hand side. Diameter measurements are represented on the Map as rings and can be toggled on/ off by clicking on the associated measurement in the table.

The '**Your Map**' page automatically updates as you add measurements, extend or cut out blood vessels and place markers. It shows the Map you will see during surgery overlaid on a synthetic X-ray image. It can be viewed from different angles by dragging the image with the mouse.

Size devices

This page opens with a straightened wire view ('straightened CurviPlanar Reconstruction') to help you find the optimal implantable device sizes by measuring vessel diameters relative to, and lengths along, the wires. It opens with the view along the first wire that was inserted. Click '**Use other wire**' to measure along the other wire.



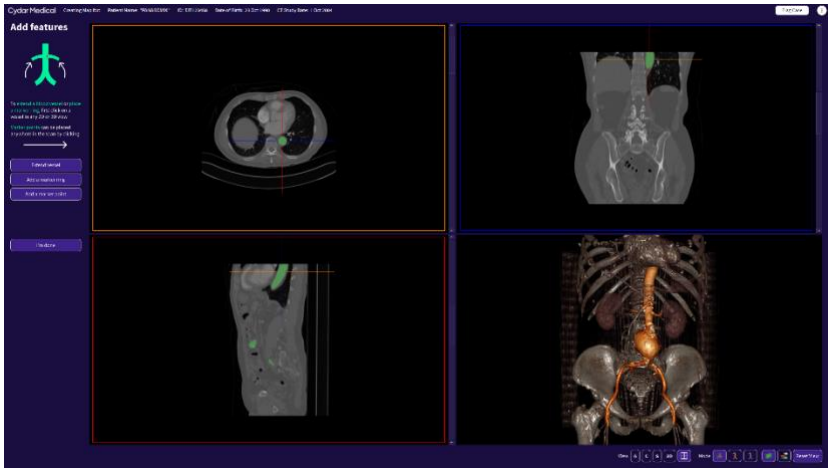
1. To measure vessel diameters along the wire, got to the top right pane, which is a slice orthogonal (perpendicular) to the wire, and click and drag. You can scroll up and down the wire in the top right panel or jump to a point by clicking on the wire in either the straightened wire view (left pane) or the 3D (lower right pane) view.
2. To measure vessel lengths along the wire, click and drag vertically in the straightened wire view (left pane). The scroll bar rotates the view around the wire to help you identify vessel branches.

When measurements are made, you will be prompted to label it and save. Measurements will appear in the Your Map page.

You can also use standard MPR (MultiPlanar Reformatted) views to measure straight line distances by clicking '**Switch to MPR view**'. To measure distances on the MPR view, click and drag the crosshairs to obtain the preferred view then click and drag away from the crosshairs to measure.

Add features

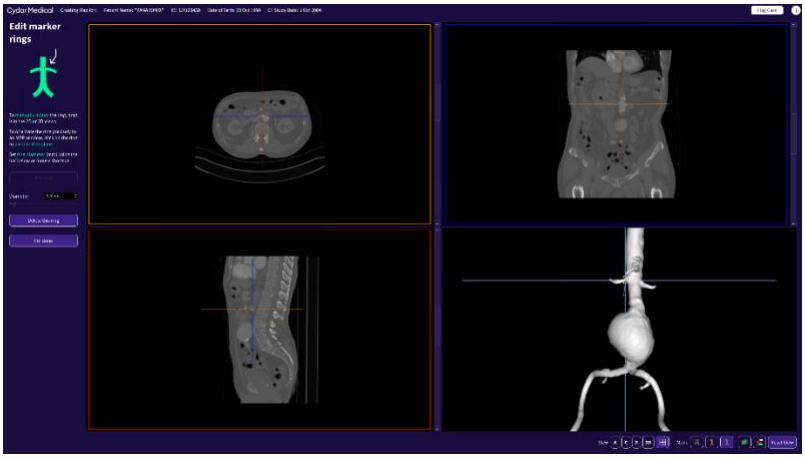
This page allows you to extend blood vessels on the Map, place marker rings on branch vessels in the Map, and manually place small marker spheres into the Map.



To extend a blood vessel or place a marker, first click on a vessel in any 2D or 3D view then click '**Extend vessel**', '**Add a marker ring**' or '**Add a marker point**'.

Edit marker rings

When a marker ring is placed, the Augmented Intelligence will position the ring automatically based on its learning from previous cases. You should check the position and be prepared to manually edit the ring using the following controls:

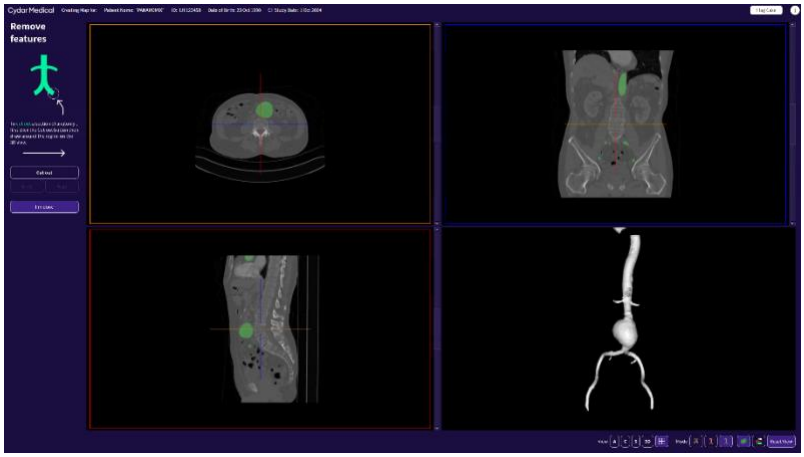


1. Drag it in either the 2D or 3D views.
2. To orientate the ring precisely to align with an MPR window, click on the ring to pin it to that plane. A ring 'pinned' to a plane is shown in blue.
3. To set the ring diameter, scroll on the horizontal bar.
4. To delete a ring, click on the '**Delete this ring**' button

Remove features

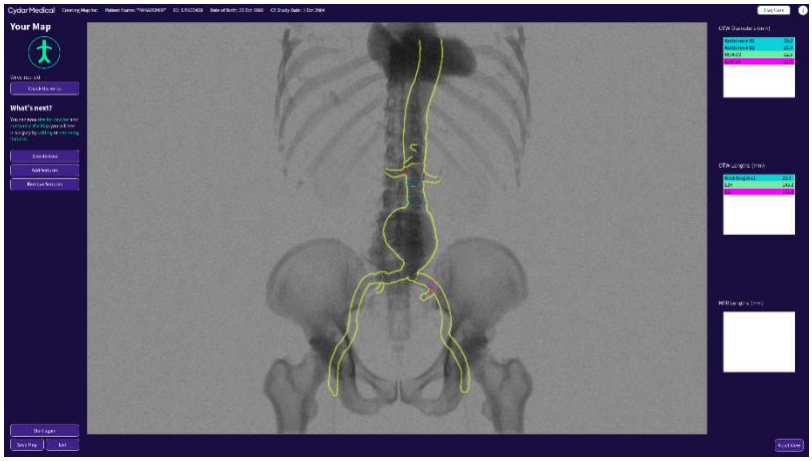
To cut out a section of anatomy, first click on '**Cut Out**' then draw around it on the 3D view.

To delete or edit a marker ring from this page, first click on the ring and this will take you to the Edit marker rings page.



Save and exit

When you are satisfied with the Map and toggled the measurements to have the preferred rings visible for intra-operative overlay, click '**Save Map**'. This will return you to your Cydar Vault account and make the Map available for operative use.



Intra-operative workflow

1. Check the Cydar Appliance

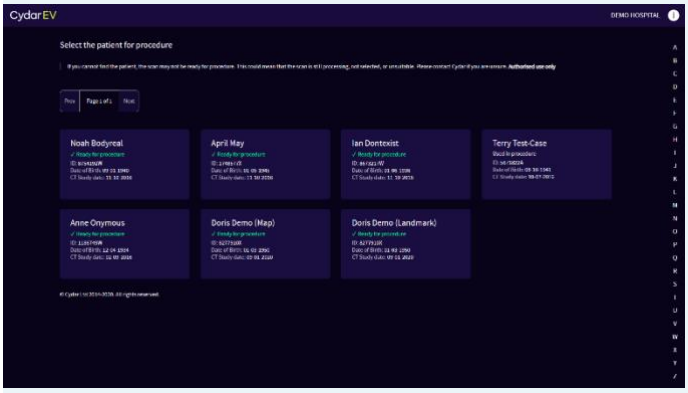
When ready to start a procedure, ensure that the Cydar Appliance is turned on and the display is visible. If using a mobile C-arm, check:

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

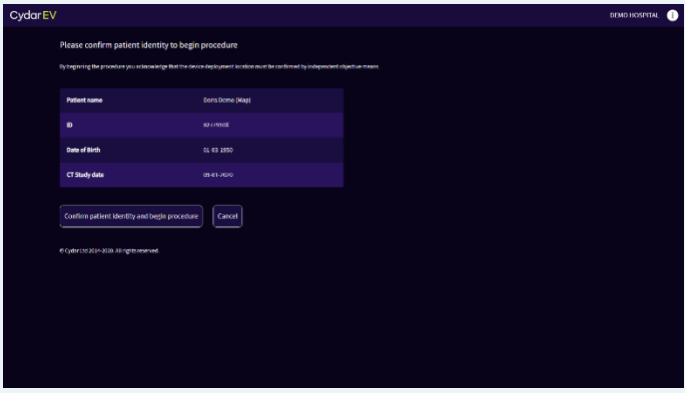
Tapping the touchscreen or clicking the remote control starts *Cydar EV Maps*.

2. Select the patient, check, and confirm

Using the touchscreen or remote control, select the correct patient Map from the Patient List and confirm that the patient identifiers from the CT scan in the Cydar Vault match the patient on the operating table.



Step 1. Select the correct patient in the Patient List and select the preferred CT scan



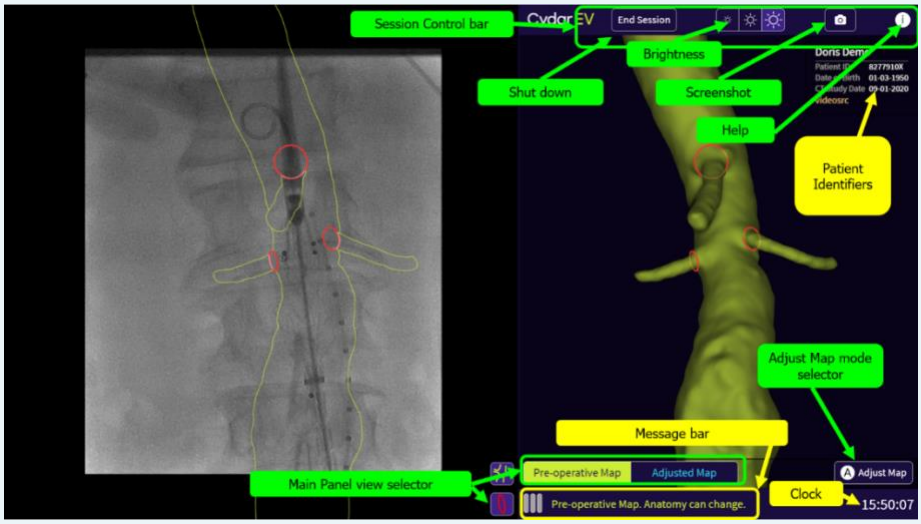
Step 2. Check again that the patient identifiers on the CT scan match those of the patient on the operating table and select '**Confirm patient identity and begin procedure**' or '**Cancel**'

3. Intraoperative User Interface

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

The Main panel. Always shows the live video from the X-ray set. If Image Tracking is confident of the patient position, it overlays either the Pre-operative Map in green as seen here or the Adjusted Map in blue

The Map Panel. Displays a 3D render of the Pre-operative Map shown from the same perspective as the Main Panel. If Image Tracking cannot verify a Map to show on the Main Panel, the Map Panel displays the Last Verified Map with its timestamp



User Information (yellow boxes):

- Patient Identifiers from the CT scan
- The Message bar shows Intraoperative Messages
- The Clock shows that Cydar EV Maps is functioning

User Controls (green labels):

- Session Control bar: buttons for **End session** (shut down); **Brightness** (dim, medium, bright); **Save Image** (screenshot); and **Help** (online support, contact and product details)
- Adjust Map selector (bottom): displays virtual wires and the control points used to Adjust the Map
- Main Panel View selector (bottom). Buttons for Map outline on/ off, Vessel Rings on/ off; Adjusted Map on/ off (toggles Pre-operative Map or Adjusted Map)

4. Image Tracking

Image Tracking is the computer vision that watches the live X-ray imaging to locate the patient's position in 3D space (translation in 3 axes, rotation in 3 axes and magnification). Image Tracking starts automatically when X-ray fluoroscopy images appear on the screen and continues until turned off by 'End Session'.

Whenever Image Tracking sees enough vertebral anatomy to be highly confident (>99.8%) of the patient position, it will automatically display the selected Map (i.e. Pre-operative or Adjusted) as an overlay superimposed on the X-ray imaging in the Main Panel. The same Map is shown rendered 3D in the Map Panel on the right. When the view changes, for example when the C-arm or patient moves, the current Map is automatically removed, while Image Tracking searches for a new solution. It takes approximately 5 seconds for Image Tracking to search, verify and confirm before displaying a new Map.

Image Tracking will not display Maps if the C-arm angle relative to the patient is greater than 70 degrees lateral (LAO or RAO).

If there is not enough vertebral anatomy on the screen for Image Tracking to be highly confident of the patient's position, it will not overlay a Map, and will instead display the message 'Image Tracking cannot verify Map on the live X-ray image' and show the Last Verified Map in the right-hand map panel. Image Tracking will continue to check the live fluoroscopy image and will display a new overlay as soon as it sees enough vertebral anatomy.

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 two or more vertebrae from T10 to L5 are visible. More vertebral anatomy visible on screen improves performance
- Avoid steep lateral X-ray views beyond 70 degrees obliquity

5. Pre-operative and Adjusted Maps

The Pre-operative Map (green)

Cydar Vault sends the Pre-operative Map to the Cydar Appliance. Pre-operative Maps are always shown in green.

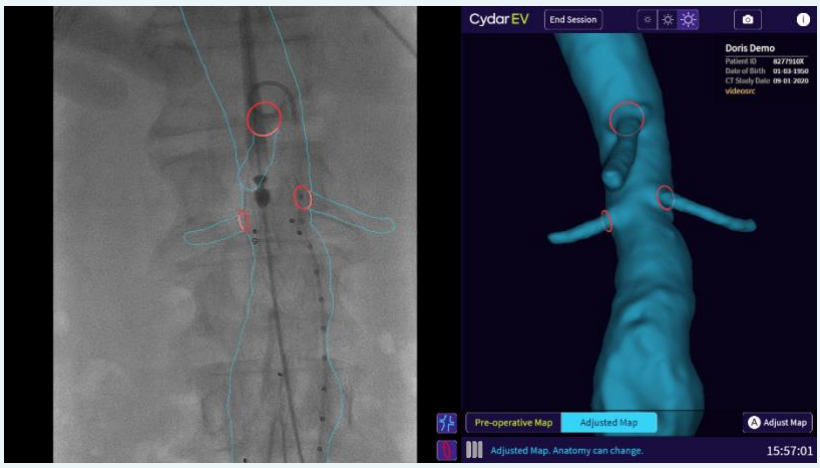
Because blood vessel anatomy may have changed since the pre-operative Map was created, and because stiff wires and delivery systems inside the blood vessels often straighten them and displace branches: **it is therefore mandatory for users to check the real-time anatomy with a suitable imaging technique, such as contrast angiography, before deploying any invasive medical device.**

The Adjusted Map (blue)

The Adjust Map button is found in the lower right of the Map panel. Clicking '**Adjust Map**' (remote shortcut A) reveals control points along the virtual wires inside the Map. Arrow and rotate buttons in the Map panel enable you to move these control points on the virtual wires to non-rigidly (plasticine-like) deform the Map.

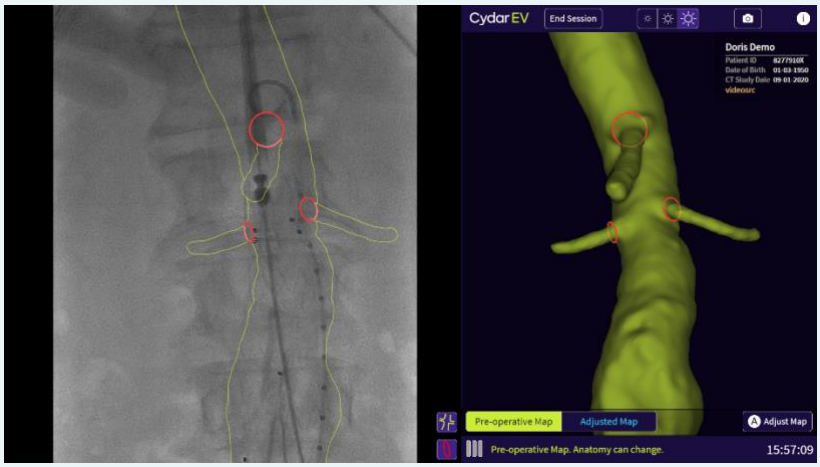
You should use the Adjust Map feature to update the Map for changes during surgery caused by stiff wires deforming the real blood vessels.

The resulting Adjusted Map is shown in blue. The Adjusted Map can be repeatedly adjusted, or reset to the Pre-operative Map, at any point during the procedure, for example if more 3D information becomes apparent from a different 2D fluoroscopy perspective.



Adjusted Maps are shown in blue and represent the clinical user's adjustments to the Pre-operative Map

The original Pre-operative Map remains available throughout the procedure. To switch Maps, toggle the view selector in the Main Panel between the Pre-operative Map (green), which always remains unchanged, and the Adjusted Map (blue) which represents your latest adjustments to the Map.

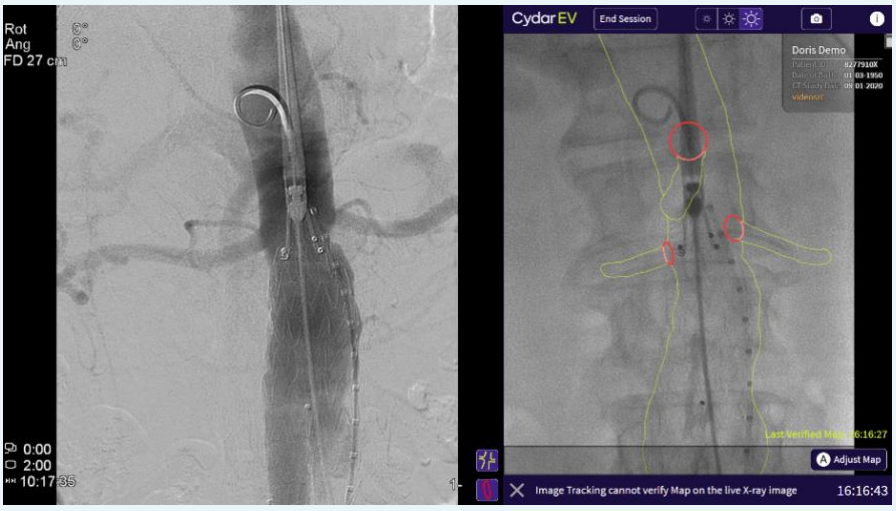


The Pre-operative Map remains available throughout by toggling the Map view selector from Adjusted Map to Pre-operative Map

How to check for vessel deformation using contrast angiography and Adjust the Map

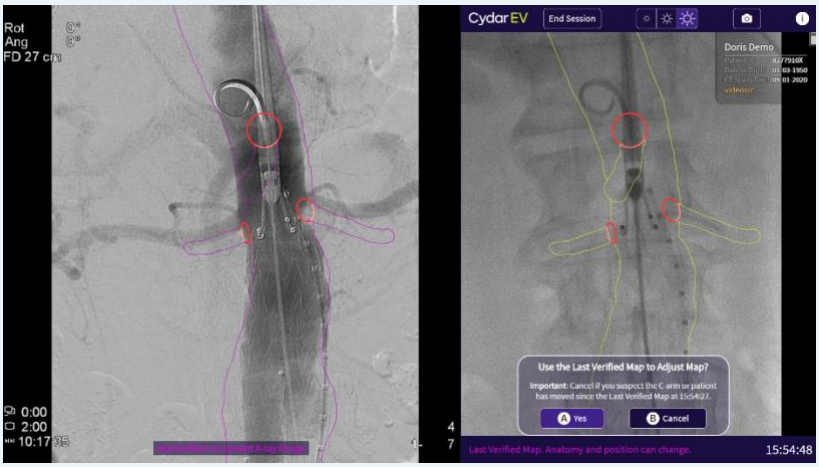
To assess vessel deformation and to Adjust the Map, you need to see both the contrast angiogram and the Map on the screen at the same time.

1. Ensure Image Tracking is displaying a Map on screen then perform a Digital Subtraction Angiogram (DSA). If the subtraction is effective, the vertebrae will be invisible and so Image Tracking will remove the Map on the Main Panel and instead display the Last Verified Map in the Map Panel on the right. Select **'Adjust Map'** on the bottom right of the Map Panel.



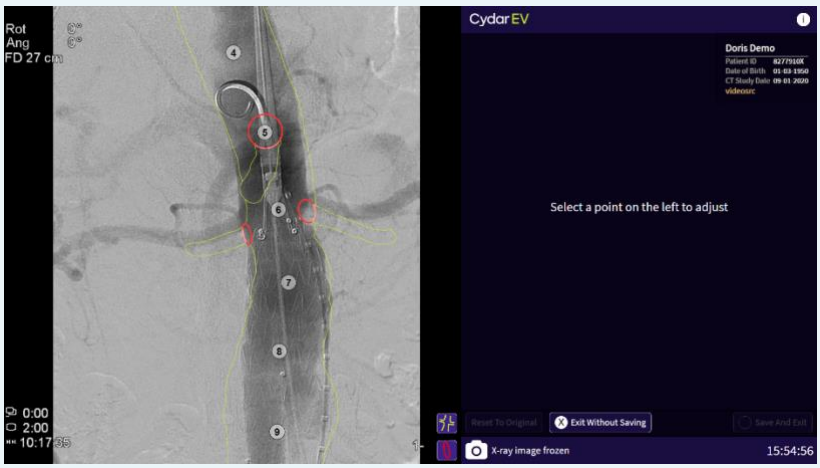
Checking real-time anatomy using DSA. No Map is displayed on the Main Panel because the vertebral anatomy is subtracted. The Last Verified Map is shown in the Map Panel with its timestamp in yellow. The Adjust Map button is bottom right

2. A warning panel asks you to confirm if you are satisfied that the Last Verified Map is valid for the Main Panel view. Click '**Yes'** (or remote shortcut A) if you are satisfied. Click '**Cancel'** (or remote shortcut B) if you suspect that the C-arm or patient may have moved since the Last Verified Map.

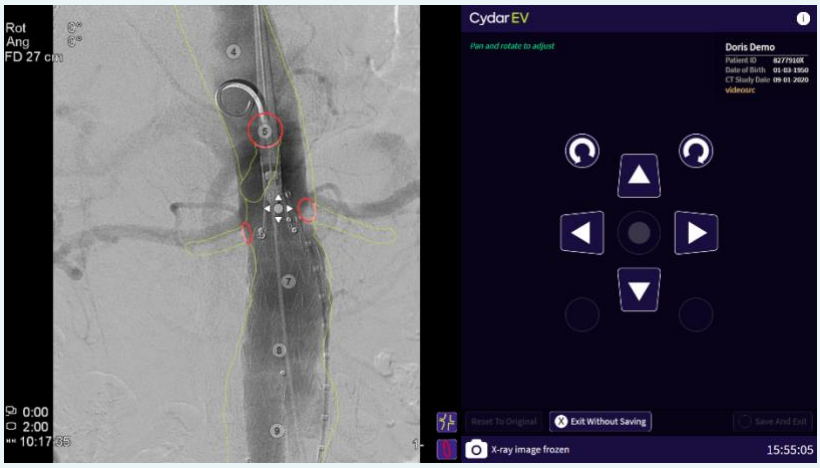


Use Last Verified Map only if confident that the patient or C-arm has not moved since the timestamped Last Verified Map in the right-hand map Panel. It is typical for stiff wires to displace the renal arteries in a cranial direction as seen here. Use the outline view as well as the rings to Adjust the Map, because renal arteries with anterior origins may be mistaken as being lower than they are if using only the DSA skyline view and rings.

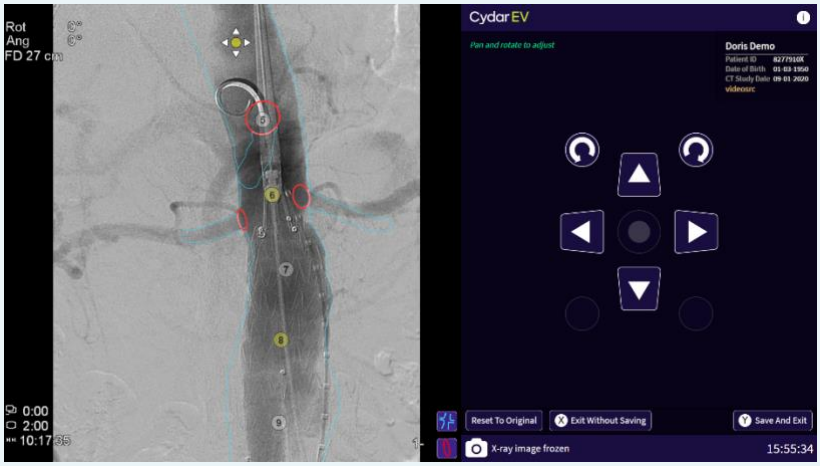
3. Select a control point on the virtual wires and use the arrow keys to translate and rotate that segment of the Map. When a segment has been adjusted, it is 'pinned' which means that adjustments in neighbouring segments along the virtual wire will not move it. **It is recommended to adjust key segments such as the renal and visceral branches first.**



Select an adjustment point on the Main Panel to start adjusting the Map. Use the outline view as well as the rings to Adjust the Map, because renal arteries with anterior origins may be mistaken as being lower than they actually are if using only the DSA skyline view and rings.



Using either the touchscreen or remote control, the arrow keys translate and rotate segments of the vessel along the Virtual Wire. Once a segment is adjusted, it is 'pinned' and will not move when other segments are adjusted. Adjust the clinically most important segments first as here with the aortic segment at the level of the renal branches



When Adjusted to your satisfaction, click Save and Exit (remote control shortcut Y) to return to the live view

6. End Session

When finished, please click '**End Session**' in the Session Control bar. If no user or new imaging activity is detected for a prolonged period, *Cydar EV Maps* will start an automatic standby sequence.

Recommended use of Cydar EV Maps to reduce radiation exposure and iodinated contrast use in 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 magnification.

Tip: Image Tracking conveys the current 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 Adjust the Map accordingly before deploying the main body. Then use the Adjusted 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 Adjust the Map to the DSA as anteriorly placed renal artery origins may be higher than appears on a skyline DSA view.

Tip: Think of Adjusting the Map like drawing on the screen; with the added advantage that it remains just as valid even if the patient or C-arm moves

4. For fenestrated and branched EVAR, use the Adjusted 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. Adjust Map to act as a marker for iliac limb deployment.

Tip: When adjusting iliacs in the Map, toggle off the Outline on the View Selector and Adjust using just the iliac Vessel Ring

Appendix A: System Requirements

To access the Cydar Vault, you need:
A modern web browser, such as:

- Internet Explorer 11 or later
- Microsoft Edge (any version)
- Firefox 60 or later
- Chrome 48 or later

A network connection that supports:

- 10Mbps bandwidth or greater both directions
- Outbound connections using HTTPS to the Cydar Vault at the URL provided

Glossary

Cydar Appliance	The Cydar computer and interface in the operating room with video-in connection (DVI) to the X-ray set video feed; Ethernet to Cydar Cloud via the Hospital network; the display monitor (DP/ HDMI)
Cydar Vault	The Hospital-specific cloud repository containing patient data such as uploaded CT scans and Maps,
Compute Cloud	The high-performance computing resource that powers Cydar EV Maps
Cydar Gateway	A PACS node hosted inside the Hospital Network which enables authorized Clinical Users on the Cydar Vault to retrieve CT scans
X-ray set	The X-ray fluoroscopy set (either fixed or mobile)
X-ray image	The X-ray fluoroscopy image
Image Tracking	The computer vision that watches the X-ray imaging during surgery and locates the patient's position in 3D space.
Map	Dynamic, patient-specific, virtual 3D model of the plan before surgery (Pre-operative Map), updated by the events during surgery (Adjusted Map). Each Map contains the following virtual elements: • Blood vessels • Guide wires • Measurements (optional) • Markers (optional)
Pre-operative Map	Patient-specific, virtual 3D model of the plan before surgery Always shown in green when superimposed on X-ray images or rendered as a 3D volume
Adjusted Map	A non-rigidly (plasticine-like) deformed Map representing the physician's adjustments to the Pre-operative Map based on their interpretation of vessel deformation. Always shown in blue when superimposed on X-ray images or rendered as a 3D volume
Wires	Imaginary lines placed inside selected vessels by Cydar EV Maps to represent a possible guidewire position. Used for diameter and length measurements and to Adjust Map
Marker Rings	Rings placed in vessels in the Map. Often used as reference points to mark vessel ostia

Regulatory Information

CE
2797

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

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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.