

PHILIPS

SyncVision

Precision guidance
system

SyncVision quick guide

Version 4.2



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Main menu

New procedure

Start a new procedure and enter procedural details (use SyncVision on each case, not just interventions).

Continue last procedure

Continue with the last performed procedure's saved information.

Procedure management

View or export past procedures. The system allows for backup, retrieval of old procedures, export of screenshots and AVI files.

Application settings

Change system configurations.

Exit

Shut down/log off the system.



Procedure details form

Procedure identification

Free text field that is auto-populated with a date/time stamp which can be changed.

Performing physician

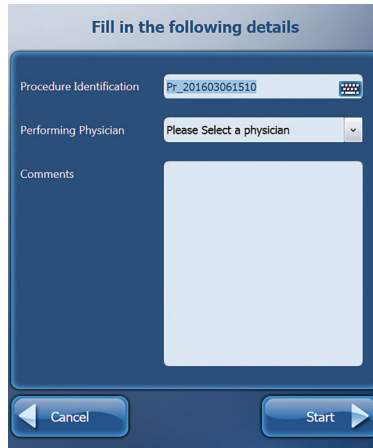
A drop-down menu containing a physicians list. Add a new physician to the list by selecting the “Add a New Physician...” option from the bottom of the list.

Comments

Free text field to add information about the case. When finished, press “Start” to begin a new procedure.

Start

Begins a new procedure.



The screenshot shows a dialog box titled "Fill in the following details". It contains three main sections: "Procedure Identification" with a text field containing "Pr_201603061510" and a keyboard icon; "Performing Physician" with a dropdown menu showing "Please Select a physician"; and "Comments" with a large empty text area. At the bottom, there are two buttons: "Cancel" with a left-pointing arrow and "Start" with a right-pointing arrow.

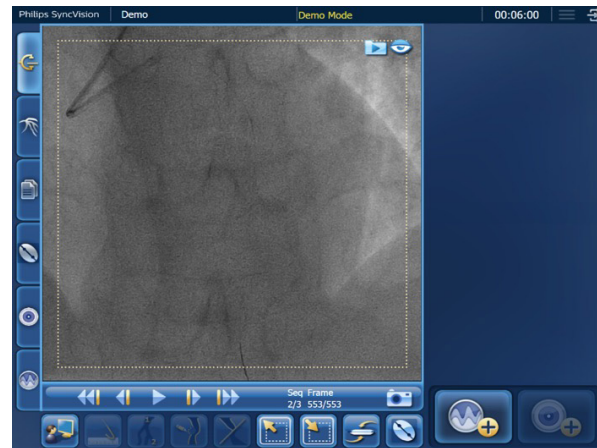
iFR Co-registration

Preparation ground rules

Keep collimator open, FOV 20cm/8" and eliminate any radiopaque artifact (metallic objects) from view, set fluoro at 15 frames per second (fps), do not use steep angles. Ensure guide catheter tip and distal guidewire tip are visible within the frame.

Philips pressure guidewire prep

1. Prepare the pressure wire according to instruction for use.
 - The software automatically detects when Philips s5/Core/IntraSight system is in iFR/FFR mode by detecting one of the following triggers:
 - Valid Pd value ($Pd \geq 10$)
 - Zeroing request
- Screen will automatically switch, to "Physiology Co-reg Mode Display".
2. Normalize the pressure wire and advance the pressure sensor three vessel diameters after the lesion.
3. Flush contrast out of the guiding catheter and wait for the waveforms to stabilize.
4. Press "iFR Spot" (or "Record" for Core system) to determine the iFR value.
5. Press the "Live" button to prepare for pull-back. Ensure the guide catheter and guide wire tip are visible and fully within the image.



iFR Co-registration

iFR pullback and recording process start

1. iFR pullback must be done without movement of x-ray equipment, c-arm, field of view or table.
2. Once blue line appears, begin steady pullback at approximately 2 mm/sec
3. There is a minimum of 7 seconds of fluoro to qualify as a valid pullback. If the pullback is completed in less than 7 seconds of fluoro, the system will not advance to the angiogram acquisition stage. You will have to re-advance and follow the pullback steps again.

4. Initiate fluoro and perform iFR pullback under continuous fluoro at 15fps, press “iFR Pullback” (or “Pullback” for Core system).
5. Once the software detects the commencement of a recorded iFR/FFR pullback in conjunction with live X-ray images, the software will indicate that the pullback is being recorded.

iFR pullback and recording process stop

1. Once at the guiding catheter press “Stop”.
2. Step off fluoro.
3. Check for drift.
4. Perform a cine angiography without movement of the x-ray or c-arm.



iFR Co-registration

Angiogram selection

1. Either perform an cine angiogram immediately following the pullback, or use a previous angiogram by selecting the “Use Last Angio” button **1**.
2. The new cine angiogram or previous angiogram must be done at the same field of view, C-arm and table position as the iFR pullback.
3. After the new angiogram is performed or a previous angiogram is selected, the system automatically generates the co-registration results.

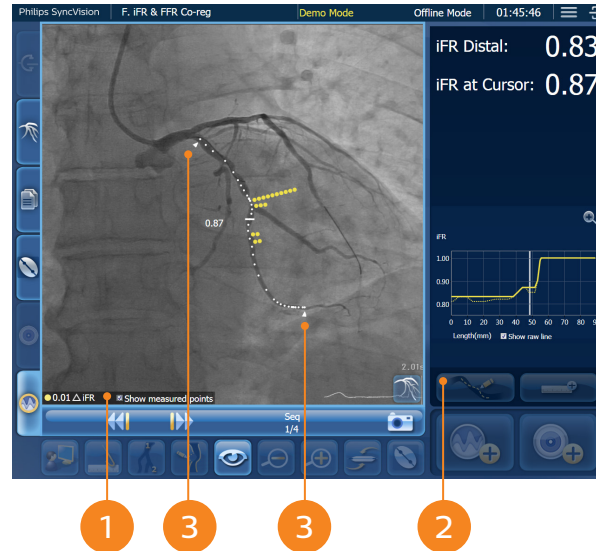


iFR Co-registration

Co-registration roadmap review

Assess the results by:

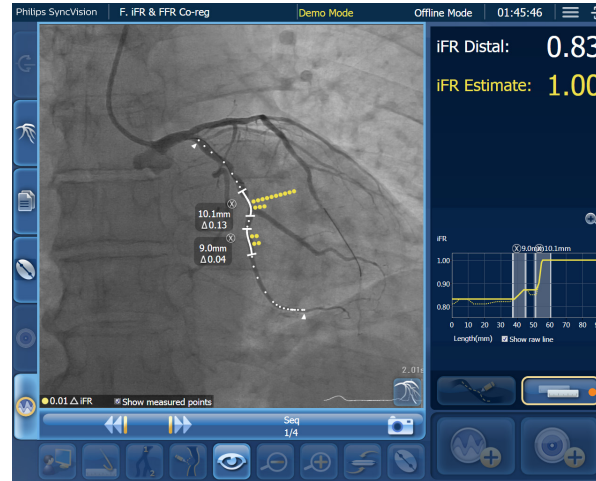
1. Reviewing the display of the measured physiology values location obtained during pullback by checking the “show measured points” box **1**.
2. Ensuring proper pathway.
 - If automatic pathway is inaccurate, first press the “Edit Pathway” button to re-draw **2**.
 - If necessary, select a new angiogram and draw the pathway by pressing the “Automatic Selection” button.
3. Ensuring that the co-registered region covers the analyzed vessel length by identifying the distal (start point) and proximal (end point) boundaries of the pullback **3**.



iFR Co-registration

Length measurements

1. Click and drag along angio to create first length measurement and review iFR estimate.
2. Press the “Multiple Length Measurements” **1** button and then click and drag to create multiple measurements and review iFR estimate.

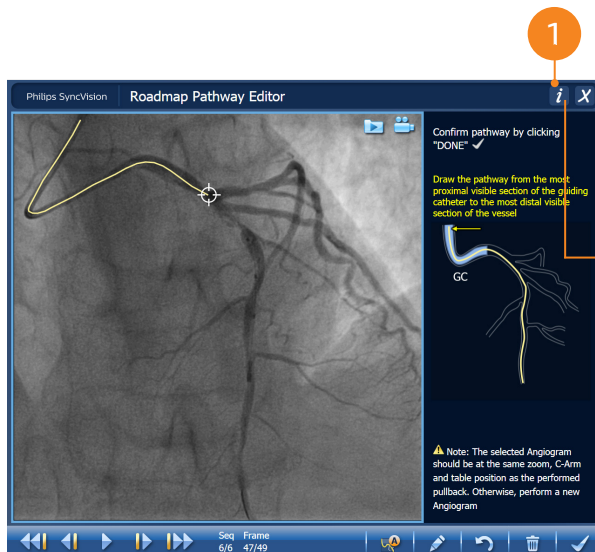


Editor

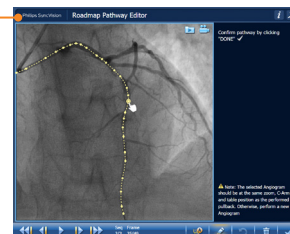
For iFR and IVUS Co-registration

The roadmap pathway editor works the same for iFR Co-registration and IVUS Co-registration.

- To change the roadmap image, browse between angiograms and frames, acquire a new angiogram and select the roadmap image frame.
- To edit the pathway, delete the pathway and manually draw the pathway by clicking along the vessel or edit the pathway and adjust the line to the correct location on the vessel.
- Ensure that the pathway accurately follows the contour of the vessel of interest.



The information button **1** opens an information window with explanations on the editor controls and workflow. In addition, it provides illustrated examples of typical pathways drawings.



IVUS Co-registration

Preparation ground rules

Keep collimator open, FOV 20cm/8” and eliminate any radiopaque artifact (metallic objects) from view, set fluoro at 15 frames per second (fps), do not use steep angles. Ensure guide catheter tip and distal guidewire tip are visible within the frame.

Eagle Eye Platinum catheter preparation

1. Connect only the Eagle Eye Platinum catheter according to instruction for use.
2. The software automatically detects when Philips s5/Core/IntraSight system is in IVUS mode by detecting a live IVUS image generated by the Eagle Eye Platinum catheter.
3. Once the software detects that the Philips system is in live IVUS mode, it will automatically switch to the IVUS Co-registration mode display. If the screen does not automatically switch, activate IVUS mode using the “Activate IVUS Mode” button **1**.
4. Ensure the guiding catheter and guide wire tip are visible and fully within the image with no radiopaque artifact (metallic objects) presence..
5. Do not change the zoom, collimator, table or the C-arm setting during the pullback.
6. Pullback should be performed while under continuous fluoro at a frame rate of 15 fps.



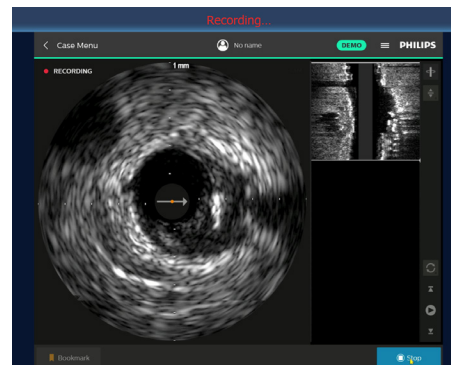
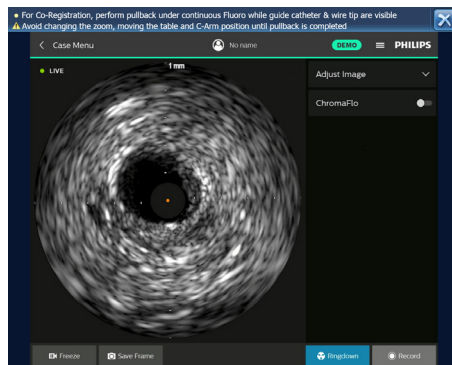
IVUS Co-registration

IVUS pullback and recording process start

1. Perform IVUS pullback under continuous fluoro at 15 fps.
2. To start your pullback recording, press “Record” (or “Record Loop” for Core system).
3. Begin steady pullback at approximately 1 mm/sec. for a minimum of 7 seconds.
4. Once the software detects the commencement of a recorded IVUS pullback in conjunction with live X-ray images, the software will indicate to the user that a IVUS pullback is being recorded.

IVUS pullback process and recording process stop

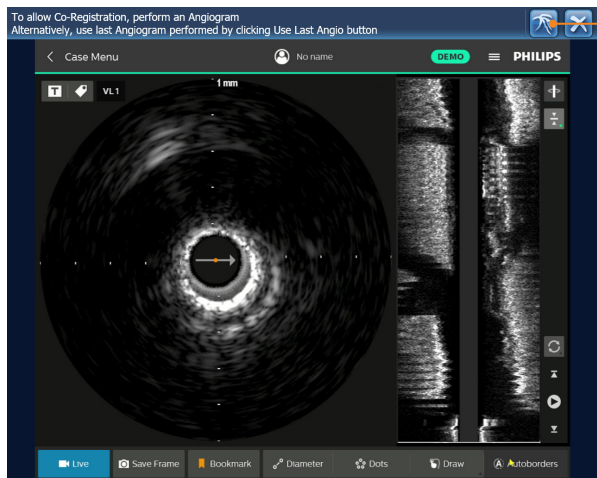
1. Once at the guiding catheter press “Stop”.
2. Step off fluoro.



IVUS Co-registration

Angiogram selection

1. Either perform an cine angiogram immediately following the pullback, or use a previous angiogram by selecting the “Use Last Angio” button **1**.
2. The new cine angiogram or previous angiogram must be done at the same field of view, C-arm and table position as the iFR pullback.
3. After the new angiogram is performed or a previous angiogram is selected, the system automatically generates the co-registration results.



IVUS Co-registration

Co-registration roadmap review

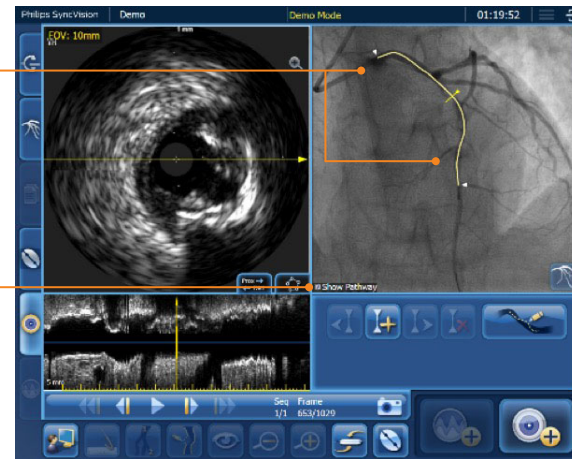
Assess the results by:

- Ensuring that the co-registered region covers the analyzed vessel length by identifying the distal (start point) and proximal (end point) boundaries of the pullback.
- Reviewing the pathway line display to visualize the pathway (yellow line) on the roadmap image in the “IVUS Co-registration” result tab.
- Reviewing the fully automated workflow once the results are displayed for the first time. The visual pathway is also displayed on the roadmap image and disappears after the first click on the screen.

Co-registration region indication

The user can turn on/off the pathway display by clicking the “Show Pathway” checkbox.

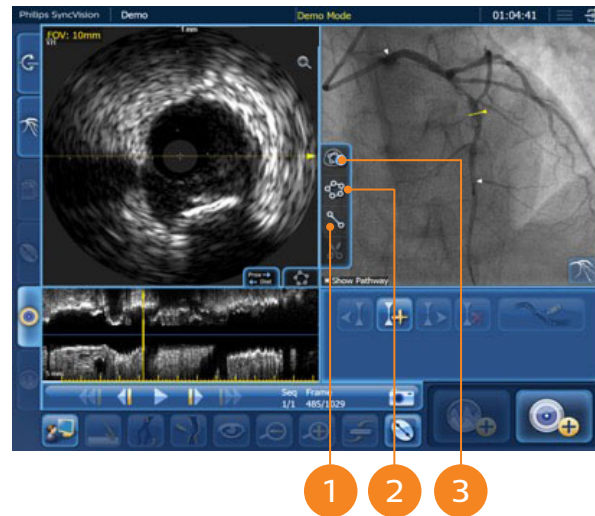
Show Pathway



IVUS Co-registration

Length and IVUS measurements

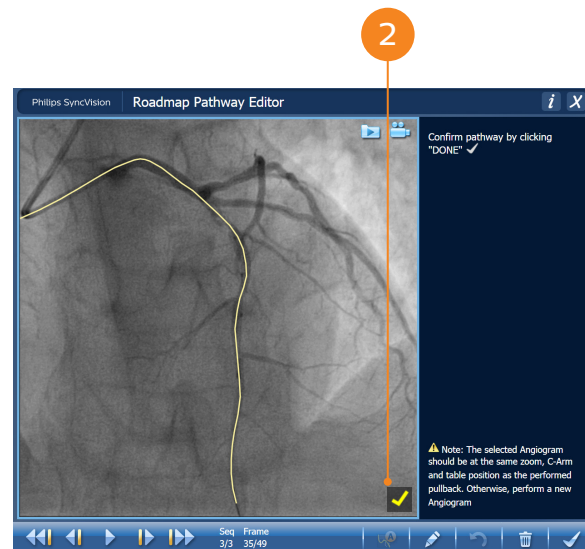
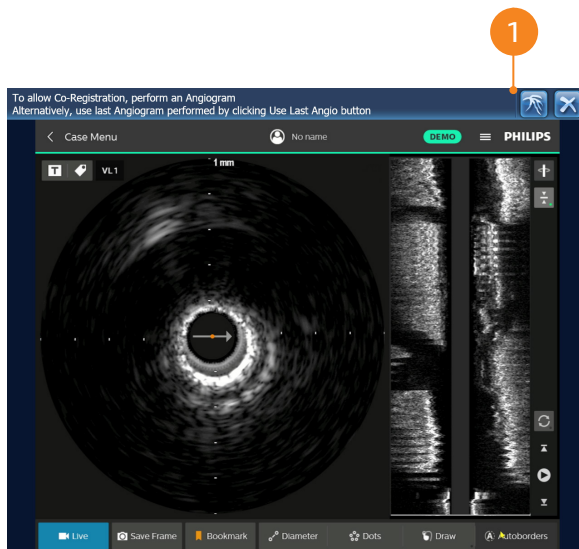
1. Angiogram, cross-sectional and longitudinal views are now co-registered.
2. Perform up to two diameter measurements for each IVUS frame.
3. To measure the vessel diameter click on the **1** button. Click on the desired start point, and click on the end point to set the measurement line. Alternatively, click on the start point and drag to the end point.
 - Each diameter measurement is color-coded (orange/yellow) and respectively displayed in the information box.
4. The area measurements are color-coded and can be performed either automatically or manually.
 - For automatic area measurement press on the “Automatic Area Measurement” **3** button.
 - For manual measurement press on the “Add Area Measurement” **2** button.
5. For length measurements either on the co-registration roadmap or the co-registered longitudinal display, click and hold at the desired start location and begin dragging the mouse/joystick. To save the length measurement, click on the “Add Bookmark” button.



Tri-registration

Roadmap set-up and workflow

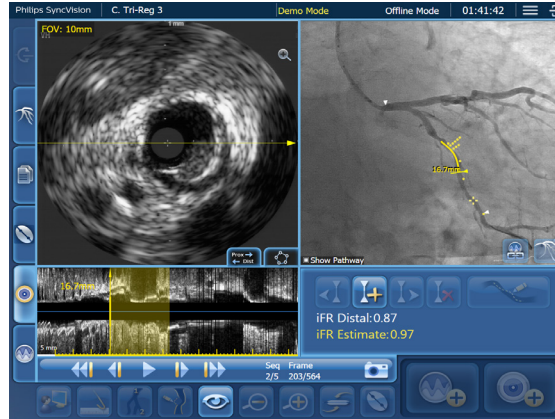
1. Perform either an iFR or IVUS Co-registration to begin tri-registration process . Do not change c-arm/table/zoom post 1st co-Reg completion.
2. Perform complimentary, 2nd co-registration. Select “Use Last Angiogram” ① button. A pathway screen is displayed. Use frame/sequence arrows and search for the frame with the yellow ② check at the bottom right of image. Confirm pathway, then select next.
3. If the frame with the yellow check mark was properly selected, then the tri-registration process is complete. If not, then go to the roadmap Pathway Editor screen, navigate to correct frame with yellow check mark and select “Automatic Selection” button and approve.



Tri-registration

Tri-registration results

1. On the results screen, do IVUS measurements and length measurements to review iFR estimate and plan treatment strategy.
2. After completion of the tri-registration, the user can toggle between a physiology Co-registration sequence and an IVUS Co-registration sequence while indicating the closest corresponding point along the Roadmap that has an associated IVUS image/physiological value by pressing the appropriate corresponding sequence button.



Go to corresponding angiogram



Go to corresponding physiology Co-registration



Go to corresponding IVUS Co-registration

Angio+ features

Review stored angiograms and perform measurements

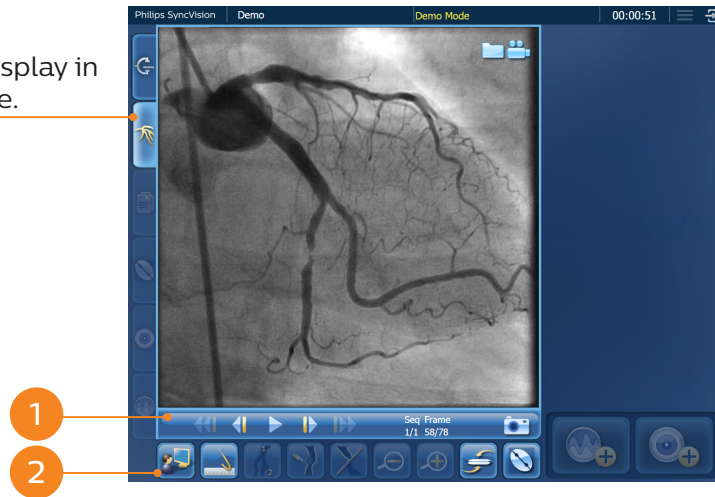
Using the navigation bar **1**, browse through the angiograms stored in the angiograms tab by reviewing sequences and frames.

Activate control room mode

Clicking “control room mode” **2** prevents from changing the display to Live mode to do post analysis measurements.



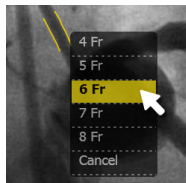
Live images display in fluoro and cine.



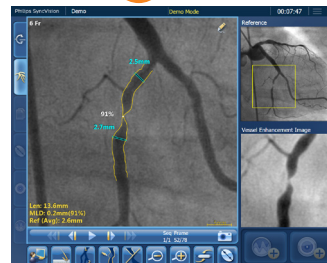
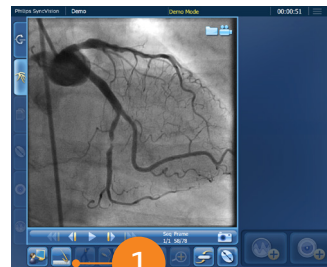
Angio+ features

Calibrated quantitative coronary analysis (QCA)

1. Select the “GC calibration” **1** button.
2. Calibrate the sequence by clicking on guide catheter (GC) and selecting appropriate size.
 - Select a frame where the GC tip is visible.
 - Left click on a straight section of GC close to the distal tip for accurate calibration.



3. Perform QCA by left clicking on lesions provides:
 - % stenosis
 - the diameter of the proximal and distal references, and the average diameter
 - the length between the two references
4. To highlight potential stent location, click and drag along the analyzed vessel.
5. To extend the yellow lines click along the vessel.



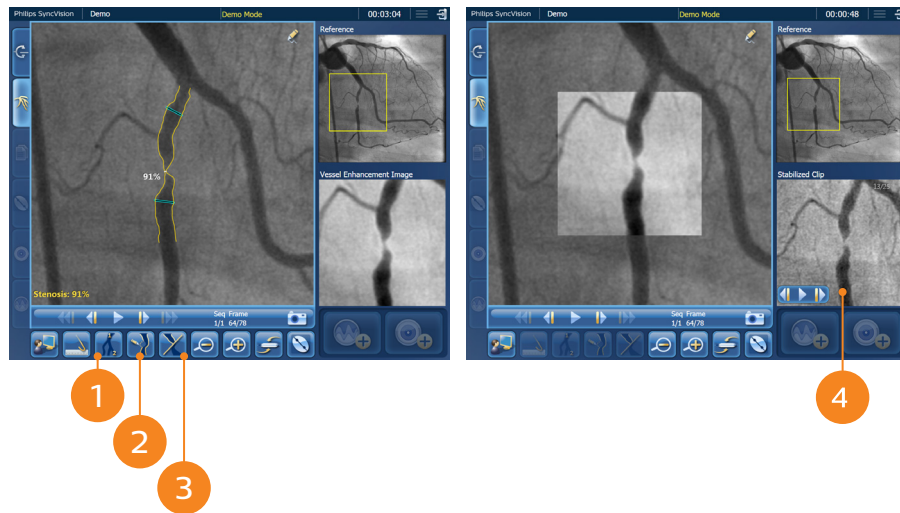
Angio+ features

Advanced QCA

1. Press “Two-Click QCA” button **1** to change which vessel is analyzed in bifurcation.
2. You can manually correct the edges of the lesion by pressing the “Manually Correct Edges” button **2** to re-draw vessel edges by starting and finishing on the original yellow line to adjust the vessel edges.
3. Press and hold “Hide Vessel Analysis” **3** to remove borders temporarily.

Vessel Enhancement

1. Right click on the angiogram image to enhance the area of interest.
2. Select additional targets to continue vessel enhancement
3. Observe dynamic flow in stabilized clip in Mini View **4**.
 - Enlarge stabilized clip by clicking it.



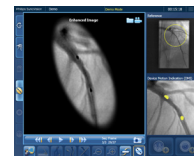
Note that for the QCA and Vessel Enhancement to be saved, the user must press the snapshot button.

Angio+ features

Activate Device Detection

1. Clicking on the “Device Detection” button **1** tells SyncVision to locate two radiopaque markers in the region of interest (view on screen).
 - Device Detection occurs live in both fluoro and cine.
2. Each time the user goes off of live X-ray, SyncVision will generate one of the three analyses aside.

In case of poor image quality or the presence of radiopaque objects in the image (e.g., CABG wires), adjust the ROI to exclude the opaque elements if possible.



Device positioning



Device inflation



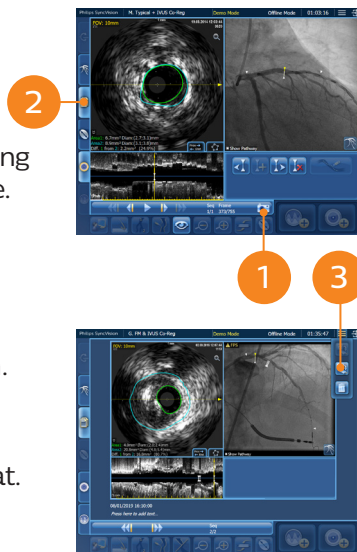
Device enhancement

1

Organizing and exporting data

Save snapshots and report tabs

1. Use the “Snapshot” button **1** to capture screenshots during the procedure and during the review of the procedure in offline mode.
2. Only saved snapshots will be displayed in the “Reports” tab **2**.
3. To export snapshots to a USB drive, enter the procedure in offline mode and use the “Export All Reports” option.
 - Export all reports button **3** appears in the “More” panel in offline mode.
 - The reports are exported in jpg format.
 - The “Export All” reports is available only from the “Reports” tab.



4. Exporting AVI:
 - Clicking on the top button on the screen will allow you to export AVI only in offline mode.
 - Clicking in the middle button on the screen will allow you to export reports from the “Reports” tab into a flash drive. You can delete sequences with the “Delete Sequence” button.
 - The system would create on the flash drive a SyncVision folder containing different sub-folders for each feature: “Angiogram,” “Deployments,” “FM Co-Reg,” “IVUS Co-Reg,” and “Reports”.
5. All exported reports are saved in the USB drive to the following destination: <Drive:>\SyncVision\ Procedure ID\Sequence Type

Organizing and exporting data

Backup and retrieve

1. Backup procedures from the local storage to a predefined backup storage **1**.
2. Retrieve procedure from the backup storage back to the local storage for review and analysis **2**.

Search by Procedure ID

<input type="checkbox"/>	★	Procedure Identification	Start Time	Last Modified	Physician	Backed Up
<input checked="" type="checkbox"/>	☆	Case 13	11/03/2019 13:26:26	11/03/2019 13:26:26	Unknown	
<input type="checkbox"/>	☆	Case 12	11/03/2019 13:26:15	11/03/2019 13:26:15	Unknown	
<input checked="" type="checkbox"/>	☆	Case 11	11/03/2019 13:25:58	11/03/2019 13:25:58	Unknown	
<input type="checkbox"/>	☆	Case 10	11/03/2019 13:25:47	11/03/2019 13:25:47	Unknown	
<input checked="" type="checkbox"/>	☆	Case 9	11/03/2019 13:25:26	11/03/2019 13:25:30	Unknown	
<input type="checkbox"/>	☆	Case 8	11/03/2019 13:25:13	11/03/2019 13:25:13	Unknown	
<input type="checkbox"/>	☆	Case 7	11/03/2019 13:25:02	11/03/2019 13:25:02	Unknown	
<input type="checkbox"/>	☆	Case 6	06/03/2019 10:17:58	06/03/2019 10:17:58	Unknown	
<input type="checkbox"/>	☆	Case 5	06/03/2019 10:17:51	06/03/2019 10:17:51	Unknown	
<input type="checkbox"/>	☆	Case 4	06/03/2019 10:17:44	06/03/2019 10:17:44	Unknown	
<input type="checkbox"/>	☆	Case 3	06/03/2019 10:17:37	06/03/2019 10:17:37	Unknown	
<input type="checkbox"/>	☆	Case 2	06/03/2019 10:17:30	06/03/2019 10:17:30	Unknown	
<input type="checkbox"/>	☆	Case 1	06/03/2019 10:17:19	06/03/2019 10:17:19	Unknown	

3 items are selected

Local Storage • Backup Storage

Backup Procedures

1

Search by Procedure ID

<input type="checkbox"/>	★	Procedure Identification	Start Time	Last Modified	Physician	Stored Locally
<input checked="" type="checkbox"/>	☆	Case 13	11/03/2019 13:26:26	11/03/2019 13:27:37	Unknown	
<input type="checkbox"/>	☆	Case 11	11/03/2019 13:25:58	11/03/2019 13:27:37	Unknown	✓
<input type="checkbox"/>	☆	Case 9	11/03/2019 13:25:26	11/03/2019 13:27:37	Unknown	✓

1 items are selected

Local Storage • Backup Storage

Retrieve Procedure

2

