

PHILIPS

IntraSight

Interventional
applications platform

Mobile

Mobile series 5 in-service guide



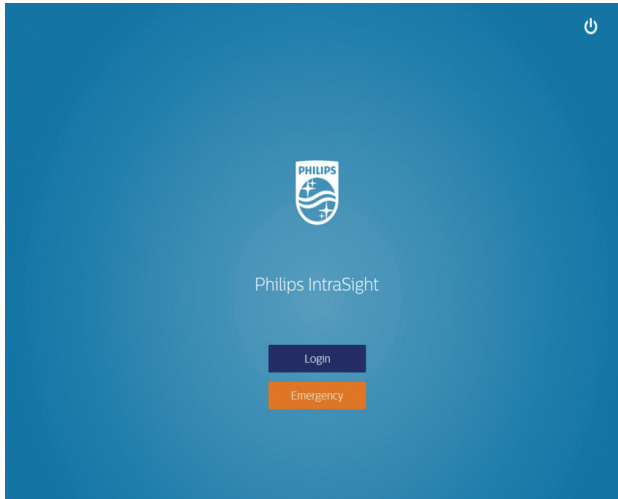
Part 1: How to power up and prepare mobile system for use

1. Power system on by pressing the power button located at the lower right corner of the monitor.

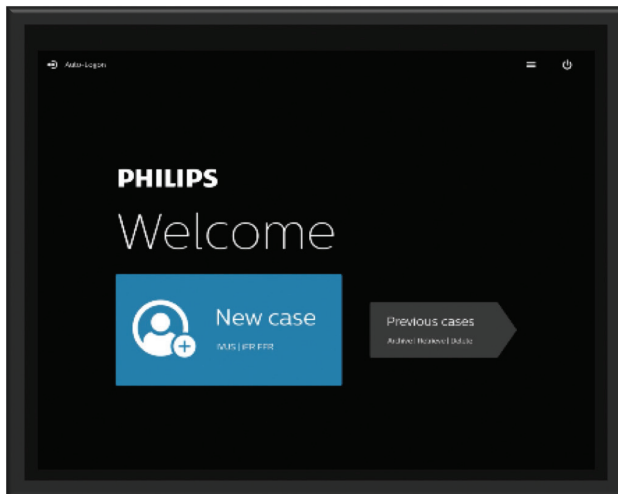


2. Once the system has powered on, there are three options for users to access the system:

- a. The Service option should only be accessed by Field Service Engineers or Philips Sales Team through FSE guidance.
- b. The Emergency option allows immediate access to start a new case, however, there is no access to previous cases.
- c. Account Login, which – upon installation an FSE will set-up an Admin account so the hospital can create a user account, allowing automatic login.



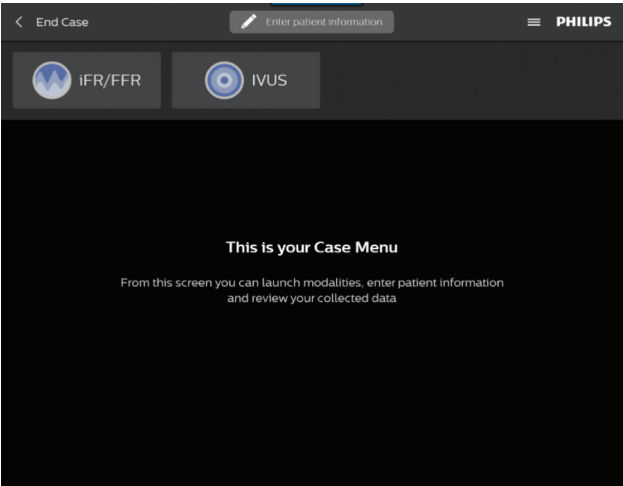
3. IntraSight home screen. Users have two options:
- a. Start a new case, or
 - b. Access a previous case



4. Shared case menu

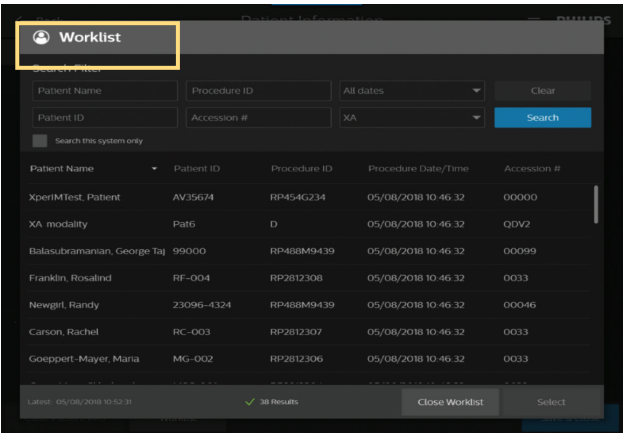
The Case Menu is the “home screen” that enables users to enter patient information, access IVUS or iFR/FFR from a single, central location.

Select the Enter patient information box.



5. Patient information - worklist

Worklist must be enabled through DICOM settings and will appear in the patient information menu.



6. Patient information - manual

Patient Information

Patient Name	-	Patient Name
Patient ID *	-	Last name
Sex	-	
Date of Birth	-	First name
Accession #	-	
Procedure ID	-	Middle name
Procedure	-	
Physician	-	

Clear Patient Info **Worklist** **Save & Close**

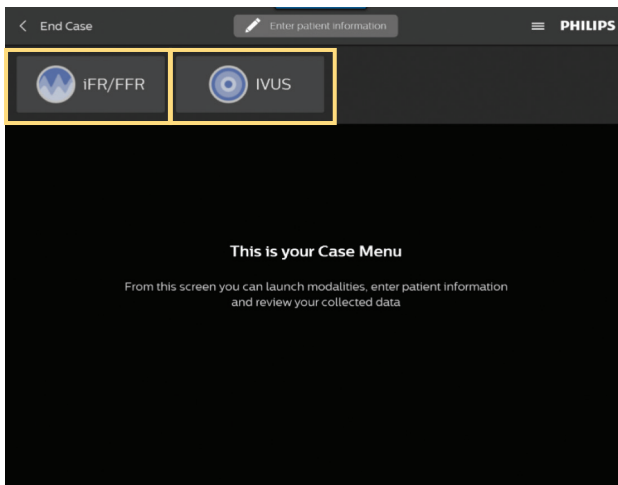
TAB q w e r t y u i o p ↩

CAPSLOCK a s d f g h j k l ENTER

↑ z x c v b n m . , ↑

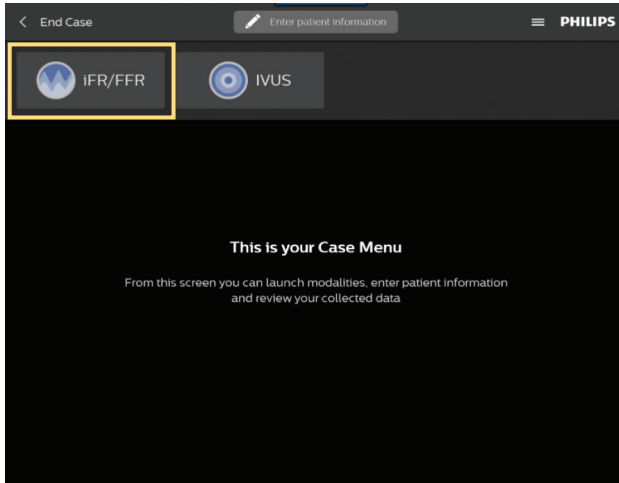
123 123 📄

Once patient information has been entered, select **Save & Close** and select either the **iFR/FFR** or **IVUS** icon to initiate the procedure.

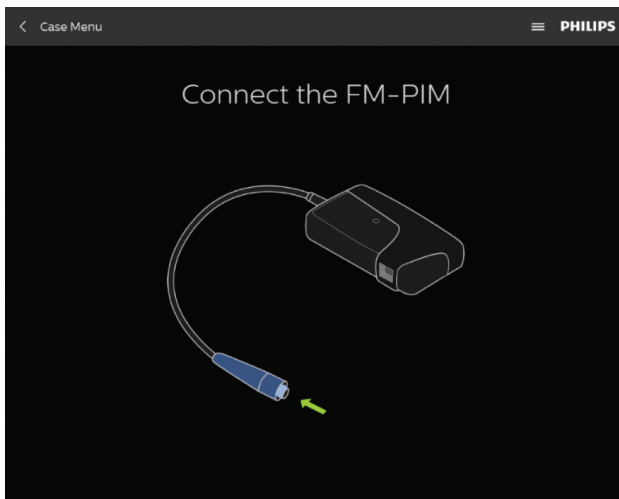


Part 2: How to initiate an iFR/FFR case

1. Click the iFR/FFR button.

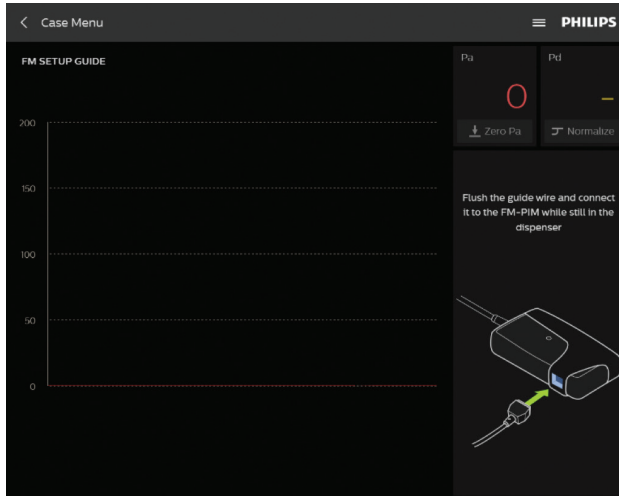


2. The system will now prompt the user to connect the necessary accessories to perform the selected workflow. If the FM-PIM is not connected to the system when the iFR/FFR option is selected, the user is prompted to connect it.

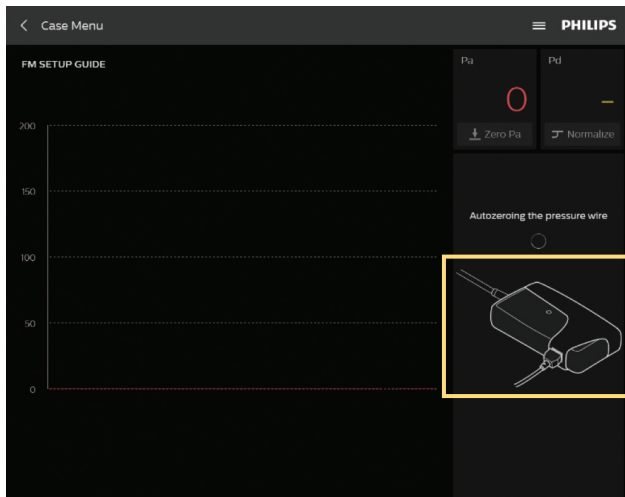


****Note, FM-PIM operates the pressure wires for both iFR and FFR modalities, however, an adapter is required to accommodate the Verrata Plus pressure guide wire.***

3. On the right side of the screen, the user is prompted to flush the pressure wire and connect it to FM-PIM.



4. Once the wire is connected and signal detected, the display shows the pressure wire being autozeroed for five wave-forms.



5. Once the pressure wire has autozeroed, the system is ready. It will highlight the Normalize button to blue and provide instructions that indicate the next logical step. Notice the display on the right side of the screen which demonstrates optimal device positioning to ensure normalization accuracy.



6. After optimal normalization has been performed the user is presented with three physiologic assessment options. The blue buttons will continue indicating the next step in the workflow, the user has the option of performing an iFR Spot measurement, an iFR Pullback or FFR.



Part 3: iFR measurement workflow

1. iFR Spot- after five stable waveforms are detected the resulting iFR measurement is performed and displayed. The result is displayed in the upper right hand corner.

Select iFR Spot:



iFR Spot results:



Note: The iFR measurement may take up to 25 cardiac cycles, depending on the stability of the pressure readings. The iFR measurement algorithm will stop once a stable result has been obtained. The iFR measurement is the average of the recorded data cycles.

2. iFR Pullback- enables iFR measurements to be recorded along a length of vessel. It provides iFR data that can be used to determine the degree of disease in the vessel (based on the “Distal iFR” value located at the most distal location in the pullback) as well as, the relative significance of individual lesions or diseased segments along the length of the vessel.

Select iFR pullback:



3. Following normalization or an iFR spot check, select iFR Pullback. Once iFR Pullback has been initiated and the trend line appears, the clinician can pull the pressure wire back at 1mm per second across the length of the vessel to be assessed. Bookmarking is an active feature during iFR pullback. They will be numbered sequentially through the exam and can be seen during the run review.

iFR pullback results:



4. The iFR pullback provides clinicians with a physiologic profile of the entire vessel that facilitates precise identification of physiologically significant stenoses.



At pullback completion, press the Stop button. It is suggested that the user performs a normalization check after obtaining the iFR value by pulling the guide wire back to the tip of the guide catheter, pressing Live and verifying that Pa is still equal to Pd.

The iFR results are displayed throughout the measurement.

Physiology measurements are displayed at the bottom right corner, with the most recent at the top.

Users can utilize the toggle bar at the bottom of the screen to maneuver throughout the data.

* iFR is backed by more than 4500 patients of outcome data from two large randomized, controlled trials.

1. Davies JE, Sen S, Dehbi H-M, et al. Use of the instantaneous wave-free ratio or fractional flow reserve in PCI. *N Engl J Med* 2017;376:1824-34.
2. Gotberg M, Christiansen EH, Gudmundsdottir LJ, et al. Instantaneous wave-free ratio versus fractional flow reserve to guide PCI. *N Engl J Med* 2017;376:1813-23.

Part 4: FFR measurement workflow

1. The third physiology option following normalization is FFR. Users will advance the pressure wire to the location of interest. Induce hyperemia and select the FFR button.

The Save Frame button is available on all the Live Runs/Video Loops and 99 frames can be saved per case.



2. As the FFR measurement is taking place, users can add bookmarks throughout and easily stop the measurement from the bottom right screen option.



3. The FFR run results are then displayed.

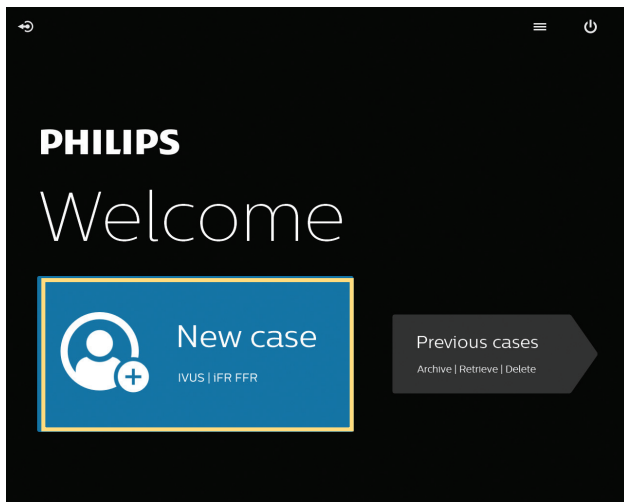


Users can scroll through the measurement and the cursor populates with the associated FFR data points allowing for easy identification of the FFR value. Further investigation of any particular area of interest is available simply by selecting the white FFR location bar with the mouse and scrolling throughout the waveform.

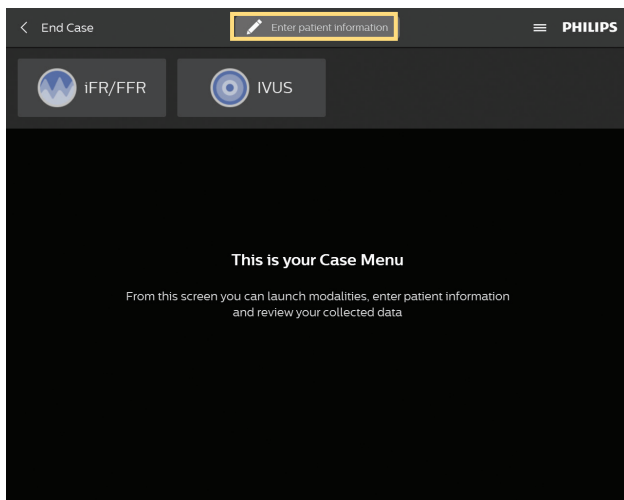
In addition, the navigation bar along the bottom allows the user to easily zoom in and out of the measurement.

Part 5: How to run an IVUS case

1. If starting a new case, select the icon below. However, if you already have started a physiology case, you may select the IVUS icon as shown in step 4 and forgo entering patient information, as it will have already been created.



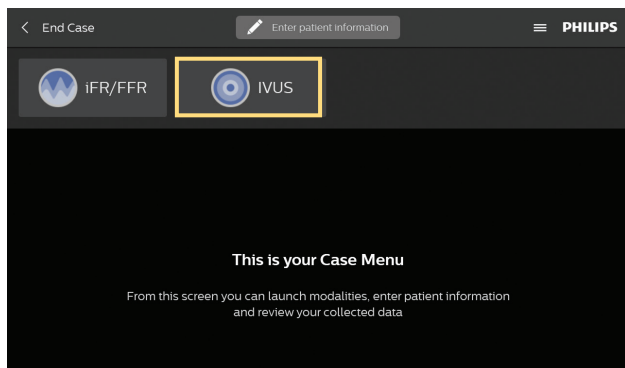
2. Enter patient information by clicking the pencil icon.



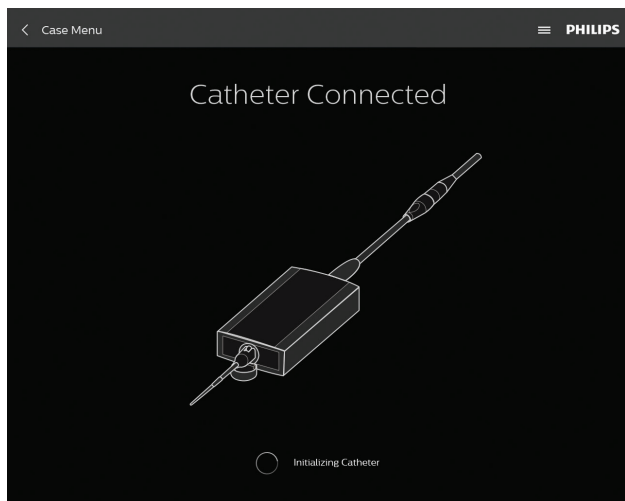
Note: Patient ID is a required field.

3. Flush catheter lumen using saline, per your standard procedure, and proceed to the next step.

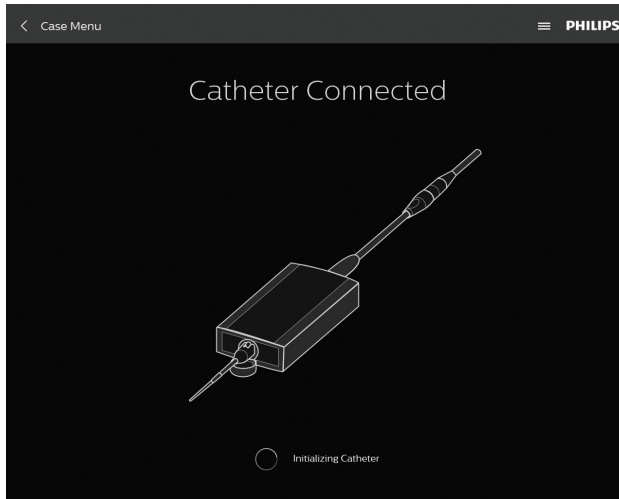
- Click the IVUS button.



- Plug the catheter into PIM (Patient Interface Module).
Verify that the catheter has been detected.



6. Verify that the catheter has been detected.

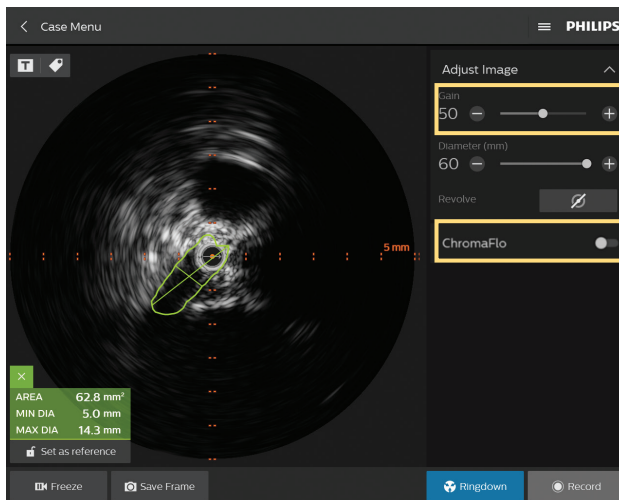


7. Adjust image settings if/as necessary.

ChromaFlo*: turn on/adjust sensitivity/region of interest.

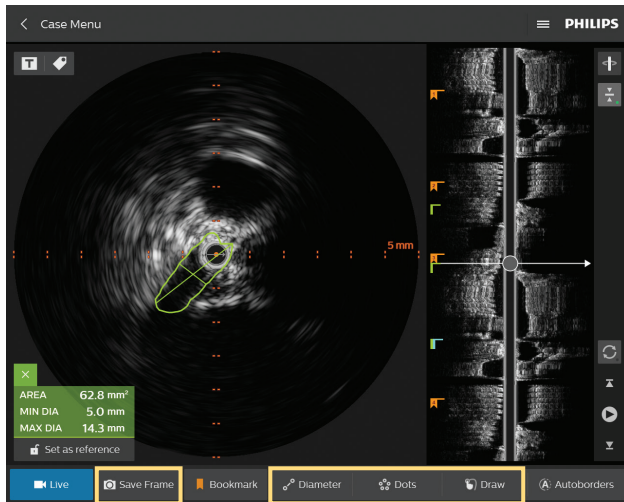
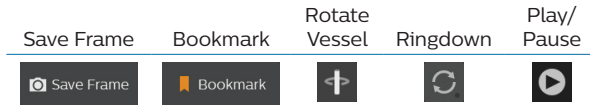
Gain: increase the reflectivity of the screen

Diameter: increase or decrease the catheter diameter for various views.



*Available only on Eagle Eye Platinum, PV.018, and PV.014.

8. Advance catheter distal to lesion.

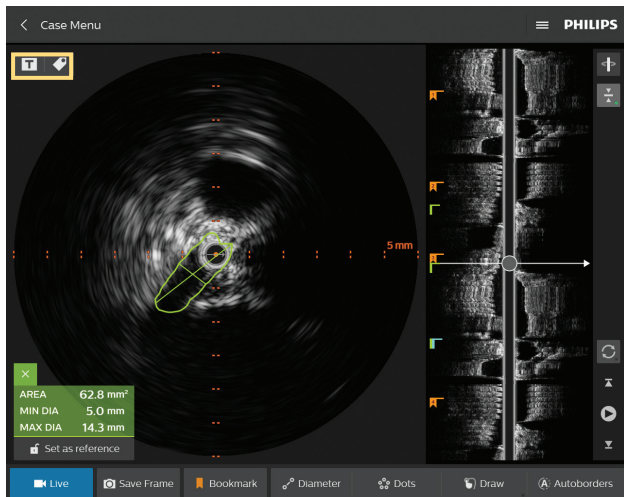


9. Review recording and take measurements using Diameter, Area or Dots.

10. Measuring: measurements are automatically saved. You have the option of saving another image by selecting Save Frame.

Diameter, Dots and Draw: to activate multiple diameter, dots or draw measurements, you will need to re-click on the tool.

11. Labeling images: add label by using the keyboard and/or select from the available options. Click save and drag the new label to desired location on the image.



Note: “Create title name” refers to renaming the video loop. “Create annotation” refers to labeling a frame.

Select by procedure type: Coronary, venous, thoracic abdominal, arterial LE, AV access.

Title this video loop

VL 1

Coronary Venous Thoracic Abdominal Arterial LE AV Access

Time/Side	Segment	Vessel	Description
Pre	Prox	Aorta	Neck
Post	Mid	Celiac	TRUE lumen
Left	Distal	SMA	FALSE lumen
Right		Renal vein	Dissection
		Renal artery	Thrombus
		Bifurcation	Seal Zone

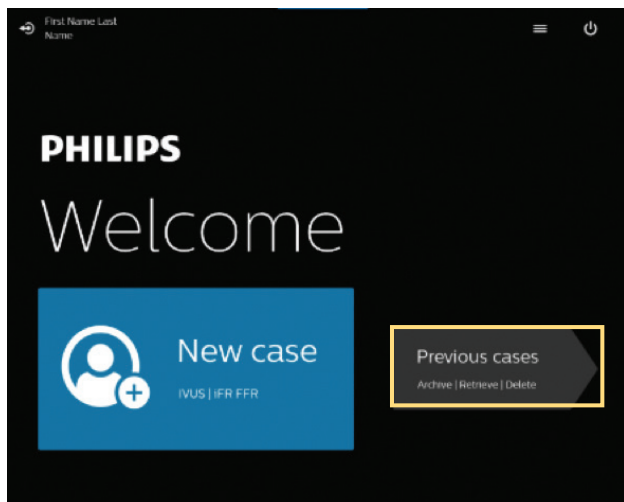
12. Editing and deleting a measurement: press on a measurement line or border on the touchscreen and drag it to a desired location.

To delete, press X.

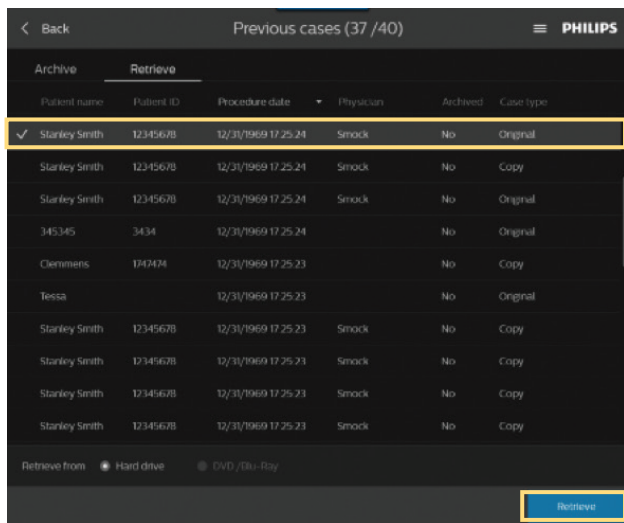
Part 6: Archiving and case retrieval

1. Case Retrieval: To access previously recorded cases, select the previous case tab, select a case from the list of patients, and then select the retrieve button.

Select Retrieve from Welcome screen:



Select Case from list and then Retrieve:

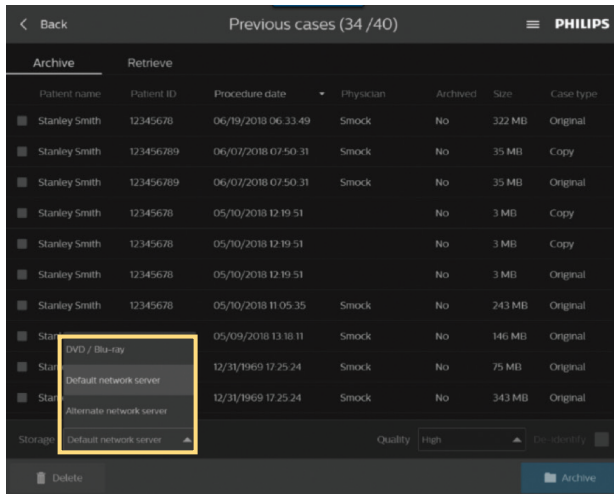


2. Archive

Cases can be archived using any of the following:

- a. Recordable DVD, Blu-ray drive
- b. DICOM Network Interface Port

Multiple cases can be archived and deleted at one time to DVD/Blu-ray or DICOM network:



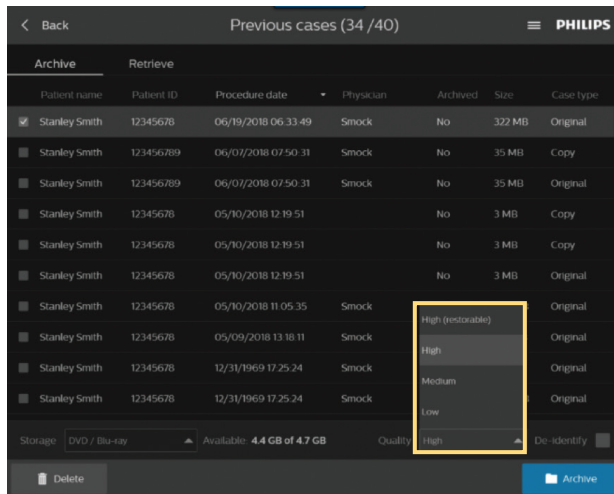
Multiple compression settings:

High quality increases file size, low quality decreases file size.

Additionally, archiving to DVD/Blu-ray using a High quality setting increases archiving speed and file size compared to a high (restorable) setting.

A maximum of 40 patient cases can be stored on the system's hard drive. Saving to a hard drive is faster than saving to a DVD or Blu-ray. However, archiving a case to a DVD allows for viewing or exporting of images or video loops on other PCs.

Archive a case to a DICOM Server by selecting network server option from Storage option list, located above Delete button, provided DICOM has been connected by FSE.



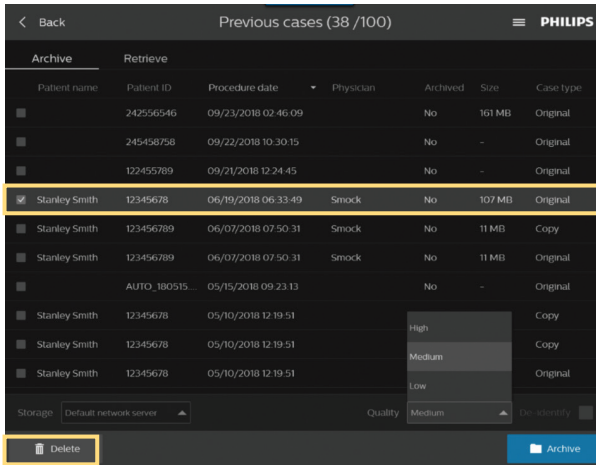
Note: the HIGH restorable compression setting option allows the user the ability to retrieve a case back onto an IntraSight system and it must be selected prior to archiving. The process of retrieval can be lengthy, as much as 15 minutes, therefore care should be taken as to the impact on case/lab workflow.

3. Removing patient information/archived DVD/Blu-ray.

When archiving a case, all protected patient information can be removed by selecting the "De-identify" feature. A short case note can be entered instead of the patient name, if desired.

4. Archiving a case: DVD/Blu-ray quality options are High (restorable) meaning data can be restored from the disk onto an IntraSight system for review.

Case deletion:

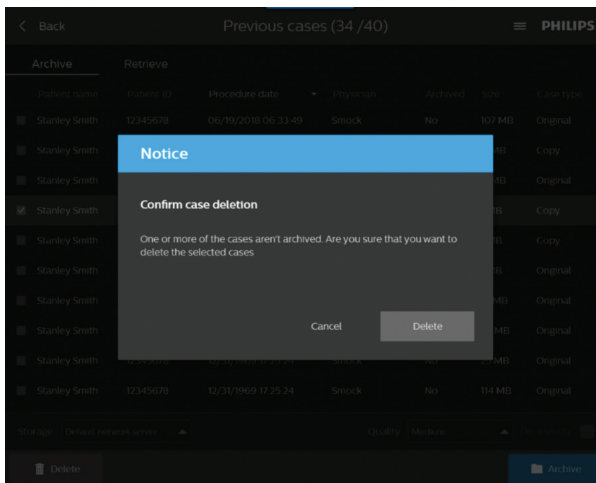


To delete the current case, do the following:

- Select the case (checkmark) in the list item to be deleted.
- Select Delete, located on lower left corner of screen. A message displays, prompting the user to delete the specific case.
- To delete, select the Video Loop or case then select the delete button.

Select the case from the list item to be deleted.

Select Delete, located on lower left corner of screen. A message displays prompting the user to delete the specific case. A Delete Case dialog prompt displays requesting the user to confirm deletion.

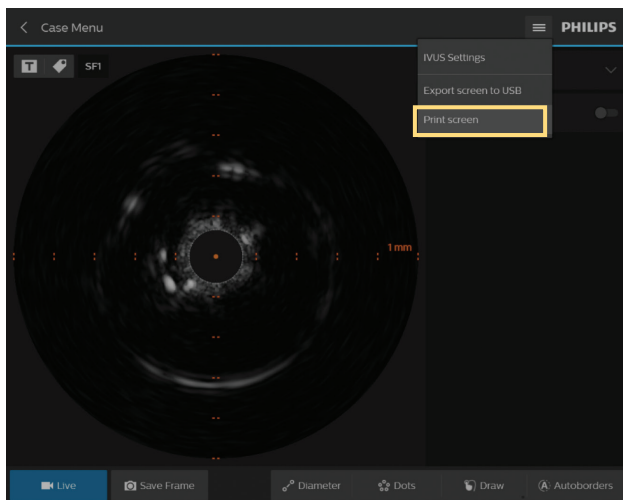


Part 7: Print screens and exporting images to USB

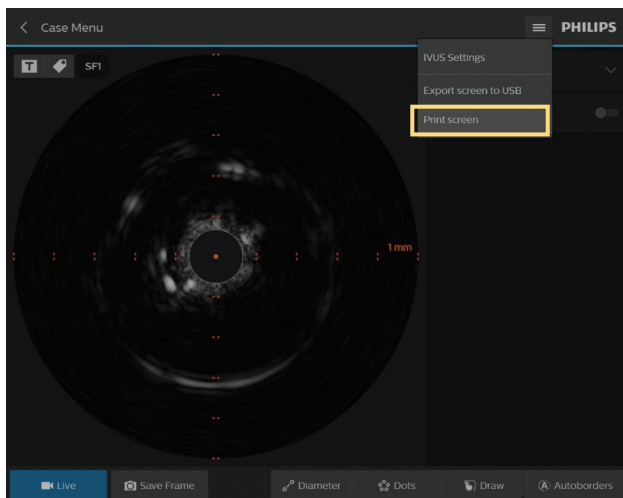
1. Print screen: to print a screen using the USB port on the back of the screen, ensure a printer is connected by cable to the USB port on back of Panel PC.

Once a printer is connected, a Print screen option displays, located in the three line icon, positioned on the upper right corner of the screen, next to the Philips logo.

Select Print screen to print image.



2. Exporting screen image directly to USB: insert a USB drive into the USB port at the back of the panel PC. At a screen image of your choice, select Export screen to USB option from the three line icon, located next to the Philips logo. The image will export directly to the USB drive.



Part 8: Bedside control - Touch Screen Module (TSM)

1. Two monitor consoles, main monitor and bedside controller (TSM), are included with the IntraSight system.



2. Both monitor screens are synchronized, they display matching screen states in real time. Screen display options and functions may be selected by touching the Panel PC or the TSM screen.
3. The bedside controller, due to the screen size, has limited quantity of information presented on the screen due to smaller screen.
4. The main monitor screen's information header including Patient name/ID, system setting drop down menu, and Philips logo are not displayed on the bedside controller screen.

5. Additionally, the main monitor screen displays menu ribbon horizontally; the bedside controller screen displays menu ribbon vertically.



Part 9: How to turn off the system after use

1. Press the power button.
2. Unplug the system power cord.
3. Clean and decontaminate system using medical grade disinfectant after every case.

For full operating instructions, please refer to the operator's manual.



Notes

[illegible]

