

Interventional Applications Platform

IntraSight

IntraSight integrated series 5 in-service guide

REA 20.7 mm MN DIA 5.0 mm MAX DIA 5.2 mm

Dors

8.8 mm² (425%)

24115

Draw

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

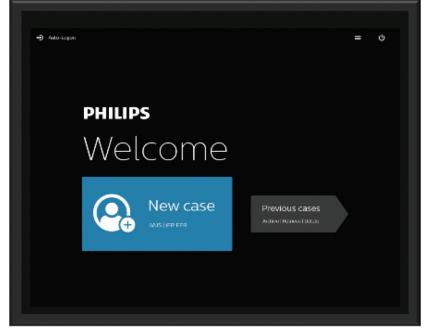
1. The system power for the Philips system should be turned on at the beginning of each day and turned off at the end. Turn the system on by using the power button located on the front of the workstation.



- 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.



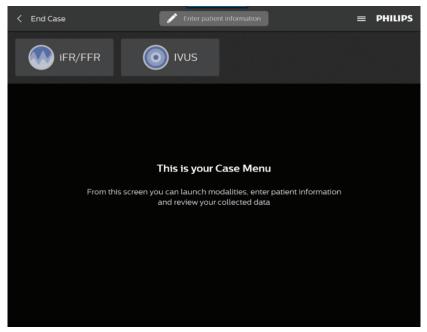
- 3. IntraSight home screen. Users have two options:
 - a. Start a new case, or
 - b. Access a previous case



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.

| S Worklist | | | | | | |
|-----------------------------|--------|------------|---------------|------------|--------|--|
| Search Filter | | | | | | |
| | | | | | | |
| | | | | | Search | |
| | | | | | | |
| Patient Name 👻 | | | | | | |
| XperIMTest, Patient | | RP454G234 | 05/08/2018 10 | | | |
| XA modality | | | 05/08/2018 10 | | | |
| Balasubramanian, George Taj | | RP488M9439 | 05/08/2018 10 | | | |
| Franklin, Rosalind | | RP2812308 | 05/08/2018 10 | | | |
| Newgirl, Randy | | RP488M9439 | 05/08/2018 10 | | 00046 | |
| Carson, Rachel | | | 05/08/2018 10 | | | |
| Goeppert-Mayer, Maria | MG-002 | RP2812306 | 05/08/2018 10 | | | |
| | | | | e Worklist | | |

6. Patient information - manual

Patient information can be typed-in manually or entered via worklist.

| < Back | Patient Information | ≡ PHILIPS |
|--|---------------------|--------------|
| 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 | tyuiop | •8 |
| CAPSLOCK a s d f | g h j k l EN | TER |
| transformation to the second | bnm,. | • |
| .123 | | |

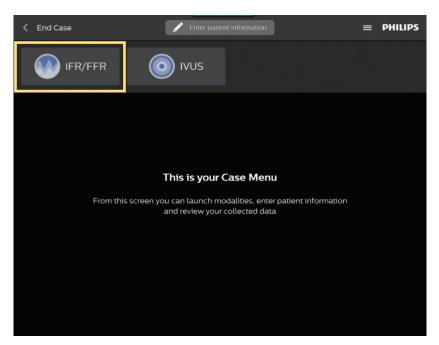
7. Shared case menu

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

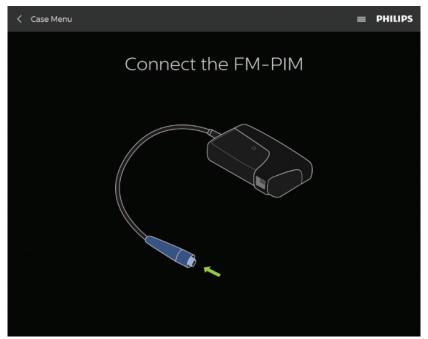
| < End Case | Finter patient information | ≡ PHILIPS |
|------------|---|-----------|
| ifr/ffr | | |
| | | |
| | | |
| | This is your Case Menu | |
| From thi | is screen you can launch modalities, enter patient informat and review your collected data | ion |
| | | |
| | | |
| | | |
| | | |

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.

| < Case Menu | = | ■ PHILIPS |
|----------------|--|--------------------|
| FM SETUP GUIDE | | Pd |
| | 0 | |
| | <u> </u> | J → Normalize |
| | | |
| | Flush the guide w it to the FM-PIM dispe | while still in the |
| | | |
| | | 0 |
| | | |
| | | |

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

| < (| Case Menu | ≡ | ■ PHILIPS |
|------|------------|------------------|---------------|
| FM S | ETUP GUIDE | | Pd |
| | | 0 | — |
| | | <u>↓</u> Zero Pa | J → Normalize |
| | | | |
| | | Autozeroing the | pressure wire |
| | | C |) |
| | | | |
| | | \sim | ° |
| | | | \mathcal{L} |
| | | // | and - |
| | | | |
| | | | |
| | | | |

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.

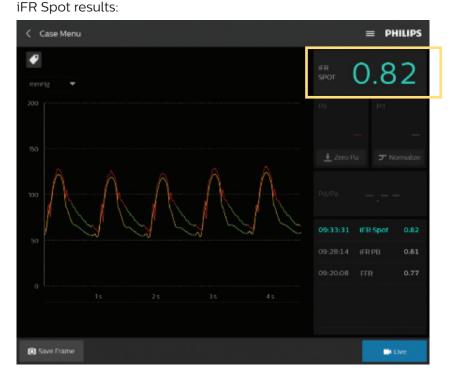


Part 3: iFR measurement workflow

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:



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. 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:

| < Case Menu | ≡ PHILIPS |
|--|----------------------|
| er v | ISTAL 0.81 |
| 100 0 90 0 81 x 0 80 | |
| 0.70 0.60 0s 10s 20s 30s 40s 50s 60s 70s 80s 90s 100s 110s | |
| munitig 👻 | 09:28:14 IFR PB 0.81 |
| | 09:20:08 FFR 0.77 |
| | |
| o 11 | |
| Save Frame | H Live |

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 IJ, 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.

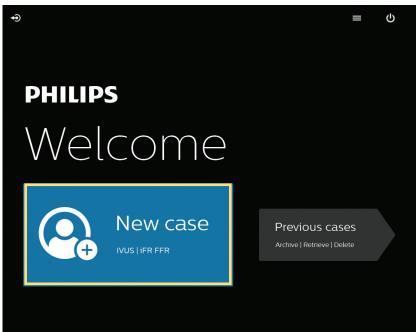


Users can scroll through the measurement and the cursor populates with the associated FFR data points allowing for easy identification of the FFR value. Further investigation of any particular area of interest is available simply by selecting the white FFR location bar with the mouse and scrolling throughout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

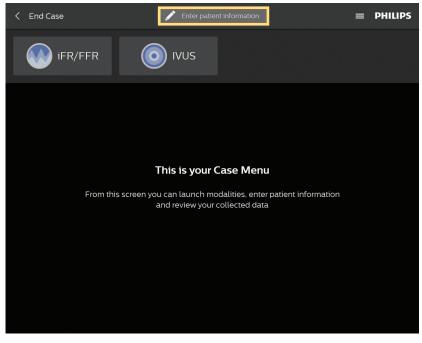
In addition, the navigation bar along the bottom allows the user to easily zoom in and out of the measurement.

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.



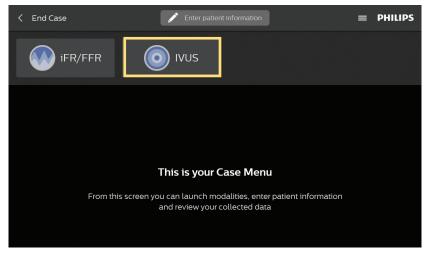
2. Enter patient information by clicking the pencil icon.



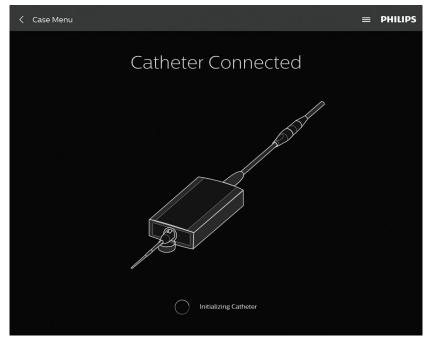
Note: Patient ID is a required field.

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

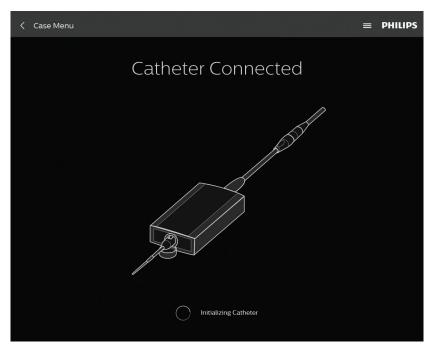
4. Click the IVUS button.



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

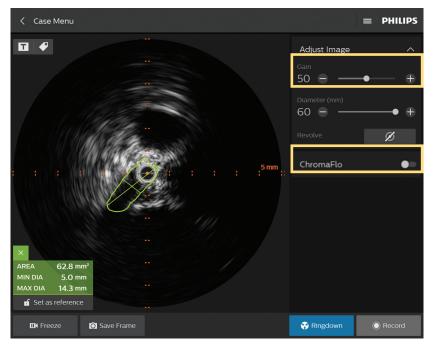


6. Verify that the catheter has been detected.



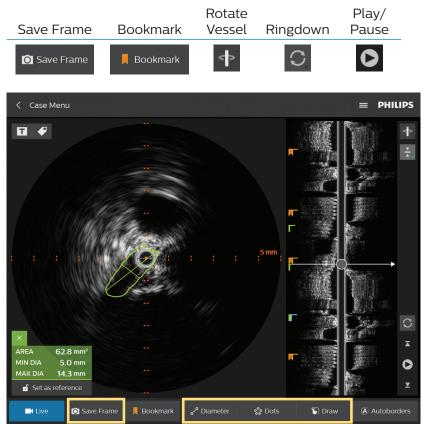
Adjust image settings if/as necessary.
 ChromaFlo*: turn on/adjust sensitivity/region of interest.
 Gain: increase the reflectivity of the screen

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



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

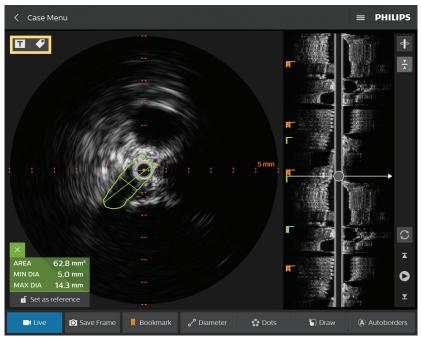
8. Advance catheter distal to lesion.



- 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: Clic | k to enter label | | ✓ | | | | |
| Coronary | Venous Thorac | cic Abdominal Art | terial 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:

| < | Back | | Previous cas | es (37 /40) | | = | PHILIPS |
|--------------|------------------|----------|---------------------|-------------|----|----------|----------|
| | Archive | Retrieve | | | | | |
| | | | Procedure date 🔹 | | | | |
| \checkmark | Stanley Smith | 12345678 | 12/31/1969 17:25:24 | Smock | ND | Original | |
| | Stanley Smith | 12345678 | 12/31/1969 17:25:24 | | | | |
| | Stanley Smith | | | | | | |
| | | | 12/31/1969 17 25.24 | | | Original | |
| | | | 12/31/1969 17 25 23 | | | | |
| | Tessa | | 12/31/1969 17:25:23 | | | | |
| | Stanley Smith | | 12/31/1969 17 25 23 | | | | |
| | Stanley Smith | | | | | | |
| | Stanley Smith | | | | | | |
| | Stanley Smith | | | | | | |
| Re | strieve from 🔹 F | | | | | | |
| | | | | | | | 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:

| < | Back | | Previous cases | s (34 /40) | = | PHILIPS |
|-----|------------------------|--------------|---------------------|------------|--------|----------|
| | Archive | Retrieve | | | | |
| | | | | | | |
| | Stanley Smith | 12345678 | 06/19/2018 06:33:49 | | 322 MB | Original |
| | Stanley Smith | | | | 35 MB | Сору |
| | Stanley Smith | 123456789 | 06/07/2018 07:50:31 | | 35 MB | Original |
| - | Stanley Smith | 12345678 | 05/10/2018 12:19:51 | | 3 MB | |
| | Stanley Smith | | 05/10/2018 12:19:51 | | 3 MB | |
| | Stanley Smith | | 05/10/2018 12:19:51 | | 3 MB | Original |
| | Stanley Smith | 12345678 | 05/10/2018 11:05:35 | | 243 MB | Original |
| | Stanl DVD / Blu-ray | | | | 146 MB | Original |
| | Stanl Default netwo | | 12/31/1969 17:25:24 | | 75 MB | Original |
| - | Stanl Alternate netv | | 12/31/1969 17:25:24 | | 343 MB | Original |
| Sto | Default netwo | ork server 🔺 | | | | |
| | 蘭 Delete | | | | | Archive |

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.

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.

| < | Back | | Previous cases | s (34 /40) | | = | PHILIPS |
|-----|---------------|-----------|----------------------------|------------|------------------|--------|------------|
| | Archive | Retrieve | | | | | |
| | | | | | | | Case type |
| × | Stanley Smith | | 06/19/2018 06 33 49 | | | 322 MB | Original |
| | Stanley Smith | | | | | 35 MB | Сору |
| | Stanley Smith | 123456789 | | | | 35 MB | Original |
| | Stanley Smith | | 05/10/2018 12:19:51 | | | 3 MB | Сору |
| | Stanley Smith | | 05/10/2018 12:19:51 | | | 3 MB | Сору |
| | Stanley Smith | | 05/10/2018 12:19:51 | | | 3 MB | Original |
| | Stanley Smith | | 05/10/2018 11:05:35 | Smock | High (restorable | | Original |
| | Stanley Smith | | 05/09/2018 13:18:11 | Smock | High | | Original |
| | Stanley Smith | | 12/31/1969 17:25:24 | Smock | Medium | | Original |
| | Stanley Smith | | | Smock | | | Original |
| Sto | | | Wailable: 4.4 GB of 4.7 GB | Quality | Low High | ۵. | e-identify |
| | 🛅 Delete | | | | | | Archive |

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.

 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.

| _ | | 7 11. | | | | | |
|-----|---------------|--------------|---------------------|-----------|--------|--------|----------|
| < | Back | | Previous cases | (38 /100) | | = | PHILIPS |
| | Archive | Retrieve | | | | | |
| | | | Procedure date 👻 | | | | |
| | | 242556546 | 09/23/2018 02:46:09 | | | 161 MB | Original |
| | | | 09/22/2018 10:30:15 | | | | Original |
| - | | 122455789 | 09/21/2018 12:24:45 | | No | | Original |
| | Stanley Smith | 12345678 | 06/19/2018 06:33:49 | Smock | No | 107 MB | Original |
| | Stanley Smith | 123456789 | 06/07/2018 07:50:31 | Smock | No | 11 MB | Сору |
| | Stanley Smith | | | | | 11 MB | Original |
| | | AUTO_180515 | | | | | Original |
| | Stanley Smith | | 05/10/2018 12:19:51 | | | | |
| | Stanley Smith | 12345678 | 05/10/2018 12:19:51 | | Medium | | |
| - | Stanley Smith | | 05/10/2018 12:19:51 | | | | Original |
| Sto | | | | | | | |
| | 蕑 Delete | | | | | | Archive |

Case deletion:

To delete the current case, do the following:

- a. Select the case (checkmark) in the list item to be deleted.
- b. Select Delete, located on lower left corner of screen. A message displays, prompting the user to delete the specific case.
- c. 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.

| < | Back | | Previous ca | ises (34 /40 |)) | = | PHILIPS |
|-----|------|---------------------------|--|--------------------|--------------------|--------|----------------|
| | | | | | | | |
| | | | | | | | Case type |
| 10 | | 12345678 | 06/19/2018 06:33:49 | Smock | No | 107 MB | Original |
| | | Notice | | | | 4B | Сору |
| 10 | | | | | | 4B | Original |
| 88 | | Confirm ca | se deletion | | | в | Сору |
| | | One or more delete the se | of the cases aren't arch lected cases | ived. Are you sure | e that you want to | B | Copy |
| 11 | | | | | | в | Original |
| 11 | | | | | | мв | Original |
| | | | | Cancel | | мв | Original |
| 0 | | | | | | | Original |
| | | | | | | | Original |
| Ste | | | | | | | er aler dity - |
| | | | | | | | Archive |

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.

Case Menu

VUS Settings

Export screen to USB

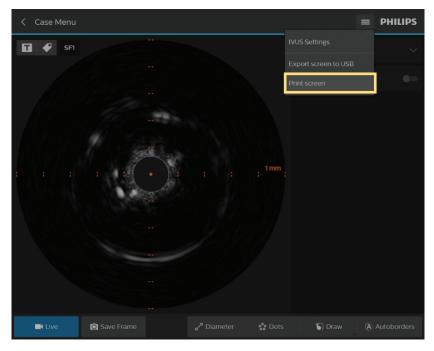
Print screen

Print screen

Imm

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.

| < Case Menu | | ≡ PHILIPS |
|---|-----------------------|-----------------------------------|
| IFR PB 2: | ifr Distal | 0.81 |
| 100 0.90 0.80 | Pa <u>↓</u> Zero F | Pd Pd Pa Pa Normalize |
| 0.70 0.60 0.5 0.5 0.5 0.5 0.5 0.5 0.5 0. | | |
| mmHg 🔻 | 10:09:54 | IFR PB 0.81 |
| 300 | | IFR PB 0.83 |
| | | IFR Spot 0.80 |
| | | iFR Spot 0.82 |
| | | |
| O Save Frame | | Live |

2. The smaller bedside touchscreen controller (TSM) is located in the procedure room, attached to the bedside rail of patient table, for the convenience of doctor and/or technician.

| < Case Menu | IFR PB 2: | ifr Distal | 0.81 |
|----------------|------------------------------------|---------------|---------------|
| | 100 < 0.81 090 x | | |
| | 0.80 | 🛓 Zero F | |
| 🖸 Save Frame | 0.60 0s 55 10s 15s 20s 25s 30s 35s | | |
| | mmHg 🔻 | 10:09:54 | IFR PB 0.81 |
| • FFR | | 10:08:43 | IFR PB 0.83 |
| • IFR Pullback | | | IFR Spot 0.82 |
| • IFR Spot | и и | | |

- 3. Both monitor screens are synchronized, they display matching screen states in real time. Screen display options and functions can be selected by touching the bedside controller screen in examination room (or using keyboard and/or mouse for the main monitor in control room).
- 4. The bedside controller, due to the screen size, has limited to quantity of information presented on the screen due to smaller screen.
- 5. 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.

6. 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. Go to the home page.
- 2. Click on the power icon on the top right corner and confirm shutdown.

| ↔ Auto-Logon | | | ≡ () | |
|--------------|---------------------------------|------------------|--------------|--|
| | | | | |
| l l | Notice | | | |
| \ | Shutdown confirmation | sustam | | |
| | serect shut down to turn on the | | | |
| | | Cancel Shut down | SeS elete | |
| | | | | |
| | | | | |

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



©2020 Koninklijke Philips N.V. All rights reserved. Approved for external distribution. D060874-00 052021 Philips 3721 Valley Centre Drive, Suite 500 San Diego, CA 92130 USA www.philips.com/IntraSight