PHILIPS

Instructions for use

IntraSight Plus

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Contents

1 Introduction

Carefully read and review the entire Instructions for Use before attempting to operate the system. An electronic copy of these instructions can be found at:

www.philips.com/ifu

1.1 About these Instructions for Use

These Instructions for Use are intended to assist you in the safe and effective operation of the system. Important safety information is provided in the following ways:

WARNING

A warning alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the operator or patient.

CAUTION

A caution alerts you when special care is necessary for the safe and effective use of the system. Failure to observe a caution may result in moderate personal injury or damage to the equipment, and presents a remote risk of more serious injury or environmental pollution.

NOTE ***Notes highlight other points as an aid to the operator.***

These Instructions for Use may describe some products or features that are not available in all countries. Please contact your local sales representative for the availability of products and features in your region. For support or availability of remote service features, please contact your local service organization representative.

1.2 Intended purpose & Indications for use

Intended purpose

IntraSight Plus is a multi-function system intended to be used as an adjunct diagnostic tool for qualitative and quantitative evaluation of vascular morphology in coronary arteries and peripheral vasculature in patients eligible for endovascular procedures.

The system, when configured with optional features, can also be used for:

- quantitative evaluation of coronary physiology,
- quantitative evaluation of coronary artery dimensions,
- enhanced visualization of therapy delivery in coronary arteries, and co-registration of an x-ray image with coronary intravascular ultrasound and/or coronary physiology in patients eligible for percutaneous coronary intervention.

Indications for use

The IntraSight Plus IVUS function is indicated for use in patients with vascular disease to assess the nature and extent of the disease and to assess the need for additional treatment post percutaneous intervention. In patients undergoing percutaneous interventions, including stent implantation, IVUS can assist in guiding the procedure. IVUS is obtained with a compatible ultrasound catheter and used as an adjunct to examine vascular morphology in the coronary arteries and vessels of the peripheral vasculature.

The IntraSight Plus FFR and iFR functions are indicated for use in patients with signs of coronary artery disease undergoing coronary catheterization procedures to assess the hemodynamic significance of coronary lesions that may contribute to myocardial ischemia and to evaluate the physiological gain post percutaneous intervention. FFR and iFR are obtained with a compatible pressure guide wire.

IntraSight Plus with the SyncVision Software QCA function is indicated for use in patients with signs of coronary artery disease undergoing coronary catheterization procedures to assist in identifying coronary lesions that may contribute to myocardial ischemia .

1.3 User populations

User	Primary Interactions	Education	Training	Unique Characteristics
Physician (sterile)	Operates in the sterile field to lead the procedure, deliver catheters, pressure guide wires, cardiovascular devices, and make/interpret images and measurements to make treatment decisions; may control the system from within sterile field.	Doctor of Medicine (MD with interventional training)	In-service provided by Philips sales representative	- Time sensitive - Needs to know how to operate a variety of equipment and devices
Nurse/ Technologist (sterile)	Assists physician within the sterile field during procedure; prepares and assists with use of PIMs, catheters, pressure guide wires, and cardiovascular devices; may control the system from within sterile field.	Registered Nurse (RN) Registered Technician (RT)	In-service provided by Philips sales representative	- Time sensitive - Needs to know how to operate a variety of equipment and devices - Delivers medications - Typically has to multitask
Nurse/ Technologist (non-sterile)	Documents the procedure; prepares and delivers medication; operates the system outside of the sterile field or from the control room; delivers catheters, pressure guide wires, and cardiovascular devices to the sterile field; monitors the patient; archives studies.	Registered Nurse (RN) Registered Technician (RT) Fellow Resident Nurse Practitioner (NP) Physician Assistant (PA)	In-service provided by Philips sales representative	- Time sensitive - Needs to know how to operate a variety of equipment and devices - Delivers medications - Typically has to multitask

1.4 Patient population

The system is intended for patients with vascular disease who are eligible for endovascular procedures.

1.5 Clinical applications

The system is used to evaluate vascular morphology in the coronary arteries and vessels of the peripheral vasculature. IntraSight Plus provides a range of imaging and physiology applications:

- QCA/VE
- iFR
- FFR
- IVUS
- Device Detection

Refer to the *Applications* section in Chapter 3 for more details.

1.6 Intended clinical benefits

The intended clinical benefit is to provide clinicians additional diagnostic information on vascular disease over that provided by angiography alone, to better inform planning and treatment decisions.

The system, when configured with the optional co-registration feature, provides clinicians with improved localization of disease characteristics over that provided by angiography alone, to better inform planning and treatment decisions.

The system, when configured with the optional x-ray enhancement features, provides clinicians with improved visualization to better inform planning and treatment decisions.

1.7 Contraindications

There are no known contraindications for the IntraSight Plus system itself. Please consult catheter and guide wire Instructions for Use packaged with each disposable.

1.8 Possible adverse reactions

The IntraSight Plus system itself does not have direct contact with the patient. Please consult catheter and guide wire Instructions for Use packaged with each disposable.

1.9 European database of medical devices

The summary of safety and clinical performance is available in the European database on medical devices (EUDAMED) at the following URL:

ec.europa.eu/tools/eudamed

1.10 Compatibility

X-ray systems

IntraSight Plus is compatible with Philips X-ray systems. To determine if a specific X-ray system is compatible, contact Philips technical support.

Catheters

IntraSight Plus is compatible with the following catheters:

- Eagle Eye Platinum
- Pioneer Plus
- Reconnaissance PV .018 OTW
- Refinity
- Visions PV .035
- Visions PV .018
- Visions PV .014 Platinum
- Visions PV .014P RX

Pressure guide wires

IntraSight Plus is compatible with the following pressure guide wires:

- OmniWire

1.11 Training

Do not attempt to operate the system without adequate training in accordance with local laws or regulations.

Federal (USA) law restricts this device to sale by or on the order of a physician. Only physicians or other persons with adequate medical training in catheter or pressure guide wire insertion procedures should use the system. Only those personnel who are familiar with its operation and who have been trained to perform the procedures for which this device is intended should use the system.

The facility's management should assess the initial and continuous training needs of the system users.

For safe and effective use of the system, Philips recommends that each user of the equipment reviews the procedures and safety precautions on at least an annual basis. Contact a Philips representative for refresher training options.

It is highly recommended that users be provided adequate time to participate in training and learn how to provide feedback on image quality.

1.11.1 Using demonstration mode (option)

You can use the system in a dedicated demonstration mode (demo mode) for training and demonstration purposes. Demo mode allows you to initiate a prerecorded study from a dedicated demonstration database without affecting the stored data of real patients. When using demo mode with the system integrated with a Philips X-ray system, pre-defined patient details are used.

NOTE ***Demo mode is intended for system demonstration purposes only. All data displayed is prerecorded data from actual anonymous clinical studies. Any new data created or any change made to existing data in demo mode is deleted when you leave demo mode.***

NOTE ***Any changes made to application settings while in Demo Mode will also apply in Clinical Mode. Before using the system clinically, review and adjust settings as needed to ensure they align with your workflow.***

When using demo mode, an indicator is always displayed to remind you that you are using the system in demo mode.

You can access demo mode from the login screen. To enter demo mode, select Log in as a demo user in the top right of the screen.

You cannot access Demo Mode while the system is performing background tasks, such as archiving or importing data. You must allow all running jobs to finish before entering demo mode.

For more information, see *12.7 Using the job viewer on page 128*.

NOTE ***To protect real patient data when using demo mode, all connections to PACS, worklist management databases, and the X-ray system are disabled, and real patient studies stored in the system are hidden.***

Actions and procedures in demo mode operate in the same way as for live studies. Refer to the relevant sections within these Instructions for Use for more information about studies and applications.

To leave demo mode, select the system menu in the top right of the procedure home screen and select **Log Off Demo User**.

1.12 Installation

The Philips system must be installed by a qualified Philips representative. In the event the system needs to be relocated or modified, please contact Philips technical support prior to any relocation or modification. Warning: System is intended to be a stationary system. No part of the system (in particular monitors and workstation) should be transported by the user with the exception of parts that are portable during normal use (e.g., PIMs, MMTSM, disposables).

1.13 Warranty

NOTE ***The manufacturer's specifications and policies are subject to change. Philips reserves the right to make changes in the products described in this manual in order to improve design or performance. Reproduction or distribution of any portion of this manual without the prior written consent of Philips is prohibited.***

Philips makes no warranty, representation or condition of any kind, expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the misuse of the system or the reuse of the catheter. Philips assumes no responsibility or liability for incidental or consequential damages which may result from reuse or misuse of the catheter.

Limited warranty

Subject to the conditions and limitations on liability stated herein, Philips (“Philips”) warrants that the Philips Interventional Applications Workspace - IntraSight Plus (the “Workspace”) as so delivered, shall materially conform to Philips’s then current specifications for the Workspace, for a period of one year from the date of delivery. Any liability of Philips with respect to the Workspace or the performance thereof under any warranty, negligence, strict liability or other theory will be limited exclusively to Workspace repair, replacement or, if replacement is inadequate as a remedy or, in the opinion of Philips, impractical, to refund of the price paid for the Workspace. Except for the foregoing, the Workspace is provided “as is” without warranty of any kind, express or implied, including without limitation, any warranty of fitness, merchantability, fitness for a particular purpose or non-infringement. Further, Philips does not warrant, guarantee, or make any representations regarding the use, or the results of the use, of the Workspace or written materials in terms of correctness, accuracy, reliability, or otherwise. Buyer understands that Philips is not responsible for and will have no liability for any items or any services provided by any persons other than Philips. Philips shall have no liability for delays or failures beyond its reasonable control.

Additionally, this warranty does not apply if:

1. The Workspace is operated in other than a manner prescribed by Philips in the Instructions for Use, and/or supplements.
2. The Workspace is operated in a manner that is not in conformance with purchase specifications and specifications contained in the Instructions for Use, and/or supplements.
3. The Workspace is not maintained in accordance with procedures in the Instructions for Use, and/or supplements.
4. The Workspace is repaired, altered, or modified in any way by other than Philips authorized personnel, or without Philips authorization.

Contact Philips Field Service for instructions and issuance of a Return Material Authorization if claims under this warranty become necessary and if the Workspace or components of the Workspace are to be returned. The Workspace or components will not be accepted for warranty purposes unless the return has been authorized by Philips.

Workspace parts or components repaired or replaced under warranty bear the same warranty expiration date as the original equipment, or 90 days, whichever is longer. Consumable parts (data disks, batteries, among others) are warranted only against defects in materials and workmanship. Workspace parts purchased outside the original warranty period are warranted for a period of 90 days, subject to all of the restrictions contained in this Limited Warranty. Use of unauthorized replacement parts may void the warranty. In all cases, Philips will be the sole judge as to what constitutes warrantable damage.

2 Safety

Philips products are designed to meet stringent safety standards. All medical electrical equipment requires proper installation, operation, and maintenance to ensure personal safety and correct operation.

Only qualified and authorized personnel may operate, repair, or maintain this equipment. “Qualified” means those legally permitted to operate this type of medical electrical equipment in the jurisdictions in which the equipment is being used, and “authorized” means those authorized by the owner of the equipment.

Personnel operating the equipment and personnel in the examination room must observe all laws and regulations that apply to the operation of this equipment. If in doubt, do not use it.

Philips makes no warranty, representation or condition of any kind, expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the misuse of the system.

2.1 Reporting a serious incident

If a serious incident (death or any intervention) has occurred and the device was in use at any time, it should be reported to the manufacturer immediately and/or the competent authority of the Member State in which the user and/or patient is established.

A serious incident means any incident that directly or indirectly led, might have led, or in case of recurrence, could lead to any of the following:

- Intervention to prevent a serious injury
- The death of a patient, user, or other person
- The temporary or permanent serious deterioration of a patient’s, user’s, fetus, or other person’s state of health
- Serious public health threat

2.2 Warnings and Cautions

CAUTION

Avoid spilling or dropping any foreign material onto components. It is important to be especially careful with the keyboard, controller, workstation, and monitor. If there has been spillage:

- ***Over IPX4 components: These components need to be cleaned according to section 15.7.***
- ***Keyboard and mouse: Disconnect the component and order a replacement part.***
- ***IPX1 / IPX0 components, like monitor and workstation, must be unplugged from power as soon as spillage is determined. Contact technical support.***

WARNING

Do not place the isolation transformer on the floor. The unit must remain on an elevated surface. Danger: Risk of explosion if used in the presence of flammable anesthetics, or other flammable gases or liquids.

WARNING

The Philips system must be properly grounded to avoid electrical shock. To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth. Note: In the USA and Canada, reliable grounding can only be achieved when this equipment is connected to a receptacle marked “hospital only” or “hospital grade.”

CAUTION

Do not obstruct the mains power cord.

WARNING

To prevent compromising patient isolation, the system operator must not simultaneously touch the patient and/or any implanted catheter or pressure guide wire and any part of the system hardware or connector interface.

CAUTION

The Philips system must have the original power cord, or installed electrical power in a Philips system, and must be used at all times. The system is protected against the voltages of defibrillation; still, it is recommended that the catheter be disconnected from the patient interface module prior to defibrillation.

CAUTION

The Philips system is intended to be used in diagnostic and interventional catheterization laboratories. The electrical installation shall include means to limit the chassis and enclosure leakage currents within the patient environment which may result from potential differences between the protective earths between the medically used (exam) room and the non-medically used (control) room. The system can safely be connected to equipment within the patient environment that complies with the requirements of IEC 60601-1:2005+A1:2020, Annex I, Table I.1, Situation No. 3c. The feasible solutions include either the use of a separating device to isolate ground loop currents or the connection of an additional protective earth connection on Philips connected equipment located within the patient environment.

The system has to be installed to 60601-1:2005+A1:2020, Clause 16 (Medical Systems) including the use of an isolation transformer and potential equalization on the control console system and other peripheral devices.

CAUTION

The Philips system is a high-gain wide-band patient connected intravascular ultrasound (IVUS) and functional measurement (FM) system intended for use during endovascular procedures. As such, the system is susceptible to in-band (5-60MHz) reciprocal interfering signals. Reciprocal interference is non-synchronous to the IVUS system and typically transient in nature. When local intensities are sufficiently high, non-synchronous in-band transient interference is visible on the IVUS display as random "speckle" like noise, or faint, intermittent radial spokes or rings. This type of electromagnetic interference is an annoyance to the operator but typically does not render the device unusable. Non- transient (modulated continuous wave transmitters) with in-band center frequency carriers can, under high local intensity levels, "white out" the IVUS image. Under this extreme condition the IVUS system is rendered inoperable. Whenever electromagnetic interference renders the IVUS system inoperable, the appropriate action is to identify the source of the interfering signal and reduce the in-band local intensity levels sufficient to operate the IVUS system.

CAUTION

This device is not intended for use in the presence of flammable substances which could cause combustion.

CAUTION

Non-Medical equipment supplied as part of the Philips System is intended to be connected to a multiple socket-outlet isolation transformer. If any Philips or customer-supplied equipment is connected directly to a wall outlet or a multi-socket outlet, this may result in excessive leakage current per IEC 60601-1 and presents a risk of electric shock to the operator and/or patient. The user must verify that the leakage current remains below the IEC 60601-1 limits.

WARNING

Do not connect a multiple socket-outlet or extension cord to the system. This may exceed the safety limits of the system and void the warranty.

WARNING

The Philips system contains no user-serviceable components. To avoid electric shock, do not remove any panels or covers. In the event of malfunction or system damage, turn the system off, unplug the system from the power receptacle, and contact a qualified service person and Philips Customer Service.

WARNING

Changes to IT networks including network configuration updates, equipment disconnection, equipment update or upgrade, or additional equipment connection to IT networks could result in previously unidentified risks to patients, operators, or third parties. Unidentified risks should be identified, analyzed, evaluated, and controlled.

WARNING

No modification of this equipment is allowed.

CAUTION

Philips should be contacted to requalify the system any time an equipment change or significant upgrade is made to the connected hemodynamic monitoring system.

WARNING

This system is NOT explosion proof. This instrument has been designed and manufactured to minimize the hazard, but the risk, although low, has not been completely eliminated. An explosion risk can exist in sufficiently high atmospheric concentrations of such anesthetics or agents, mixed with air, or with oxygen or with nitrous oxide. The probability of occurrence of the ignition of such anesthetic mixtures depends upon their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures, and potential sparking. Sparks can be caused where electrical circuits are opened or closed by the operation of switches, connectors, fuses, or over- current releases and the like.

Operator action: The operator shall observe care when using this instrument in areas in which flammable anesthetics or flammable agents for disinfection or cleaning are applied. In the event, the atmospheric concentrations of the flammable agents are elevated, the unit should not be powered OFF if running, or should not be powered ON if it is OFF.

CAUTION

This equipment is not suitable for use in the presence of RF Electrosurgical equipment or Magnetic Resonance Imaging equipment.

CAUTION

The system PIMs are strongly attracted to the magnetic field of Stereotaxis units. Observe caution handling these devices when less than 110 cm (43 inches) from the center of these fields to prevent damage to the device or personal injury should these devices become free inside these very strong magnetic fields.

For reliable operation, the PIMr must be further than 110 cm (43 inches) from the center of the magnetic field of a Stereotaxis unit. Inside of this limit the image may become frozen on the display until the unit is moved to outside this limit. Placing the PIMr inside this limit may damage the PIMr.

WARNING

This device is not intended for monitoring vital signs and critical care parameters such as heart rate or patient blood pressure.

2.3 Electrical safety

Type CF Equipment: The heart symbol with the paddles on each side indicates that the patient interface module meets all requirements for IEC 60601-1 type CF classification. This device is protected against the voltages of defibrillation. However, it is recommended to disconnect the catheter or pressure guide wire from the patient interface module prior to defibrillation. If medically possible, remove the catheter from the patient prior to defibrillation.

The system is installed according to IEC 60601-1 requirements, including the use of an isolation transformer and potential equalization on the control console and workstation.

The workstation is connected directly to a protected power supply through an isolation transformer. Other parts may be connected to the isolation transformer, depending on the installation.

NOTE ***Do not switch the system off using the power switch on the isolation transformer. Keep the isolation transformer attached to a mains power outlet and switched on, even when the system is not in use.***

You should only switch the system on and off using the designated power switches described in these Instructions for Use. For information, see *4 Starting and stopping the system on page 32* .

Item	Specification
Patient leakage current	<10 µA
Patient leakage current	<300 µA
Patient attached input	The system's patient inputs are defibrillation proof and have been tested to comply to the tests defined in IEC60601-1 Ed3.2 clause 8.5.5.
System chassis inputs	Mains inputs of the system have undergone dielectric strength testing at 1.5kV AC per IEC60601-1 Ed3.2 clause 8.8.3.

2.4 Electromagnetic compatibility (EMC)

The Philips system is medical electrical equipment and needs special precautions regarding EMC and needs to be installed according to EMC information provided in this manual. This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses, and can radiate radio frequency energy. Other equipment may also interfere with this equipment and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.

Consult the manufacturer or Field Service technician for help.

Do not attempt to replace any cables or accessories with non-Philips-approved components as this may affect EMC performance.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this equipment including the cables specified herein. Otherwise, degradation of the performance of this equipment could occur.

WARNING

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2.5 Hazardous substances

2.5.1 California's Proposition 65

WARNING

California's Proposition 65 requires Philips to provide reasonable safety warning information when a released substance is above safe harbor levels. The internal components of this product may contain substances that, when exposed, are known to the State of California to cause cancer or reproductive harm. Based on the risk assessment performed by Philips, there is no risk or low risk to patient or hospital staff. Service personnel may be exposed to internal components while servicing the equipment. For information about risks to service personnel, refer to the service documentation.

For more information on California's Proposition 65, see the following websites:
www.philips.com/about/sustainability

www.p65warnings.ca.gov

2.5.2 REACH declaration

REACH requires Philips to provide chemical content information for Substances of Very High Concern (SVHC) if they are present above 0.1% of the product weight. The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH website for the most up-to-date list of products containing SVHC above the threshold:

www.philips.com/reach

2.5.3 Perchlorate materials

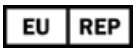
In this product, perchlorate material is present in lithium coin cells and batteries. Special handling may apply for these materials. For more information, refer to the following website:

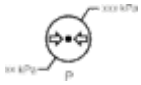
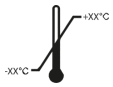
www.dtsc.ca.gov/hazardouswaste/perchlorate

2.6 Product symbols

This section provides information about symbols used on the product. For more information about symbols used on Philips products, refer to the following website:

www.symbols.philips.com

Symbol	Standard	Reference	Title	Description
	ISO 15223-1	5.1.6	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	None	N/A	Part number	Part number
	ISO 15223-1	5.7.10	Unique device identifier	Unique device identifier
	ISO 15223-1	5.7.7	Medical device	Medical device
	ISO 15223-1	5.1.2	Authorized representative in the European Union	Indicates the Authorized representative in the European Union.
	ISO 15223-1	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	21 CFR 801.15 (c)(1)(I)F	N/A	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician	N/A

Symbol	Standard	Reference	Title	Description
	ISO 15223-1	5.1.8	Importer	Indicates the entity importing the medical device into the locale.
	ISO 7000	2794	Packaging unit	To indicate the number of pieces in the package
	ISO 15223-1	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1	5.3.9	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage
	ISO 15223-1	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
IPX4	IEC 60529	5.1	Degrees of protection provided by enclosures (IP Code)	Repels splashing water, from any angle.
CE 2797	EU MDR	(EU) 2017/ 745	CE Marking of Conformity	European mark affirming product conformity to health, safety and environmental protection standards.
UK CA 0086	Medical Devices Regulations 2002	SI 2002/ 618	UK Conformity Assessed	UK mark affirming product conformity to health, safety and environmental protection standards.
	ISO/IEC 17067	ISO/IEC 17067	TUV Rheinland Mark	Meets TUV safety requirements.
	IEC 60601-1	Table D.2, Symbol 10	Follow instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1	5.4.3	Electronic instructions for use	To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form. www.philips.com/ IFU
	ISO 15223-1	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and cautions that cannot, for a variety of reasons, be presented on the medical device itself.
			Stand-by	(mode on power/on-off switch): To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption

Symbol	Standard	Reference	Title	Description
			Write and read data into and from store	(for bi-directional digital signal): To identify the control or the indicator for writing or reading (retrieving) data to/from a storage device.
			Input/output	(for bi-directional analog signal): To identify a combined input/output connector or mode.
			Output	(for analog signal): To identify an output terminal when it is necessary to distinguish between inputs and outputs.
			Equipotentiality	To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.
			Protective earth (ground)	To identify any terminal which is intended for connection to an external conductor for protection against electrical shock in case of a fault, or the terminal of a protective earth (ground) electrode.
			Caution, static magnetic field hazard	To identify areas with potentially hazardous static magnetic fields and forces in an installation.
			Defibrillation-proof type CF applied part	To identify a defibrillation-proof type CF applied part complying with IEC 60601-1.
			Input for the catheter connector	
	ISO 60417	6414	Waste electrical and electronic equipment	To indicate that separate collection for waste electric and electronic equipment (WEEE) is required.
			General symbol for recovery/ recyclable	To indicate that the marked item or its material is part of a recovery or recycling process.
			ESD Susceptibility Symbol/ Electrostatic sensitive devices	To indicate packages containing electrostatic sensitive devices. Observe precautions for handling electrostatic discharge sensitive devices
			Alternating Current	
			Direct Current	

3 About IntraSight Plus

Philips IntraSight Plus is a multi-modality, application-based platform providing a range of imaging, physiology and co-registration tools. It can be used as a stand-alone system or integrated with a compatible interventional X-ray system. For information about compatible X-ray systems, see *1.10 Compatibility on page 11*.

Philips IntraSight Plus provides qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature in adult patients eligible for endovascular procedures. It is used to support conventional angiographic procedures, providing images of vessel lumen and wall structures.

3.1 Equipment in the examination room

The main components of the system in the examination room are:

- Main display
- Patient interface module
- Touch screen module

Bedside utility box

Each component is described in more detail in the following sections. The arrangement of equipment in the examination room can be customized to suit your needs.

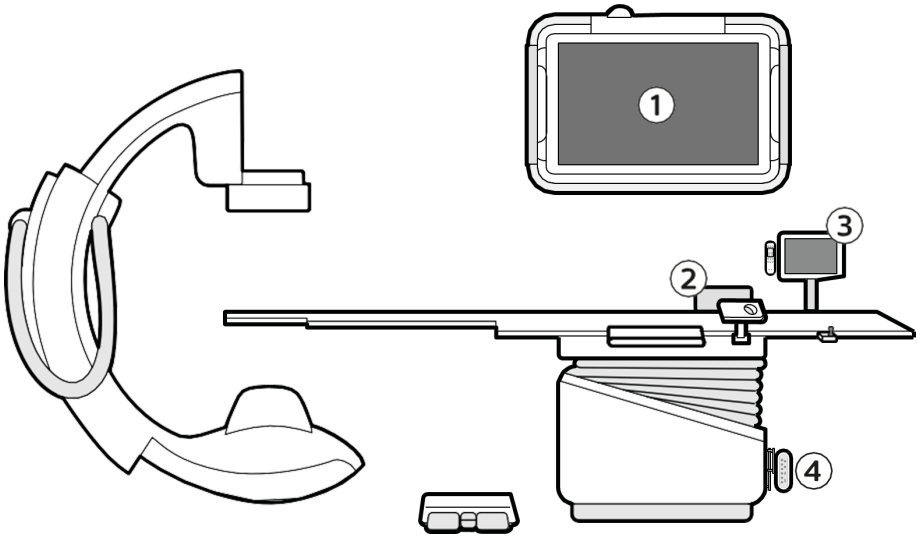


Figure 1 Typical system configuration in the examination room

Legend	
1	Main display
2	Patient interface module
3	Touch screen module
4	Bedside utility box

3.1.1 Main display

IntraSight Plus may use a dedicated monitor, mounted with the other X-ray system displays or it may be integrated into a multi-application display, depending on the configuration of your X-ray system and your examination room.

WARNING

Only Philips-approved medical-grade monitors shall be used in any area that has the potential of patient contact. This area is defined as the patient environment and represents a cone extending 1.5 meters in all directions from the patient table. Please see IEC 60601-1:2005 A1:2012 for further information.

CAUTION

Improper adjustment of the monitor settings may result in degraded image quality.

3.1.2 Patient interface module

Catheters and pressure guide wires connect to the patient interface module (PIM). The system supports three types of PIM:

- IVUS PIM (SA-PIM)
- Rotational IVUS PIM (PIMr) (also referred to as SpinVision)

Functional measurement PIM (FM-PIM)

For IVUS imaging catheters including rotational imaging catheters, the PIM excites the catheter's transducer elements to transmit ultrasonic energy to the surrounding tissue. The PIM amplifies and processes the resultant echo signals from the transducer.

For functional measurement such as iFR and FFR, the FM-PIM connects the pressure guide wire to the system allowing measurement values to be recorded.

IVUS PIM (SA-PIM)

For IVUS procedures (not rotational IVUS), the synthetic aperture PIM (SA-PIM) is used.

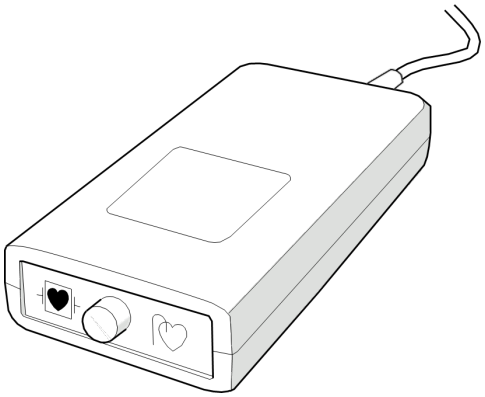


Figure 2 IVUS PIM (SA-PIM)

Rotational IVUS PIM (PIMr)

The rotational IVUS option is required when using a Refinity rotational imaging catheter for intravascular ultrasound imaging. This option consists of a rotational IVUS patient interface module (PIMr), known as SpinVision, which can be connected to the existing system PIM cable.

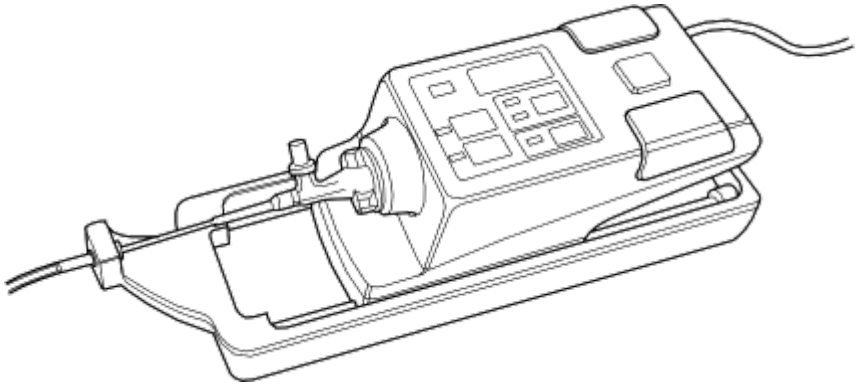


Figure 3 Rotational IVUS PIM (PIMr)

Functional measurement PIM (FM-PIM)

The functional measurement patient interface module (FM-PIM) receives real-time intravascular blood pressure signals from the pressure sensor mounted on the distal end of the compatible pressure guide wire. The information received from the pressure guide wire is processed by the FM-PIM, converted to digital format and transmitted to the IntraSight Plus system through a USB interface for display.

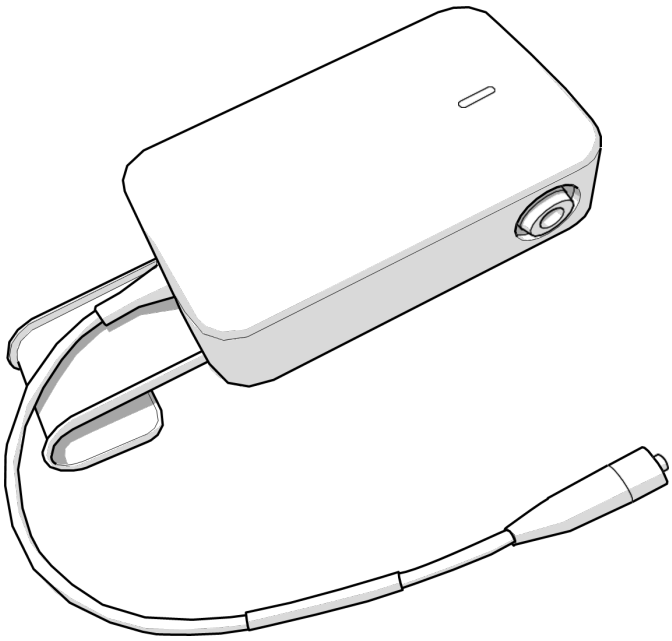


Figure 4 Functional measurement PIM (FM-PIM)

The FM-PIM has an indicator light to indicate status:

Indication	Status
Off	Power is not being received from the host system.
Solid blue	The FM-PIM is powered, functional and communicating with host system.
Flashing blue	The FM-PIM is initializing.
Solid ambe	An error has occurred.
Flashing amber	A self-test error has occurred.

3.1.3 Touch screen module

When IntraSight Plus is integrated with a Philips Azurion X-ray system, up to three multi-modality touch screen modules may be used. Using the multi-modality touch screen module, you can control functions concurrently for multiple applications, including IntraSight Plus.

For other X-ray system configurations, or in a standalone configuration, a single-modality touch screen module may be used. This allows you to control only the IntraSight Plus system.

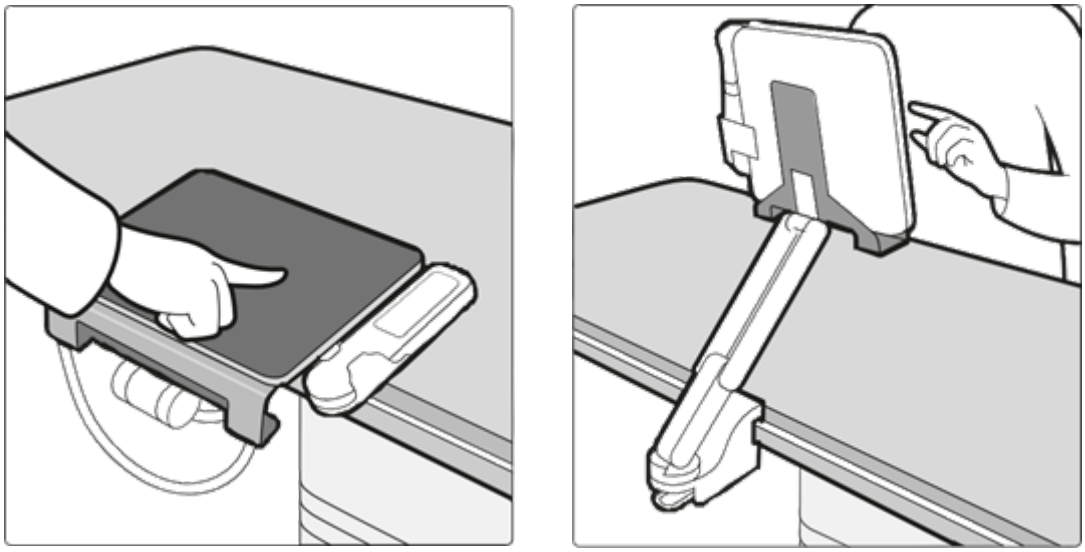


Figure 5 Touch screen module

The multi-modality touch screen module displays active and running applications in an area at the bottom of the screen. The active application is highlighted.

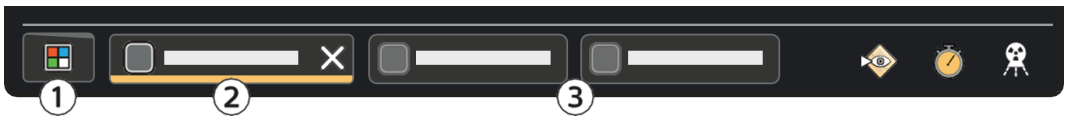


Figure 6 Multi-modality touch screen module active and running applications (with Philips Azurion X- ray systems only)

Legend	
1	Applications button (displays the X-ray system Applications window)
2	Active application tab
3	Application tabs for running applications

The touch screen module may be mounted on a swing arm that can be positioned to provide access from the same side of the tabletop or from the opposite side.

CAUTION

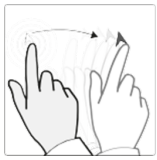
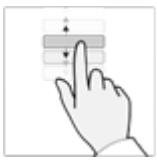
Attach the touch screen module to the bed rail using its clamp or position it so that there is sufficient slack in the cable to avoid binding during patient table movements. The touch screen module can be damaged if dropped or improperly located, potentially resulting in user or patient harm if this occurs during a procedure.

The touch screen module can be placed within the reach of the patient. The maximum temperature of the enclosure of the module can be up to 48°C (118°F). For safe use, ensure that the patient does not make contact with the module for more than 1 minute.

The touch screen module is synchronized with the main display in the examination room, ensuring that it always displays the same content but the layout may vary to accommodate the smaller screen size. The entire workflow of a study is available on the touch screen module.

Touch screen gestures

You can use touch gestures on the touch screen module.

Gesture	Action		Effect
Tap		Tap the screen on a function	
Drag		Touch an item or region in the window and move across the screen	Drags an item on the screen, or pans the image
Press		Press and hold	Displays the pointer. You can then drag the pointer to an item or region of in-terest. The pointer is hidden when you remove your finger from the screen
Slide		Touch a list item and move up or down	Touch a list item and move up or down
Stretch (Only when editing pathways or borders)		Place two fingers close together on the screen and move them apart	Zoom in at this position
Pinch (Only when editing pathways or borders)		Place two fingers a distance apart on the screen and move them towards each other	Zoom out from this position

3.1.4 Bedside utility box

The bedside utility box provides a flexible intermediary connection platform for a Philips integrated multi-modality system. It offers a manageable interface panel for connecting tableside peripherals and patient interface modules, as well as aortic signal inputs when installed. There are flexible mounting schemes to allow the installation to be adapted to various environments and needs.

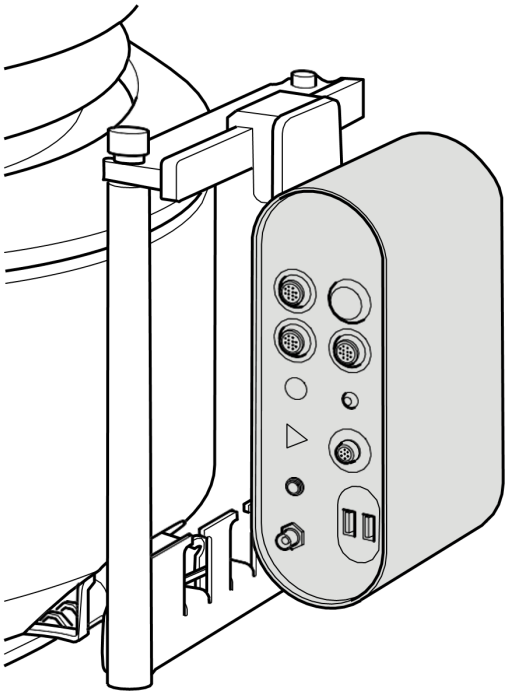


Figure 7 Bedside utility box

For more information about connections, see *18.6 Installation and equipment connections on page 178* .

3.2 Equipment in the control room

The main components of the system in the control room are:

- Control room display
- Workstation
- Keyboard and mouse
- Printer (option)

3.2.1 Control room display

The control room display is a dedicated display for IntraSight Plus and it displays the same layout and information as the main display in the examination room.

CAUTION

Improper adjustment of the monitor settings may result in degraded image quality.

3.2.2 Workstation

The IntraSight Plus workstation is a computer that performs the system processing and is connected to all the IntraSight Plus peripheral devices. A mouse and keyboard are also to be used in the control room and connected to the workstation for operating the system.

3.2.3 Printer (option)

IntraSight Plus supports the following types of printers:

- DICOM-compatible printers
- Sony UP-D25MD medical-grade printer

3.3 Applications

IntraSight Plus is intended for the qualitative and quantitative evaluation of vascular morphology. The system provides a range of imaging and physiology applications:

- QCA/Vessel enhancement (option)
- iFR (option)
  - iFR co-registration (option)
- FFR (option)
- IVUS
  - Digital IVUS
  - Rotational IVUS (option)
  - IVUS co-registration (option)
  - Tri-registration (option)
  - ChromaFlo
- Device Detection (option)

The system may include some or all of these applications, depending on its configuration and the specific options selected.

3.3.1 QCA / VE (option)

The quantitative coronary analysis (QCA) application allows you to select a vessel location and perform quantitative measurements and calculations using acquired X-ray images. The vessel enhancement (VE) function provides an enhanced image for the selected location.

QCA measurements and calculations require the x-ray image to be calibrated to allow the measurements to be expressed in units (mm or inches).

You can choose to perform vessel enhancement on the x-ray image without performing QCA.

3.3.2 iFR (option)

iFR is the instantaneous wave-Free Ratio. It is a pressure-derived physiologic index which can be used in diagnostic and interventional procedures without the need to induce hyperemia.

iFR is a proprietary technique. The measurement is performed under resting conditions and injection of vasodilators (adenosine) is not required.

Only a specific period (the wave-free period) in the diastolic portion of the heart cycle is considered. iFR is calculated using the measured distal pressure (Pd) and aortic pressure (Pa).

You can perform two types of measurements:

- Spot measurement: a static measurement, performed with the pressure guide wire in a single position.
- Pullback measurement: a dynamic measurement, performed by pulling the pressure guide wire back within a blood vessel to obtain iFR pressure measurements along the vessel, for example, on each side of a lesion.

The iFR application has a diagnostic threshold which is used as a guide for revascularization decisions.

For more information about the iFR diagnostic threshold, see *7.8 Opening a previous iFR recording for review on page 75*.

iFR co-registration (option)

When used with iFR, co-registration allows you to indicate the location of iFR measurements on the x- ray image and to perform length measurements. You can also plan treatment using virtual stents to estimate the impact in iFR measurements after treatment (iFR Estimate).

3.3.3 FFR (option)

FFR is the Fractional Flow Reserve ratio. It is a pressure-derived physiologic index used in diagnostic and interventional procedures, and is the calculated ratio of the measured pressure distal from a stenosis (Pd) and the mean aortic pressure (Pa).

FFR is measured during maximum hyperemia when blood flow to the myocardium is maximal and vascular resistance is minimal.

The FFR application has a diagnostic threshold which is used as a guide for revascularization decisions. For more information about the FFR diagnostic threshold, see *8.6 FFR guidance on page 87*.

3.3.4 IVUS

Intravascular ultrasound (IVUS) uses the acoustic impedance of vascular structures to provide cross- sectional images from inside the vessel. The IVUS catheter uses a transducer near the distal tip to emit and receive high frequency sound waves. The system analyzes the signal received by the transducer to produce a 360 degree cross-sectional image.

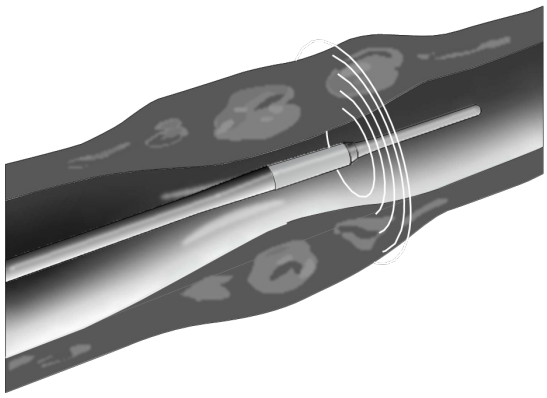


Figure 8 IVUS catheter in a vessel

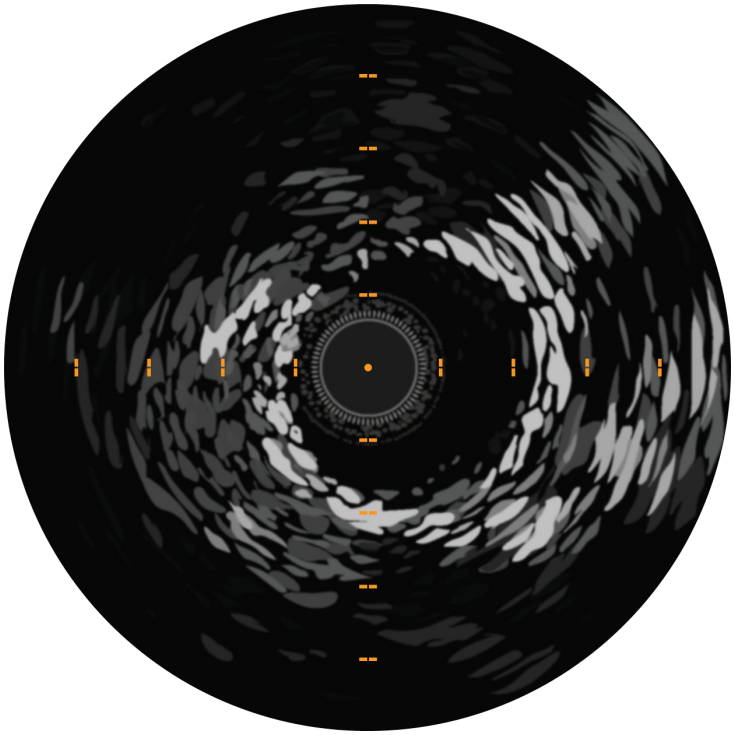


Figure 9 Example IVUS image

IVUS co-registration (option)

When used with IVUS imaging, co-registration allows you to indicate the location of an IVUS cross- sectional image on the anatomy of the x-ray image. Selecting an IVUS image from the axial view automatically retrieves the location where that image was taken on the x-ray image and indicates the corresponding location on the co-registered inline display.

Similarly, selecting a location on the x-ray image or on the inline display, indicates the same location in the IVUS images, the x-ray image and the inline display.

IVUS co-registration also allows you to perform length measurements and to plan device lengths and diameters for treatment.

IVUS co-registration is supported by the Eagle Eye Platinum catheter only.

Tri-registration (option)

For procedures with co-registered iFR measurements and co-registered IVUS images performed using the same X-ray geometry and the same x-ray image, you can combine the iFR, x-ray image, and IVUS data to achieve a tri-registered view of the procedure. This allows you to see the IVUS images and the iFR measurements on the same screen, related directly to the x-ray image.

To allow tri-registration, both the IVUS co-registration and the iFR co-registration must have the same angiographic roadmap image and pathway. The image zoom, collimation, table and C-arm positions must be the same for the IVUS pullback and the iFR pullback.

Selecting a tri-registered IVUS image or a point on the inline display, allows you to see the associated vessel location on the x-ray image and to visualize the corresponding iFR measurement values at the same location in the vessel of interest. Similarly, selecting a point on the co-registered iFR results, indicates the IVUS image associated with that anatomical location.

Tri-registration also allows you to perform length measurements to plan treatment and observe the impact of placing virtual stents on the iFR estimate.

Rotational IVUS (option)

The rotational IVUS option is required to allow use of rotational imaging catheters for IVUS imaging. This feature uses a rotational IVUS-specific patient interface module (PIMr) which can be connected to the system PIM cable.

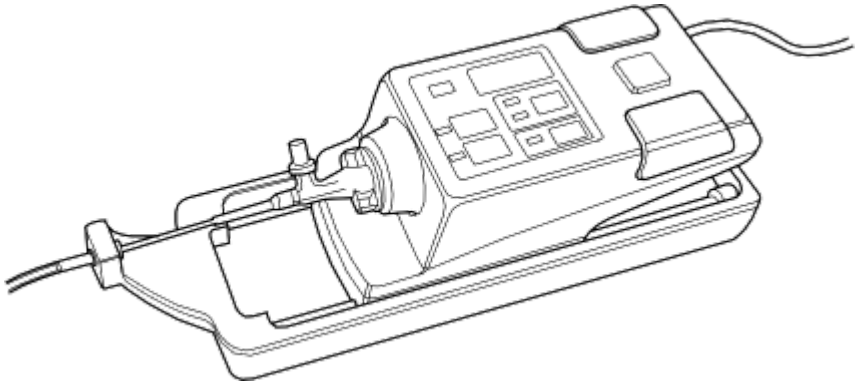


Figure 10 Optional rotational IVUS SpinVision PIM (PIMr)

ChromaFlo

ChromaFlo provides a visual representation of the presence of blood flow through the vessel. It depicts this by overlaying a two-dimensional color mapping of blood flow onto the grayscale ultrasound image.

When the ChromaFlo feature is activated, the image displays flow in the vessel with a red-to-yellow color scale in the image area. Regions with little or no presence of flow are presented with a clear or non-colored overlay. These regions appear gray in the standard display. Regions in images contain a red-yellow overlay based on the strength of the flow detected. In general, red indicates slower flow and yellow indicates faster flow.

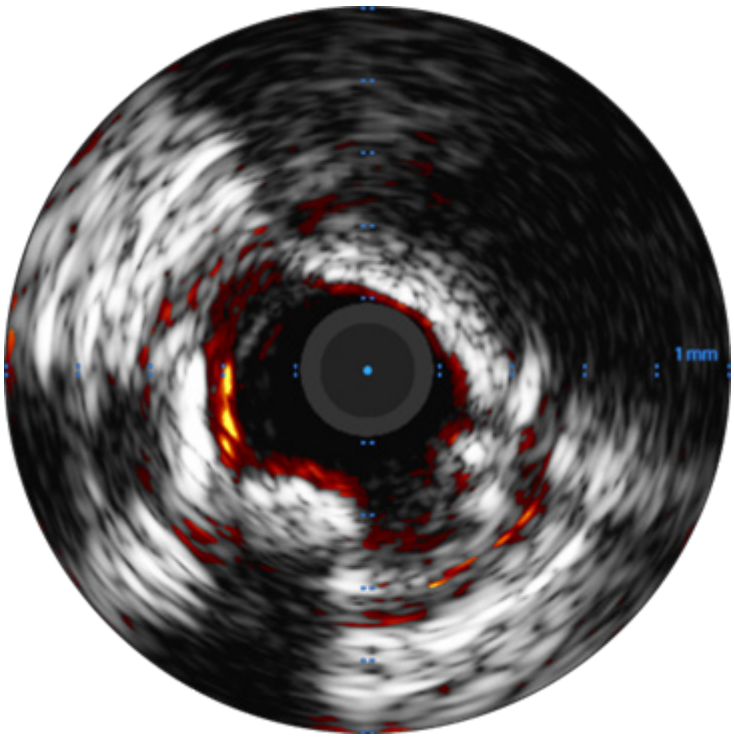


Figure 11 Example ChromaFlo image

The ChromaFlo algorithm detects the flow of particles (red blood cells) perpendicular to the imaging plane or along the long axis of the catheter. This is unlike conventional Doppler imaging in which the blood must flow toward or away from the transducer.

ChromaFlo provides a two-dimensional qualitative map of relative blood flow velocities. Due to the qualitative nature, you must not use this information to assess quantitative blood flow or to develop a numeric measure of total cross-sectional blood flow.

ChromaFlo can detect blood velocities in the following range:

- The lower limit on particle detection is between 4 cm/sec and 7 cm/sec, depending on the intervening attenuation. The upper limit is obtained with maximum tissue attenuation between the transducer and region of flow.
- The upper limit on particle detection is between 107 cm/sec and 110 cm/sec, depending on the intervening attenuation. The lower limit is obtained with maximum tissue attenuation between the transducer and region of flow.

ChromaFlo cannot be used with co-registration.

NOTE ***ChromaFlo displays a targeted region of interest and may not include the entire vessel diameter. To ensure optimal focal area, adjust the region of interest on the vessel of interest. Beyond the region of interest, any clinical phenomena can be identified using grayscale mode (ChromaFlo switched off).***

NOTE ***Available on Eagle Eye Platinum, Pioneer Plus, Visions PV .014P and PV .018, and Reconnaissance PV .018 OTW catheters.***

NOTE ***The ChromaFlo feature cannot be activated while recording. It must be activated before recording.***

NOTE ***In ChromaFlo mode, the frame rate is 22 frames per second for Eagle Eye Platinum, Pioneer Plus, Visions PV.014P, and Reconnaissance PV .018 OTW catheters, and is 20 frames per second for Visions PV .018 catheters.***

3.3.5 Device Detection (option)

The Device Detection application allows you to visualize catheters and deployed devices using X-ray images. The application detects the radiopaque markers usually found in stents and balloons and provides an enhanced and stabilized image of the detected device. You can use Device Detection to assist in deploying a device using a balloon catheter and to assist in determining whether a device has been satisfactorily deployed. The application uses fluoroscopy or exposure images and does not require a dedicated X-ray protocol.

Device Detection also allows you to visualize the movement of a device in relation to other anatomical elements such as vessels and vessel branches, and the stabilized image compensates for cardiac motion in the image.

The application automatically enhances and stabilizes the X-ray image of the detected device and generates different event detection results based on the data detected:

- Reviewing a positioning event: detecting contrast injection that generated a Device Motion Indication (DMI) image, displaying the device movement in one heart cycle and also the injection movie.
- Reviewing an inflation event: detecting a balloon inflation and generating an enhanced image of the maximum inflation of the balloon and an inflation movie.
- Reviewing an enhanced image of the focused region of interest, if no event was detected.

4 Starting and stopping the system

The system should be switched on at the start of each day and switched off at the end of each day.

4.1 Starting the system

1 To start the IntraSight Plus system, press the power button on the front of the IntraSight Plus workstation.

The requirement to log in may not be enabled in your system configuration. If you are not required to log in, the patient list or the **Welcome** screen is displayed when the workstation starts.

When the system is integrated with a Philips X-ray system, the patient list is displayed after login or auto-login.

If there is an active patient on the X-ray system, the procedure home screen is displayed.

When used with a non-Philips X-ray system, the Welcome screen is displayed after login or auto- login.

2 If the requirement to log in is enabled, select **Log In** and the login screen is displayed.

If you do not have login credentials for the IntraSight Plus system but need to perform an emergency procedure, you can click **Emergency** to immediately access the system, if this function is configured on your system.

When using the system in emergency mode, you can acquire data and perform measurements but you cannot access previous studies saved on the system or on removable media.

3 Enter your login credentials in the **Username** and Password boxes.

4 Select **Log In**.

If you enter an incorrect user name or password, an error message is displayed. If several consecutive attempts to log in are unsuccessful, your account may be locked for a period of time. If this happens, you should wait for the specified period before trying again. The number of attempts and the time you are required to wait can be configured by a system administrator. The default settings allow 5 consecutive failed attempts to log in, after which you must wait 5 minutes before trying again.

When you log into the system for the first time or if your password has expired, you are prompted to change your password.

4.2 Logging out of the system

1 Select the menu in the top right of the screen.

2 Select **Log Out...**

3 Confirm that you want to log out by selecting ***Log Off***.

4.3 Restarting the system

1 Select the menu in the top right of the screen.

2 Select Restart....

3 Confirm that you want to restart the system by selecting Restart.

4.4 Shutting down the system

NOTE ***Performing a hard shutdown (e.g., pressing the power button on the front of the IntraSight Plus workstation) can lead to loss of data. Always shutdown the system correctly as described below:***

1 Select the menu in the top right of the screen.

2 Select **Shut Down...**.

If the current study has not been ended or if there are unfinished jobs scheduled in the job viewer, the system informs you. You should take the appropriate action to complete these tasks before attempting to shut the system down.

3 Confirm that you want to shut down the system by selecting Shut Down

5 Preparing for procedures

Before starting a procedure, you should ensure the following preparations are made:

- Start the X-ray system and the IntraSight Plus system, and log in. For more information see, *4.1 Starting the system on page 32*
- Ensure the correct patient interface modules (PIMs) for the intended procedure are available.
- Obtain the catheter or pressure guide wire needed for the procedure.

5 Preparing for procedures

Before starting a procedure, you should ensure the following preparations are made:

- Start the X-ray system and the IntraSight Plus system, and log in. For more information see, *4.1 Starting the system on page 32*
- Ensure the correct patient interface modules (PIMs) for the intended procedure are available.
- Obtain the catheter or pressure guide wire needed for the procedure.

5.1 Starting a procedure with a Philips integrated x-ray system

When the IntraSight Plus system is integrated with a Philips X-ray system, the procedure is started from the X-ray system. You can use the X-ray system patient list to schedule studies and the IntraSight Plus system automatically starts studies, imports patient data, and closes studies based on your actions in the X-ray system patient list.

When images and recordings are acquired, disk space is needed to store the data. The system continually monitors the available storage disk space and notifies you if there is insufficient disk space to perform studies or if the available disk space is low. For more information, see *15.3 Storage disk space management on page 140*.

1 Prepare the patient in accordance with local operating procedures.

2 On the X-ray system, select the patient or study and start the procedure.

For information about selecting studies and starting procedures on the X-ray system, refer to the Instructions for Use provided with the X-ray system.

3 If your system has more than one procedure type license installed, select the procedure type in IntraSight Plus:

• Coronary

• Peripheral

If your system has only one procedure type license installed, the procedure type is selected automatically and you can skip this step.

The procedure home screen is displayed.

The applications and functions available depend on the procedure type selected. For example, X- ray imaging and co-registration are not available with peripheral procedures.

4 Edit or amend the patient information as desired.

For more information, see *5.4 Editing patient information on page 39*.

5 Acquire X-ray images, image sequences, and other relevant procedural data for the region of interest, as appropriate to the procedure being performed.

Note: ***X-ray images are not accessible on the IntraSight Plus system when performing peripheral procedures.***

For information about acquiring images and series, refer to the Instructions for Use provided with the X-ray system.

NOTE ***Do not use the StentBoost Live X-ray protocol to acquire images for use with IntraSight Plus as this X-ray protocol can result in errors when creating co-registered images or when using the Device Detection application.***

Acquired X-ray series are displayed as pictorials in the Series tab on the IntraSight Plus procedure home screen.

Figure 12 Series tab on the IntraSight Plus procedure home screen on the main display

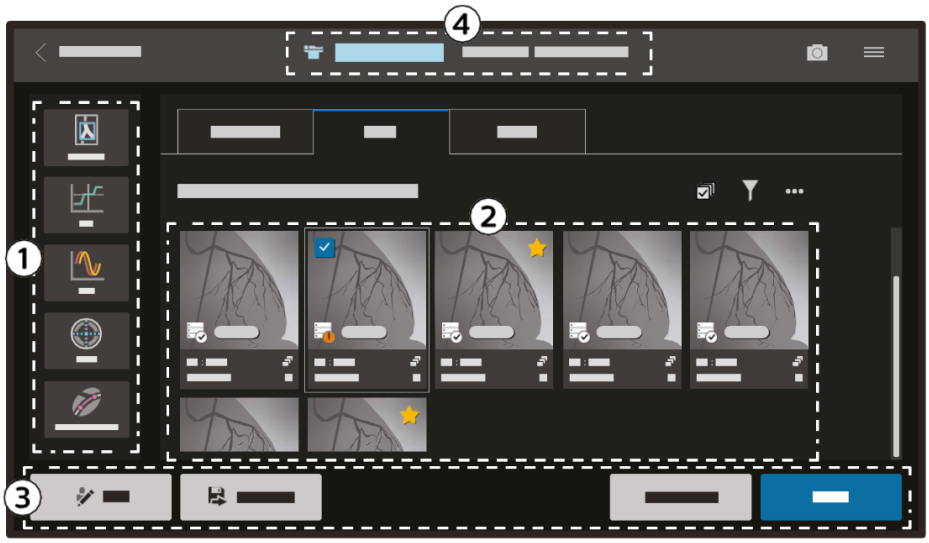


Figure 13 Series tab on the IntraSight Plus procedure home screen on the touch screen module

Legend	
1	Applications
2	Pictorials
3	Functions
4	Patient study information
5	Series preview

6 To start a quantitative coronary analysis (QCA) procedure, select the **QCA/VE** application. For more information, see *6 Performing QCA and vessel enhancement procedures on page 44*.

7 To start a functional measurement procedure, select the desired functional measurement application:

- **iFR**
- **FFR**

For more information, see:

- *7.1 Setting up the system for iFR procedures on page 55*
- *8.1 Setting up the system for FFR procedures on page 80*

8 To start an intravascular ultrasound (IVUS) procedure, select the IVUS application. For more information, see:

- *9.1 Setting up the system for IVUS procedures on page 89*
- *10.1 Setting up the system for rotational IVUS procedures on page 113*

9 To enhance the visualization of a device delivery or deployment, select the Device Detection application.

For more information, see *11 Performing Device Detection on page 120*.

10 To start a new patient study, select the new patient and start the procedure on the X-ray system.

IntraSight Plus displays a message informing you that a new patient study has started on the X-ray system. You can confirm that you want to start the new study in IntraSight Plus or you can choose to keep the existing study open in IntraSight Plus for review.

If a new patient study is started on the X-ray system for a different patient while you are using an IntraSight Plus application, the system indicates a patient mismatch between IntraSight Plus and the X-ray system. You can continue your workflow in IntraSight Plus and the patient mismatch is continually highlighted until you close the application in use.

If the X-ray system is disconnected from IntraSight Plus, you must start and stop studies manually in IntraSight Plus.

5.2 Starting a procedure with a non-Philips X-ray system

When using IntraSight Plus with a non-Philips X-ray system, the procedure is started from within IntraSight Plus and patient information is entered manually or imported from the hospital worklist.

When images and recordings are acquired, disk space is needed to store the data. The system continually monitors the available storage disk space and notifies you if there is insufficient disk space to perform studies or if the available disk space is low. For more information, see *15.3 Storage disk space management on page 140*.

1 Prepare the patient in accordance with local operating procedures.

2 At the Welcome screen, select the type of procedure to be performed.

• Coronary

• Peripheral

If your system has only one procedure type license installed, it will be the only option listed.

The applications and functions available depend on the procedure type selected. For example, X- ray imaging and co-registration are not available with peripheral procedures.

The Study Details tab on the home screen is displayed.

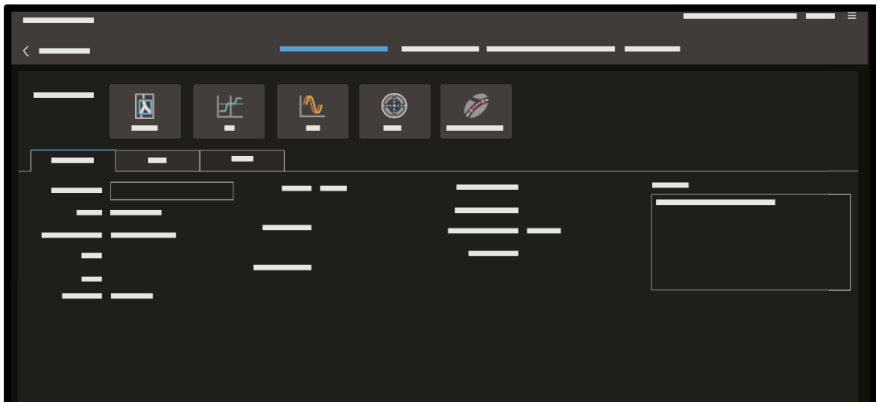


Figure 14 Study Details tab on the home screen

3 Do one of the following:

- Select **Enter Patient Information** near the top of the screen.
- Select Edit at the bottom left of the screen.

The Patient Information screen is displayed.

4 To enter the patient information manually, select each field and enter or select the desired information.

To add a patient from the hospital worklist, see *5.3 Adding a patient from the worklist on page 38*.

5 Select **Save and Close** to save the information you entered or imported. The home screen is displayed.

The patient ID must be entered before you can save the information and close the editing screen.

6 Acquire X-ray images, image sequences, and other relevant procedural data for the region of interest, as appropriate to the procedure being performed.

X-ray images are not used in peripheral procedures.

For information about acquiring images and series, refer to the Instructions for Use provided with the X-ray system.

Acquired X-ray series are displayed as pictorials in the **Series** tab on the IntraSight Plus procedure home screen.

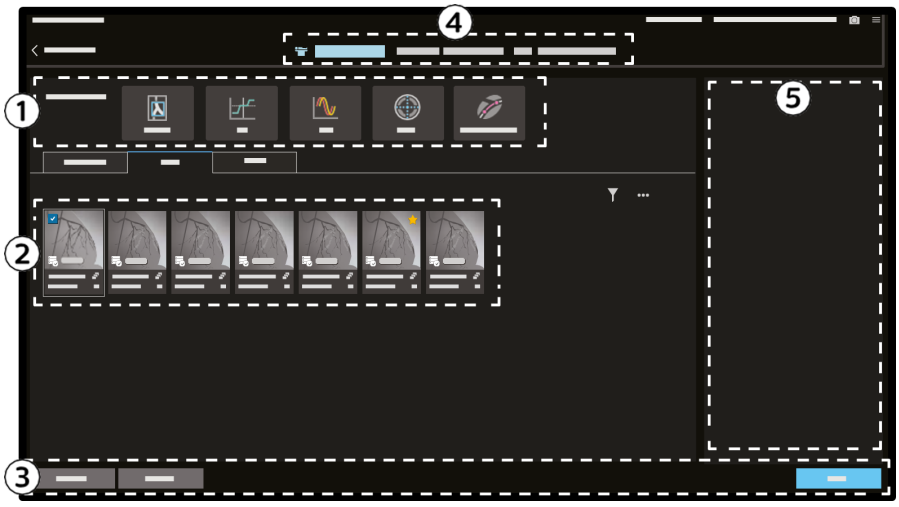


Figure 15 Series tab on the IntraSight Plus home screen on the main display

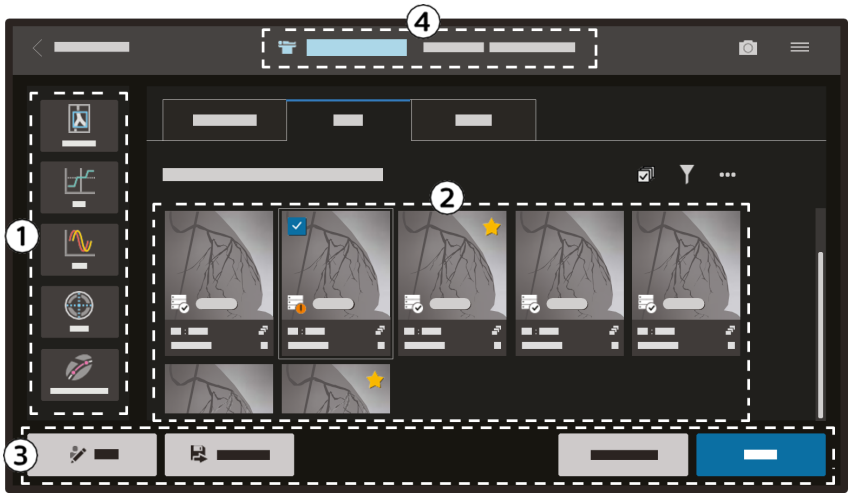


Figure 16 Series tab on the IntraSight Plus home screen on the touch screen module

7 To start a quantitative coronary analysis (QCA) procedure, select the **QCA/VE** application. For more information, see *6 Performing QCA and vessel enhancement procedures on page 44*.

8 To start a functional measurement procedure, select the desired functional measurement application:

- **iFR**
- **FFR**

For more information, see:

- *7.1 Setting up the system for iFR procedures on page 55*
- *8.1 Setting up the system for FFR procedures on page 80*

9 To start an intravascular ultrasound (IVUS) procedure, select the IVUS application.

For more information, see:

- *9.1 Setting up the system for IVUS procedures on page 89*
- *10.1 Setting up the system for rotational IVUS procedures on page 113*

10 To enhance the visualization of a device delivery or deployment, select the Device Detection application.

For more information, see *11 Performing Device Detection on page 120*.

5.3 Adding a patient from the worklist

If your system is configured with a hospital worklist manager, you can import patient information from the hospital worklist.

1 From the patient list, do one of the following:

- Select **Enter Patient Information** near the top of the screen.
- Select **Edit** at the bottom left of the screen.

The **Patient Information** screen is displayed.

2 Select **Add from Worklist**.

The hospital worklist is displayed. The hospital worklist displays the results of a default query and so the entire list may not be displayed.

3 Find the desired patient in the worklist by entering search terms like the patient's name or other information, and select **Search**.

The patients relating to your search terms are displayed in the list. You can stop a search at any time by selecting **Stop Search**.

You can start a new search by selecting **Clear All** and entering new search terms before selecting**Search** again.

4 Select the desired patient in the list.

5 To close the worklist without adding a patient, select **Cancel**.

6 To add the patient from the worklist, select **Add**.

7 Confirm that you want to add the patient by selecting **Add** in the dialog box displayed.

The patient information is added to the study information.

5.4 Editing patient information

When using the system integrated with a Philips X-ray system, patient information is managed by the X-ray system. For more information about entering patient information on your Philips X-ray system, refer to the Instructions for Use supplied with the X-ray system.

You cannot edit the patient information that is received from the Philips X-ray system or from a hospital worklist but you can edit other patient information on the IntraSight Plus system.

When using the system integrated with a non-Philips X-ray system, patient information is managed on the IntraSight Plus system.

Figure 17 **Study Details** tab on the procedure home screen

1 Select Edit in the bottom left of the procedure home screen.

The **Patient Information** screen is displayed.

2 Edit or enter patient information by selecting each field and entering or selecting the desired information.

If your system is integrated with a Philips X-ray system, you cannot select patient information that is received from the Philips X-ray system.

When you edit or enter patient information, the **Save and Close** button becomes active only when there are changes that can be saved.

3 To return to the procedure home screen without saving your changes, do the following.

a Select **Back** in the top left of the screen.

The system informs you that you have unsaved changes.

b Select **Discard Changes**.

4 To save your changes and return to the procedure home screen, select **Save and Close**.

5.5 Opening a previous study

You can open a previous study to review data.

1 Do one of the following:

- When using IntraSight Plus with a Philips X-ray system, go to the **Patients List** screen.
- When using IntraSight Plus with a non-Philips X-ray system, select **Previous Studies** at the **Welcome** screen.

The **Previous Studies** screen is displayed.

The status of each study in the patient list is indicated by a status icon.

Legend	
	In progress (current patient). [1]
	Completed
	Completing
	Completed with errors
	Imported
	Importing
	Imported with errors

[1] When using IntraSight Plus with a non-Philips X-ray system, the current (in progress) study is started from the **Welcome** screen and this icon cannot be seen in the **Previous Studies** screen.

You can sort the patient list to make studies easier to find.

- Clicking on each column heading sorts the column in ascending order.
- Clicking on the column heading again, sorts the same column in descending order. An arrow in the column heading indicates that a column has been sorted and in which order (ascending or descending).

2 To search for a study, do the following:

a Select **Search**.

b Enter the keywords for your search query.

Search results appear automatically as you enter search text.

When you enter search text, the icon changes to allow you to clear the search text if desired. You can clear the search text by selecting **Clear**.

3 Select the desired patient study in the list. Below the patient list, three tabs are displayed:

- **Study Details**: displays patient information and details of the study.
- **Series**: displays series acquired in this study.
- **History**: displays the available history of only procedures for this patient that were performed on the IntraSight Plus system.

4 Select **View**.

The procedure home screen is displayed and the same tabs are available.

5 To review a series, select the desired series in the **Series** tab and select **Open**.

If a series within a completed study is modified, the series name indicates that the series has been edited.

5.5.1 Pictorials in the Series tab

In the **Series** tab, series and images for the selected study are displayed using pictorials. Each pictorial contains information about the series or image.

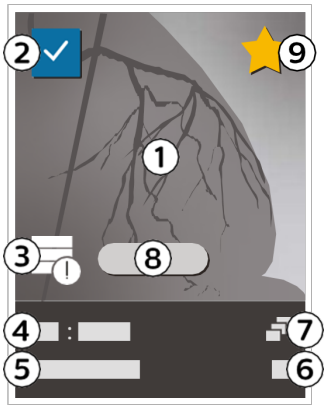


Figure 18 Pictorials in the Series tab

Legend			
1	Preview image	6	Image count or bookmark count
2	Selected series or image	7	Data type
3	Archive status	8	Co-registration or tri-registration
4	Series or image label	9	Favorite (Device Detection only)
5	Acquisition time		

Archive status

If the data has been archived to the primary archive destination, the archive status is indicated in the pictorial.

- The data was successfully archived.

- The data was not successfully archived. The archiving task failed.

The pictorial indicates the data type using icons.

Data types

The pictorial indicates the data type using icons.

Icon	Data Type	Icon	Data Type
	Exposure (cine) series		IVUS
	QCA/VE		IVUS saved frame
	VE		IVUS co-registration
	iFR spot		tri-registration
	iFR pullback		Device Detection (exposure/cine)
	iFR co-registration		Device Detection (fluoroscopy)
	FFR		Snapshot

5.6 Importing studies or series

You can import data in the form of whole studies or individual series from a network location such as a PACS or from removable media such as a DVD, Blu-ray, or a USB drive.

You can only import data that was previously exported or archived from IntraSight Plus.

5.6.1 Importing studies or series from a network location

1 Select the desired patient in the patient list.

2 Select the History tab.

The studies and series available for the selected patient are displayed. The study must have a patient ID included in the patient data to ensure that previous studies and series are displayed.

3 Select the desired study or series.

You can select more than one study or series by selecting the check mark in the top left corner of each desired series.

4 To import the study or the selected series, select Import.

5.6.2 Importing studies or series from removable media

NOTE ***USB devices may contain malicious software that could steal personal information or cause the system to malfunction. You should always scan a USB device for malicious software before connecting it to the system.***

1 If you are importing from a USB drive, insert the device into an available USB port on the IntraSight Plus system.

When importing or exporting data using a USB drive, always use a USB 3.0 port on the front of the workstation and a USB 3.0 device to ensure the data transfer speed is optimized. Using a USB port which is not USB 3.0 will result in longer import and export times.

NOTE ***The location of the USB ports in use for your system may depend on the configuration of your system. You should consult with your hospital system administrator to determine which USB port you should use.***

USB drives used with the system must be encrypted. The system prompts you to enter the drive password before you can proceed.

NOTE ***The system supports BitLocker encryption. BitLocker is a standard feature within the Microsoft Windows operating system, allowing you to encrypt your USB drive using any Windows-based computer. Other encryption tools are not supported.***

2 If you are importing from an optical disc, insert the disc into the DVD drive.

3 From the **Previous Studies screen**, select the device in the **Devices** list in the left panel.

To find studies in a folder on the removable drive, do the following:

a Select **Browse...**

b Select the desired folder on the removable drive.

c Click Select.

The studies contained in the selected folder are displayed.

5 Select the desired study in the list.

You can select more than one study at a time by selecting the check box at the left of each desired study in the list.

6 To select specific series from a study, select the desired series in the Series tab.

7 To import the study or the selected series, select Import.

5.7 Patient mismatch

When you are using IntraSight Plus with a Philips X-ray system, it is possible to select a new patient on the X-ray system while you are using an imaging or physiology application in IntraSight Plus to analyze or review data for the previous patient. This creates a patient mismatch between IntraSight Plus and the X-ray system.

If a patient mismatch is detected between the X-ray system and the IntraSight Plus system while you are using one of the IntraSight Plus imaging or physiology applications, you are notified of the mismatch, and you must take action. This may happen if the next patient is selected on the X-ray system while a procedure is being carried out or a study is being reviewed in IntraSight Plus for the current patient.

NOTE ***If a patient mismatch is detected, you should avoid acquiring X-ray images. If you acquire X- ray images while the patients are mismatched, the X-ray images are saved for the patient selected on the X-ray system and not for the patient selected in IntraSight Plus.***

When a patient mismatch is detected, a warning icon is displayed in the patient study information in the IntraSight Plus header area and the patient name is displayed in yellow. A notification is also displayed informing you that a mismatch has been detected and that you should take action.

If the mismatch is detected while you are recording data in IntraSight Plus, the notification is displayed when the recording is stopped.

If you select the current IntraSight Plus patient on the X-ray system again to resolve the mismatch, the notification displayed in IntraSight Plus is automatically cancelled, the patient name is displayed in blue in the patient study information area, and the warning icon is no longer displayed.

If you have not acquired any data for the current patient in IntraSight Plus, you can select OK to acknowledge the notification. The current IntraSight Plus application is closed and you can select how you want to proceed.

If you have acquired data for the current IntraSight Plus patient or are reviewing a study and you want to continue to do so, you can select OK to acknowledge the notification and complete the task. When you exit the current application, IntraSight Plus prompts you to select which patient you want to use in IntraSight Plus.

6 Performing QCA and vessel enhancement procedures

The QCA/VE application allows you to enhance images and perform measurements of vessels and stenoses in coronary arteries.

6.1 Analyzing series

NOTE ***The displayed measurements and calculated values are rounded.***

1 Select the QCA/VE application.

The **CINE SELECT** screen is displayed and the last acquired exposure series is displayed with guidance for you to select a target point on the image. You can select a different exposure series or you can acquire a new series if desired.

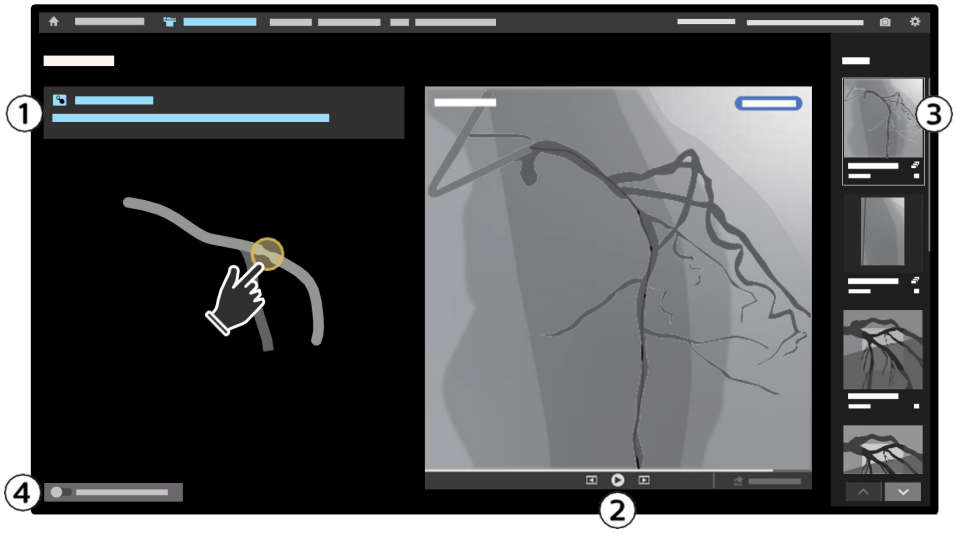


Figure 19 CINE SELECT screen

Legend	
1	Guidance
2	Last acquired exposure series
3	Series panel
4	**Vessel Enhancement Only** selector

A series for analysis must contain a minimum of 3 image frames.

2 If the exposure series displayed is unsuitable, do one of the following:

- Select an existing series to analyze from the Series panel on the right of the screen.
- Acquire a new series on the X-ray system. For more information about acquiring X-ray images, refer to the Instructions for Use provided with the X-ray system.

NOTE ***The shutters for the X-ray images should be positioned parallel to the image edges and not at an angle. Angled shutters can cause the QCA analysis to fail.***

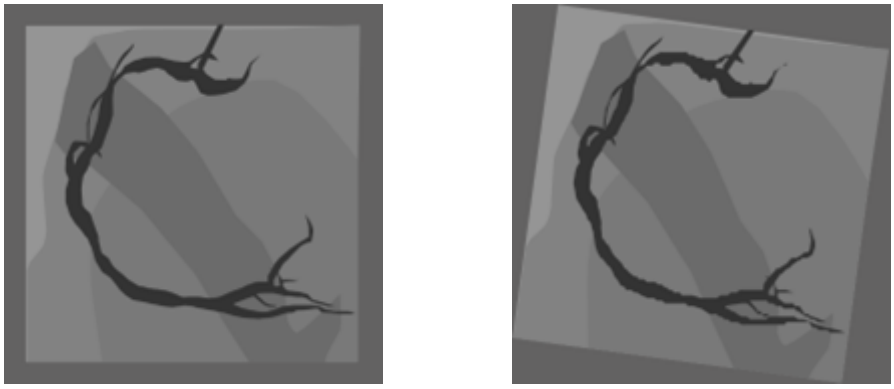


Figure 20 Correct X-ray shutter alignment (left) and incorrect X-ray shutter alignment (right)

3 Select a suitable image frame using the navigation toolbar below the series or using the mouse scroll wheel.

	Play the series.
	Pause the series.
	Move to the previous image.
	Move to the next image.

WARNING

QCA should be performed on an angiographic frame in which the vessel is predominately in the plane of the X-ray image and the vessel segment of interest is filled with contrast. If the vessel is not in the image plane (segments of the vessel are further away from or closer to the X-ray detector), then foreshortening can occur, which may lead to inaccurate QCA measurements.

4 Select a target point on the image.

The review screen is displayed.

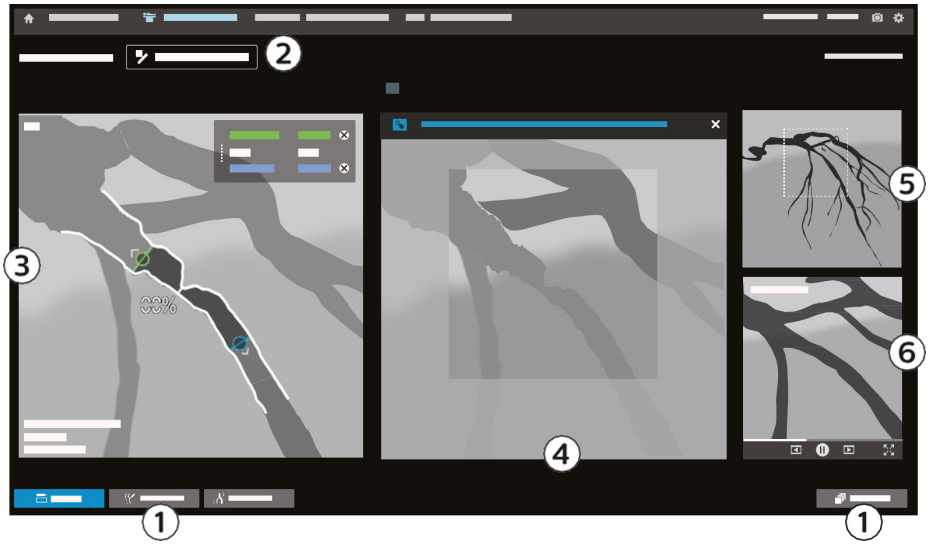


Figure 21 QCA/VE application screen layout on the main display

Figure 22 QCA/VE application screen layout on the touch screen module

Legend	
1	Function controls
2	Series label
3	Measurement results view
4	Enhanced image view
5	X-ray series orientation view
6	Enhanced stabilized movie
Note:	In a 5:4 monitor layout, two additional image but- tons are positioned below UI element 3. These buttons allow the user to expand both the stabilized clip image and the reference image.

5 Review the uncalibrated results and the enhanced region of interest.

The review screen displays the initial uncalibrated results showing the calculated percentage of stenosis for the vessel of interest. Measured results are not available until the analysis is calibrated.

6 To enlarge the enhanced stabilized movie of the region of interest, select the enlarging control.

7 To restore the enhanced stabilized movie to its original size, select the restoring control.

8 To calibrate the results and provide measurements, do the following:

a Select **Calibrate**.

The **QCA Calibration** panel is displayed.

b Select an image frame showing the tip of the guide catheter where it is clearly visible.

c Select the tip of the guide catheter on the image.

A menu of catheter sizes is displayed. Catheter sizes are expressed using French (Fr) units.

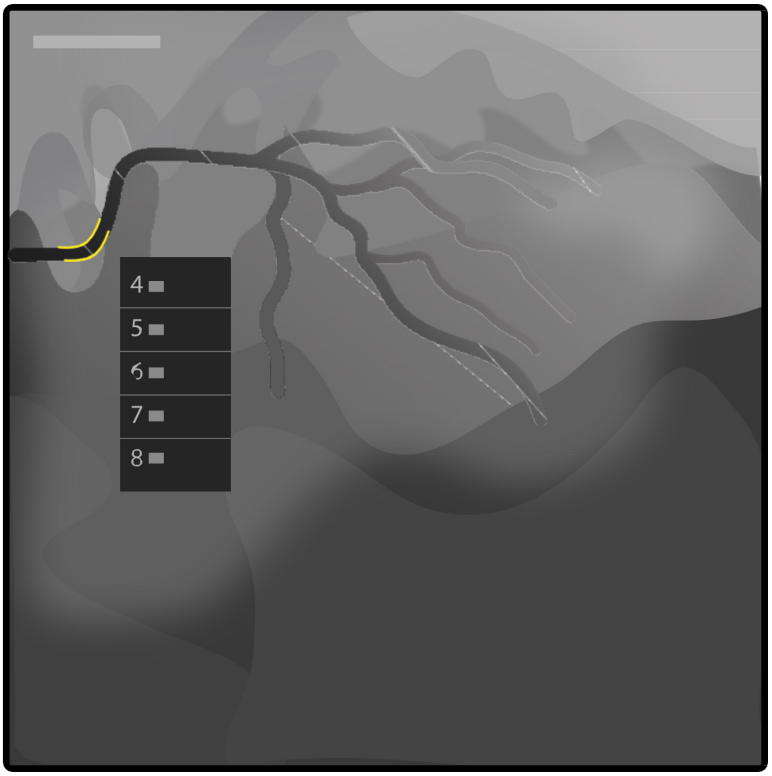


Figure 23 Catheter size menu with the guide catheter tip highlighted

WARNING

Incorrect calibration of the guide catheter may lead to incorrect QCA measurements. Select the tip of the guide catheter in an angiographic frame where it is clearly visible and confirm that its edges are accurately outlined. To increase calibration accuracy, use large diameter guide catheters (for example, 6, 7, or 8 Fr).

d Select the size of the catheter in use.

WARNING

Confirm that the correct guide catheter size has been selected and is displayed in the upper- left corner of the calibration x-ray image screen. Incorrect guide catheter size selection may lead to incorrect QCA measurements.

e To close the QCA Calibration panel without calibrating, select Cancel Calibration.

f To reset the calibration and select a new catheter size, select Reset and select the catheter tip and size again.

g To save the calibration, select Save and Close.

The QCA Calibration panel is closed and the review screen is displayed again.

Measurement values are displayed on the review screen showing the length of the analyzed vessel segment (LENGTH), the minimum lumen diameter (MLD), and the diameters of the proximal and distal reference points (PROX. REF. and DIST. REF.).

The minimum lumen diameter is the location in the analyzed vessel with the smallest diameter.

Figure 24 Minimum lumen diameter (white), proximal reference (green) and distal reference (blue) points

You can drag the panel displaying the measurement results to a new location if it is interrupting the view of the region of interest on the X-ray image.

9 To adjust the proximal reference (**PROX. REF.**) and distal reference (**DIST. REF.**) points, drag each point to the desired position.

The measurements relating to the new positions are displayed automatically.

10 To remove the proximal reference or distal reference from the analysis, select **Clear** beside the reference point to be removed.

If only one reference point is used, the percentage stenosis for the minimum lumen diameter is calculated as a percentage of the single reference point. If two reference points are provided, the percentage stenosis for the minimum lumen diameter is a percentage of the average of both reference points.

11 To add the proximal reference or distal reference point back into the image, select the desired reference below the measurements.

12 To extend the segmentation region, click on the vessel outside the existing segmentation region. The segmentation region extends to the selected point.

13 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre-defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

14 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

15 To start a new analysis, select **New QCA/VE**.

16 To return to the procedure home screen, select **Home**.

6.1.1 Editing the vessel border

If the automatic segmentation does not follow the vessel border at a particular point, you can edit the vessel border to manually adjust the segmentation to provide corrected measurements.

1 Select **Edit Borders**.

2 To zoom the image in or out to achieve the desired view, use the mouse scroll wheel.

On the touch screen module, you can zoom in and out of the image using the pinch and stretch gestures. For more information, see *Touch screen gestures on page 25*.

3 To pan the image to achieve the desired view, hold down the right mouse button and drag the image or use two fingers on the touch screen module to drag the image to the desired position.

4 Drag the desired vessel border line to a new position.

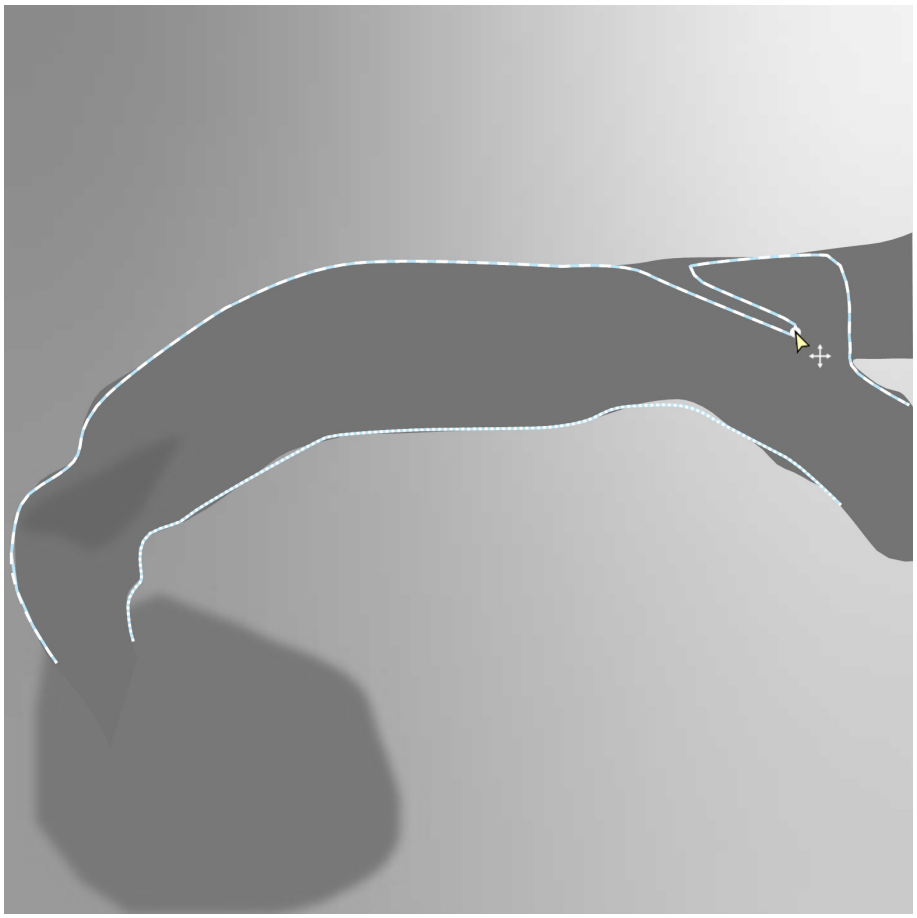


Figure 25 Dragging the vessel border

To edit the vessel border using the touch screen module, select the border that you want to edit and then position the pointer by selecting and holding the yellow ring. The yellow ring shrinks in size onto the pointer indicating that you are now controlling the pointer without having your finger directly over the pointer. This functionality allows you to control the pointer while still being able to see it.

Figure 26 Touch screen module control

5 To undo your edit, select **Undo Edit**.

6 To redo an undone edit, select **Redo Edit**.

7 To close the **Edit Borders** panel without saving your changes, select **Cancel**.

8 To close the **Edit Borders** panel and save your changes, select **Done**.

6.1.2 Editing a vessel bifurcation

When a vessel bifurcation has been analyzed, you can change which branch of the bifurcation is included in the analysis.

1 Select **Edit Bifurcation**.

Guidance is displayed to assist you in selecting the desired vessel path.

2 Select the proximal reference point within the area of interest. A marker is placed on the selected proximal location **(1)**.

3 Select the distal reference point in the desired bifurcation vessel branch. A marker is placed on the selected branch location **(2)**.

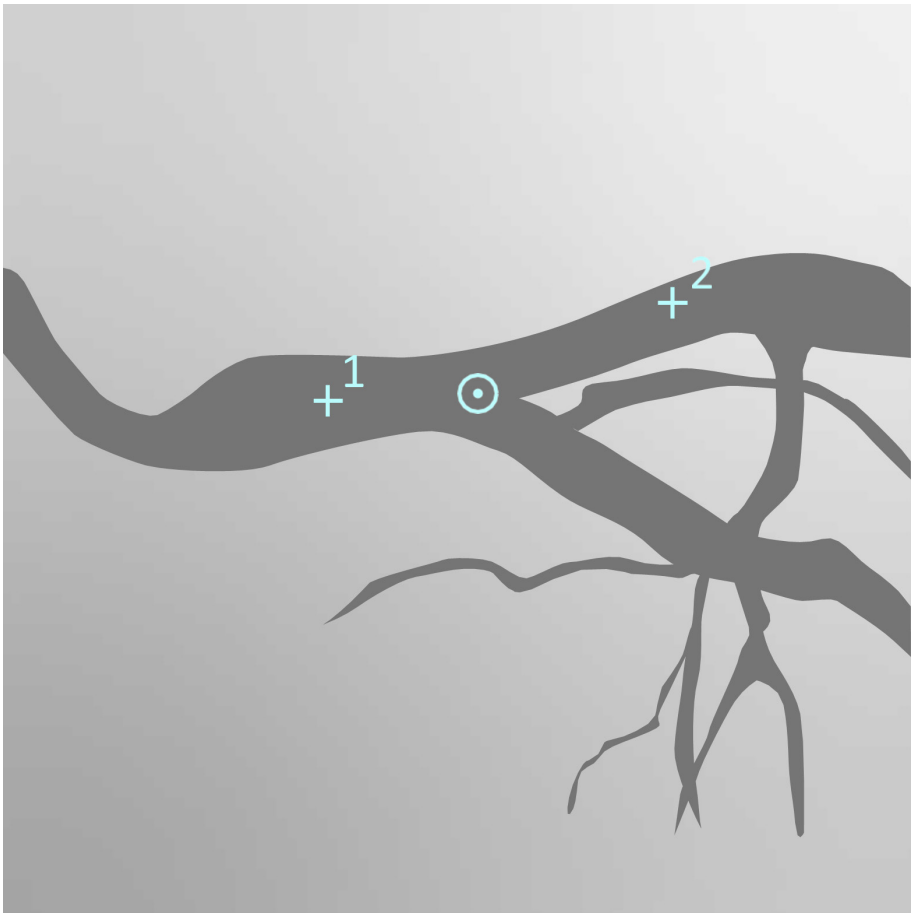


Figure 27 Proximal and distal markers

4 To adjust the marker positions, drag each marker to the desired location.

5 To return to the **QCA/VE** screen without saving the edited bifurcation, select **Cancel**.

6 To proceed and save the edited bifurcation, select **Update QCA**. The **QCA/VE** screen is displayed showing the updated results.

6.2 Enhancing the vessel image without analysis

You can enhance the image of a vessel without performing quantitative coronary analysis (QCA), for example, when viewing a previously placed stent.

1 Select the **QCA/VE** application.

The **CINE SELECT** screen is displayed and the last acquired exposure series is displayed with guidance for you to select a target point on the image. You can select a different exposure series or you can acquire a new series if desired.

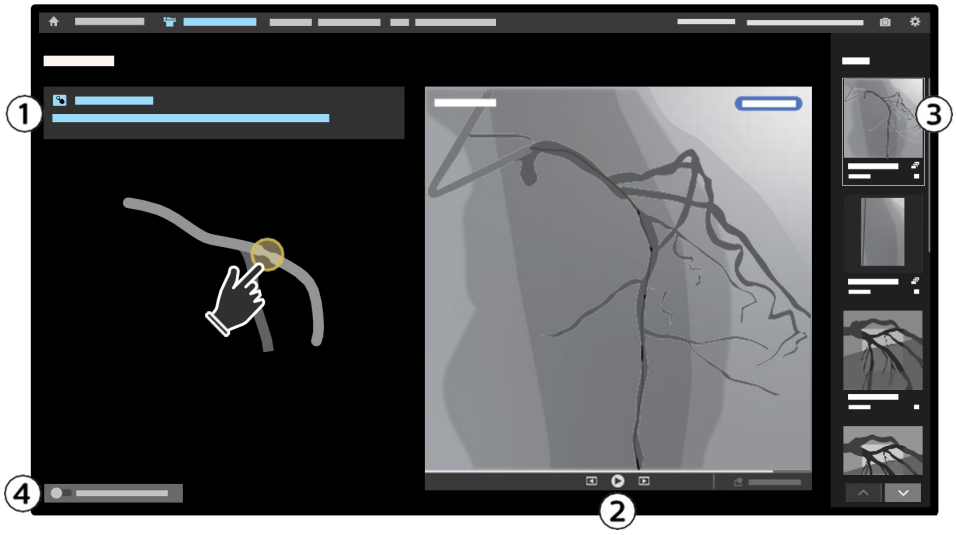


Figure 28 **CINE SELECT** screen

Legend	
1	Guidance
2	Last acquired exposure series
3	**Series** panel
4	**Vessel Enhancement Only** selector

2 If the exposure series displayed is unsuitable, do one of the following:

- Select an existing series to analyze from the Series panel on the right of the screen.

  Acquire a new series on the X-ray system. For more information about acquiring X-ray images, refer to the Instructions for Use provided with the X-ray system.

3 Select **Vessel Enhancement Only**.

The displayed guidance changes indicating that you should select a target point on the image to be enhanced.

If the selected X-ray series has been acquired without contrast, the system detects this and automatically selects Vessel Enhancement Only.

4 Select a suitable image frame using the navigation toolbar below the series or using the mouse scroll wheel.

5 Select the target point on the vessel of interest.

The review screen is displayed showing the selected vessel of interest with the image enhanced.

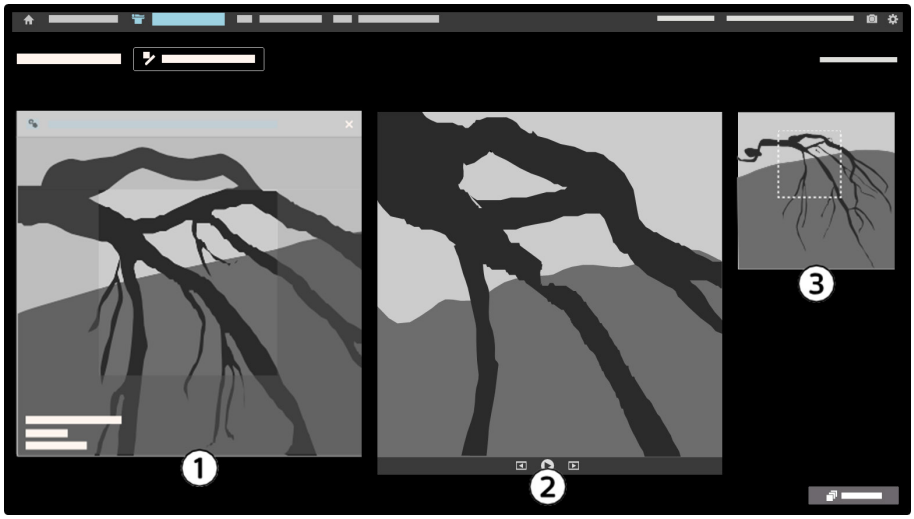


Figure 29 Vessel enhancement review screen

Legend	
1	Enhanced image view
2	Enhanced stabilized movie
3	Angiogram reference view (main display only)

6 To enhance an additional area of the image, select the desired area in the enhanced image view.

7 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre- defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

8 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

9 To return to the procedure home screen, select **Home**.

6.3 Opening a previous QCA/VE series for review

You can open a previous QCA/VE series, allowing you to review the recording and measurement values.

1 In the patient list, select the desired patient study and select **View**.

The selected study opens and the procedure home screen is displayed.

2 Select the desired series in the **Series** tab.

Pictorials in the **Series** tab identify **QCA/VE** series in the relevant series names. You can also see a preview of the data which indicates that the series is a QCA/VE series.

3 Select **Open**.

Series marked as **QCA/VE** open automatically in the **QCA/VE** application. You cannot edit the previous QCA/VE series or adjust the QCA measurement but you can create more VE results. If you need to make adjustments to the measurement, you should create a new measurement.

6.4 Adjusting the QCA/VE application settings

You can customize the settings used during QCA analysis to suit the way you want to work and to provide the information on the screen that you want to see.

When you open the settings menu for an application, you must select the settings on the main . A dialog panel is displayed on the touch screen module, informing you that settings should be selected on the main display. If you close the dialog panel on the touch screen module, the application settings menu on the main display is also closed. When you close the application settings menu on the main display, the dialog panel on the touch screen module is also closed.

1 Select the **QCA/VE** application.

2 To open the settings menu for QCA, select **QCA Settings** in the top right corner of the QCA/VE application screen.

3 Using the **Default Vessel Length (mm)** drop-down list, select the default vessel segmentation length that is displayed when reviewing calibrated QCA measurements.

You can select a value between 10 mm and 35 mm. The default value is 25 mm.

4 Using the **On Screen Ruler (mm)** drop-down list, select the default scale used on the on-screen ruler when reviewing calibrated QCA measurements.

You can select a value between 2 mm and 20 mm. The default value is 5 mm.

5 Select the **Guiding Catheters (Fr)** sizes that you want displayed in the calibration list when calibrating a QCA analysis.

The default selected sizes are 4 Fr, 5 Fr, 6 Fr, 7 Fr, and 8 Fr.

6 To close the menu, select **Close**.

7 Performing iFR measurements

The iFR application allows you to perform functional measurements without administering a hyperemic agent to help you determine if treatment is necessary.

The system calculates the instantaneous wave-Free Ratio (iFR) using only the wave-free period of the aortic and distal pressure cycles within each cardiac cycle, and displays the value during data acquisition or while reviewing a study.

You can perform two types of measurements:

- Spot measurement: a static measurement, performed with the pressure guide wire in a single position.

Pullback measurement: a dynamic measurement, performed by pulling the pressure guide wire back within a blood vessel to obtain iFR pressure measurements along the vessel, for example, on each side of a lesion.

You can perform iFR pullback measurements with or without co-registration. A co-registered iFR result allows you to see the associated vessel location of the selected measurement point on the x-ray image and to perform accurate length measurements.

7.1 Setting up the system for iFR procedures

Pressure guide wires connect to the system through a patient interface module (PIM). The PIM is typically left connected to the bedside utility box between studies, but may need to be reconnected if removed after a study or if a cable becomes disconnected.

Before a PIM is connected to the system and a catheter or pressure guide wire type configured, the system displays guidance for connecting the PIM. Before connecting or placing the PIM, inspect it and its cable for damage and do not use if damage is found.

WARNING

Defibrillator protection requires the use of OmniWire and FM-PIM including specified cables. The use of any accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the system as re-placement parts for internal components, may result in de-creased defibrillator protection and increased electro-magnetic emissions or decreased electro-magnetic immunity of the system.

CAUTION

The PIM's cable may be damaged if equipment is rolled on it. Do not pull on the cable, place the cable in a high traffic area, or use excessive force as this may cause damage. If the PIM is dropped, there could be damage to the body or internal electronics. Do not use the PIM if the outer case, cable, or connectors appear damaged.

CAUTION

If used in the sterile field, place the PIM in a sterile barrier pouch or bag using standard sterile techniques.

CAUTION

Attach the PIM to the bed rail using its clamp or place in the use location so that there is sufficient slack in the cable to avoid binding during patient table movements. The PIM or cable can be damaged if dropped or improperly located, potentially resulting in user or patient harm if this occurs during a procedure.

CAUTION

The PIM can be damaged if contrast fluid or saline enter the wire connector port. This may cause irregular or permanent loss of communication with the pressure guide wire leading to inaccurate measurements. The PIM should not be placed below an IV pole where liquids such as saline or contrast may drip onto the PIM or into the connector port and cause damage.

1 Select the iFR application.

2 Ensure you are using the FM-PIM for the procedure.

iFR procedures require the functional measurement PIM (FM-PIM).

Animated guidance is displayed to assist you if the PIM is not connected.

3 Align the markers on the cable connector of the short cable attached to the PIM with the connector at the patient end of the PIM cable from the system, and slide the connections together until you hear a click.

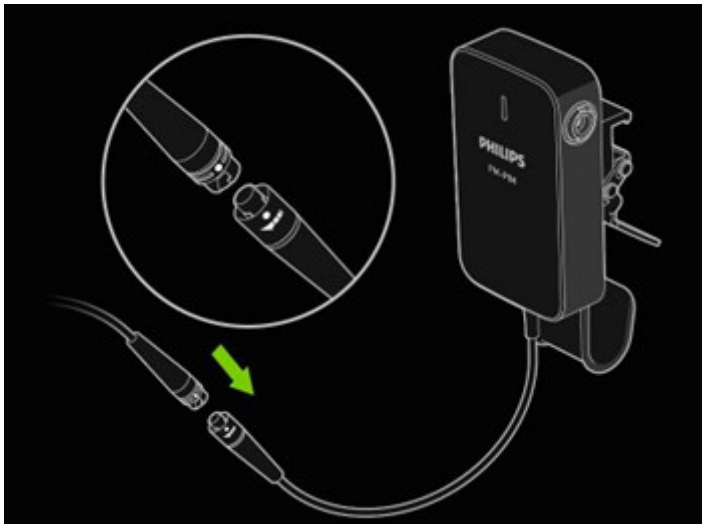


Figure 30 Animated guidance for connecting the FM-PIM

The system detects the PIM and displays the next appropriate guidance step.

4 Prepare and connect the pressure guide wire to the PIM.

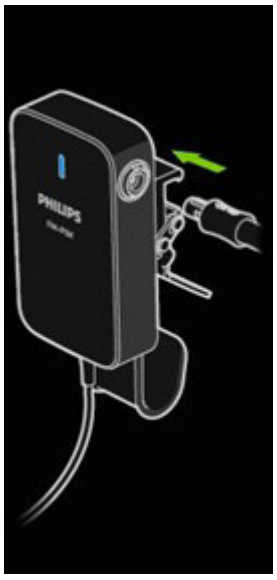


Figure 31 Animated guidance for connecting the pressure wire

CAUTION

The PIM can be damaged if contrast fluid or saline enter the wire connector port. This may cause irregular or permanent loss of communication with the pressure guide wire leading to inaccurate measurements. Care should be taken to not expose the pressure guide wire plug to fluid that can be transferred to the PIM when connecting the wire.

NOTE ***Refer to the pressure guide wire Instructions for Use for directions before and during the procedure. Refer to the catheter or pressure guide wire label for specific insertion instructions. Consult the catheter or pressure guide wire package insert for a full description of warnings, precautions, and use instructions.***

Once the pressure guide wire is connected, the system initializes and autozeroes the pressure guide wire.

5 Verify that the connections are secure.

The system recognizes the installed pressure guide wire for each study until a different type is installed. Any user-defined values are reset to the default values at the beginning of each study.

6 Introduce the pressure guide wire through the hemostatic valve of the guide catheter and into the patient.

7 Position the pressure guide wire so that the pressure sensor, which is proximally adjacent to the radiopaque tip, is located just outside the opening of the guide catheter.

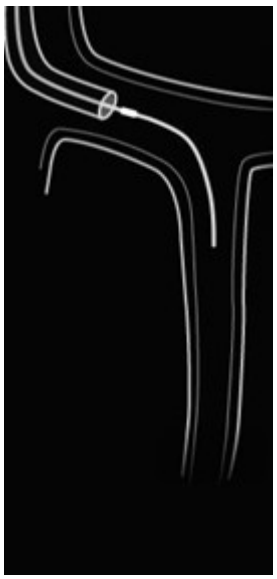


Figure 32 Animated guidance for advancing the pressure guide wire

8 Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve.

Follow the applicable hospital procedures and refer to the Instructions for Use provided with the guide catheter and pressure guide wire.

WARNING

Flushing the guide catheter, removing the introducer needle, and tightening the hemostatic valve are important steps to get an accurate Pa pressure and therefore an accurate normalization, iFR measurement, or FFR measurement.

9 Once the pressure waveforms are stable, normalize the pressure guide wire by selecting **Normalize**.

The distal pressure **Pd** is equalized to the aortic pressure **Pa** resulting in a pressure gradient **Pd/Pa** of 1.0.

After normalization is completed, the live screen is displayed. A snapshot of the normalization screen is created automatically and stored in the **Series** tab as evidence of the normalization.

10 Verify that **Pd** is equal to **Pa**, the **Pd/Pa** ratio is approximately 1.0, and that the **Pa** and **Pd** waveforms overlap and have similar shapes.

If the **Pd/Pa** ratio is not approximately 1.0, you should repeat the normalization step.

WARNING

Normalization adjusts the distal pressure (Pd) measurement from the pressure guide wire to match the aortic pressure (Pa) reading and adjusts the time delay between the Pd and Pa signals to synchronize their display. After normalization, the Pd/Pa ratio should be approximately 1.0 and the Pd and Pa waveforms should overlap in order to obtain accurate measurements. Repeat normalization if this results is not obtained. Discontinue use of the system and contact technical support if normalization fails after multiple attempts

7.2 Using the iFR live screen

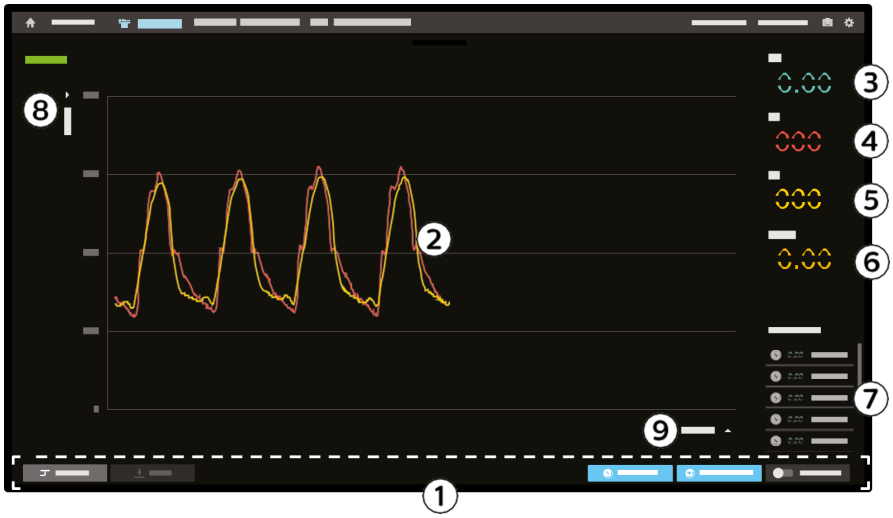


Figure 33 iFR live screen layout on the main display

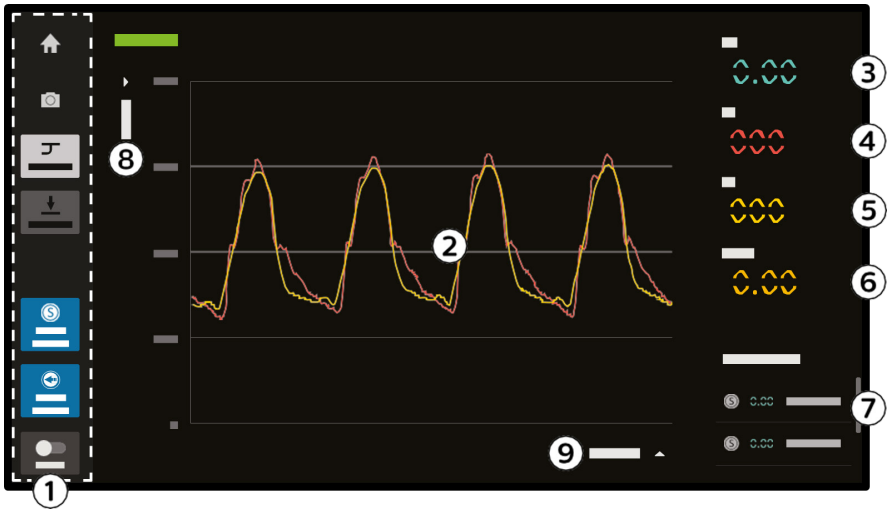


Figure 34 iFR live screen layout on the touch screen module

Legend			
1	Function controls	6	Pd / Pa ratio
2	Cardiac waveforms: Pa (red) and Pd (yellow)	7	Previous series
3	iFR value	8	Pressure range (0-200 mmHg or 0-300 mmHg)
4	Pa value (mmHg)	9	Sweep speed
5	Pd value (mmHg)		

1 To change the pressure range used to display the waveforms, select a new range using the pressure range control at the top left of the recording.

2 To adjust the sweep speed of the live waveform trace, select the desired sweep speed using the sweep speed control at the bottom right of the graph.

3 To display a different iFR measurement recording from the same study, select the desired measurement recording in the **Previous series** list.

7.3 Balancing aortic pressure

The aortic pressure can be balanced (zeroed) to ensure the correct display of the aortic transducer pressure signal.

1 Open the pressure transducer to air so that no pressure is being applied.

2 Zero the hemodynamic monitoring system.

For more information, refer to the Instructions for Use provided with the hemodynamic monitoring system.

3 Select **Zero Pa** on the live waveform screen. Note: Utilization of **Zero Pa** in FM-PIM on the IntraSight Plus system is optional, as it has been previously conducted on the hemodynamic system.

4 Close the valve on the pressure transducer.

5 Verify that the **Pa** value displayed on IntraSight Plus matches the hemodynamic monitor reading.

7.4 Performing iFR spot measurements

An iFR spot measurement is a measurement at a single location in the vessel of interest.

NOTE ***The displayed measurements and calculated values are rounded.***

1 Select the iFR application.

WARNING

The patient's respiration can affect the accuracy of physiological measurements. Ensure breathing is consistent during the measurement.

2 Ensure the patient interface module for functional measurements (FM-PIM) remains connected to the system and the pressure guide wire is connected to the FM-PIM.

For more information about connecting the patient interface module, see *7.1 Setting up the system for iFR procedures on page 55*.

3 Using fluoroscopy, advance the pressure guide wire beyond the lesion of interest, positioning the pressure sensor at the point where you want to perform the measurement, distal to the lesion.

Typically, you should advance the pressure guide wire a distance of at least 3 times the vessel diameter, beyond the lesion of interest.

4 Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve.

Follow the applicable hospital procedures and refer to the Instructions for Use provided with the guide catheter and pressure guide wire.

WARNING

Flushing the guide catheter, removing the introducer needle, and tightening the hemostatic valve are important steps to get an accurate Pa pressure and therefore an accurate normalization, iFR measurement, or FFR measurement.

5 Observe the live iFR value to confirm that it is stable and that the patient is not experiencing hyperemia from the saline flush.

WARNING

Flushing with contrast or saline can induce a short-term hyperemia that lowers the Pd and Pa pressure readings resulting in incorrect iFR measurements. The live iFR value should be checked for stability before making a measurement.

6 Select **Record Spot**.

The system records a minimum of five cardiac cycles and stops recording automatically when a stable measurement result has been achieved. The measured iFR Spot value and the recorded cardiac cycles are displayed. The iFR measurement value is the average of the recorded data cycles. If irregular cardiac cycles result in an unstable iFR result, the iFR value is not displayed and the iFR measurement should be repeated after reviewing the recorded waveforms.

Individual cardiac cycles that meet the following criteria are excluded from iFR spot measurements and are colored grey in the waveform display:

- Cycles shorter than 0.4 seconds (heart rate > 150 beats per minute)
- Cycles longer than 2 seconds (heart rate < 30 beats per minute)
- Cycles without a viable diastolic (wave-free) period over which iFR can be calculated
- Cycles with a single cycle iFR value difference more than ± 0.15 from the average value determined during the iFR calculation

The wave-free period of each cardiac cycle is displayed in green. This is the part of the cardiac cycle waveform that is used to calculate the iFR value.

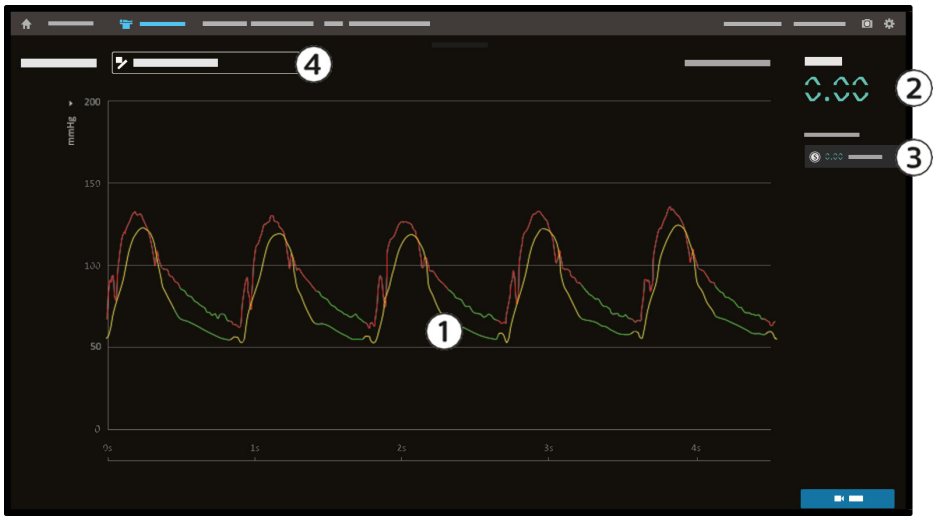


Figure 35 iFR application spot measurement review screen layout on the main display

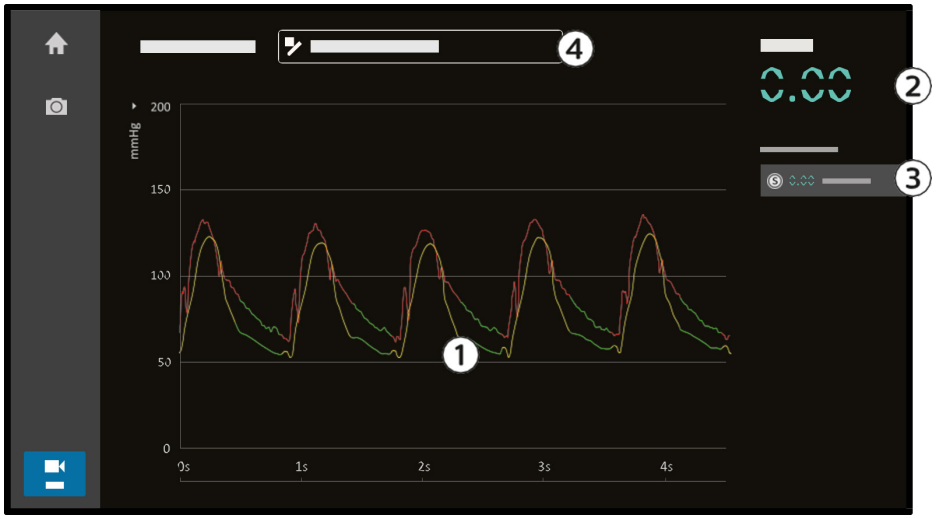


Figure 36 iFR application spot measurement review screen layout on the touch screen module

Legend	
1	Cardiac waveforms: Pa (red), Pd (yellow), wave- free period (green)
2	iFR spot value
3	Previous series
4	Series label

7 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre- defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

8 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

9 To return to the live waveform display, select **Live**.

10 After completing the iFR assessment of a vessel, return the pressure guide wire sensor to the normalization location and confirm that the **Pd/Pa** ratio is still 1.0 and that the **Pd** and **Pa** waveforms still overlap and have a similar appearance.

WARNING

If the normalization check Pd/Pa ratio is not equal to 1.0 or the waveforms do not overlap and have a similar appearance, then the previous iFR measurements may not be accurate. Consider normalizing and repeating the iFR measurements.

7.5 Performing iFR pullback measurements with co-registration

An iFR pullback measurement is a dynamic measurement, performed by pulling the pressure guide wire back within a blood vessel to obtain iFR pressure measurements along the blood vessel, for example, on each side of a lesion.

When performed with co-registration enabled, you can visualize each individual measured point in relation to the anatomy on the x-ray image and perform length measurements using virtual stents.

WARNING

Poor X-ray image quality or low frame rate (<15 fps) may lead to co-registration failure or inaccurate co-registration results. The presence of CABG wires, additional guide wires, pacing leads, surgery clips, or other metallic objects within the X-ray image may also lead to co-registration failure or inaccurate co-registration results. Ensure the guide catheter, guide wire tip, and the iFR pressure sensor are fully visible within the fluoroscopy images. Failure to do so may result in inaccurate co- registration.

NOTE ***The shutters for the X-ray images should be positioned parallel to the image edges and not at an angle. Angled shutters can cause the co-registration to fail. Use the X-ray mode that provides the highest image quality and set the X-ray field of view to 18-22 cm. On a Philips Azurion X-ray system, enable Fluoroscopy Flavor 3 or SyncVision/Co-Registration mode for optimal settings.***

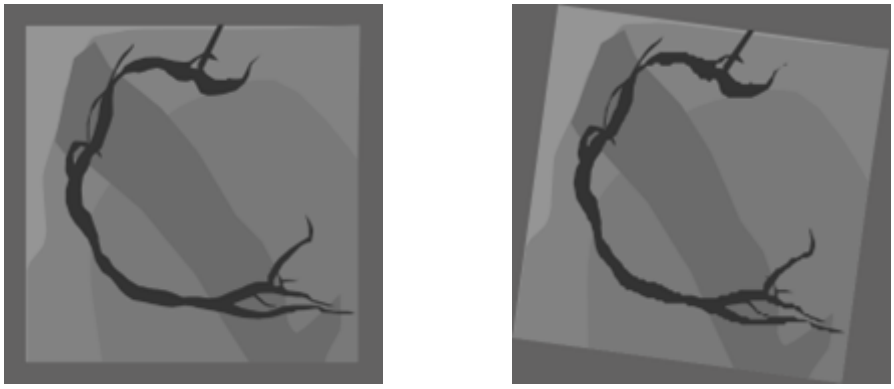


Figure 37 Correct X-ray shutter alignment (left) and incorrect X-ray shutter alignment (right)

NOTE ***The displayed measurements and calculated values are rounded.***

1 Select the **iFR** application.

WARNING

The patient's respiration can affect the accuracy of physiological measurements. Ensure breathing is consistent during the measurement.

2 Ensure the patient interface module for functional measurements (FM-PIM) remains connected to the system and the pressure guide wire is connected to the FM-PIM.

For more information about connecting the patient interface module, see *7.1 Setting up the system for iFR procedures on page 55*.

3 Switch on **Co-registration** if disabled.

4 Advance the pressure guide wire distal of all stenoses in the vessel of interest.

5 Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve.

Follow the applicable hospital procedures and refer to the Instructions for Use provided with the guide catheter and pressure guide wire.

WARNING

Flushing the guide catheter, removing the introducer needle, and tightening the hemostatic valve are important steps to get an accurate Pa pressure and therefore an accurate normalization, iFR measurement, or FFR measurement.

6 Observe the live iFR value to confirm that it is stable and that the patient is not experiencing hyperemia from the saline flush.

WARNING

Flushing with contrast or saline can induce a short-term hyperemia that lowers the Pd and Pa pressure readings resulting in incorrect iFR measurements. The live iFR value should be checked for stability before making a measurement.

7 Select **Record Pullback**.

The system starts recording measurements and a graph is displayed showing the measurements being recorded. The cardiac cycles are displayed below the graph.

Record Pullback is enabled when the system detects sufficient cardiac cycles to calculate Pd/Pa. The time taken for this is influenced by the selected MAP period.

8 When the countdown timer reaches zero, start fluoroscopy and slowly pull the pressure guide wire proximally across the length of vessel to be assessed.

NOTE ***Do not pull the pressure guide wire back until you see the blue graph line starting to be displayed.***

WARNING

Changes in the X-ray geometry or patient positioning during the pullback recording may lead to inaccurate co-registration results. Avoid changing the zoom or collimator and do not move the patient table or C-arm while recording a pullback and then making an x-ray image.

WARNING

A pullback rate faster than the recommended speed of 2 mm/sec, a non-continuous pullback, or a pullback that is performed under less than 7 seconds of live fluoroscopy may lead to co- registration failure or inaccurate co-registration results.

Perform the pullback under continuous fluoroscopy at an approximate speed of 2 mm/sec. The X- ray frame rate should preferably be set to 15 fps, but no less than 7.5 fps.

The trend line (solid line) and the raw data line (dotted line) are displayed as you pull the pressure guide wire through the vessel.

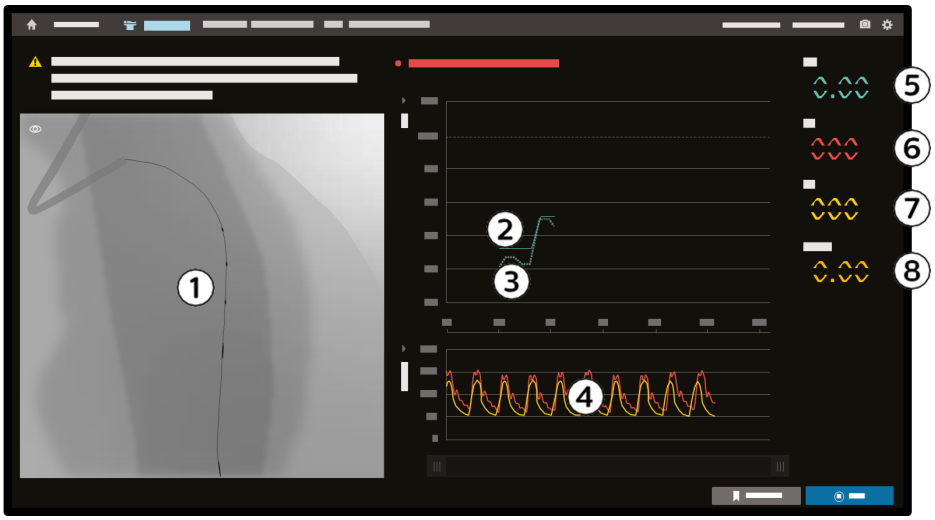


Figure 38 Recording a pullback on the main display

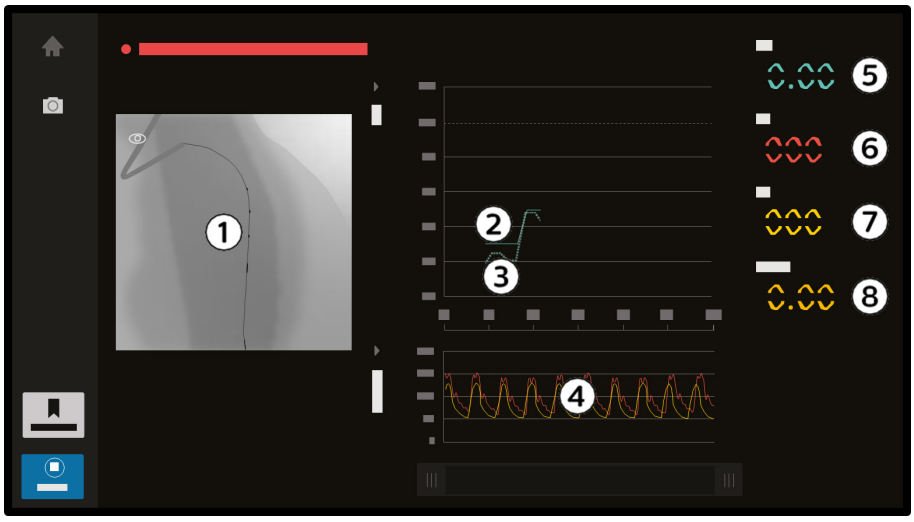


Figure 39 Recording a pullback on the touch screen module

Legend			
1	Live fluoroscopy image	5	iFR value
2	Trend line (solid line)	6	Aortic pressure (Pa)
3	Raw data line (dotted line)	7	Distal pressure (Pd)
4	Cardiac cycles	8	Pd / Pa

9 To place bookmarks on the graph during the recording activity, select **Bookmark**. A bookmark is added to the graph at that time point in the recorded data.

10 Once the pullback is completed, select **Stop** or stop performing fluoroscopy.

The pullback recording ends automatically if fluoroscopy is ended before selecting **Stop**. The **CINE SELECT** screen is displayed.

Figure 40 **CINE SELECT** screen

Legend	
1	Guidance
2	Last acquired exposure series
3	**Series** panel

11 Acquire a cine image or select an existing one in the **Series** list.

WARNING

The x-ray image must be acquired at the same zoom level, C-arm position, and patient table position as was used for the fluoroscopy while recording the pullback. Changing these settings between recording the pullback and x-ray image, or selecting an older x-ray image with different settings, may lead to inaccurate co-registration results.

When using IntraSight Plus with a Philips X-ray system, only compatible cine images are displayed when **Showing compatible series** is switched on in the **Series** list. You can display incompatible series by switching **Showing compatible series off**.

If you are using the automatic workflow and you selected/acquired an angiogram (cine with contrast), the system automatically generates the pathway on the roadmap and displays the co- registration results.

If you are using the semi-automatic workflow or acquired a zero-contrast cine, you can review and

Confirm the pathway or edit the pathway to correct how it is displayed. For more information, see *7.5.1 Editing the pullback pathway on page 69*.

NOTE ***A "Zero Contrast" co-registration workflow can be performed by selecting or creating a "dry" cine series (a recording that does not contain contrast and is not an x-ray image) from the Series list. You are prompted to confirm the pathway or edit the pathway to correct how it is displayed. This workflow can be facilitated by recording the cine series with a pressure guide wire or catheter in place to mark the pullback path.***

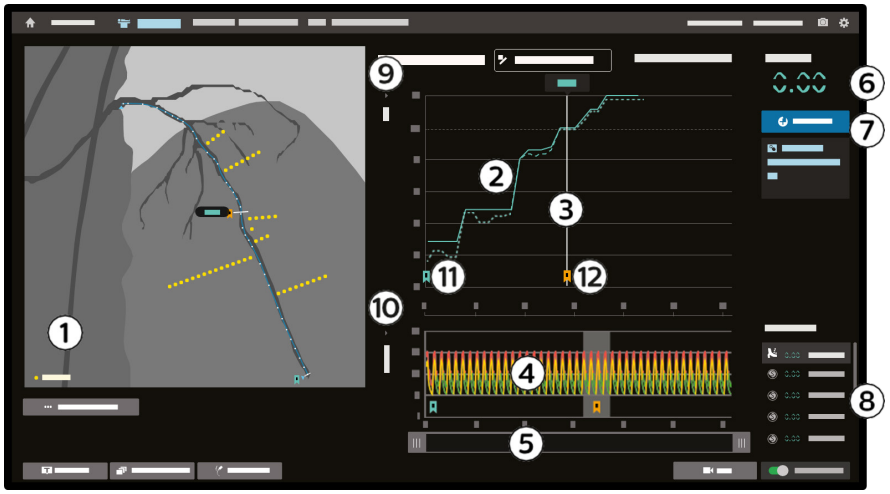


Figure 41 iFR co-registration results screen on the main display

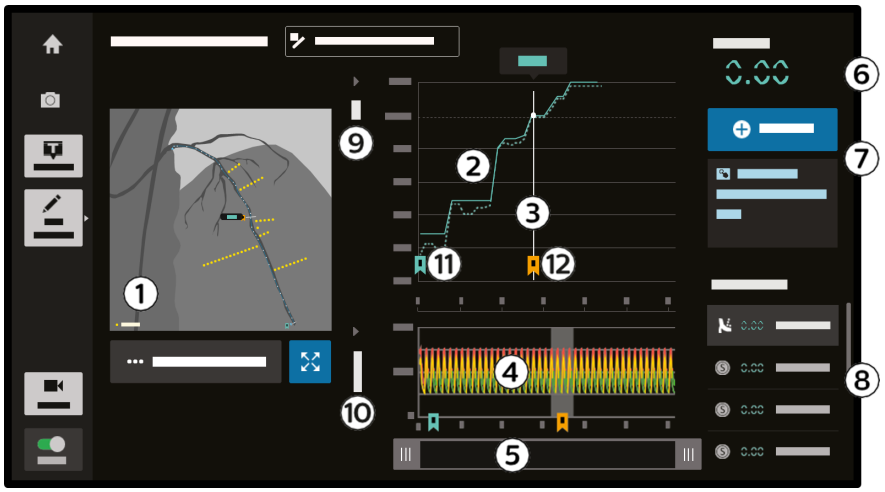


Figure 42 iFR co-registration results screen on the touch screen module

Legend			
1	Roadmap	7	Virtual stent controls
2	Trend line (solid line)	8	Previous series
3	Cursor line	9	iFR range
4	Cardiac cycles	10	Pressure range
5	Navigation bar	11	iFR distal flag (blue flag)
6	iFR distal value	12	Bookmark (orange flag) (visible in the roadmap, trend line graph, and cardiac cycles)

The cursor line is displayed at the iFR distal flag, corresponding to the **iFR Distal** value displayed in the top right of the review screen.

Individual cardiac cycles that meet any of the following criteria are excluded from the iFR pullback measurement and are colored grey in the waveform display:

- Cycles shorter than 0.4 seconds (heart rate ≥ 150 beats per minute)
- Cycles longer than 2 seconds (heart rate ≤ 30 beats per minute)
- Cycles 50% longer or shorter than the mean cardiac cycle length for the pullback
- Cycles without a viable diastolic (wave-free) period over which iFR can be calculated

CAUTION

Under certain limited conditions, such as when the pullback pathway appears from the selected X-ray viewing angle as a straight line or a near-perfect curve, the system may be unable to perform co-registration. In such cases, a message is displayed. If this occurs, repeat the pullback measurement using a different angiographic view or view the pullback result without co- registration.

WARNING

iFR Estimate is provided as a theoretical reference ONLY and does NOT represent a prediction on the results of post-PCI functional outcome or physiological measurement. Actual comparison to post-PCI iFR results may vary based on standards of care, disease type, and corresponding procedural details. Therefore, the operator should not use this value to make treatment decisions without supporting clinical evidence.

CAUTION

A looped or curved pressure guide wire at its radiopaque distal part during pressure guide wire pullback may lead to inaccurate calibration of the co-registration sequence resulting in inaccurate length measurement and trend line calibration.

12 Verify that the co-registration pathway and the measured points are correctly placed on the roadmap along the pullback route.

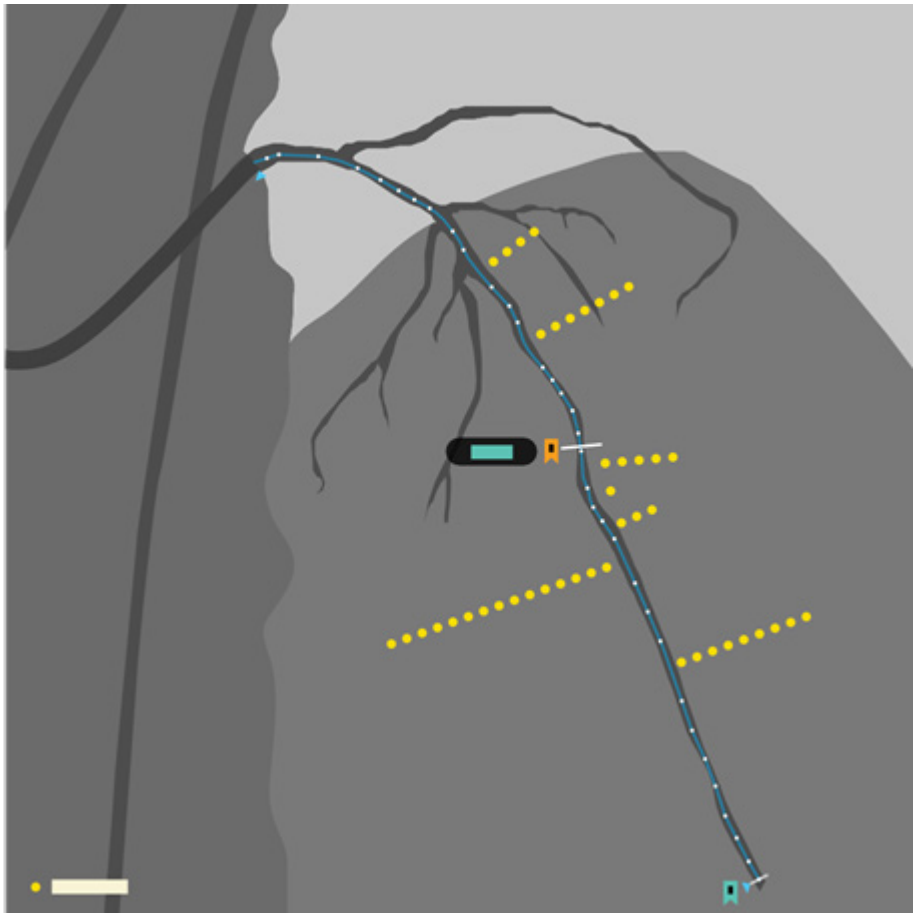


Figure 43 Co-registration pathway (blue line), measured points (white dots), and iFR delta step indicators (yellow dots)

Measured points are represented as white dots on the vessel pathway. These are the points along the pullback pathway where measurements were recorded. The density of measured points indicates the speed of the pullback at that position in the vessel. Where points are close together, the pullback rate was slower than where dots appear further apart or there may be some vessel foreshortening in the image.

The yellow dots on the roadmap indicate where the measured iFR value has dropped by a predetermined amount between two adjacent measured points. This is the iFR delta step size. Each dot represents a drop in the iFR value of the selected iFR delta step size. For example, if a step size of 0.01 is selected and 5 yellow dots are visible at a single location on the vessel path, this indicates that the system detected an iFR value drop of 0.05 at this location (5 x 0.01).

The iFR drop between two adjacent measured points is rounded to two decimal places for representation by the yellow dots. For example, if a step size of 0.01 is selected, a measured point which does not display any yellow dots could have an iFR drop of up to 0.0049 and a measured point with one yellow dot could have an iFR drop of between 0.0050 and 0.0149.

WARNING

When dropped packages or cycles are detected, iFR co-registration results may be missing some information due to the dropped packages or cycles. Ensure all signals are consistently detected and without interruptions to maintain accurate co-registration outcomes.

You can choose to edit the pullback pathway or to change the roadmap being used. For more information see:

- *7.5.1 Editing the pullback pathway on page 69*
- *7.5.2 Changing the roadmap on page 70*

13 To check if there is any drift, confirm that the pressure gradient **Pd/Pa** is approximately equalized to 1.0 at the guide catheter tip meaning that the distal pressure **Pd** is equal to the aortic pressure **Pa**.

14 Review the iFR pullback results to determine the significance of the stenoses.

WARNING

The trend line presents a simplified view of the pullback that facilitates reviewing changes in the iFR value within the pullback. The raw data line records the actual iFR value at each measurement point and should be used to assess the quality and accuracy of the pullback results. Differences between the trend line and raw data line should be assessed to determine the acceptability of the measurement results. The trend line always moves upward and never decreases, which is the main difference between the trend line and the raw values.

15 To change the **iFR delta step size**, do the following:

a Select **iFR settings** at the top right of the screen.

The **iFR settings** panel is displayed.

b Select the desired **iFR delta step size** setting.

c Select **Close** to close the **iFR settings** panel.

NOTE ***The iFR delta step size resets to 0.01 when the currently viewed series is closed.***

16 To show or hide the pathway on the roadmap, select **Roadmap Options** and check or uncheck **Pathway**.

17 To show or hide the measured points on the roadmap, select **Roadmap Options** and check or uncheck **Measured points**.

18 To plan a treatment strategy, place virtual stents by doing the following:

a Move the cursor line to the desired point on the graph or on the roadmap where the virtual stent should be placed.

b Select **Virtual Stent**.

A virtual stent of zero length is placed at the selected location.

You can place a virtual stent by positioning the pointer at the desired location and pressing and holding the left mouse button. On the touch screen module, you can place the virtual stent by selecting and holding at the desired location.

c Set the virtual stent to the desired length by dragging the left and right markers to the desired positions.

You can drag the left and right markers on the graph or on the roadmap.

The system indicates the estimated change in iFR value of placing a stent of the selected length at the selected location.

d To place an additional virtual stent, select **Stent**.

e Position the virtual stent in the same way as the previous virtual stent.

You can repeat this process for up to four virtual stents.

The system calculates and displays the estimated change in iFR value for each virtual stent and the new estimated overall iFR value.

Each virtual stent is identified by a letter and a unique color, and is displayed on the graph and on the roadmap at the selected location along the vessel path.

You can drag a label to a new location if it is interrupting the view of the region of interest.

f To delete a virtual stent, select **Clear** next to the virtual stent you want to delete.

g When you have finished placing virtual stents, select **Done**.

h To hide a virtual stent and exclude it from the iFR estimate, deselect the check box beside the desired virtual stent in the list at the right of the screen.

You can include the virtual stent in the iFR estimate again by reselecting the check box for the desired virtual stent.

The iFR estimate may not exactly match calculations based on the iFR delta step due to rounding.

19 To inspect a different location in the waveform, drag the cursor line to the desired location on the trend line.

The trend line indicates pullback length but the waveform indicates the time taken for the visible cardiac cycles.

20 To change the time period displayed in the waveform, drag the right and left sides of the navigation bar to increase or decrease the visible waveform time period.

You can double-click on the navigation bar to display the full recording.

21 To view the pullback results without the co-registration data, switch off **Co-registration**.

You can view the co-registration data again by switching **Co-registration** on again.

22 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre- defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

23 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

24 To return to the live waveform display, select **Live**.

25 After completing the iFR assessment of a vessel, return the pressure guide wire sensor to the normalization location and confirm that the **Pd/Pa** ratio is still approximately 1.0 and that the **Pa** and Pd waveforms still overlap and have a similar appearance.

WARNING

If the normalization check Pd/Pa ratio is not equal to 1.0 or the waveforms do not overlap and have a similar appearance, then the previous iFR measurements may not be accurate. Consider normalizing and repeating the iFR measurements.

7.5.1 Editing the pullback pathway

If you want to edit the position of the pathway, you can change it on the roadmap. This function is only available when you initially review the results after making a measurement. It is not available when you open a previous measurement to review it.

Figure 44 Editing the pathway

1 Select **Edit Pathway**.

An editable image of the pathway is displayed with guidance.

To pan the image to achieve the desired view, hold down the right mouse button and drag the image or use two fingers on the touch screen module to drag the image to the desired position.

To zoom the image in or out to achieve the desired view, use the mouse scroll wheel.

To zoom on the touch screen module, use two-finger pinch and stretch gestures. For more information, see *Touch screen gestures on page 25*.

2 To reposition the pathway along the vessel of interest, select the pathway and drag along the vessel of interest.

Animated guidance is provided on the main display to assist you.

On the touch screen module, you can view the animated guidance by selecting the information icon.

Draw the pathway from the most proximal visible section of the guide catheter to the most distal visible section of the vessel, ensuring the pathway remains within the vessel of interest.

When you select the pathway and drag the pointer, the pathway line changes to a broken line, indicating that you are editing the pathway. When you release the left mouse button, the pathway line changes back to a solid line.

To edit the pathway using the touch screen module, select and hold the yellow ring without covering your view of the pointer. The yellow ring shrinks in size toward the pointer location, indicating that you can drag the pointer while still being able to view it. When you have edited the pathway, remove your finger from the touch screen module to stop editing the pathway.

3 To undo your edit, select **Undo Edit**.

4 To redo an undone edit, select **Redo Edit**.

5 To delete the pathway, do the following:

   a Select **Delete Pathway**.

   b Draw the new pathway from the most proximal visible section of the guide catheter to the most distal visible section of the vessel.

6 To reset the pathway and remove all your edits, select **Reset Pathway**.

7 To close the editing screen without saving your changes, select **Exit Without Save**.

8 To save your edited pathway and update the co-registration results, select **Update Co-reg.**

7.5.2 Changing the roadmap

You can overlay the iFR co-registration results on a different angiographic roadmap for the same patient. This function is only available when you initially review the results after making a measurement. It is not available when you open a previous measurement to review it.

1 Select **Change Roadmap**.

2 Acquire a cine image or select an existing one in the **Series list**.

The x-ray image must be acquired at the same zoom level, C-arm position and table position as used for the fluoroscopy in the iFR pullback. The system uses an image from the x-ray image to overlay the co-registration results. This is known as the roadmap.

When using IntraSight Plus with a Philips X-ray system, only compatible cine images are displayed when **Showing compatible series** is switched on in the Series list. You can display incompatible series by switching **Showing compatible series off**.

WARNING

The x-ray image must be acquired at the same zoom level, C-arm position, and patient table position as was used for the fluoroscopy while recording the pullback. Changing these settings between recording the pullback and x-ray image, or selecting an older x-ray image with different settings, may lead to inaccurate co-registration results.

3 To return to the co-registration results without changing the roadmap, select **Return**.

4 To update the co-registration results and use the new roadmap, select **Update Co-reg**

7.6 Performing iFR pullback measurements without co-registration

An iFR pullback measurement is a dynamic measurement, performed by pulling the pressure guide wire back within a blood vessel to obtain iFR pressure measurements along the blood vessel, for example, on each side of a lesion.

NOTE ***The displayed measurements and calculated values are rounded.***

1 Select the **iFR** application.

WARNING

The patient's respiration can affect the accuracy of physiological measurements. Ensure breathing is consistent during the measurement.

2 Ensure the patient interface module for functional measurements (FM-PIM) remains connected to the system and the pressure guide wire is connected to the FM-PIM.

For more information about connecting the patient interface module, see *7.1 Setting up the system for iFR procedures on page 55*.

3 Switch off **Co-registration** if enabled.

4 Advance the pressure guide wire distal of all stenoses in the vessel of interest.

5 Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve.

Follow the applicable hospital procedures and refer to the Instructions for Use provided with the guide catheter and pressure guide wire.

WARNING

Flushing the guide catheter, removing the introducer needle, and tightening the hemostatic valve are important steps to get an accurate Pa pressure and therefore an accurate normalization, iFR measurement, or FFR measurement.

6 Observe the live iFR value to confirm that it is stable and that the patient is not experiencing hyperemia from the saline flush.

WARNING

Flushing with contrast or saline can induce a short-term hyperemia that lowers the Pd and Pa pressure readings resulting in incorrect iFR measurements. The live iFR value should be checked for stability before making a measurement.

7 Select **Record Pullback**.

The system starts recording measurements and a graph is displayed showing the measurements being recorded. The cardiac cycles are displayed below the graph.

8 Using fluoroscopy, slowly pull the pressure guide wire proximally across the length of vessel to be assessed.

NOTE ***Do not pull the pressure guide wire back until you see the blue graph line starting to be displayed.***

Perform the pullback slowly and steadily.

The trend line (solid line) and the raw data line (dotted line) are displayed as you pull the pressure guide wire through the vessel.

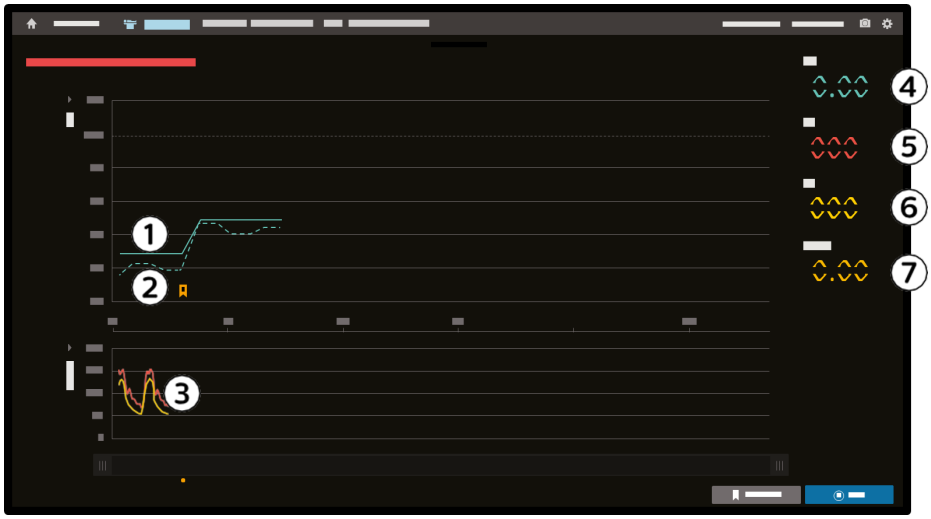


Figure 45 Recording a pullback on the main display

Figure 46 Recording a pullback on the touch screen module

Legend			
1	Trend line (solid line)	5	Aortic pressure (Pa)
2	Raw data line (dotted line)	6	Distal pressure (Pd)
3	Cardiac cycles	7	Pd / Pa
4	iFR value		

9 To place bookmarks on the graph during the recording activity, select **Bookmark**. A bookmark is added to the graph at that time point in the recorded data.

10 Once the pullback is completed, select **Stop**.

The cursor line is displayed at the iFR distal flag, corresponding to the **iFR Distal** value displayed in the top right of the review screen.

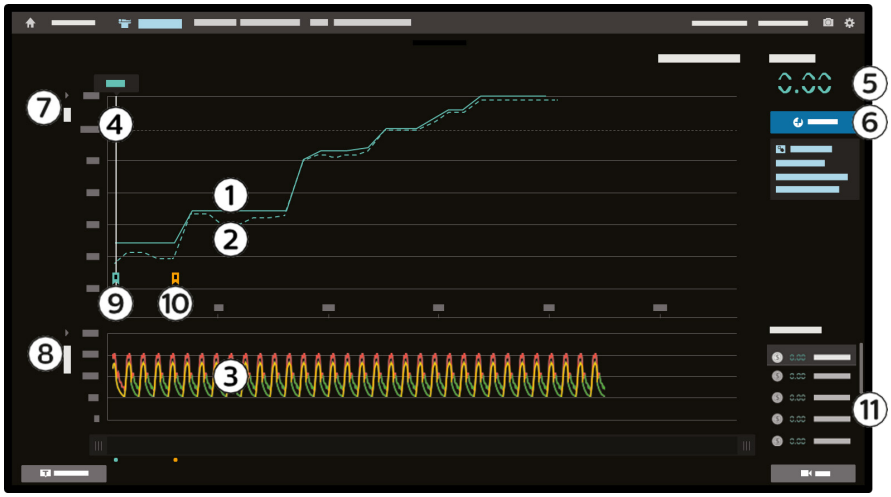


Figure 47 iFR pullback results on the main display

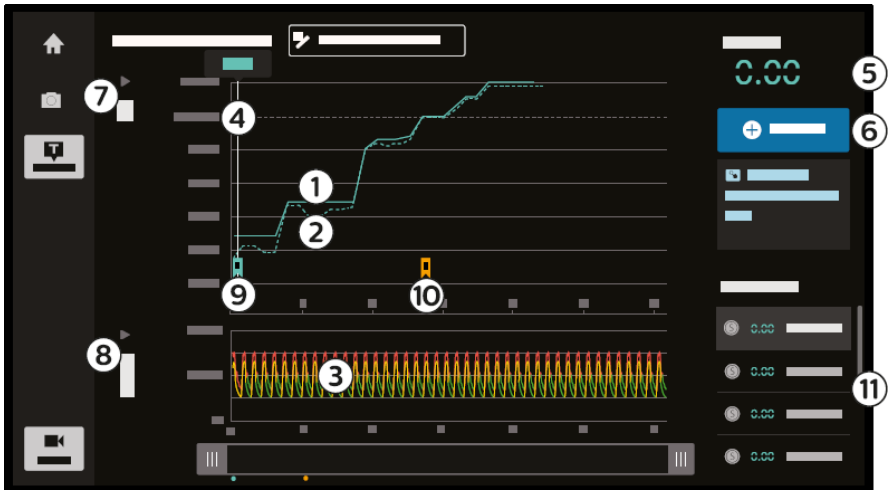


Figure 48 iFR pullback results on the touch screen module

Legend			
1	Trend line (solid)	7	iFR range
2	Raw data line (dotted)	8	Pressure range
3	Cardiac waveforms: Pa (red), Pd (yellow), wave- free period (green)	9	iFR distal flag (blue flag)
4	Cursor line	10	Bookmark (orange flag)
5	iFR distal value	11	Previous measurements
6	Segment controls		

Individual cardiac cycles that meet any of the following criteria are excluded from the iFR pullback measurement and are colored grey in the waveform display:

- Cycles shorter than 0.4 seconds (heart rate ≥ 150 beats per minute)
- Cycles longer than 2 seconds (heart rate ≤ 30 beats per minute)
- Cycles 50% longer or shorter than the mean cardiac cycle length for the pullback
- Cycles without a viable diastolic (wave-free) period over which iFR can be calculated

11 To check if there is any drift, confirm that the pressure gradient Pd/Pa is approximately equalized to 1.0 at the guide catheter tip meaning that the distal pressure Pd is equal to the aortic pressure **Pa.**

12 Review the iFR pullback results to determine the significance of the stenoses.

WARNING

The trend line presents a simplified view of the pullback that facilitates reviewing changes in the iFR value within the pullback. The raw data line records the actual iFR value at each measurement point and should be used to assess the quality and accuracy of the pullback results. Differences between the trend line and raw data line should be assessed to determine the acceptability of the measurement results. The trend line always moves upward and never decreases, which is the main difference between the trend line and the raw values.

13 To plan a treatment strategy, place segments by doing the following:

a Move the cursor line to the desired point on the graph or on the image where the segment should be placed.

b Select **Segment** .

A segment is placed at the selected cursor location.

You can place a segment by positioning the pointer at the desired location and pressing and holding the left mouse button. On the touch screen module, you can place the segment by selecting and holding at the desired location.

c Drag the left and right markers at each end of the segment to the desired positions on the graph.

The system indicates the estimated change in iFR value of placing a stent at the selected location.

d To place an additional segment, select **Segment**.

e Position the segment in the same way as the previous one.

You can repeat this process for up to four segments.

The system calculates and displays the estimated change in iFR value for each segment and the new **iFR Estimate** value.

Each segment is identified by a letter and a unique color, and is displayed on the graph at the selected location along the vessel path.

f To delete a segment, select **Clear** next to the segment you want to delete.

g When you have finished placing segments, select **Done**.

h To hide a segment and exclude it from the iFR estimate, deselect the check box beside the desired segment in the list at the right of the screen.

You can include the segment in the iFR estimate again by reselecting the check box for the desired segment.

14 To change the time period displayed in the waveform, drag the right and left sides of the navigation bar to increase or decrease the visible waveform time period.

You can double-click on the navigation bar to display the full recording.

15 To inspect a different location in the waveform, drag the cursor line to the desired location on the trend line.

The trend line indicates pullback time. The waveform indicates the time taken for the visible cardiac cycles.

16 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre- defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

17 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

18 To return to the live waveform display, select **Live**.

19 After completing the iFR assessment of a vessel, return the pressure guide wire sensor to the normalization location and confirm that the **Pd/Pa** ratio is still approximately 1.0 and that the Pa and Pd waveforms still overlap and have a similar appearance.

WARNING

If the normalization check Pd/Pa ratio is not equal to 1.0 or the waveforms do not overlap and have a similar appearance, then the previous iFR measurements may not be accurate. Consider normalizing and repeating the iFR measurements.

7.7 Adding annotations to the results

You can add annotations to highlight features or measurement data to assist in determining treatments.

You can add annotations to the iFR pullback for co-registered and non-co-registered recordings but only to the graph area.

1 Select **Annotate**.

2 Enter the desired annotation text in the **Annotation** field.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre-defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

3 To close the dialog panel without saving the annotation text, select **Cancel**.

4 To save the annotation text, select **Done**. The annotation is placed on the image.

5 To move the annotation, drag it to the desired position.

6 To edit an annotation, select the desired annotation and select **Edit**.

Figure 49 Selected annotation

7 To delete an annotation, select the desired annotation and select **Delete**.

7.8 Opening a previous iFR recording for review

You can open a previous iFR recording, allowing you to review the recording and measurement values.

You cannot access the live screen when reviewing a previous study and for co-registered data, you cannot edit the pathway or change the roadmap.

1 In the patient list, select the desired patient study and select **View**.

The selected study opens and the procedure home screen is displayed.

2 Select the desired series in the **Series** tab.

Pictorials in the **Series** tab identify **iFR** series in the relevant series names. You can also see a preview of the recorded data which indicates that the series is an iFR series.

3 Select **Open**.

Series marked as iFR open automatically in the **iFR** application.

4 To display a different iFR measurement recording from the same study, select the desired recording in the **Previous series** list.

5 To view the pullback results without the co-registration data, switch off **Co-registration**.

You can view the co-registration data again by switching **Co-registration** on again.

7.9 iFR guidance

Pressure-derived indices provide physicians with a quantitative measurement for guiding treatment decisions. The iFR measure is taken during the wave-free period of the cardiovascular pressure cycle during which time, the resistance across both the epicardial vasculature and myocardial microvasculature is naturally low and stable. Under these conditions, pressure is proportional to coronary flow meaning that the iFR measurement helps identify flow-limiting, ischemia causing lesions.

Randomized clinical trials

Two large, multi-center, randomized studies (DEFINE FLAIR1, NCT 02053038; iFR-SWEDEHEART2, NCT 02166736) were performed to prospectively assess the risk of major adverse cardiac events (MACE) with iFR-indicated versus FFR-indicated coronary revascularization. Subjects with coronary artery disease were randomly assigned in a 1:1 ratio to undergo either iFR-indicated (cut-point 0.89) or FFR-indicated (cut-point 0.80) revascularization of intermediate-grade stenoses. The primary endpoint of both trials was the 1-year risk of MACE, which is a composite of death from any cause, non-fatal myocardial

infarction, or unplanned revascularization. The trials were designed to show the non-inferiority of iFR to FFR with a non-inferiority margin of 3.4% for DEFINE FLAIR and 3.2% for iFR-SWEDEHEART. The tables presented in this section show the results from the DEFINE FLAIR and iFR-SWEDEHEART studies, respectively.

	DEFINE FLAIR	iFR-SWEDEHEART
Sites (n)	49	14
Countries (n)	19	3
Subjects (n)	2,492	2,037
Per Protocol Analysis iFR Subjects (n)	1,141	1,012
Per Protocol Analysis FFR Subjects (n)	1,176	1,007

DEFINE FLAIR: Per protocol risk difference at 12 months				
	iFR Num/total, (%)	FFR Num/Total, (%)	Percent Difference, (95% CI)	P-value
Primary Endpoint MACE	77/1,141 (6.7)	83/1,176 (7.1)	-0.31 (-2.37 to 1.75)	0.77
Death from any cause	21/1,140 (1.8)	13/1,173 (1.1)	0.73 (-0.25 to 1.75)	0.14
Nonfatal myocardial infarction	31/1,141 (2.7)	28/1,174 (2.4)	0.33 (-0.95 to 1.62)	0.61
Unplanned revascularization	46/1,140 (4.0)	63/1,175 (5.4)	-1.33 (-3.05 to 0.39)	0.13

iFR-SWEDEHEART: Per protocol hazard ratio at 12 months				
	iFR Num/total, (%)	FFR Num/Total, (%)	Hazard Ratio (95% CI)	P-value
Primary Endpoint MACE	68/1,012 (6.7)	61/1,007 (6.1)	1.12 (0.79-1.58)	0.53
Death from any cause	15/1,012 (1.5)	12/1,007 (1.2)	1.25 (0.58-2.66)	0.57
Nonfatal myocardial infarction	22/1,012 (2.2)	17/1,007 (1.7)	1.29 (0.68-2.44)	0.42
Unplanned revascularization	47/1,012 (4.6)	46/1,007 (4.6)	1.04 (0.69-1.57)	0.84

Both studies demonstrated that an iFR-guided revascularization strategy was non-inferior to an FFR- guided strategy with respect to 1-year MACE:

- DEFINE FLAIR: The upper limit of the 95% confidence interval was 1.8 percentage points which is within the non-inferiority margin of 3.4 percentage points
- iFR-SWEDEHEART: The upper limit of the 95% confidence interval was 2.8 percentage points which is within the non-inferiority margin of 3.2 percentage points

Usage guidance

The use of iFR with the dichotomous cut-point of 0.89 is considered appropriate for use in the same cases for which FFR with a cut-point of 0.80 would be.

The 2021 ACC/AHA/SCAI and the 2024 ESC guidelines on myocardial revascularization recommend using iFR to guide the revascularization decision in patients with undocumented ischemia and angiographically intermediate stenoses (Class 1, Level A). [3], [4]

Clinicians may choose to treat ischemic lesions when the distal iFR value is equal to or less than 0.89. Alternatively, clinicians may choose to defer non-ischemic lesions when the distal iFR value is higher than 0.89.

iFR value	Interpretation
iFR > 0.89	Indicates that a lesion is not flow-limiting, ischemia causing
iFR ≤ 0.89	Indicates that a lesion is flow-limiting, ischemia causing

References

[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 May 11;376(19):1824-1834.

[2] Götberg M, Christiansen EH, Gudmundsdottir IJ, et al. Instantaneous Wave-free Ratio versus Fractional Flow Reserve to Guide PCI. N Engl J Med. 2017 May 11;376(19):1813-1823.

[3] Vrints C, Andreotti F, Koskinas KC, et al. 2024 ESC Guidelines for the management of chronic coronary syndromes. European Heart Journal. vol. 45,36 (2024): 3415-3537.

[4] Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization. J Am Coll Cardiol. 2022 Jan;79(2):e21–129.

7.10 Adjusting the iFR application settings

You can customize the settings used during iFR procedures to suit the way you want to work and to provide the information on the screen that you want to see.

When you open the settings menu for an application, you must select the settings on the main . A dialog panel is displayed on the touch screen module, informing you that settings should be selected on the main display. If you close the dialog panel on the touch screen module, the application settings menu on the main display is also closed. When you close the application settings menu on the main display, the dialog panel on the touch screen module is also closed.

The iFR settings menu contains two tabs: Display and Co-registration. If your system does not include the co-registration option, the Co-registration tab is not displayed.

7.10.1 Adjusting the iFR display settings

1 Select the iFR application.

2 To open the settings menu for iFR, select **iFR settings** in the top right corner of the iFR application screen.

The **Display** tab is displayed by default.

3 Using the **MAP period** drop-down list, select the number of cardiac cycles used to calculate the average Pa and Pd values and to calculate Pd/Pa.

The default setting is 1 cardiac cycle.

The new **MAP period** setting is applied to new recordings in the current study acquired after the setting was changed.

4 Using the **Display iFR raw value** setting, select whether to display the raw iFR measurement values above the cursor on the trend line graph by default.

- On: the iFR raw values are displayed by default.
- Off: the iFR raw values are not displayed by default.

The default setting is **Off**.

5 To close the menu, select **Close**.

7.10.2 Adjusting the iFR co-registration settings

1 Select the **iFR** application.

2 To open the settings menu for iFR, select **iFR settings** in the top right corner of the iFR application screen.

The Display tab is displayed by default.

3 Select the **Co-registration** tab.

4 Using the **Enable Co-registration** by default setting, select whether to enable co-registration by default when the iFR application is started in a new study.

- On: co-registration is switched on by default.
- Off: co-registration is switched off by default. The default setting is On.

5 Using the Co-registration workflow drop-down list, select whether to use an automatic or semi- automatic workflow.

The default setting enables automatic workflow.

6 Using the **iFR delta step size** drop-down list, select the iFR drop value that is represented by each marker dot.

The yellow dots on the roadmap indicate where the measured iFR value has dropped by a predetermined amount between two adjacent measured points. This is the iFR delta step size. Each dot represents a drop in the iFR value of the selected iFR delta step size. For example, if a step size of 0.01 is selected and 5 yellow dots are visible at a single location on the vessel path, this indicates that the system detected an iFR value drop of 0.05 at this location (5 x 0.01).

The iFR drop between two adjacent measured points is rounded to two decimal places for representation by the yellow dots. For example, if a step size of 0.01 is selected, a measured point which does not display any yellow dots could have an iFR drop of up to 0.0049 and a measured point with one yellow dot could have an iFR drop of between 0.0050 and 0.0149.

The default setting is 0.01.

NOTE ***The iFR delta step size resets to 0.01 when the currently viewed series is closed.***

7 Using the **Display pathway** setting, select whether to display the pathway by default in the co- registration results screen.

- **On**: the co-registration pathway is displayed by default.
- **Off**: the co-registration pathway is not displayed by default.

The default setting is **Off**.

8 Using the **Display truly measured points** setting, select whether to display the measured points by default in the co-registration results screen.

- **On**: the measured points are displayed by default.
- **Off**: the measured points are not displayed by default.

The default setting is **On**.

9 To close the menu, select **Close**.

8 Performing FFR measurements

The FFR application allows you to perform functional measurements to help you assess the hemodynamic significance of lesions and vessels and to determine if treatment is necessary.

8.1 Setting up the system for FFR procedures

Pressure guide wires connect to the system through a patient interface module (PIM). The PIM is typically left connected to the bedside utility box between studies, but may need to be reconnected if removed after a study or if a cable becomes disconnected.

Before a PIM is connected to the system and a catheter or pressure guide wire type configured, the system displays guidance for connecting the PIM. Before connecting or placing the PIM, inspect it and its cable for damage and do not use if damage is found.

WARNING

Defibrillator protection requires the use of OmniWire and FM-PIM including specified cables. The use of any accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the system as re-placement parts for internal components, may result in de-creased defibrillator protection and increased electro-magnetic emissions or decreased electro-magnetic immunity of the system.

CAUTION

The PIM's cable may be damaged if equipment is rolled on it. Do not pull on the cable, place the cable in a high traffic area, or use excessive force as this may cause damage. If the PIM is dropped, there could be damage to the body or internal electronics. Do not use the PIM if the outer case, cable, or connectors appear damaged.

CAUTION

If used in the sterile field, place the PIM in a sterile barrier pouch or bag using standard sterile techniques.

CAUTION

Attach the PIM to the bed rail using its clamp or place in the use location so that there is sufficient slack in the cable to avoid binding during patient table movements. The PIM or cable can be damaged if dropped or improperly located, potentially resulting in user or patient harm if this occurs during a procedure.

CAUTION

The PIM can be damaged if contrast fluid or saline enter the wire connector port. This may cause irregular or permanent loss of communication with the pressure guide wire leading to inaccurate measurements. The PIM should not be placed below an IV pole where liquids such as saline or contrast may drip onto the PIM or into the connector port and cause damage.

1 Select the **FFR** application.

2 Ensure you are using the FM-PIM for the procedure.

FFR procedures require the functional measurement PIM (FM-PIM). Animated guidance is displayed to assist you if the PIM is not connected.

3 Align the markers on the cable connector of the short cable attached to the PIM with the connector at the patient end of the PIM cable from the system, and slide the connections together until you hear a click.

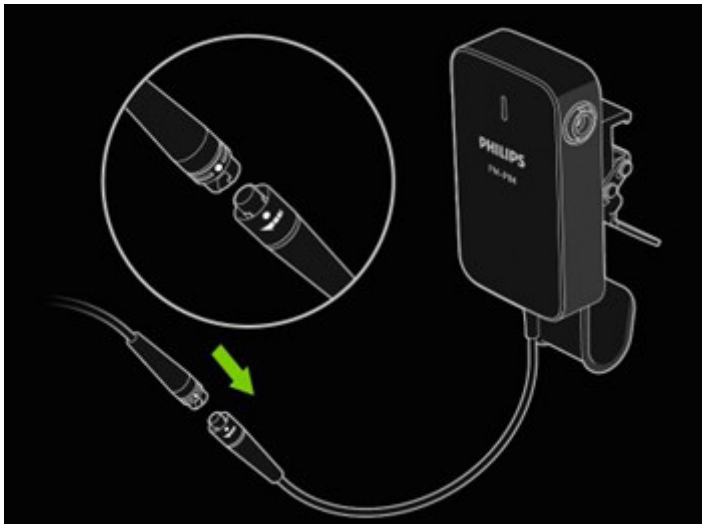


Figure 50 Animated guidance for connecting the FM-PIM

The system detects the PIM and displays the next appropriate guidance step.

4 Prepare and connect the pressure guide wire to the PIM.

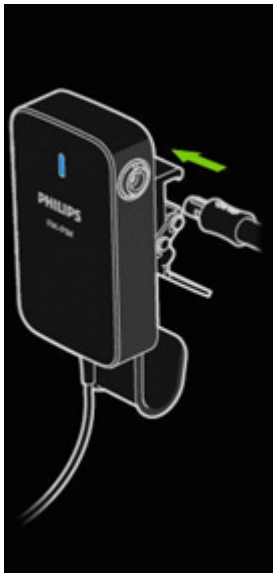


Figure 51 Animated guidance for connecting the pressure guide wire

CAUTION

The PIM can be damaged if contrast fluid or saline enter the wire connector port. This may cause irregular or permanent loss of communication with the pressure guide wire leading to inaccurate measurements. Care should be taken to not expose the pressure guide wire plug to fluid that can be transferred to the PIM when connecting the wire.

NOTE ***Refer to the pressure guide wire Instructions for Use for directions before and during the procedure. Refer to the catheter or pressure guide wire label for specific insertion instructions. Consult the catheter or pressure guide wire package insert for a full description of warnings, precautions, and use instructions.***

Once the pressure guide wire is connected, the system initializes and autozeroes the pressure guide wire.

5 Verify that the connections are secure.

The system recognizes the installed pressure guide wire for each study until a different type is installed. Any user-defined values are reset to the default values at the beginning of each study.

6 Introduce the pressure guide wire through the hemostatic valve of the guide catheter and into the patient.

7 Position the pressure guide wire so that the pressure sensor, which is proximally adjacent to the radiopaque tip, is located just outside the opening of the guide catheter.

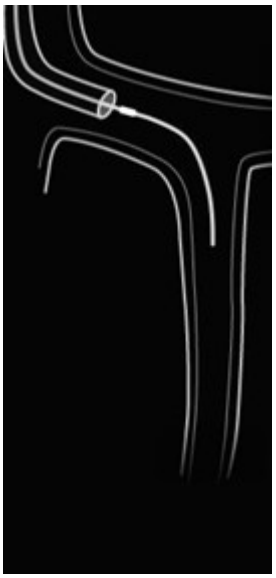


Figure 52 Animated guidance for advancing the pressure wire

8 Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve.

Follow the applicable hospital procedures and refer to the Instructions for Use provided with the guide catheter and pressure guide wire.

WARNING

Flushing the guide catheter, removing the introducer needle, and tightening the hemostatic valve are important steps to get an accurate Pa pressure and therefore an accurate normalization, iFR measurement, or FFR measurement.

9 Once the pressure waveforms are stable, normalize the pressure guide wire by selecting **Normalize**.

The distal pressure **Pd** is equalized to the aortic pressure **Pa** resulting in a pressure gradient **Pd/Pa** of 1.0.

After normalization is completed, the live screen is displayed. A snapshot of the normalization screen is created automatically and stored in the **Series** tab as evidence of the normalization.

10 Verify that **Pd** is equal to **Pa**, the **Pd/Pa** ratio is approximately 1.0, and that the Pa and Pd waveforms overlap and have similar shapes.

If the **Pd/Pa** ratio is not approximately 1.0, you should repeat the normalization step.

WARNING

Normalization adjusts the distal pressure (Pd) measurement from the pressure guide wire to match the aortic pressure (Pa) reading and adjusts the time delay between the Pd and Pa signals to synchronize their display. After normalization, the Pd/Pa ratio should be approximately 1.0 and the Pd and Pa waveforms should overlap in order to obtain accurate measurements. Repeat normalization if this results is not obtained. Discontinue use of the system and contact technical support if normalization fails after multiple attempts

8.2 Using the FFR live screen

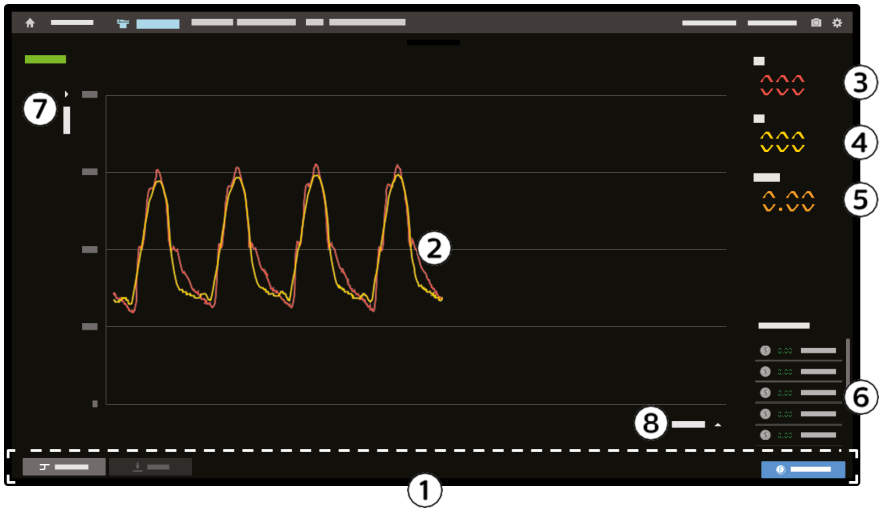


Figure 53 FFR live screen layout on the main display

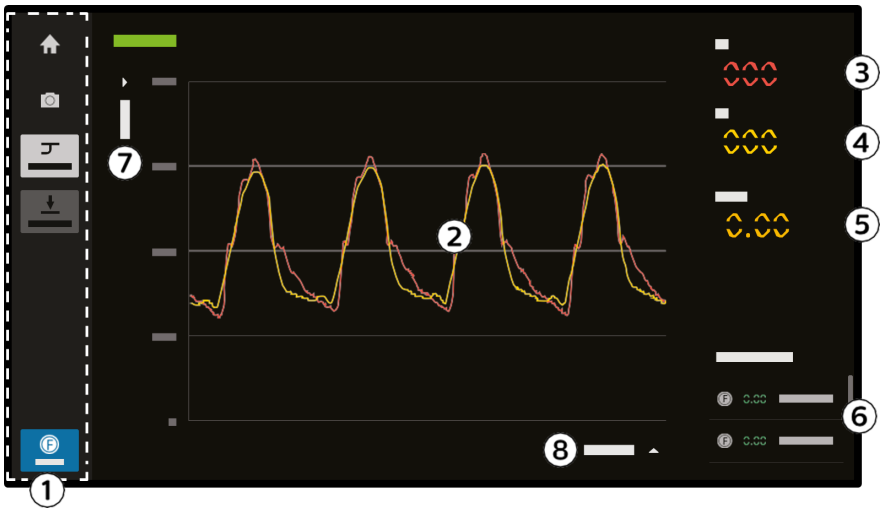


Figure 54 FFR live screen layout on the touch screen module

Legend			
1	Function controls	5	Pd / Pa ratio
2	Cardiac waveforms: Pa (red) and Pd (yellow)	6	Previous series
3	Pa value (mmHg)	7	Pressure range (0-200 mmHg or 0-300 mmHg)
4	Pd value (mmHg)	8	Sweep speed

1 To change the pressure range used to display the waveforms, select a new range using the pressure range control at the top left of the recording.

2 To adjust the sweep speed of the live waveform trace, select the desired sweep speed using the sweep speed control at the bottom right of the graph.

3 To display a different FFR measurement recording from the same study, select the desired recording in the **Previous series** list.

8.3 Balancing aortic pressure

The aortic pressure can be balanced (zeroed) to ensure the correct display of the aortic transducer pressure signal.

1 Open the pressure transducer to air so that no pressure is being applied.

2 Zero the hemodynamic monitoring system.

For more information, refer to the Instructions for Use provided with the hemodynamic monitoring system.

3 Select **Zero Pa** on the live waveform screen. Note: Utilization of **Zero Pa** in FM-PIM on the IntraSight Plus system is optional, as it has been previously conducted on the hemodynamic system.

4 Close the valve on the pressure transducer.

5 Verify that the **Pa** value displayed on IntraSight Plus matches the hemodynamic monitor reading.

8.4 Performing FFR measurements

NOTE ***The displayed measurements and calculated values are rounded.***

1 Select the **FFR** application.

WARNING

The patient's respiration can affect the accuracy of physiological measurements. Ensure breathing is consistent during the measurement.

2 Ensure the patient interface module for functional measurements (FM-PIM) remains connected to the system and the pressure guide wire is connected to the FM-PIM.

For more information about connecting the patient interface module, see *8.1 Setting up the system for FFR procedures on page 80*.

3 Using fluoroscopy, advance the pressure guide wire beyond the lesion of interest, positioning the pressure sensor at the point where you want to perform the measurement, distal to the lesion.

4 Administer the hyperemic agent in accordance with hospital protocols.

5 Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve.

Follow the applicable hospital procedures and refer to the Instructions for Use provided with the guide catheter and pressure guide wire.

WARNING

Flushing the guide catheter, removing the introducer needle, and tightening the hemostatic valve are important steps to get an accurate Pa pressure and therefore an accurate normalization, iFR measurement, or FFR measurement.

6 When the waveforms are stable, select **Record**. Pressure measurements are recorded.

7 To place a bookmark on the graph during the recording activity, select **Bookmark**.

A bookmark is added to the graph at that time point in the recorded data. You can place more than one bookmark on the graph.

8 Select **Stop**.

WARNING

Continue recording until a lowest FFR value is displayed and the Pd/Pa value begins to increase (intracoronary bolus injection) or until maximum hyperemia and a lowest FFR value is displayed (intravenous infusion).

The recording is stopped and a portion of the recorded graph is displayed centered on the lowest measured FFR value.

The FFR value is the lowest measured Pd/Pa ratio and is displayed with the associated Pa and Pd values.

The FFR value is also bookmarked automatically on the graph so that you can see when it occurred in the recording.

Figure 55 FFR results screen on the main display

Figure 56 FFR results screen on the touch screen module

Legend			
1	Cardiac waveforms	6	Pa value (mmHg)
2	FFR value (green flag)	7	Pd value (mmHg)
3	Bookmark (orange flag)	8	Previous measurements
4	Cursor line	9	Pressure range
5	FFR value	10	Navigation bar

9 To inspect a different location in the waveform, drag the cursor line to the desired location on the trend line.

10 To change the time period displayed in the waveform, drag the right and left sides of the navigation bar to increase or decrease the visible waveform time period.

You can double-click on the navigation bar to display the full recording.

11 To change the pressure range used to display the waveforms, select a new range using the pressure range control at the top left of the recording.

12 To view the measured **Pd/Pa** value at a different location on the recording, drag the cursor line to the desired location.

The measured **Pd/Pa** value and the associated **Pa** and **Pd** values for the selected location are displayed above the cursor line.

13 To relocate the FFR value bookmark to a new location, drag the cursor line to the desired location on the recording and select **Relocate FFR**.

14 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre-defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

15 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

16 To return to the live waveform display, select **Live**.

17 After completing the FFR assessment of a vessel, return the pressure guide wire sensor to the normalization location and confirm that the **Pd/Pa** ratio is still approximately 1.0 and that the Pa and Pd waveforms still overlap and have a similar appearance.

WARNING

If the normalization check Pd/Pa ratio is not equal to 1.0 or the waveforms do not overlap and have a similar appearance, then the previous FFR measurements may not be accurate. Consider normalizing and repeating the FFR measurements.

18 To return to the procedure home screen, select **Home**.

8.5 Opening a previous FFR recording for review

You can open a previous FFR recording, allowing you to review the recording and measurement values. You cannot access the live screen when reviewing a previous study.

1 In the patient list, select the desired patient study and select **View**.

The selected study opens and the procedure home screen is displayed.

2 Select the desired series in the **Series** tab.

Pictorials in the **Series** tab identify **FFR** series in the relevant series names. You can also see a preview of the recorded data graph which indicates that the series is an FFR series.

3 Select **Open**.

Series marked as **FFR** open automatically in the **FFR** application.

4 To display a different FFR measurement recording from the same study, select the desired recording in the **Previous series** list.

8.6 FFR guidance

Pressure-derived indices provide physicians with a quantitative measurement for guiding treatment decisions. FFR aims to measure the ratio of maximum blood flow in a stenotic artery relative to the flow in the same artery if the stenosis would be absent. In practice, FFR is measured under a hyperemic state to reach a minimum and constant microvascular resistance. During maximum hyperemia induced by administration of a vasodilating drug, it can be assumed that flow is proportional to pressure and the microvascular pressure is the same with and without the ischemia-causing lesions.

As a result, FFR is calculated as the ratio:

- Pd / Pa = Mean distal pressure during maximum hyperemia / Mean aortic pressure during maximum hyperemia

Usage guidance

Clinicians may choose to treat ischemic lesions when the distal FFR value is equal to or less than 0.80. Alternatively, clinicians may choose to defer non-ischemic lesions when the distal FFR value is higher than 0.80.

The 2021 ACC/AHA/SCAI and the 2024 ESC guidelines on myocardial revascularization recommend using FFR to guide the revascularization decision in patients with undocumented ischemia and angiographically intermediate stenoses (Class 1, Level A).

FFR value	Interpretation
FFR > 0.80	Indicates that a lesion is not flow-limiting, ischemia causing
FFR ≤ 0.80	Indicates that a lesion is flow-limiting, ischemia causing

8.7 Adjusting the FFR application settings

You can customize the settings used during FFR procedures to suit the way you want to work and to provide the information on the screen that you want to see.

When you open the settings menu for an application, you must select the settings on the main . A dialog panel is displayed on the touch screen module, informing you that settings should be selected on the main display. If you close the dialog panel on the touch screen module, the application settings menu on the main display is also closed. When you close the application settings menu on the main display, the dialog panel on the touch screen module is also closed.

1 Select the **FFR** application.

2 To open the settings menu for FFR, select **FFR settings** in the top right corner of the FFR application screen.

3 Using the **MAP period** drop-down list, select the number of cardiac cycles used to calculate the average Pa and Pd values and to calculate Pd/Pa.

The default setting is 1 cardiac cycle.

4 Using the **Venous pressure (mmHg)** selector, adjust the assumed venous pressure used to calculate FFR.

The assumed venous pressure can be set from 0 to 50 mmHg, in 1 mmHg increments. Changing the venous pressure results in a change to the calculated FFR value. The new venous pressure setting is applied to new recordings in the current study acquired after the setting was changed.

Adjusting the venous pressure (Pv) affects the FFR value through the following equation:

- FFR = (Pd - Pv) / (Pa - Pv)

The default venous pressure (Pv) value is 0 mmHg. The venous pressure resets to 0 mmHg when a new study is started.

5 Using the **Gradient Display** drop-down list, select whether to hide the gradient value, or whether to show the mean or peak gradient value.

- **Off**: the gradient value is not displayed.
- **Mean**: displays the difference between the mean pressures (Pa(mean) - Pd(mean)).
- **Peak**: displays the difference between the peak pressures (Pa(peak) - Pd(peak)).

The default setting is **Off**.

6 To close the menu, select **Close**.

9 Performing IVUS procedures

Images can be recorded by either saving a single frame or recording a video loop of multiple frames.

The imaging catheters used for acquiring intravascular ultrasound (IVUS) images are designed for placement using standard intra-operative or percutaneous techniques by suitably trained physicians. The frequency and duration of use is at the discretion of the physician and depends upon the procedure being performed.

9.1 Setting up the system for IVUS procedures

Imaging catheters connect to the system through the patient interface module (PIM). The PIM is typically left connected to the bedside utility box between studies, but may need to be reconnected if removed after a study.

Before a PIM is connected to the system and a catheter type configured, the system displays guidance for connecting the PIM. Before connecting or placing the PIM, inspect it and its cable for damage and do not use if damage is found.

CAUTION

The PIM's cable may be damaged if equipment is rolled on it. Do not pull on the cable, place the cable in a high traffic area, or use excessive force as this may cause damage. If the PIM is dropped, there could be damage to the body or internal electronics. Do not use the PIM if the outer case, cable, or connectors appear damaged.

CAUTION

If used in the sterile field, place the PIM in a sterile barrier pouch or bag using standard sterile techniques.

CAUTION

Attach the PIM to the bed rail using its clamp or place in the use location so that there is sufficient slack in the cable to avoid binding during patient table movements. The PIM or cable can be damaged if dropped or improperly located, potentially resulting in user or patient harm if this occurs during a procedure.

CAUTION

The PIM can be damaged if contrast fluid or saline enter the catheter connection port. This may cause image quality issues. The PIM should not be placed below an IV pole where liquids such as saline or contrast may drip onto the PIM or into the connection port causing damage.

1 Select the **IVUS** application.

2 Ensure you are using the FM-PIM for the procedure.

- IVUS procedures require the SA-PIM.
- Rotational IVUS procedures require the rotational PIM (PIMr).

Animated guidance is displayed to assist you if the PIM is not connected.

3 Align the markers on the cable connector of the short cable attached to the PIM with the connector at the patient end of the PIM cable from the system, and slide the connections together until you hear a click.

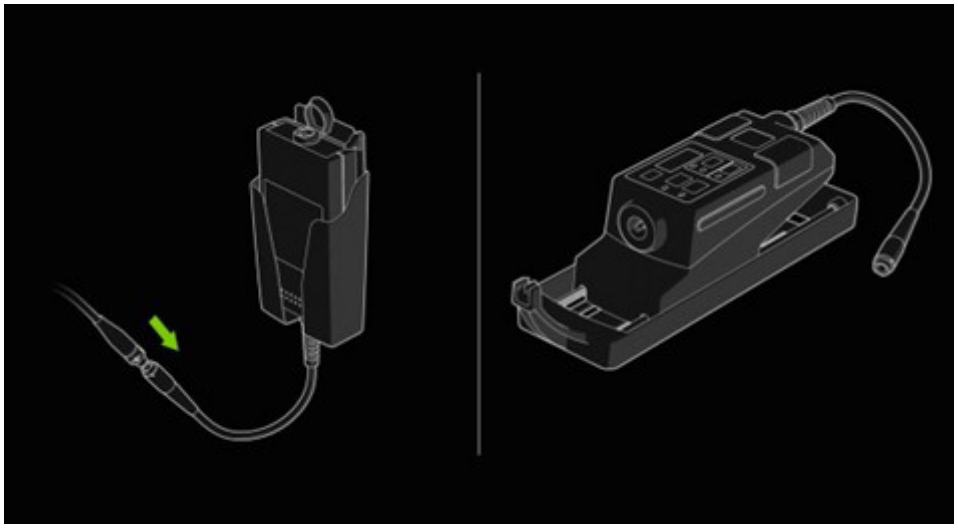


Figure 57 Animated guidance for connecting the PIM - the SA-PIM is shown on the left side of the image

The system detects the PIM and displays the next appropriate guidance step.

4 Prepare and connect the catheter to the PIM.

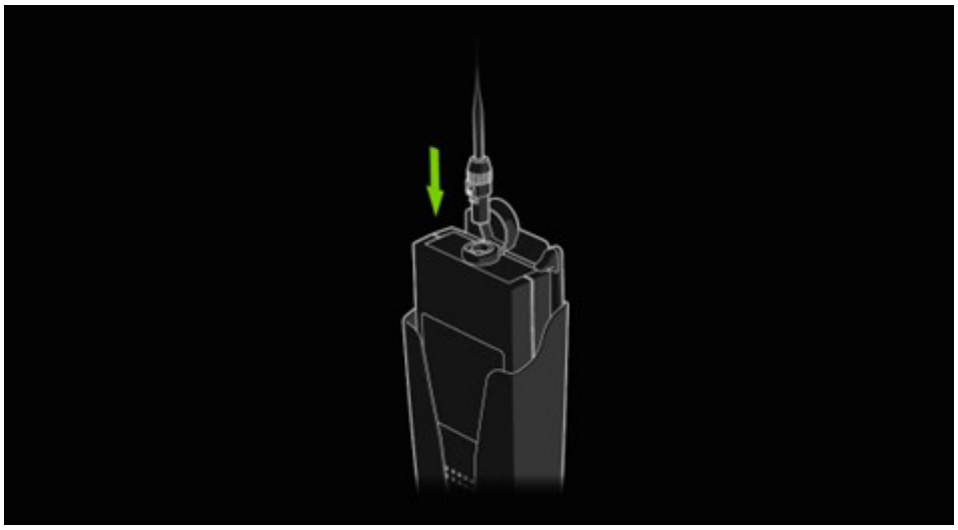


Figure 58 Animated guidance for connecting the catheter

NOTE ***Refer to the pressure guide wire Instructions for Use for directions before and during the procedure. Refer to the catheter or pressure guide wire label for specific insertion instructions. Consult the catheter or pressure guide wire package insert for a full description of warnings, precautions, and use instructions.***

CAUTION

The PIM can be damaged if contrast fluid or saline enter the catheter connection port. This may cause image quality issues. Care should be taken to not expose the catheter plug to fluid that can be transferred to the PIM when connecting the catheter.

Once the catheter is connected, the system initializes the catheter and the live screen is displayed. Imaging cannot start until the catheter is connected to the PIM.

5 Verify that the connections are secure.

The system recognizes the installed pressure guide wire for each study until a different type is installed. Any user-defined values are reset to the default values at the beginning of each study.

9.2 Using the IVUS live screen

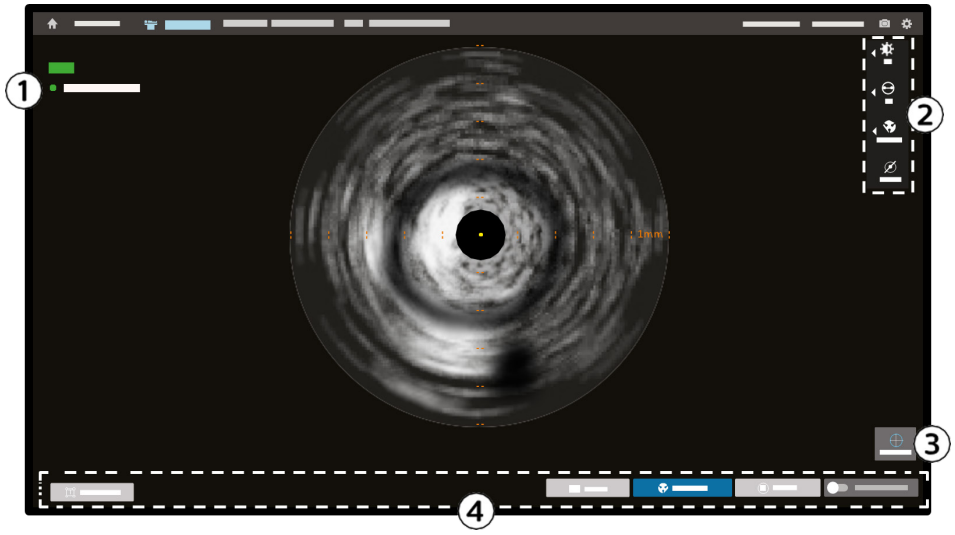


Figure 59 IVUS live screen

Legend	
1	Series label
2	Image adjustment menu
3	ChromaFlo
4	Function controls

1 Ensure the patient interface module for IVUS imaging (SA-PIM) is connected to the system and the imaging catheter is connected to the SA-PIM.

2 Using fluoroscopy, insert the imaging catheter following the catheter guide wire Instructions for Use packaged with the catheter

3 To adjust the image gain and field of view, do the following:

a To adjust the gain of the catheter, select **Gain** and move the slider to the desired setting.

b To adjust the field of view of the catheter, select **FOV** and move the slider to the desired setting.

4 When the IVUS transducer is outside the guiding catheter, select the **Ringdown** mode you want to use.

- To use adaptive ringdown, select **Adaptive**.
- To use manual ringdown, select **Manual**.

The imaging catheter emits ultrasound energy and that energy accumulates at the catheter surface. This accumulation of energy appears as a bright ring artifact at the center of a tomographic image, and is called ringdown. Manual ringdown uses one reference point obtained when **Ringdown** is selected during live imaging. Adaptive ringdown continuously updates the reference as imaging is performed

5 To reduce artifacts in the IVUS image, switch on the **Ringdown** function.

6 To rotate the image around its center, do the following:

a Select **Revolve**.

Directional arrows are displayed on the screen with numbering to facilitate communication about revolving the image.

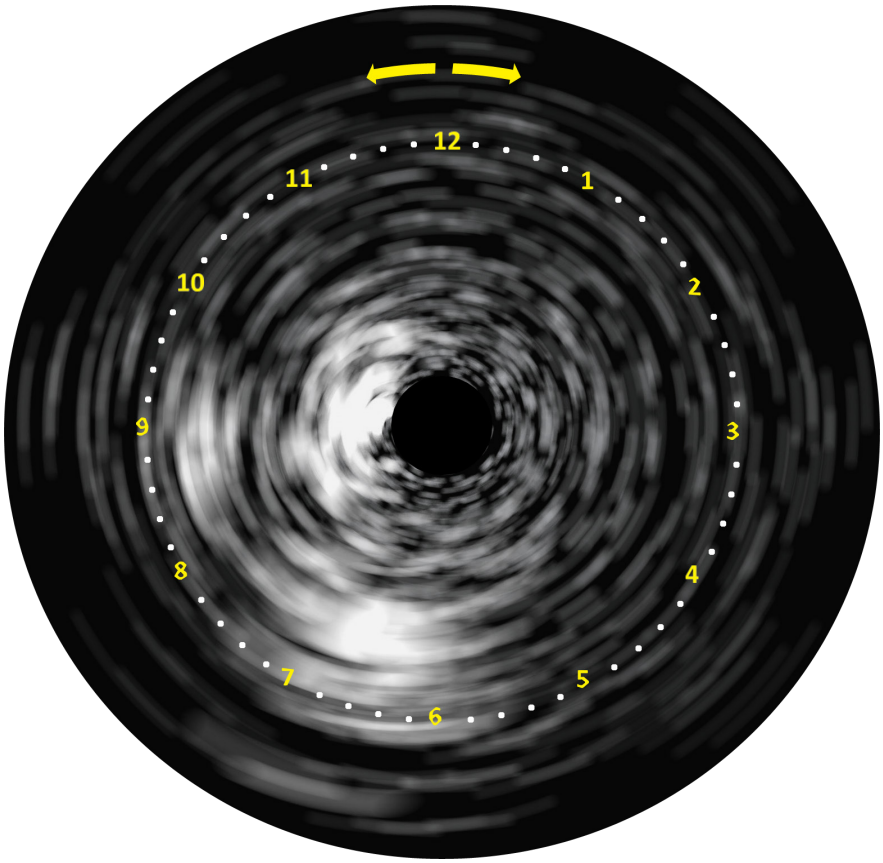


Figure 60 Screen markers for revolving the image

b Drag one of the directional arrows to the desired position.

The image rotates around the center.

c When the image is rotated to the desired position, select **Done**.

The **Revolve** function is also available in IVUS review screens.

7 To use the ChromaFlo function to assist in identifying the vessel lumen, do the following:

a Select **ChromaFlo**.

b To adjust the **Region**, expand the control and move the slider to the desired setting.

c To adjust the **Sensitivity**, expand the control and select the desired setting.

ChromaFlo cannot be used with co-registration.

For more information, see *ChromaFlo on page 30*.

8 To display a static image frame on the live screen, select **Freeze**. A static image is displayed.

To return to the IVUS live screen, select **Live**.

9 To capture an image to archive, do one of the following:

- Select **Snapshot**. This option captures an image of the full screen and can be archived as SC DICOM or PNG formats. A snapshot cannot be opened again in the IVUS application.
- Select **Save Frame**. This option saves only the tomographic image frame and can be archived as IVUS/US DICOM or PNG formats. This frame can be opened again in the IVUS application.

9.3 Recording IVUS images with co-registration

When performed with co-registration, the location of IVUS images can be identified in relation to the anatomy of interest on the selected x-ray image and you can perform accurate length measurements.

WARNING

Poor X-ray image quality or low frame rate (<15 fps) may lead to co-registration failure or inaccurate co-registration results. The presence of CABG wires, additional guide wires, pacing leads, surgery clips, or other metallic objects within the X-ray image may also lead to co-registration failure or inaccurate co-registration results. Ensure the guide catheter, guide wire tip, three IVUS markers, and the transducer are fully visible within the fluoroscopy images. Failure to do so may result in inaccurate co-registration.

NOTE ***The shutters for the X-ray images should be positioned parallel to the image edges and not at an angle. Angled shutters can cause the co-registration to fail. Use the X-ray mode that provides the highest image quality and set the X-ray field of view to 18-22 cm. On a Philips Azurion X-ray system, enable Fluoroscopy Flavor 3 or SyncVision/Co-Registration mode for optimal settings.***

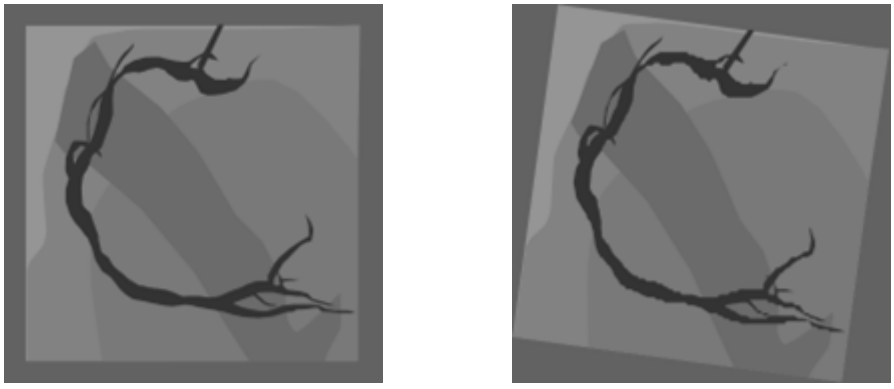


Figure 61 Correct X-ray shutter alignment (left) and incorrect X-ray shutter alignment (right) Co-registration can only be performed using the Eagle Eye Platinum catheter.

1 Select the **IVUS** application.

2 Confirm that an IVUS image is displayed.

3 Switch on **Co-registration** if it is disabled.

4 To make a recording, do the following:

a Start fluoroscopy on the X-ray system.

b Select **Record**.

c Slowly and steadily, pull the catheter back through the vessel.

Perform the pullback under continuous fluoroscopy with a field of view of 18-22 cm and a frame rate of 15 fps (fluoro flavor 3 when used with a Philips Azurion x-ray system). Minimize metallic objects in the field of view. Pullback should be performed in a slow (up to 5 mm/sec), continuous, and steady pace with a minimum of uneven movement. Do not change the zoom, collimation, table position, or C-arm position during the procedure, and ensure the catheter tip and guide catheter are both visible in the field of view. The pullback recording ends if you stop performing fluoroscopy before selecting **Stop**.

NOTE ***Pulling back faster than 5 mm/sec or a non-continuous pullback or a pullback that is performed under less than 4 seconds of live fluoroscopy, may lead to a failure or inaccurate co-registration results.***

WARNING

A pullback rate faster than the recommended speed of up to 5 mm/sec, a non-continuous pullback, or a pullback that is performed under less than 4 seconds of live fluoroscopy may lead to co-registration failure or inaccurate co-registration results.

WARNING

Changes in the X-ray geometry or patient positioning during the pullback recording may lead to inaccurate co-registration results. Avoid changing the zoom or collimator and do not move the patient table or C-arm while recording a pullback and then making an x-ray image.

WARNING

Making a recording while pushing the catheter forward instead of pulling it back may lead to co-registration failure or inaccurate co-registration results. Verify that the proximal (P) and distal (D) labels on the ILD align correctly with the respective P and D markers on the roadmap to ensure accurate co-registration. Misalignment may result in incorrect anatomical mapping and impact procedural outcomes.

d To apply bookmarks during the recording, select **Bookmark** at each desired position.

e Select **Stop** to stop recording or stop performing fluoroscopy.

5 Acquire an x-ray image of the vessel or select an existing x-ray image in the **Series** list.

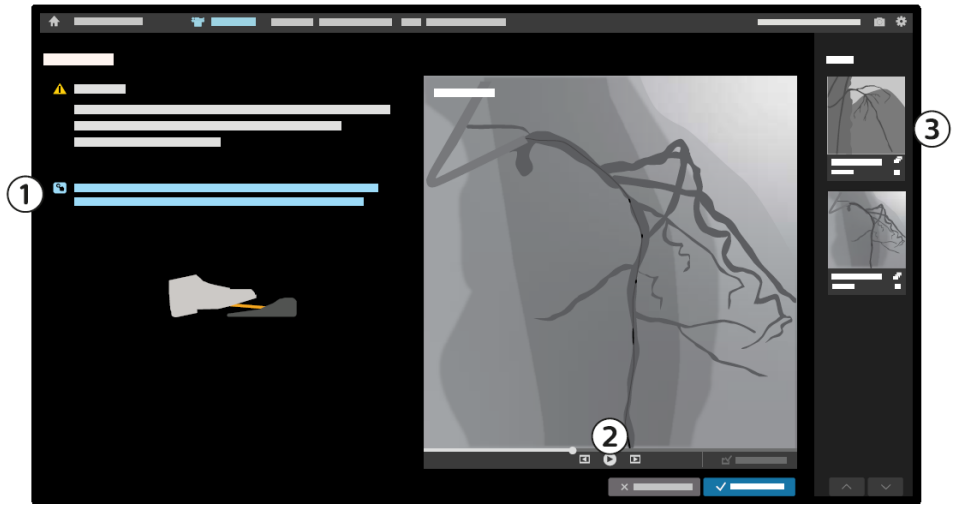


Figure 62 **CINE SELECT** screen

Legend	
1	Guidance
2	Last acquired exposure series
3	**Series** panel

WARNING

The x-ray image must be acquired at the same zoom level, C-arm position, and patient table position as was used for the fluoroscopy while recording the pullback. Changing these settings between recording the pullback and x-ray image, or selecting an older x-ray image with different settings, may lead to inaccurate co-registration results.

When using IntraSight Plus with a Philips X-ray system, only compatible x-ray images are displayed when **Showing compatible series** is switched on in the **Series** list. You can display incompatible series by switching **Showing compatible series** off.

If you selected an existing x-ray image in the **Series**, select **Perform Co-reg**.

If you are using the automatic workflow, the system automatically generates the pathway on the x-ray image and displays the co-registration results.

If you are using the semi-automatic workflow, you can review and **Confirm** the pathway or edit the pathway to correct how it is displayed.

For more information, see *7.5.1 Editing the pullback pathway on page 69*.

NOTE ***A "Zero Contrast" co-registration workflow can be performed by selecting or creating a "dry" cine series (a recording that does not contain contrast and is not an x-ray image) from the Series list. You are prompted to confirm the pathway or edit the pathway to correct how it is displayed. This workflow can be facilitated by recording the cine series with a pressure guide wire or catheter in place to mark the pullback path.***

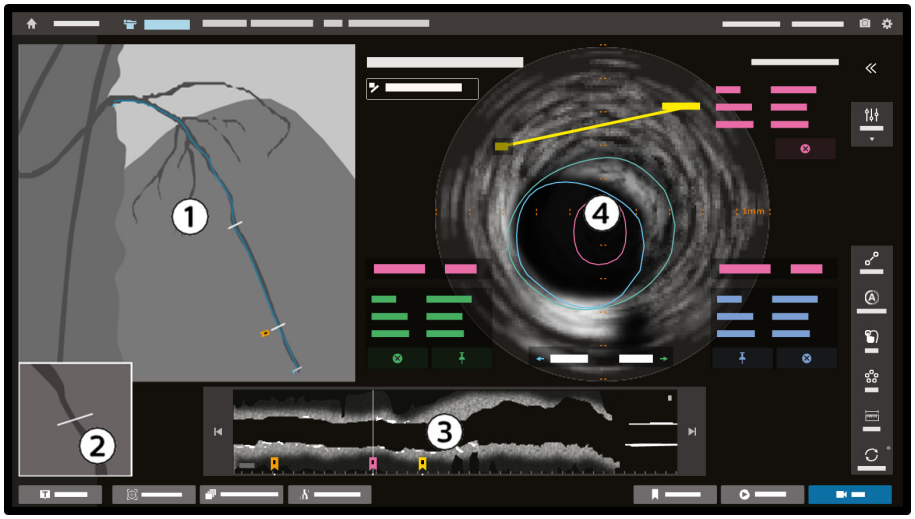


Figure 63 IVUS with co-registration results

Legend	
1	Roadmap
2	Zoomed roadmap view (visible when dragging the cursor line)
3	Inline display
4	4 IVUS images (with example measurements)

CAUTION

Under certain limited conditions, such as when the pullback pathway appears from the selected X-ray viewing angle as a straight line or a near-perfect curve, the system may be unable to perform co-registration. In such cases, a message is displayed. If this occurs, repeat the pullback measurement using a different angiographic view or view the pullback result without co- registration.

7 To perform length measurements, do the following:

a Move the cursor line to the desired point on the inline display or on the roadmap where the length segment should be placed.

b Select **Length**.

A measurement of zero length is placed at the selected location.

You can place a length measurement by positioning the pointer at the desired location and pressing and holding the left mouse button. On the touch screen module, you can place the length measurement by selecting and holding at the desired location.

c Set the measurement start and end points by dragging the left and right markers to the desired positions.

You can drag the left and right markers on the inline display or on the roadmap. The length is displayed on the inline display and on the roadmap.

d To place an additional length measurement, select **Add Length.**

e Position the length measurement in the same way as the previous one.

You can repeat this process for up to four length measurements.

Each length measurement is identified by a letter and a unique color, and is displayed on the inline display and on the roadmap at the selected location along the vessel path.

You can drag a label to a new location if it is interrupting the view of the region of interest.

f To delete a length measurement, select **Clear** next to the length measurement you want to delete.

g When you have finished placing length measurements, select **Done**.

8 To view the pullback results without the co-registration data, switch off **Co-registration**.

You can view the co-registration data again by switching **Co-registration** on again.

9 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre- defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

10 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

11 To return to the procedure home screen, select **Home**.

9.3.1 Editing the pullback pathway

If you want to edit the pathway, you can edit it on the roadmap. This function is only available when you review the results after making a recording. It is not available when you open a previous recording to review it.

Figure 64 Editing the pathway

1 Select **Edit Pathway**.

An editable image of the pathway is displayed with guidance.

To pan the image to achieve the desired view, hold down the right mouse button and drag the image or use two fingers on the touch screen module to drag the image to the desired position.

To zoom the image in or out to achieve the desired view, use the mouse scroll wheel.

To zoom on the touch screen module, use two-finger pinch and stretch gestures. For more information, see *Touch screen gestures on page 25*.

2 To reposition the pathway along the vessel of interest, select the pathway and drag along the vessel of interest.

Animated guidance is provided on the main display to assist you.

On the touch screen module, you can view the animated guidance by selecting the information icon.

Draw the pathway from the most proximal visible section of the guide catheter to the most distal visible section of the vessel, ensuring the pathway remains within the vessel of interest.

When you select the pathway and drag the pointer, the pathway line changes to a broken line, indicating that you are editing the pathway. When you release the left mouse button, the pathway line changes back to a solid line.

To edit the pathway using the touch screen module, select and hold the yellow ring without covering your view of the pointer. The yellow ring shrinks in size toward the pointer location, indicating that you can drag the pointer while still being able to view it. When you have edited the pathway, remove your finger from the touch screen module to stop editing the pathway.

3 To undo your edit, select **Undo Edit**.

4 To redo an undone edit, select **Redo Edit**.

5 To delete the pathway, do the following:

6 To reset the pathway and remove all your edits, select **Reset Pathway**.

7 To close the editing screen without saving your changes, select **Exit Without Save**.

8 To save your edited pathway and update the co-registration results, select **Update Co-reg**.

9.3.2 Changing the roadmap

You can overlay the IVUS co-registration results on a different angiographic roadmap for the same patient. This function is only available when you review the results after making a recording. It is not available when you open a previous recording to review it.

1 Select **Change Roadmap**.

2 Acquire a cine image or select an existing one in the **Series** list.

The x-ray image must be acquired at the same zoom level, C-arm position and table position as used for the fluoroscopy during the IVUS recording. The system uses an image from the x-ray image to overlay the co-registration results. This is known as the roadmap.

When using IntraSight Plus with a Philips X-ray system, only compatible cine images are displayed when **Showing compatible series** is switched on in the **Series** list. You can display incompatible series by switching **Showing compatible series** off.

WARNING

The x-ray image must be acquired at the same zoom level, C-arm position, and patient table position as was used for the fluoroscopy while recording the pullback. Changing these settings between recording the pullback and x-ray image, or selecting an older x-ray image with different settings, may lead to inaccurate co-registration results.

3 To return to the co-registration results without changing the roadmap, select **Return**.

4 To update the co-registration results and use the new roadmap, select **Update Co-reg**.

9.4 Recording IVUS images without co-registration

1 Select the **IVUS** application.

2 Switch off **Co-registration** if it is enabled.

3 Confirm that an IVUS image is displayed.

4 Using fluoroscopy, insert the imaging catheter following the catheter guide wire Instructions for Use packaged with the catheter

5 To make a recording, do the following:

a Select **Record**.

b Slowly and steadily, pull the catheter back through the vessel.

c To apply bookmarks during the recording, select **Bookmark** at each desired position.

d Select **Stop** to stop recording.

9.5 Recording IVUS images with tri-registration

If you have a co-registered iFR series which was recorded using the same X-ray system geometry, you can combine the data with a co-registered IVUS recording. This is known as tri-registration.

In order to achieve a tri-registered view, the following conditions must be met:

- The same angiographic roadmap image must be used for the co-registered iFR data and the co- registered IVUS data.
- The co-registered iFR series must be created before the co-registered IVUS recording.
- The X-ray system zoom, table position, and C-arm position must be the same for the co-registered iFR data and the co-registered IVUS data.

When reviewing tri-registered data, you cannot edit the pullback pathway or change the roadmap image.

1 Record IVUS images with co-registration in the normal way until you reach the **CINE SELECT** screen. For more information, see *9.3 Recording IVUS images with co-registration on page 93*.

2 At the **CINE SELECT** screen, select the desired co-registered iFR series in the **Series** panel.

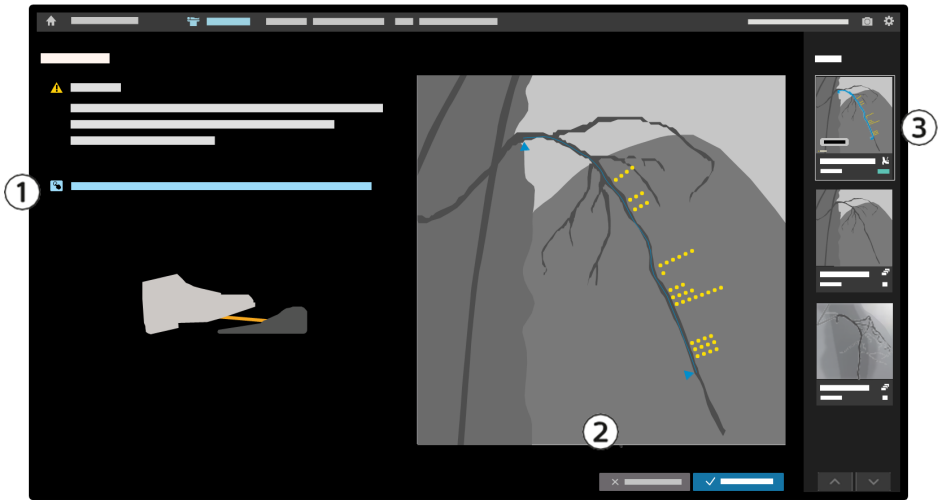


Figure 65 **CINE SELECT** screen

Legend	
1	Guidance
2	Last acquired exposure series
3	**Series** panel

When using IntraSight Plus with a Philips X-ray system, only compatible x-ray images are displayed when **Showing compatible series** is switched on in the **Series** list. You can display incompatible series by switching **Showing compatible series** off.

When a co-registered iFR series is selected in the **Series** panel, the system detects that tri-registration is possible and the function button labels at the bottom of the screen change to reflect the availability of tri-registration.

WARNING

The x-ray image must be acquired at the same zoom level, C-arm position, and patient table position as was used for the fluoroscopy while recording the pullback. Changing these settings between recording the pullback and x-ray image, or selecting an older x-ray image with different settings, may lead to inaccurate co-registration results.

3 Select **Perform Tri-reg**.

The tri-registration results screen is displayed.

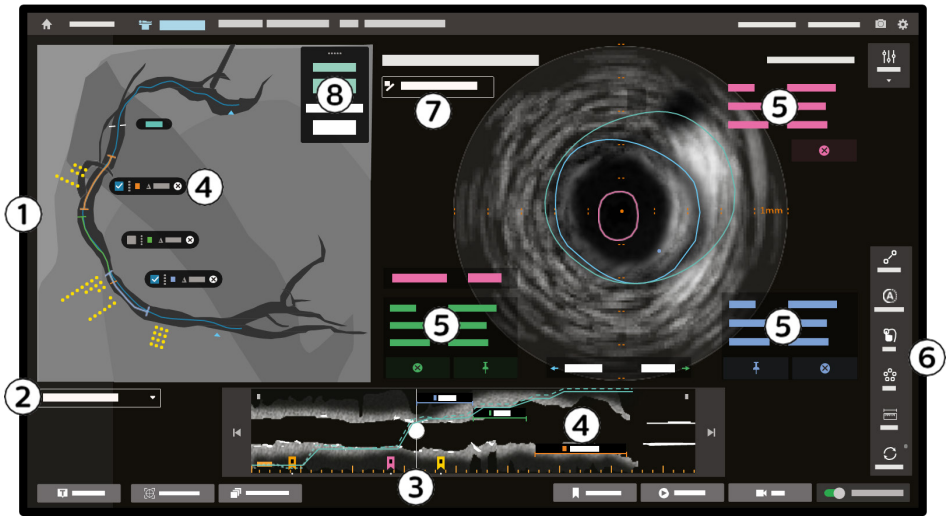


Figure 66 Tri-registration results screen

Legend			
1	Roadmap	5	Measurements
2	**Roadmap Options** menu	6	Measurement functions menu
3	Cursor on the inline display	7	Series label
4	Virtual stents	8	iFR distal and estimate values

The roadmap image is displayed at the left of the screen. The roadmap image displays the measured points and the iFR delta indicators from the iFR pullback recording combined with the pullback pathway from the IVUS recording.

The inline display at the bottom of the screen includes an overlay of the iFR graph. This overlay is the portion of the iFR graph relating to the IVUS pullback pathway. Any parts of the iFR graph which relate to positions in the anatomy which are not part of the IVUS co-registration pathway are omitted from the inline display.

It is unlikely that the iFR co-registration and IVUS co-registration segments will cover identical regions of the vessel, so it is possible to have measured points and iFR delta indicators displayed on the roadmap image that do not lie in the IVUS co-registration region and to have parts of the IVUS co-registration region at either end with no iFR delta indicators or measured points. Blue triangles indicate the start and end of the IVUS co-registration region. You can navigate using the cursor and perform measurements within this region.

The yellow dots on the roadmap indicate where the measured iFR value has dropped by a predetermined amount between two adjacent measured points. This is the iFR delta step size. Each dot represents a drop in the iFR value of the selected iFR delta step size. For example, if a step size of 0.01 is selected and 5 yellow dots are visible at a single location on the vessel path, this indicates that the system detected an iFR value drop of 0.05 at this location (5 x 0.01).

The iFR drop between two adjacent measured points is rounded to two decimal places for representation by the yellow dots. For example, if a step size of 0.01 is selected, a measured point which does not display any yellow dots could have an iFR drop of up to 0.0049 and a measured point with one yellow dot could have an iFR drop of between 0.0050 and 0.0149.

You can only achieve tri-registration when creating or reviewing a new recording. During your review of the new recording, you can change the roadmap image used by selecting Change Roadmap and selecting a new roadmap image but once you leave the IVUS application, the Change Roadmap function is no longer available. You cannot open an existing co-registered IVUS recording with an existing co-registered iFR pullback series to achieve a tri-registered view.

4 To plan a treatment strategy, place length segments by doing the following:

a Move the cursor line to the desired point on the inline display or on the roadmap where the length segment should be placed.

b Select **Length**.

A length segment of zero length is placed at the selected location.

You can place a length segment by positioning the pointer at the desired location and pressing and holding the left mouse button. On the touch screen module, you can place the length segment by selecting and holding at the desired location.

c Set the length segment to the desired length by dragging the left and right markers to the desired positions.

You can drag the left and right markers on the inline display or on the roadmap.

The system indicates the estimated change in iFR value of placing a length segment of the selected length at the selected location.

d To place an additional length segment, select **Add Length**.

e Position the length segment in the same way as the previous length segment.

You can repeat this process for up to four length segments.

The system calculates and displays the estimated change in iFR value for each length segment and the new estimated overall iFR value.

Each length segment is identified by a letter and a unique color, and is displayed on the inline display and on the roadmap at the selected location along the vessel path.

You can drag a label to a new location if it is interrupting the view of the region of interest.

f To delete a length segment, select **Clear** next to the length segment you want to delete.

g Then you have finished placing length segments, select **Done**.

h To hide a length segment and exclude it from the iFR estimate, deselect the check box beside the desired length segment in the roadmap.

You can include the length segment in the iFR estimate again by reselecting the check box for the desired length segment.

The iFR estimate may not exactly match calculations based on the iFR delta step due to rounding.

5 To show or hide the pathway on the roadmap, select **Roadmap Options** and check or uncheck **Pathway**.

6 To show or hide the measured points on the roadmap, select **Roadmap Options** and check or uncheck **Measured points**.

7 To view the pullback results without the co-registration data, switch off **Co-registration**.

You can view the co-registration data again by switching **Co-registration** on again.

8 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre- defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

9 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

10 To return to the procedure home screen, select **Home**.

9.6 Reviewing a previous IVUS recording

You cannot access the live screen when reviewing a previous study and for co-registered data, you cannot edit the pathway or change the roadmap.

1 Open the desired study for review by following steps 1-3 in *Opening a previous IVUS recording* (page 119).

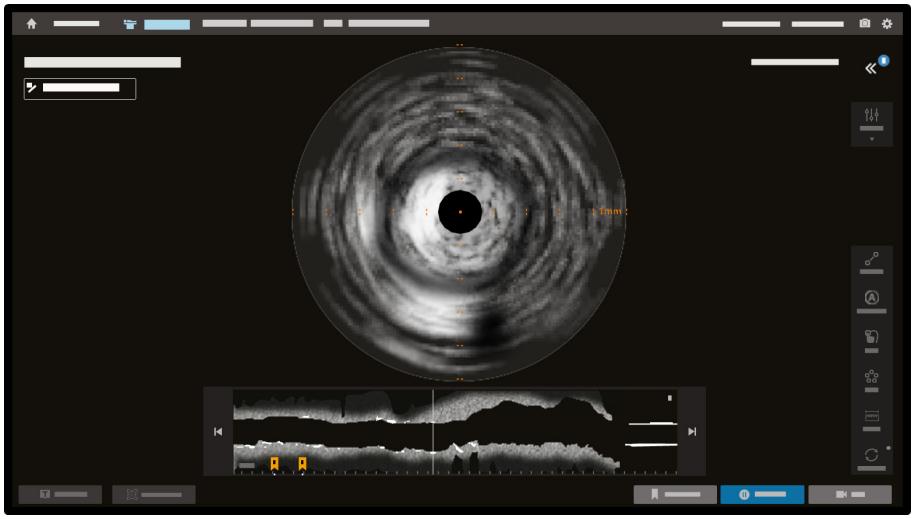


Figure 67 Reviewing the IVUS recording

2 To pause the playback, select **Pause**.

3 To move between individual image frames, do the following:

- To move through the frames, drag the frame marker to the desired position on the inline display.

- To move forward by one frame, select **Next Fr.**.

- To move backward by one frame, select **Prev Fr.**.

- To cycle through the images in playback mode, select **Playback**.

4 To place a bookmark on an image frame, navigate to the desired image frame and select **Bookmark**.

A bookmark is placed on the inline display and in the co-registered results at the location of the selected image frame.

5 To cycle through a specific range of adjacent frames, position the cursor line at the desired position on the inline display and select **Rapid review**.

For more information about settings related to rapid reviewing, see *9.10.1 Adjusting the IVUS display settings on page 110*.

6 To change the orientation of the inline display in relation to the cross-sectional tomographic image, do the following:

a Select **Rotate ILD**.

An arrow with a circular control is displayed.

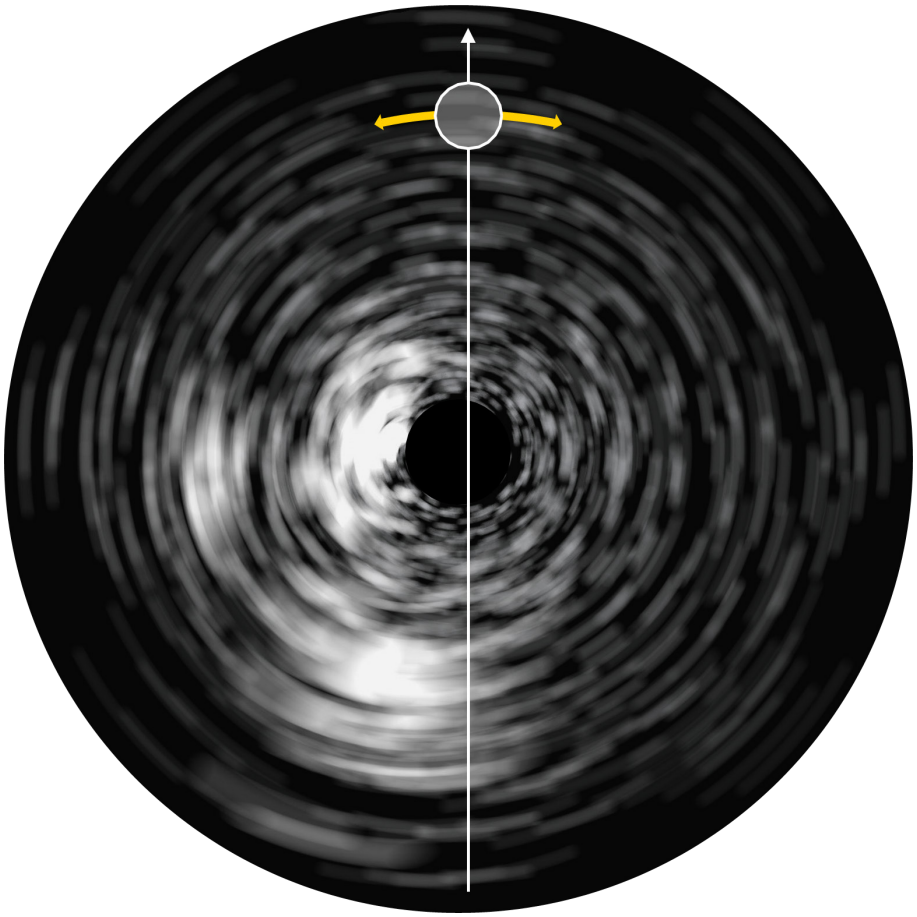


Figure 68 Rotating the inline display

Rotating the inline display allows complete vessel visualization. An arrow on the cross-sectional tomographic image corresponds to the angle represented by the cursor line in the inline display. The default position of the arrow is pointing to the right.

b Drag the circular control to orient the arrow in the desired direction.

The arrow rotates around the center of the cross-sectional image and the inline display updates as you drag the arrow to the new position.

c To keep the inline display oriented in the new direction, select **Done**.

The arrow in the center of the cross-sectional image indicates the orientation of the inline display.

7 To rotate the image around its center, do the following:

a Select **Revolve**.

Directional arrows are displayed on the screen with numbering to facilitate communication about revolving the image.

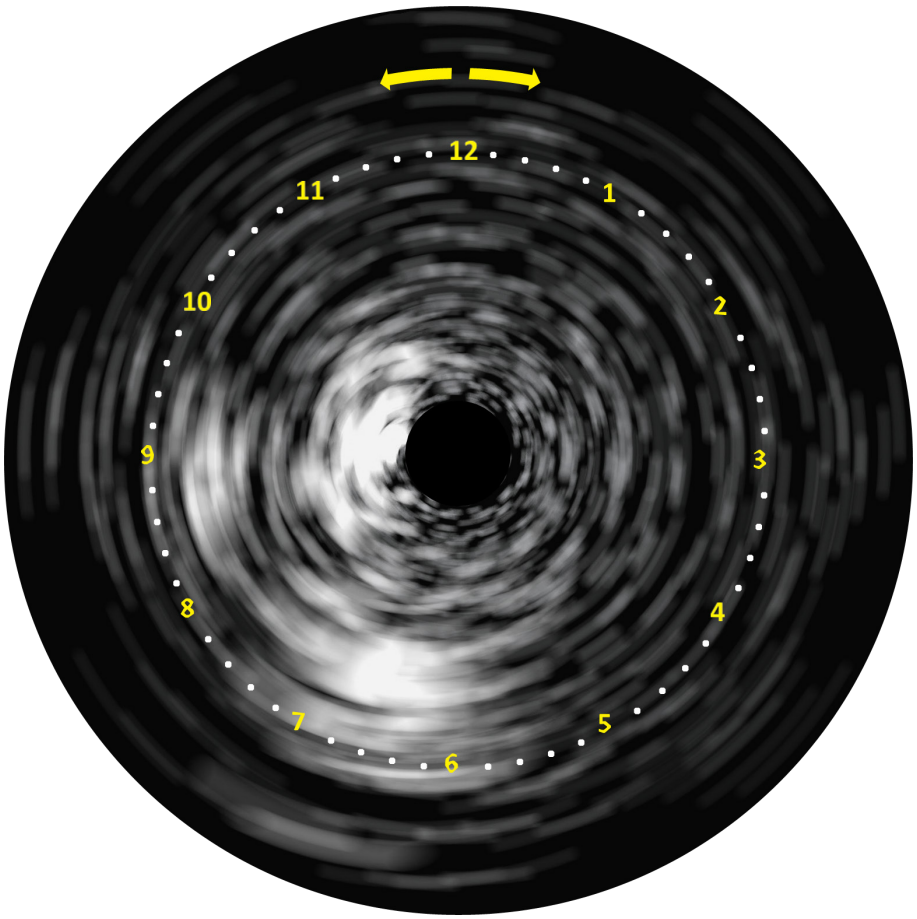


Figure 69 Screen markers for revolving the image

b Drag one of the directional arrows to the desired position.

The image rotates around the center.

c When the image is rotated to the desired position, select **Done**. The **Revolve** function is also available in IVUS review screens.

8 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre-defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

9 To capture an image to archive, do one of the following:

- Select **Snapshot**. This option captures an image of the full screen and can be archived as SC DICOM or PNG formats. A snapshot cannot be opened again in the IVUS application.

- Select **Save Frame**. This option saves only the tomographic image frame and can be archived as IVUS/US DICOM or PNG formats. This frame can be opened again in the IVUS application.

10 To return to the procedure home screen, select **Home**.

9.7 Making length measurements in co-registered IVUS images

1 Move the cursor line to the desired point on the inline display or on the roadmap where the length segment should be placed.

2 Select **Length**.

A measurement of zero length is placed at the selected location.

You can place a length measurement by positioning the pointer at the desired location and pressing and holding the left mouse button. On the touch screen module, you can place the length measurement by selecting and holding at the desired location.

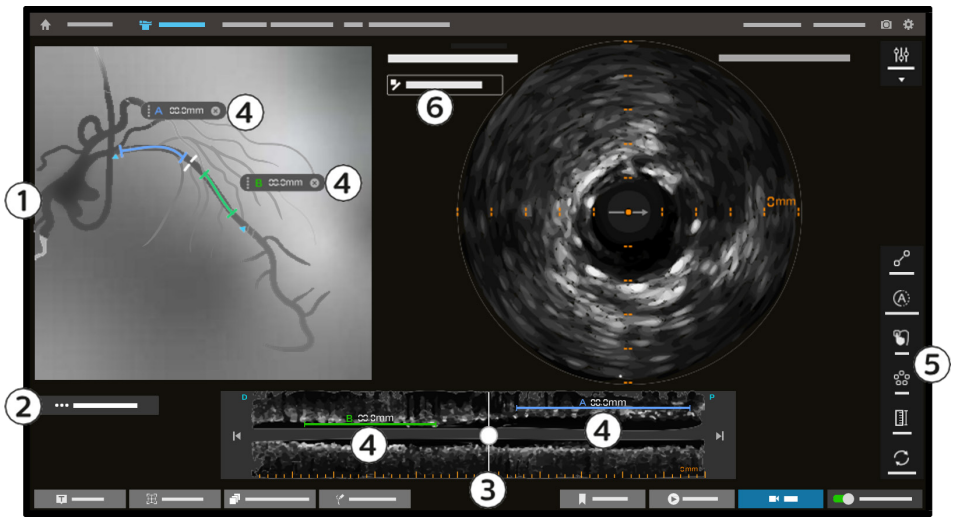


Figure 70 Length measurements in co-registered IVUS images on the main display

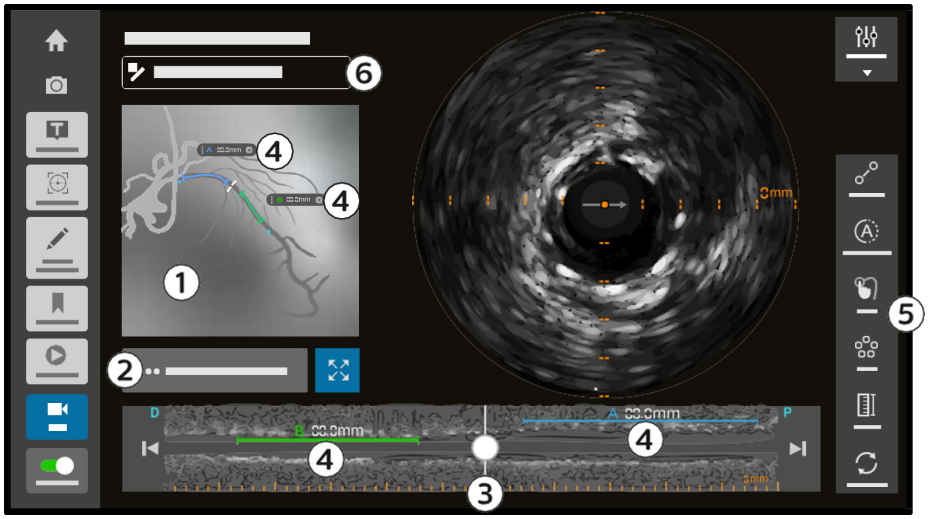


Figure 71 Length measurements in co-registered IVUS images on the touch screen module

Legend			
1	Roadmap	4	Length measurements
2	**Roadmap Options** menu	5	Measurement functions menu
3	Cursor on the inline display	6	Series label

3 Set the measurement start and end points by dragging the left and right markers to the desired positions.

You can drag the left and right markers on the inline display or on the roadmap. The length is displayed on the inline display and on the roadmap.

4 To place an additional length measurement, select **Add Length**.

5 Position the length measurement in the same way as the previous one. You can repeat this process for up to four length measurements.

Each length measurement is identified by a letter and a unique color, and is displayed on the inline display and on the roadmap at the selected location along the vessel path.

You can drag a label to a new location if it is interrupting the view of the region of interest.

6 To delete a length measurement, select **Clear** next to the length measurement you want to delete.

7 When you have finished placing length measurements, select **Done**.

9.8 Creating measurements and annotations

You can create measurements on the IVUS image to determine diameters and areas, to assist you in determining appropriate treatments.

The accuracy of measurements depends upon your familiarity with the measurements being created and on your interpretation of ultrasound images.

When a measurement is created, a bookmark is placed on the inline display and in the co-registered results at the location of the selected image frame.

NOTE ***The displayed measurements and calculated values are rounded.***

1 Open the desired IVUS recording for review.

For more information, see *9.9 Opening a previous IVUS recording on page 110*.

2 Review the recording and select an image frame.

3 To create a diameter measurement, do the following:

a Select **Diameter**.

b Select a start point on the image.

c Select an end point on the image.

The measurement is displayed and a bookmark is added to the inline display to indicate the frame where the measurement was placed.

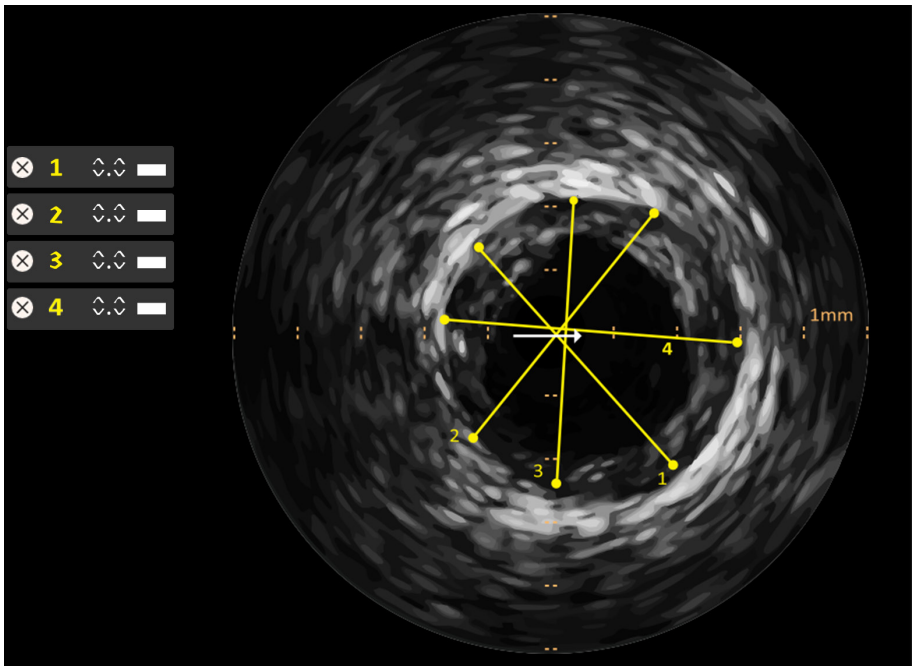


Figure 72 Diameter measurements

You can also create the measurement by dragging the cursor from the start point to the desired end point instead of individually selecting each point.

d To create additional diameter measurements, repeat the process.

You can create up to four diameter measurements.

e To edit the start and end points of a measurement, drag each point to the desired location.

f To delete a measurement, select **Clear** beside the desired measurement.

To automatically measure the vessel wall and lumen areas of interest, select **Autoborders**.

The vessel wall and lumen are automatically detected on the selected image frame and the measurements are displayed.

WARNING

Measurements placed using Autoborders should be reviewed for clinical accuracy and edited if necessary to prevent measurement errors.

5 To create an area measurement, do the following:

a Select **Draw**.

b Select the starting point for the outline of the area to be measured and drag the cursor to draw the outline of the desired area.

The area of the enclosed outline is displayed with the maximum and minimum diameters indicated. Each area measurement is bookmarked on the inline display to indicate the frame where the measurement was placed. For peripheral procedures, the effective diameter is also indicated. The effective diameter is the equivalent diameter of the vessel if the vessel was circular in cross-section, based on the circumference of the non-circular vessel.

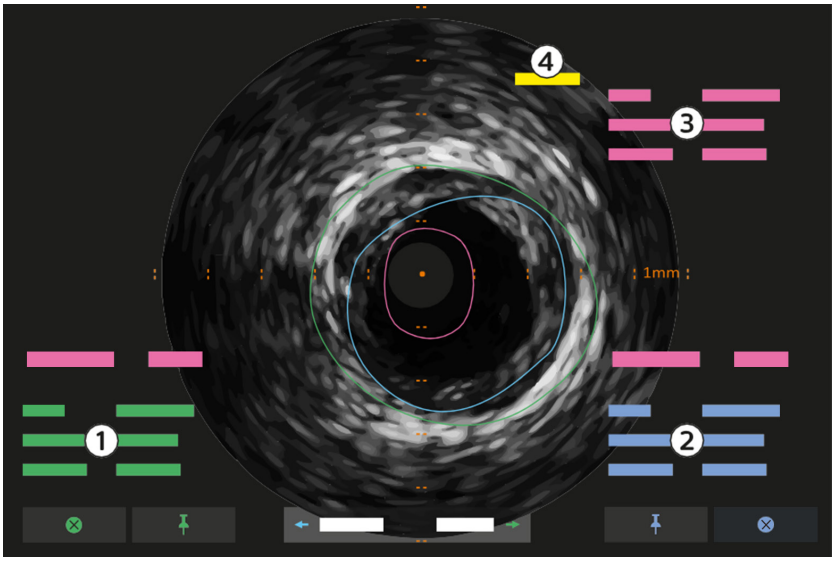


Figure 73 Area measurements

Legend	
1	First area measurement
2	Second area measurement
3	Pinned area measurement
4	Annotation

You can pin an area measurement as a reference overlay so that it remains visible when you navigate to another image frame.

c To pin the area measurement as a reference overlay, visible on all images in the recording, select the **Pin** icon.

d To replace a pinned reference measurement with another measurement, select the pin icon for the new measurement and confirm the action by selecting **Replace**.

e To edit an area measurement, select the desired area measurement and drag the outline to the new desired shape before selecting **Done**.

f To delete a measurement, select **Clear** beside the desired measurement.

6 To create an area measurement by placing dots on the selected image frame instead of drawing a line, do the following:

a Select **Dots**.

b Place your first dot by selecting the desired location on the image.

c Continue placing dots around the edge of the area to be measured.

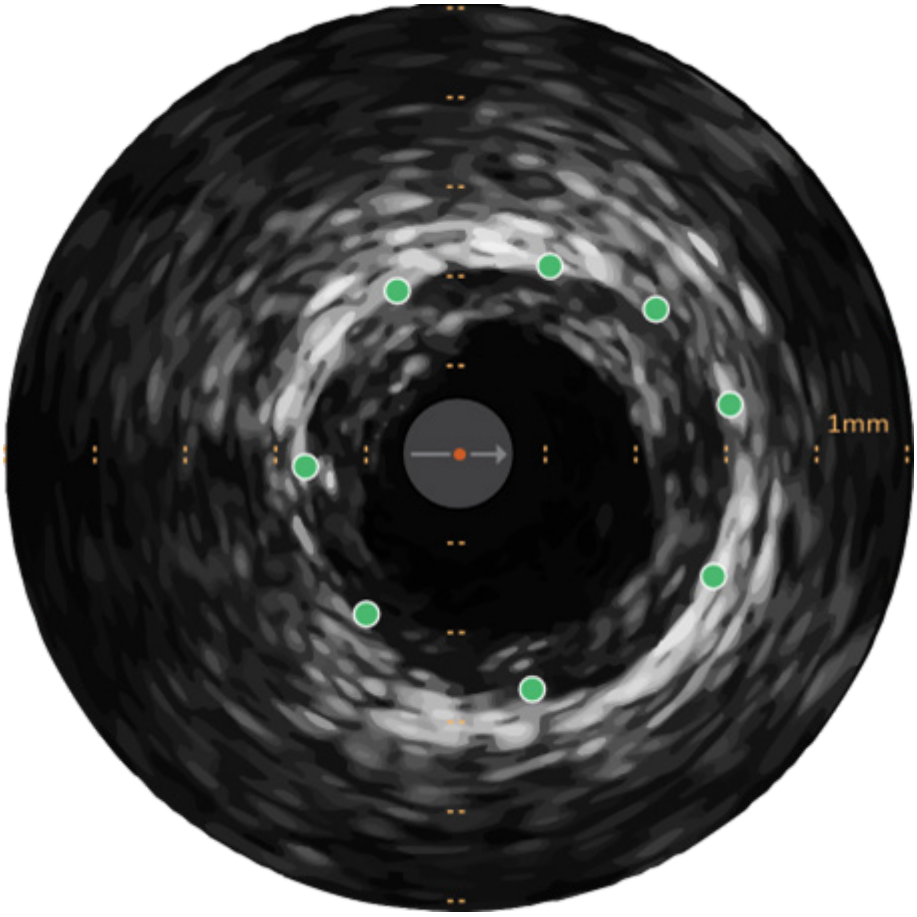


Figure 74 Using the **Dots** tool to mark an area

d When all the desired dots have been placed, select **Done**.

The dots change to a line passing through all of the selected locations and the measurements for the selected area are displayed.

e To edit an area measurement, select the desired area measurement and drag the outline to the new desired shape before selecting **Done**.

7 To add an annotation, do the following:

a Select **Annotate**.

b Enter the desired annotation text in the **Annotation** field.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre-defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

c To close the dialog panel without saving the annotation text, select **Cancel**.

d To save the annotation text, select **Done**. The annotation is placed on the image.

e To move the annotation, drag it to the desired position.

f To edit an annotation, select the desired annotation and select **Edit**.

Figure 75 Selected annotation

f To delete an annotation, select the desired annotation and select **Delete**.

9.9 Opening a previous IVUS recording

You can open a previous IVUS recording, allowing you to review the recording and measurement values.

You cannot access the live screen when reviewing a previous study and for co-registered data, you cannot edit the pathway or change the roadmap.

1 In the **Patients List**, select the desired patient study and select **View**. The selected study opens and the procedure home screen is displayed.

2 Select the desired series in the **Series** tab.

Pictorials in the **Series** tab identify **IVUS** series in the relevant series names. You can also see a preview of the recorded data which indicates that the series is an IVUS series.

3 Select **Open**.

Series marked as IVUS open automatically in the IVUS application.

9.10 Adjusting IVUS application settings

You can customize the settings used during IVUS procedures to suit the way you want to work and to provide the information on the screen that you want to see.

When you open the settings menu for an application, you must select the settings on the main. A dialog panel is displayed on the touch screen module, informing you that settings should be selected on the main display. If you close the dialog panel on the touch screen module, the application settings menu on the main display is also closed. When you close the application settings menu on the main display, the dialog panel on the touch screen module is also closed.

The **IVUS settings** menu contains three tabs: **Display**, **Co-registration**, and **Archive**. If your system does not include the co-registration option, the **Co-registration** tab is not displayed.

You can only access IVUS settings from the live or review screens. You cannot access the settings while recording IVUS images.

9.10.1 Adjusting the IVUS display settings

1 Select the **IVUS** application.

2 To open the settings menu for IVUS, select **IVUS settings** in the top right corner of the IVUS application screen.

If you accessed the settings while in the IVUS live screen, the screen switches to a freeze mode where the image is static.

3 Using the **Area Diameter Lines** setting, select whether to display the maximum and minimum diameter measurements automatically for all area measurements.

- **On**: maximum and minimum diameter measurements are displayed for all area measurements.
- **Off**: maximum and minimum diameter measurements are not displayed for all area measurements.

The default setting is **On**.

4 Using the **Graticules** setting, select whether to show the graticules on cross-sectional tomographic images by default.

- **On**: the graticules are displayed.
- **Off**: the graticules are not displayed.

  The default setting is **On**.

5 Using the Compressed ILD setting, select whether to show the image in the inline display compressed or uncompressed.

- **On**: the image in the inline display is compressed.
- **Off**: the image in the inline display is not compressed.

The default setting is **On**.

6 To adjust the setting used for the **Rapid review** function, do the following:

a Select the number of frames to include in the rapid review iteration cycle using the upper drop-down list in the **Rapid review** section.

b Select the desired playback speed for the rapid review iteration cycle (in frames per second) using the lower drop-down list in the **Rapid review** section.

The default setting is 7 frames at 30 fps.

7 For the **Autoborders** function, select which borders to draw on top of the tomographic image using the drop-down list in the **Autoborders** section.

The default setting is to draw the vessel and lumen borders.

8 Using the **Automatic IVUS Playback** setting, select whether to automatically play back IVUS recordings when they are opened for review.

- **On**: recordings are automatically played back when opened.
- **Off**: recordings are paused when opened.

The default setting is **On**.

9 Using the **Display effective diameter** setting, select whether to display effective diameter measurements in the measurements panel for peripheral procedures.

- **On**: effective diameter measurements are displayed.
- **Off**: effective diameter measurements are not displayed.

The default setting is **On**.

10 To close the menu, select **Close**.

9.10.2 Adjusting the IVUS co-registration settings

1 Select the **IVUS** application.

2 To open the settings menu for IVUS, select **IVUS settings** in the top right corner of the IVUS application screen.

If you accessed the settings while in the IVUS live screen, the screen switches to a freeze mode where the image is static.

3 Select the **Co-registration** tab.

4 Using the **Enable Co-registration** by default setting, select whether to enable co-registration by default when the IVUS application is used when a new study is started.

- **On**: co-registration is switched on by default.
- **Off**: co-registration is switched off by default.

The default setting is **On**.

5 Using the **Co-registration** workflow drop-down list, select whether to use an automatic or semi-automatic workflow.

The default setting is to use the automatic workflow.

6 Using the **Playback recording** drop-down list, select whether to view frames by time or by position when reviewing recordings.

The default setting is to view time-based frames.

7 Using the **Display pathway** setting, select whether to display the pathway by default in the co- registration results screen.

- **On**: the co-registration pathway is displayed by default.
- **Off**: the co-registration pathway is not displayed by default.

The default setting is **Off**.

8 To close the menu, select **Close**.

9.10.3 Adjusting IVUS archive settings

You can adjust the settings for IVUS images to include graticules, measurements, and annotations on archived images and videos.

1 To open the settings menu for IVUS, select **IVUS settings** in the top right corner of the IVUS application screen.

If you accessed the settings while in the IVUS live screen, the screen switches to a freeze mode where the image is static.

2 Select the **Archive** tab.

3 To include graticules, measurements, or annotations on archived image frames, set each of the desired options in the **Saved frame options**.

- **Yes**: the image element is included in archived images.
- **No**: the image element is not included in archived images.

The default setting is **Yes**.

4 To include graticules, measurements, or annotations on archived videos, set each of the desired options in the Video loop options.

- **Yes**: the image element is included in archived videos.
- **No**: the image element is not included in archived videos.

The default setting is **Yes**.

5 To close the menu, select **Close**.

10 Performing rotational IVUS

The ability to perform an automatic or manual pullback is integrated into the rotational IVUS patient interface module (PIMr).

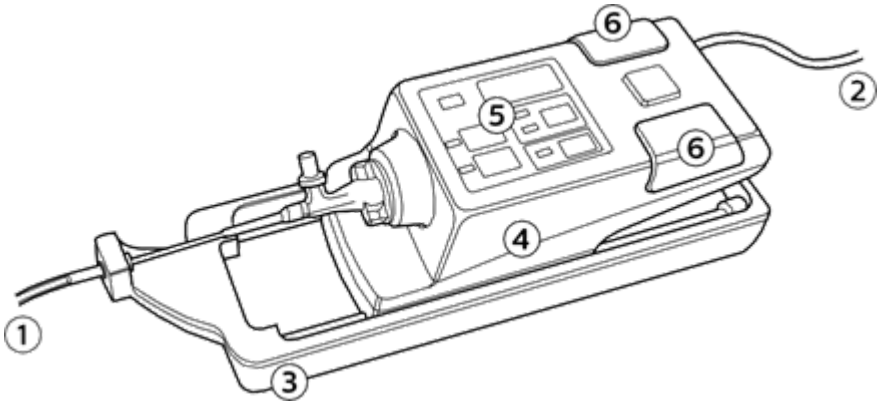


Figure 76 PIMr for rotational IVUS

Legend			
1	Imaging catheter	4	Sled
2	PIMr power supply cable	5	PIMr controls
3	Chassis	6	Grips

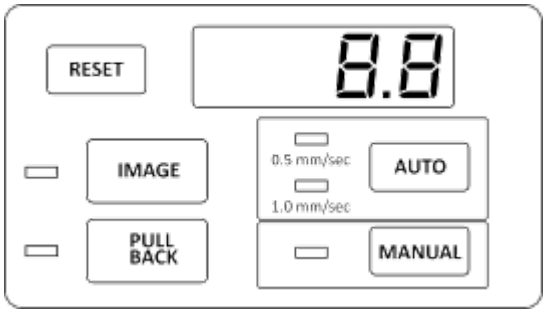


Figure 77 PIMr controls

The PIMr incorporates the following controls:

- **Reset**: Resets the LED distance display to zero.
- **Image**: Press once to begin imaging. Press a second time to stop imaging. The rotational catheter rotates while in imaging mode.
- **Pullback**: Press to begin an automatic pullback. Press again to stop the pullback.
- **Auto**: Provides two automatic pullback rates (1.0 and 0.5 mm/sec).
- **Manual**: Allows manual control of pullbacks.

10.1 Setting up the system for rotational IVUS procedures

Imaging catheters connect to the system through the rotational patient interface module (PIMr). The PIMr is typically left connected to the bedside utility box between studies, but may need to be reconnected if removed after a study.

Before a PIM is connected to the system and a catheter type configured, the system displays guidance for connecting the PIM. Before connecting or placing the PIM, inspect it and its cable for damage and do not use if damage is found.

CAUTION

The PIM's cable may be damaged if equipment is rolled on it. Do not pull on the cable, place the cable in a high traffic area, or use excessive force as this may cause damage. If the PIM is dropped, there could be damage to the body or internal electronics. Do not use the PIM if the outer case, cable, or connectors appear damaged.

CAUTION

The PIM can be damaged if contrast fluid or saline enter the catheter connection port. This may cause image quality issues. The PIM should not be placed below an IV pole where liquids such as saline or contrast may drip onto the PIM or into the connection port causing damage.

CAUTION

The top surface of SpinVision (PIMr) Models 808884001 and 808884001-R can become hot to the touch during prolonged periods of use.

1 Select the **IVUS** application.

2 Ensure you are using the FM-PIM for the procedure.

- IVUS procedures require the SA-PIM.
- Rotational IVUS procedures require the rotational PIM (PIMr).

Animated guidance is displayed to assist you if the PIM is not connected.

3 Align the markers on the cable connector of the short cable attached to the PIMr with the connector at the patient end of the PIMr cable from the bedside utility box, and slide the connections together until you hear a click.

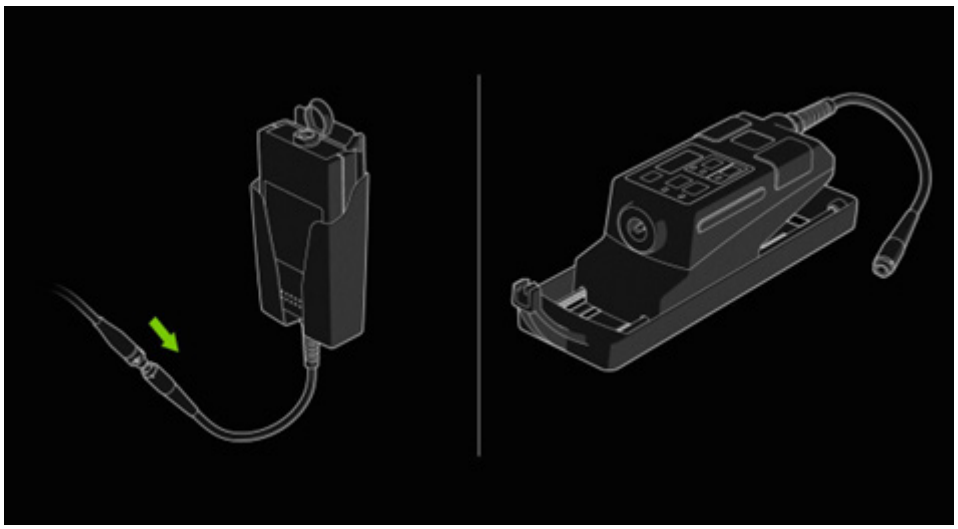


Figure 78 Animated guidance for connecting the PIM - the PIMr is shown on the right side of the image

The system detects the PIMr and displays the next appropriate guidance step.

4 Insert the PIMr into a sterile barrier pouch or bag using standard sterile techniques and place it near the patient in a stable location that is clear of items that may interfere with, or prevent, smooth movement during use.

CAUTION

If used in the sterile field, place the PIM in a sterile barrier pouch or bag using standard sterile techniques.

CAUTION

Always ensure that the PIMr is placed in a stable location and is clear of items that may interfere with or prevent smooth movement during use. The PIMr's weight will transfer as the device performs a pullback which could cause movement of the PIMr and the catheter.

WARNING

There is a significant risk to the patient's safety if the PIMr is moved while being used with a patient, causing the catheter to be displaced in the body. Ensure that the PIMr is securely placed in a stable location at all times.

5 Prepare and connect the catheter to the PIMr.

Connect the catheter by inserting the proximal end of the catheter through the sterile barrier into the front of the PIMr and then rotating the port clockwise 30 degrees until the marker dot on the catheter aligns with the tip of the arrow on the PIMr. The flushing port on the catheter should face up. Attach the clear part of the catheter telescoping hub to the arm at the front of the PIMr.

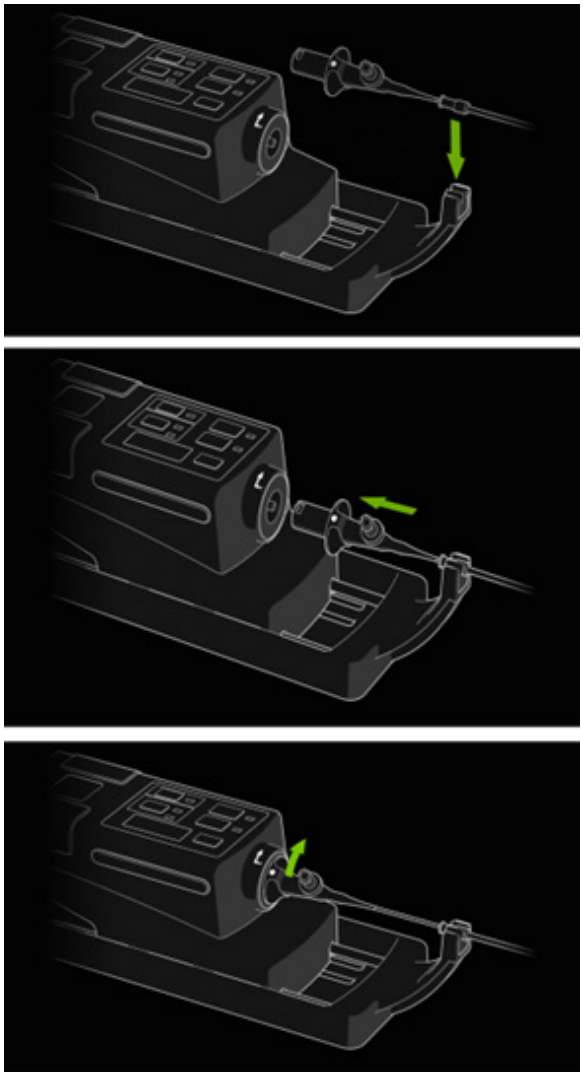


Figure 79 Animated guidance for connecting the catheter

NOTE ***Refer to the pressure guide wire Instructions for Use for directions before and during the procedure. Refer to the catheter or pressure guide wire label for specific insertion instructions. Consult the catheter or pressure guide wire package insert for a full description of warnings, precautions, and use instructions.***

Imaging cannot start until the rotational imaging catheter is connected to the PIMr.

6 Verify that the connections are secure.

The system recognizes the installed pressure guide wire for each study until a different type is installed. Any user-defined values are reset to the default values at the beginning of each study.

7 Select **Manual** on the PIMr and move the PIMr sled to the starting position.

Guidance is displayed to assist you.

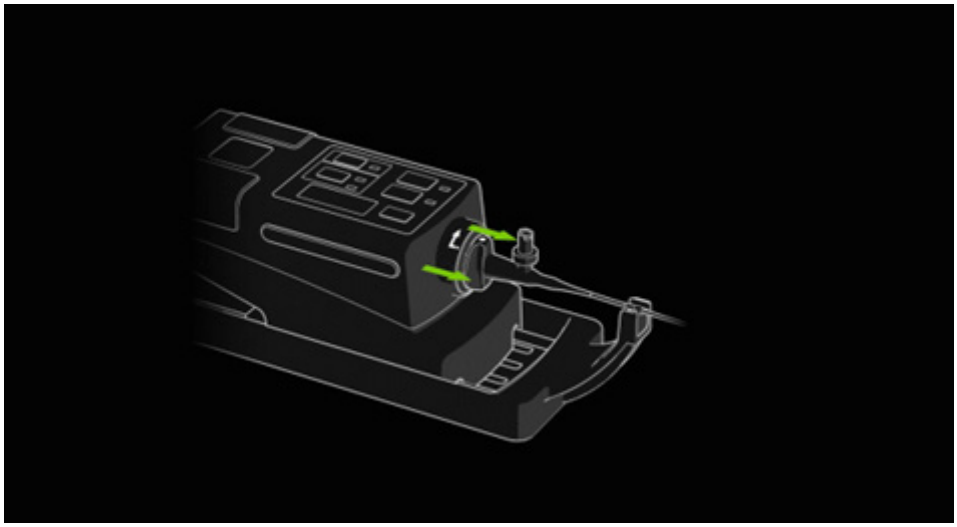


Figure 80 Animated guidance for moving the sled to the starting position

8 To start imaging, do one of the following:

- Press **Image** on the PIMr.
- Select **Image On** on the main display or on the touch screen module.

The PIMr motor rotates the catheter and the IVUS image is displayed on the main display and on the touch screen module.

WARNING

Do not advance SpinVision (PIMr) while the catheter is imaging.

9 To adjust the image gain and field of view, do the following:

a To adjust the gain of the catheter, select **Gain** and move the slider to the desired setting.

b To adjust the field of view of the catheter, select **FOV** and move the slider to the desired setting.

10 To apply time gain compensation, do the following:

a Select **TGC**.

The time gain compensation controls are displayed.

Time gain compensation allows you to compensate for ultrasonic attenuation. Tissue that is further away from the imaging catheter can be represented differently in the image from tissue of the same type and density closer to the catheter due to decreasing ultrasound wave amplitude over time. Time gain compensation allows you to adjust the gain for different layers of tissue according to their distance from the catheter so that echoes from tissue further away from the catheter that take longer to return can be represented consistently with echoes from closer tissue that return more quickly.

b Switch on time gain compensation and display the slider controls by selecting the sliders icon.

c Using the sliders, set the level of time gain compensation to apply to each radius.

d To reset the time gain compensation levels, select **Reset**.

10.2 Performing an automatic pullback

1 Select the **IVUS** application.

2 Using fluoroscopy, insert the imaging catheter following the catheter guide wire Instructions for Use packaged with the catheter

3 Select **Manual** using the PIMr controls and move the sled fully forward on the chassis to allow the full length of travel during the pullback.

4 To set the pullback speed, do one of the following:

- Press **Auto** on the PIMr until the desired speed is displayed on the PIMr.
- Select **PBR** on the main display or on the touch screen module, and select the desired speed.
  - 0.5 mm/s
  - 1.0 mm/s

  Note: Longitudinal measurements with the Philips system are limited by the maximal length of a video loop and the PIMr size. Length measurement maximum with 0.5 mm/sec pullback is 90 mm (because a video loop is limited to 180 seconds). Length measurement maximum with 1.0 mm/sec pullback is 150 mm (because of limited PIMr size).

5 Press **Reset** on the PIMr to reset the distance counter to zero.

WARNING

The distance counter must be reset to zero before performing a pullback or subsequent length measurements will be inaccurate. After resetting the distance counter, do not move the sled or begin pulling back the catheter until after recording has been started. Do not reset the distance counter while recording.

6 To start imaging, do one of the following:

- Press **Image** on the PIMr.
- Select **Image On** on the main display or on the touch screen module.

The PIMr motor rotates the catheter and the IVUS image is displayed on the main display and on the touch screen module.

WARNING

Do not advance SpinVision (PIMr) while the catheter is imaging.

7 To stop imaging at any time, do one of the following:

- Press **Image** on the PIMr.
- Select **Image Off** on the main display or on the touch screen module.

Starting or stopping imaging also starts or stops the rotation of the catheter.

NOTE ***If an image artifact is observed, it may be necessary to flush the imaging core with a 3 cc syringe of heparinized saline attached to the catheter port.***

WARNING

Do not move the PIMr chassis while recording. Moving the chassis could move the catheter within the patient, potentially leading to incorrect length measurements or patient injury.

8 To start a pullback, ensure imaging is started and do one of the following:

- Press **Pullback** on the PIMr.
- Select **Pullback** on the main display or on the touch screen module.

WARNING

Do not move the PIMr chassis while recording. Moving the chassis could move the catheter within the patient, potentially leading to incorrect length measurements or patient injury.

The PIMr provides a maximum pullback distance of 15 cm. When the maximum distance is reached, pullback stops.

NOTE ***The pullback distance may be limited to 9 cm if the acquisition rate is set at 30 fps and a pullback rate of 0.5 mm/s is used.***

9 When the desired pullback distance is reached, stop the pullback by doing one of the following:

- Press **Pullback** on the PIMr.
- Select **Stop** on the main display or on the touch screen module.

10.3 Performing a manual pullback

1 Select the **IVUS** application.

2 Using fluoroscopy, insert the imaging catheter following the catheter guide wire Instructions for Use packaged with the catheter

3 To unlock the sled, do one of the following:

- Press **Manual** on the PIMr.
- Select **PBR** on the main display or on the touch screen module, and select **Manual**,

4 Move the sled fully forward on the chassis to allow the full length of travel during the pullback.

5 Press **Reset** on the PIMr to reset the distance counter to zero.

WARNING

The distance counter must be reset to zero before performing a pullback or subsequent length measurements will be inaccurate. After resetting the distance counter, do not move the sled or begin pulling back the catheter until after recording has been started. Do not reset the distance counter while recording.

6 To start imaging, do one of the following:

- Press **Image** on the PIMr.
- Select **Image On** on the main display or on the touch screen module.

The PIMr motor rotates the catheter and the IVUS image is displayed on the main display and on the touch screen module.

7 To stop imaging at any time, do one of the following:

- Press **Image** on the PIMr.
- Select **Image Off** on the main display or on the touch screen module.

Starting or stopping imaging also starts or stops the rotation of the catheter.

NOTE ***If an image artifact is observed, it may be necessary to flush the imaging core with a 3 cc syringe of heparinized saline attached to the catheter port.***

8 To start a pullback, ensure imaging is started and do one of the following:

- Press **Pullback** on the PIMr.
- Select **Pullback** on the main display or on the touch screen module.

9 Using the grips on the side of the PIMr, gently pull the PIMr sled back at the desired speed.

NOTE ***If the PIMr sled is stationary for more than 30 seconds in manual mode, the PIMr switches to automatic mode, locking the sled in place.***

10 When the desired pullback distance is reached, stop the pullback by doing one of the following:

- Press **Pullback** on the PIMr.
- Select **Stop** on the main display or on the touch screen module.

10.4 Reviewing a rotational IVUS recording

You can open and review rotational IVUS recordings in the same way as non-rotational IVUS recordings.

For more information, see *9.9 Opening a previous IVUS recording on page 110* and *10.4 Reviewing a rotational IVUS recording on page 119*.

If you are reviewing an automatic pullback series, you can perform length measurements without having performed co-registration when recording the pullback. You cannot perform length measurements on a manual pullback series. For more information about performing measurements, see *9.8 Creating measurements and annotations on page 106* and *9.7 Making length measurements in co-registered IVUS images on page 105*.

11 Performing Device Detection

The Device Detection application automatically stabilizes and enhances visualization of device positioning and deployment within the vessel of interest during live x-ray acquisition.

Using the two radiopaque markers of the stent delivery system or balloon catheter, the application can automatically identify the location of the catheter and the device. Once the device is detected, the system generates a stream of images which are automatically overlaid and centered on the device to provide enhanced visualization.

Device detection and the resulting image enhancement is performed automatically and continuously from both fluoroscopy and exposure imaging received from the X-ray system during acquisition. When acquisition stops, the system processes the image stream to display the detected device and the detected event, for example, if contrast was injected or if a device was deployed.

For optimal performance of the Device Detection application, set the X-ray field of view between 18-25 cm and the acquisition frame rate to 15 fps.

11.1 Visualizing devices and events

When you acquire images using the Device Detection application, the system automatically detects events like stent positioning and balloon inflation. The system provides the appropriate review screen based on the event detected.

For positioning and inflation events, at least 12 image frames are required. For an enhancement event, at least 6 image frames are required

1 Select the **Device Detection** application.

Guidance is displayed to guide you in acquiring images.

2 Adjust the X-ray image so that the radiopaque markers of the balloon or stent and the movement path of the device (if recording the delivery and positioning) are clearly visible within the field of view.

NOTE ***The shutters for the X-ray images should be positioned parallel to the image edges and not at an angle. Angled shutters can cause device detection to fail.***

Figure 81 Correct X-ray shutter alignment (left) and incorrect X-ray shutter alignment (right)

3 Start acquiring X-ray images.

The Device Detection application can use either fluoroscopy or exposure (cine) images.

For information about acquiring images, refer to the Instructions for Use for the X-ray system.

NOTE ***The presence of CABG wires, additional guide wires, pacing leads, surgery clips, or other metallic objects within the X-ray image may also lead to device detection failure. The region of interest can be adjusted to exclude such items from the detection search area.***

4 To adjust the region of interest, select the device in the image and adjust the region of interest by dragging the corners of the highlighted area to the desired positions.

The system provides an editable area enclosed in a box. Adjusting the region of interest allows you to remove other radiopaque objects from the image which may interfere with the automatic detection of an event.

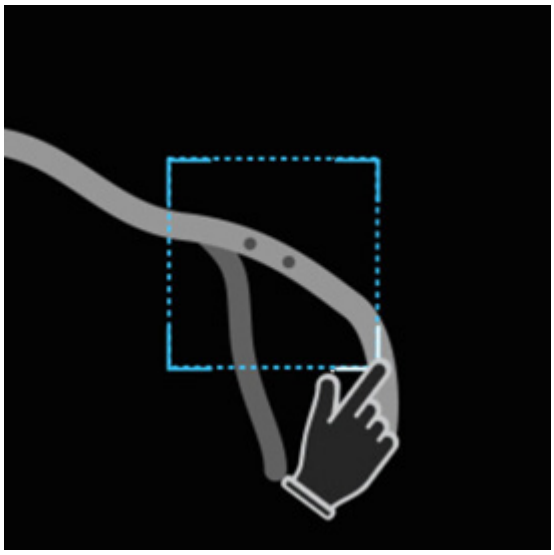


Figure 82 Adjusting the region of interest by adjusting the highlighted area

Figure 83 Adjusting the region of interest by selecting the device

5 To reset the region of interest to include the whole field of view, select **Reset ROI**.

6 Advance the device, inject contrast, or inflate the deployment balloon.

7 Stop acquiring X-ray images.

When acquisition stops, the system automatically detects the event and launches the appropriate review screen.

If you injected contrast, the system allows you to review an enhanced image showing device motion indicators and an enhanced video of the acquired X-ray series.

The device motion indicators highlight the range of detected movement of the radiopaque markers on the device in one cardiac cycle.

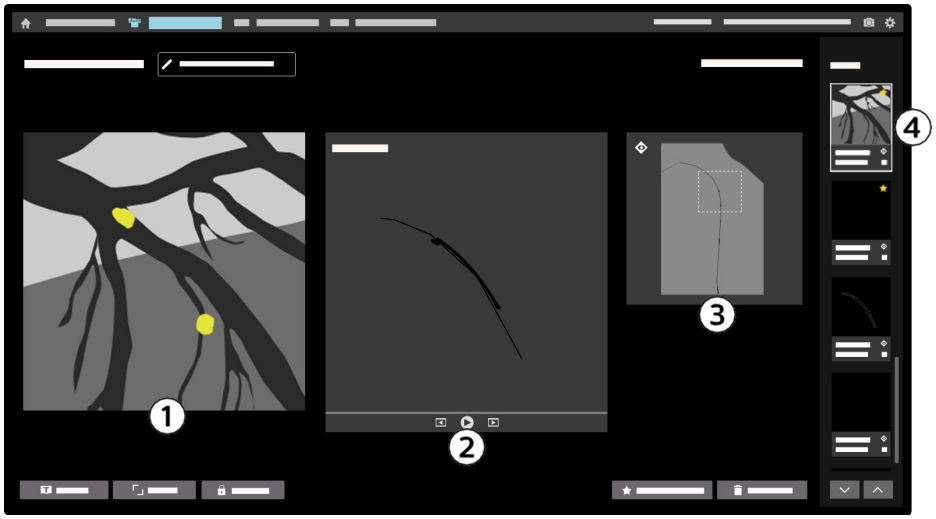


Figure 84 Reviewing positioning

Legend	
1	Device motion indication view
2	Injection movie
3	X-ray reference image view (main display only)
4	**Events** list

If you inflated a balloon to deploy a device, the system provides an image of the maximum inflation and a video of the inflation.

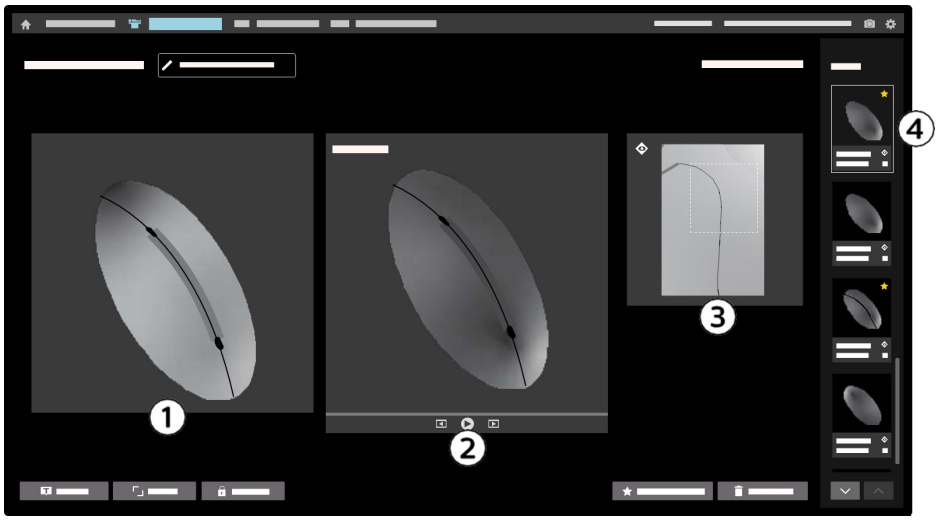


Figure 85 Reviewing inflation

Legend	
1	Max inflation image
2	Inflation movie
3	X-ray reference image view (main display only)
4	**Events** list
Note: In a 5:4 monitor layout, an additional image button is positioned below UI element 1. This button allows the user to expand the reference image.	

If no event was detected and you are using Device Detection to view enhanced images of a vessel or device, the system provides an enhanced image of the focused region of interest.

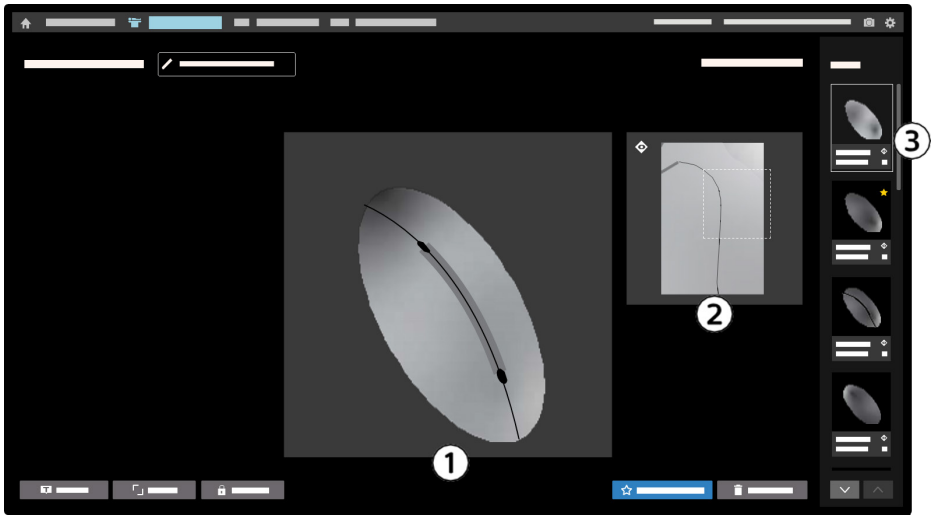


Figure 86 Reviewing enhanced images

Legend	
1	Enhanced image view
2	X-ray reference image view (main display only)
3	**Events** list

8 To stop the creation of new events select **Pause Detection**.

The system will not create new events even if X-ray images are acquired. To resume creating events, select **Resume Detection**.

9 To adjust the region of interest before the next X-ray images are acquired, select **Retarget**.

10 To acquire new images and create a new event, start and stop acquiring images again.

All acquired events from the current study are displayed in the **Events** list on the right of the screen.

11 To label the series, select the label and do the following:

a Enter a suitable label in the text field provided.

You can use the tabs below the text field to select appropriate pre-defined labels to use. Each tab contains labels appropriate for the different types of procedure available. To use these pre-defined labels, select the appropriate tab for the associated procedure, and select the desired individual label.

b To clear the text field and start labeling again, select **Clear**.

c To close the dialog panel without saving the new label text, select **Cancel**.

d To save the new label text, select **Done**.

12 To capture a snapshot of the screen, select **Snapshot**.

Snapshots provide a method of creating an image that is suitable for archiving and storing a record of measurements and other information, in a DICOM-compatible format and in a PACS. Patient information is masked and does not appear in the snapshot.

13 To save the event as a favorite, select **Mark as Favorite**.

When an event is marked as a favorite, it is automatically archived when the study ends if your system is configured to allow this.

14 To display a different event from the same study, select the desired event in the **Events** list.

15 To delete an event, select the desired event in the **Events** list and select **Delete Event**.

16 To return to the procedure home screen, select **Home**.

11.2 Opening a previous enhanced image series for review

You can open a previous enhanced image series, allowing you to review the enhanced images. In this mode, you cannot acquire new event results.

1 In the patient list, select the desired patient study and select **View**.

The selected study opens and the procedure home screen is displayed.

2 Select the desired series in the **Series** tab.

Pictorials in the **Series** tab identify **Device Detection** series in the relevant series names. You can also see a preview of the data which indicates that the series is an enhanced image series.

3 Select **Open**.

Series marked as **Device Detection** open automatically in the **Device Detection** application.

4 To display a different enhanced image series from the same study, select the desired series in the **Previous series** list.

12 Ending studies

This section provides information about ending studies and some associated tasks, like deleting, archiving, and exporting studies and data.

12.1 Ending a study with a Philips integrated X-ray system

If you are using the system integrated with a Philips X-ray system, the study is ended automatically when the study is completed on the X-ray system or when a new study is started on the X-ray system. You do not need to end the study in IntraSight Plus.

If a new study is started on the X-ray system, IntraSight Plus notifies you and prompts you to choose how you want to proceed. You can select the new study started by the X-ray system or you can continue to review the existing study in IntraSight Plus, but the existing study is ended and you will be reviewing a completed study.

12.2 Ending a study with a non-Philips X-ray system

After performing a procedure, acquiring images, or making measurements, the current study remains open until you end it. You must end a study before you can start a new one.

1 From the **Series** tab in the procedure home screen, review all the patient data, recordings, and measurements and perform any edits that are needed.

2 Select **End Procedure** in the top left of the procedure home screen. The study is ended and the data is saved to the system storage drive.

If the system storage is nearing capacity, a warning is displayed to inform you that the system is nearing the maximum storage capacity.

12.3 Protecting and unprotecting studies

If the system's storage is full, the system automatically deletes imported studies and old data that are not protected, to make space for new data. You can protect individual studies to prevent them from being automatically deleted by the system. Imported studies cannot be protected.

To ensure that data is not lost, the system can be configured to automatically archive studies and data at the end of the procedure. For more information on how to enable or disable automatic archiving, refer to the Enabling and Disabling Automatic Archiving section.

1 In the patient list, select the study that you want to protect.

You can select more than one study by selecting the check mark for each desired study at the left of the patient list.

2 To protect the study, right-click the study and select **Protect Study**.

3 To unprotect a study which is already protected, right-click the study and select **Unprotect Study**.

12.4 Archiving studies and exporting data

To save space on the system storage drive or to ensure accessibility of studies on your hospital PACS, you can archive studies to different destinations:

- Recordable DVD or Blu-ray discs (optical media)
- DICOM-compatible network location (PACS)
- Encrypted USB drive

Saving to a network or USB drive is faster than saving to optical media but archiving a case to a DVD, Blu-ray or USB drive allows you to view exported data on other computers.

NOTE ***USB devices may contain malicious software that could steal personal information or cause the system to malfunction. You should always scan a USB device for malicious software before connecting it to the system.***

You can configure the system to automatically archive studies and data.. For more information, see *14.4 Enabling and disabling automatic archiving on page 132*.

Patient data is archived in read-only format. You should archive patient data regularly to ensure that disk space is available for new studies.

NOTE ***If the system power is switched off while data is being written to the DVD or Blu-ray, you could damage the DVD or Blu-ray directory structure. DVD or Blu-ray archived cases may be inaccessible by both standard DVD or Blu-ray readers and drives. Avoid switching off the power during the archiving process, which can take up to several minutes. Should this happen, restart the system and repeat the archive of the desired cases before deleting them. You can check the progress and status of archiving jobs using the job viewer.***

1 From the **Previous Studies** screen, select the desired study.

You can select more than one study at a time by selecting the check box at the left of each desired study in the list.

2 Select **Save to...**.

A dialog panel is displayed where you can configure the data you want to save and select where you want to save the data.

3 Select the appropriate **Save** option.

If you selected specific series in the **Series** tab before selecting **Save to...**, the **Selected** series option is automatically selected.

If you selected more than one study in the patient list, the **All series** option is automatically selected.

4 Select the desired **Format** for the data to be exported.

The selected format determines the amount of compression applied to the data when it is exported. There are three formats available:

- **DICOM high resolution** - no compression
- **DICOM medium resolution** - low compression
- **DICOM low resolution** - high compression

NOTE ***If your PACS is not compatible with the DICOM high resolution setting, the system will export the data at a resolution compatible with your PACS.***

NOTE ***If you experience continuous failure to export your data in high or medium resolution, request your system administrator to increase the network timeout on your IntraSight Plus system and on your DICOM PACS network. If archiving failure persists, export data using a lower resolution (medium or low).***

5 Select the desired **Destination** to export the data to.

The default primary archive **Destination** can be configured so that studies and series archived to this destination are marked as archived in the patient list. For more information, see *14.3 Changing the primary archive destination on page 132*.

If you are exporting to a USB drive, you can select **Browse...** to navigate to a specific folder on the USB drive. The system supports only encrypted USB drives. When you select a USB destination, you must have the password for the USB drive available so you can enter it when prompted. Studies archived to DVD or Blu-ray are not encrypted. You should consider this when selecting the desired archive destination.

NOTE ***The location of the USB ports in use for your system may depend on the configuration of your system. You should consult with your hospital system administrator to determine which USB port you should use.***

NOTE ***The system supports BitLocker encryption. BitLocker is a standard feature within the Microsoft Windows operating system, allowing you to encrypt your USB drive using any Windows-based computer. Other encryption tools are not supported.***

If you selected a non-DICOM export **Format**, any available DICOM-compatible PACS destinations are disabled.

NOTE ***Only one DVD or Blu-ray archive job can be in the job queue at a time. Do not submit a second DVD or Blu-ray archive job until the first one is completed. Submitting a second DVD or Blu-ray archive job before the first one is completed will result in failure of the second DVD or Blu-ray archive job.***

When importing or exporting data using a USB drive, always use a USB 3.0 port on the front of the workstation and a USB 3.0 device to ensure the data transfer speed is optimized. Using a USB port which is not USB 3.0 will result in longer import and export times.

6 To remove identifiable patient data from the exported data, do the following:

a Select **De-identify**.

b Enter an alternative name to identify the exported data.

Do not enter the patient's name as the alternative name, or any other identifying information.

NOTE ***When handling personal data, do so in accordance with the privacy policies that apply in your healthcare environment and privacy laws that apply in your region.***

7 To close the dialog panel without exporting the data, select **Cancel**.

8 To export the data with the selected settings, select **Save**.

The study or selected data are exported. The export activity is performed as a background task by the system. You can view the status of background tasks in the job viewer.

For more information, see *12.7 Using the job viewer on page 128*.

If you have archived a study to your system's primary archive destination, the study is marked **Yes** in the **Archive** column of the patient list. The archive status is also indicated in the pictorial for the data in the **Series** tab of the procedure home screen.

For more information, see *5.5.1 Pictorials in the Series tab on page 41*.

12.5 Deleting a study

If the system storage is full, you must delete a study before you can start a new study.

1 From the **Previous Studies** screen, select the desired study.

You can select more than one study at a time by selecting the check box at the left of each desired study in the list.

2 Select the menu at the top right of the list or right-click to open the context menu.

3 Select **Delete**.

4 Confirm that you want to delete the selected study. The study is deleted.

5 To delete series from within a study, select the desired series in the **Series** tab, select the menu at the top right of the **Series** tab or right-click to open the context menu, and then select **Delete**.

6 Confirm that you want to delete the selected series. The selected series are deleted.

12.6 Printing (option)

If your system has a local or a DICOM printer installed, you can print snapshots.

1 At the procedure home screen, select the **Series** tab.

The series and images associated with the selected study are displayed.

2 Select the images that you want to print.

Images which can be printed are marked as snapshots and have the label **IMG** in their name. The print function is not enabled for other series or image types.

You can select more than one image by selecting the check box in the top left of each desired image pictorial.

3 Do one of the following:

- Open the menu in the top right of the **Series** tab and select **Print**.
- Right-click on one of the selected images and select **Print** in the context menu.

The **Print** dialog panel is displayed showing the default print settings.

4 Adjust the print settings as desired.

For more information, see *14.6.1 Changing DICOM print settings on page 134*.

5 To de-identify the images, switch on **De-identify**.

If you have performed a study with a non-Philips X-ray system without entering patient identification information, you cannot print the information. You can print the information without entering patient identification information if you choose to de-identify the image. Selecting **De-identify** allows you to print information in such cases.

6 Select **Print**.

The print job is started or queued. You can see the progress and status of print jobs in the job viewer.

For more information, see *12.7 Using the job viewer on page 128*.

12.7 Using the job viewer

The system performs some system jobs in the background, like importing, exporting, and printing. Using the job viewer, you can see import, export, and print jobs being carried out by the system. If you are logged in as an emergency user, you don't have access to the job viewer.

The job viewer displays jobs that are waiting or that resulted in errors and allows you to see completed jobs and what errors were encountered. You can also delete, abort, or repeat jobs.

The job viewer is only displayed on the main display. When the job viewer is open on the main display, a notification is displayed on the touch screen module.

1 Select the menu at the top right of the screen or at the top right of the patient list, or right-click to open the context menu.

2 Select **Open Job Viewer**. The job viewer is displayed.

The job viewer contains tabs for each type of task:

- **All**
- **Export**
- **Import**
- **Print**

Above the tabs, you can see a summary of jobs indicating how many jobs are submitted, executing, completed, failed, or canceled.

3 Select the relevant tab to find the job you are looking for.

Each tab displays the following information for each job:

- **Name**
- **Type**
- **Location**
- **Submitted Time**

The status of each job is indicated by an icon.

Icon	Status
	Completed
	Failed
	Canceled
	Submitted

Status filters are located at the top of the screen. You can select a filter to display only the jobs with a specific status.

4 To see more information about a failed or canceled job, select the job in the list and select **More Info**.

5 To change the priority of a job and execute it sooner, right-click on the job in the list and select **Execute Next**.

6 To cancel a job, select the job in the list and select **Cancel**.

7 To retry a failed job, select the job in the list and select **Retry**. **Note:** If a job fails, the study status will be marked as **Completed with Errors** or **Imported with Errors**. To resolve this, select the failed job in jobviewer and retry it to update the study status to **Completed** or **Imported**.

8 To delete a job, select the job in the list and select **Delete**.

9 To close the job viewer, select **Close Job Viewer**.

13 Using other equipment

The system is designed for use with other optional systems and equipment. These Instructions for Use provide basic information on how the system interfaces with other equipment. For information on how to use the other equipment, you should refer to the Instructions for Use supplied with the equipment.

WARNING

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 62368-1 for data processing equipment and IEC 60601-1:2005 + A1:2012 + A2:2020 for medical equipment). Furthermore all configurations shall comply with system requirements in accordance with IEC 60601, Clause 16. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for system complying with the requirements of IEC 60601-1, Clause 16. If in doubt, consult the technical services department or your local representative. In specific, AC mains powered devices are not recommended unless approved and installed by Philips.

13.1 Catheters and wires

Catheters and pressure guide wires should be selected based on the needs of the procedure. Proper handling and preparation of the catheter or pressure guide wire is critical to successful imaging and achieving accurate functional measurements.

Always prepare the catheter or the pressure guide wire in accordance with the Instructions for Use included with each device.

For a list of catheters and pressure guide wires compatible for use with IntraSight Plus, see *1.10 Compatibility on page 11*.

NOTE ***Refer to the pressure guide wire Instructions for Use for directions before and during the procedure. Refer to the catheter or pressure guide wire label for specific insertion instructions. Consult the catheter or pressure guide wire package insert for a full description of warnings, precautions, and use instructions.***

13.2 Using sterile covers with the FM-PIM

When using the FM-PIM within the sterile field, sterile covers should be used to prevent contamination of the system and maintain a sterile environment. Refer to procedures supplied by the hospital or to the instructions for use provided with the sterile covers. It is the responsibility of the hospital to supply and fit sterile covers when needed.

14 System customization

With a system administrator account, you can customize many aspects of the system's functionality to suit the way the system is used in your hospital. To change the settings described in this chapter, you must have a system administrator account. Philips SupportConnect is only displayed on the control room display.

14.1 Setting language, date and time, and number formats

You can change the language used in the system, and the way measurements, numbers, and timings are displayed, to suit your local preferences.

The system user interface supports several languages and you can change the language in use.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select **Regional Format**.

The **Regional Format** menu tab is displayed.

5 To change the language used on the system, select the desired **Language** in the drop-down list.

6 To change the way that dates are displayed, select the desired **Date format** in the drop-down list.

7 Select the desired **Time format**.

8 Select the desired format for displaying numbers using the **Number separators** drop-down lists.

9 Select the desired units used to display **Patient demographics**.

10 Close the **Regional Format** menu tab.

14.2 Setting the system date and time source

You can choose whether the date and time should be set manually or automatically.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 On the **System** menu, select **Time Synchronization**.

5 To set the date and time automatically using a time server, enable the **Time server** by selecting **Enabled**.

If the time server is enabled, the date and time is automatically synchronized after startup when a connection with the time server is established. A manually entered date and time is overwritten when the date and time are automatically synchronized. The system date and time cannot be changed manually if the time server is enabled.

If the time server is **Enabled**, ensure that the correct **Host name / IP address** for the time server is entered. You can select **Test** to test the connection to the time server.

6 To set the date and time manually, do the following:

   a Select **Disabled** for the **Time server**.

   b Select the correct **Timezone**.

   c Enter the correct **System time**.

   d Enter the correct **System date**.

7 To save your changes, select **Save**.

14.3 Changing the primary archive destination

You can configure a primary archive destination. Studies and series archived to this location are marked as archived in the patient list.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

   The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select the **Service** tab.

5 Select the **Security** menu.

6 Select the **Access** menu.

7 Select the desired **Primary archive destination**.

8 To save your changes, select **Save**.

14.4 Enabling and disabling automatic archiving

You can configure the system to automatically archive studies and data when a study is ended. Keeping automatic archiving enabled can help prevent data loss due to automatic deletion of studies by the system.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

   The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select **Auto Archive Protocol**.

5 Select an automatic archiving protocol in the list at the left of the screen.

6 To enable automatic archiving, switch on **Auto-archive**.

7 To disable automatic archiving, switch off **Auto-archive**.

8 If desired, select or change the settings of the protocol at the right of the screen.

9 Select **Save**.

14.5 Configuring network settings

You can configure standard network settings on the system, for example, to interface with the hospital worklist.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select **Network**.

The **Network** menu tab is displayed.

5 Select the **IPv4** or **IPv6** tab, depending on the networking protocol in use, and configure the IP address settings according to the requirements of your network.

Note: When IntraSight Plus is integrated with a Philips x-ray system, retrieving patient information from the x-ray system and connecting to an integrated multi-modality touch screen module requires an IPv4network address. If IPv6 is configured for DICOM network communication in a Philips integrated lab, ensure that a dual IP configuration (both IPv4 and IPv6) is implemented to maintain full functionality. If you are unsure of how to configure these settings, contact your network administrator.

6 Configure the DNS settings according to the requirements of your network.

Note: When IntraSight Plus is integrated with a Philips x-ray system, retrieving patient information from the x-ray system and connecting to an integrated multi-modality touch screen module requires an IPv4network address. If IPv6 is configured for DICOM network communication in a Philips integrated lab, ensure that a dual IP configuration (both IPv4 and IPv6) is implemented to maintain full functionality. If you are unsure of how to configure these settings, contact your network administrator.

7 To exit without saving your changes, select **Cancel**.

8 To save your changes, select **Save**.

9 Close the **Network** menu tab.

14.6 Configuring DICOM settings

You can customize the system's DICOM settings.

DICOM settings are available for the following items:

- Local system
- Worklist manager (WLM)
- Remote systems
- Removable media
- DICOM printers

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect.

The **Configuration** menu is displayed.

4 Select **DICOM Nodes**.

The **DICOM Nodes** menu tab with the **Local system** settings is displayed.

5 Configure DICOM settings for the local system by doing the following:

a Configure the local system settings according to the requirements of your network.

b To save your changes, select **Save**.

6 Configure the worklist manager settings by doing the following:

a Select the **WLM** tab.

b Enable or disable the **Worklist** using the slider switch.

c Configure the worklist manager settings according to the requirements of your network.

d To enable secure communication, select **Use authentication**.

e To enable the use of encryption, select **Use encryption**.

f To test the connection, select **Test Connection**.

The connection to the system is tested and the result is displayed.

g To save your changes, select **Save**.

7 Configure the interface with a remote system, such as a PACS, by doing the following:

a Select the **Remote systems** tab.

b Select the remote system in the list or select **Add** to add a new remote system.

c Configure the remote system settings according to the requirements of your network.

8 Configure the settings for removable media by doing the following:

a Select the **Removable** media tab.

b Configure the removable media settings according to your requirements.

9 Close the **DICOM Nodes** menu tab.

14.6.1 Changing DICOM print settings

1 Select **DICOM Nodes**.

The **DICOM Nodes** menu tab with the **Local system** settings is displayed.

2 Select the **DICOM printers** tab.

A list of configured printers is displayed at the left of the screen.

3 To change the settings for an existing configured DICOM printer, do the following:

a Select the desired printer in the list.

The **Printer settings** tab for the selected printer is displayed.

b Select the desired settings for the printer.

c To test the connection to the printer, select **Test Connection**.

d To change the settings for the print media, select the **Medium types** tab and select the desired media settings.

e To close the menu without saving your changes, select **Cancel**.

f To save your changes, select **Save**.

4 To add a new printer, do the following:

a Select **Add**.

b Enter the settings for the printer on the **Printer settings** tab.

If the printer you want to install is not displayed in the Printer type list, see *Troubleshooting printer issues on page 152*.

c Select the **Medium types** tab and select the desired media settings.

d To test the connection to the printer, select **Test Connection**.

e Select **Save**.

5 To delete a configured printer, do the following:

a Select the desired printer in the list.

The **Printer settings** tab for the selected printer is displayed.

b Select **Delete**.

c Confirm that you want to delete the printer.

14.7 Changing the default printer settings

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select the **Print Preferences** menu.

The current default print preferences are displayed.

5 To change the default printer, select the desired printer in the **Default Printer** list.

6 To change the preferences for the default printer, select the desired media, layout, and orientation settings in the fields below the **Default Printer** list.

7 To change to information displayed in the header and footer of the printed page, select the desired information to display in the **Patient details** and **Study details** sections.

The representation of the page layout displays how the data is presented on the printed page.

8 To exit without saving your changes, select **Cancel**.

9 To save your changes, select **Save**.

14.8 Configuring the audit trail settings

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select the **Audit Trail** menu.

5 To enable audit trail records to be created, set **Audit Trail Records** to **Enabled**. To disable audit trail records, set **Audit Trail Records** to **Disabled**.

6 To store audit trail records on the local system, set **Local Audit Repository** to **Enabled**.

To stop audit trail records being stored on the local system, set **Local Audit Repository** to **Disabled**.

7 To store audit trail records in a central network repository, set **Central Audit Repository** to **Enabled** and enter the relevant details for the server in the **Central Audit Repository Settings** menu.

8 To test the configuration and settings, do the following in the **Test** menu:

a If the **Central Audit Repository** setting is **Enabled**, select **Network Connection**.

b Select **Audit Trail**.

c Select **Test Connection**.

The connection to the server is tested and the result is displayed.

9 To save the settings, select **Save**. **Note:** The default audit trail records retention period is 90 days. For Department of Defense sites, the retention period can be up to 5 years. Audit log retention is only guaranteed via syslog server upload. Do not use local backup for record retention because hardware or software failures could cause audit trail records to be unretrievable

14.9 Managing user accounts

If you are a system administrator, you can manage user accounts to control access to the system. A system administrator can create, change, enable, disable, or delete user accounts.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The **Configuration** menu is displayed.

4 Select **User Account Manager**.

A menu is displayed showing system users.

5 To add a new user, do the following:

a Select **Add**.

b In the **User details** section, select **Enabled**

c Select the appropriate **User Group** for the new user.

The **User Group** selected sets the level of access that the user has within the system. Users are grouped as clinical users or system administrators. Clinical users can execute all procedural functions associated with the IntraSight Plus system. System administrators can perform all clinical user functions, and they can perform actions such as user setup and management, as well as basic system management.

d Enter the remaining mandatory user details:

– **Last name**

– **First name**

– **User Name**

e Enter a **Password** for the user to use when they log in to the system for the first time.

When a user logs into the system for the first time, they are prompted to change their password before proceeding to use the system.

f To save your changes, select **Save**.

6 To change a user's details, select the user in the list on the left of the screen and update the appropriate information in the **User details** section, before selecting **Save**.

7 To disable a user's account, select the user in the list on the left of the screen and select **Disabled** in the **User details** section, before selecting **Save**.

8 To reset a user's password, select the user in the list on the left of the screen and select **Reset Password**.

Enter a new password for the user. When the user logs into the system, they are prompted to change their password before proceeding to use the system.

9 To delete a user's account, select the user in the list on the left of the screen and select **Delete**.

14.10 Managing Security Settings and Policies

If you are a system administrator, you can manage the security settings and policies for the system.

1 From the patient list or the procedure home screen, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts.

3 Log in to Philips SupportConnect. The Configuration menu is displayed.

4 Select **Security**.

The Security menu tab with the Access Settings is displayed.

5 Configure access settings (system login, screensaver, and workflow) according to your system's requirements. To save your changes, select **Save**.

6 Configure policy settings. Select the **Policies** tab. Configure the Password Policies and Lockout Policies according to your system's requirements. To save your changes, select **Save**.

7 Configure removable media usage. Select the **Removeable Media** tab. Then enable or disable the use of optical and USB media according to your system's requirements. To save your changes, select Save.

8 Configure Department of Defense compliance. Select the **DoD Compliance** tab. Then enable or disable the DoD configuration according to your system's requirements. To save your changes, select **Save**.

When enabled, the system will automatically configure user access and security policies in compliance with Department of Defense

15 Maintenance and troubleshooting

This product requires proper operation, planned maintenance, and checks that the user must perform routinely. These tasks are essential to keep the product operating safely, effectively, and reliably.

Routine safety inspections and testing should be conducted at the intervals specified in the planned maintenance program. Trained hospital technicians should inspect and safety test all isolated connections and the system's power supply.

15.1 Service information

The system contains no user-serviceable components. To avoid electrical shock, do not remove any panels or covers. In the event of malfunction or system damage, switch the system off, disconnect the system from the power supply, and contact a Philips-qualified service person or Philips technical support.

The system must be serviced only by a Philips-qualified service person.

CAUTION

The IntraSight Plus system must be serviced only by Philips service personnel or by Philips-certified technical representative.

15.2 Planned maintenance program

Philips-qualified maintenance is performed by Philips-certified service engineers only.

A comprehensive preventive maintenance procedure must be performed annually, starting approximately 18 months after installation.

Philips-certified maintenance	Frequency
A comprehensive preventive maintenance procedure performed by Philips-qualified service engineers only.	Annually, starting 18 months post-installation

NOTE ***As part of the hospital's maintenance program, routine safety inspections and testing should be performed annually, as described in the User-performed maintenance section of the following table. Also, trained hospital technicians should conduct an annual inspection and safety test of all connections and system power supply, as described in the System electrical safety test section of the following table.***

For more information, see *2.3 Electrical safety on page 16*.

USER-PERFORMED MAINTENANCE	**Annually, starting 18 months post-installation**
Activity	**Frequency**
Archive patient studies.	Daily as used
Clean components in the patient vicinity.	Daily as used
Clean the system and monitors.	As needed
PIM cables inspection and placement.	Daily as used
Inspect and clean as needed, contrast and contaminating fluids from PIM catheter connectors. [1]	Daily as used
Verify all cable connections.	Monthly
Inspect and safety test all connections and system power supply.	Annually

[1] The catheter connector is sealed. Using a syringe containing a water and alcohol mixture to flush is acceptable. However, the unit must be set aside to dry (or high-pressure air flushed) thoroughly before use.

SYSTEM ELECTRICAL SAFETY TEST

The system electrical safety test will provide annual confirmation of the following safety requirements:

- **Protective Earth Continuity (Resistance)**: Ensures the resistance between the earth inlet connector and all exposed conductive surfaces of the system are within specification.
- **Potential Equalization Resistance**: Ensures the resistance between the Bedside Utility Box (BUB) surface and the po- tential equalization busbar at the x-ray table is within specification.
- **Earth Leakage Current**: Ensures the installed system meets the safe operating requirements.

Line voltage test and setup

Required equipment: Medical grade safety tester capable of executing the tests listed here in accordance with IEC60601-1 3.2.

1 Ensure the mains socket on the tester (for plugging in the EUT) matches the installed IntraSight Plus power cord/plug. Other power cords are not allowed for this test.

2 Power ON the analyzer.

3 Conduct a MAINS VOLT VAC measurement. Measurement limits are +/-10% per IEC60601-1 (excluding measurement uncertainty). For a voltage rating of **100-120 VAC**, the measurement limits are 100-120 VAC +/-10% (i.e., 90-132 VAC). For a voltage rating of **220-240 VAC**, the measurement limits are 220-240 +/-10% (i.e., 198-264 VAC).

WARNING

Failure to follow these instructions may pose a risk of serious injury or death. Do not continue this procedure if this voltage is not within the input voltage range indicated on the product label. This is not a product test failure. Find another wall outlet to use for system power or have the health care facility rewire the outlet if you see an error code displayed within the input range indicated on the product label +/-10%.

System Earth leakage

NOTE ***The isolation transformer power switch is to remain ON for these tests.***

1 Connect the power cord from the system's isolation transformer to the mains outlet of the safety analyzer. It is not nec- essary to turn on the isolation transformer at this time.

2 Disconnect the POAG (i.e., potential equalization conductor) cable from the BUB to the x-ray table and ensure the BUB is not in direct metal contact with the table or any other equipment (e.g., rail clamps).

3 Turn the isolation transformer power switch **ON**.

4 Conduct the following earth leakage tests. You may also optionally repeat the test with the POAG cable from the BUB to the x-ray table connected and/or remove the BUB attached to the table rail.

Test	Polarity	Earth (Ground Wire)	Neutral (L2)	Limit (µA)
1	Normal	No Earth (Open)	Yes (Closed)	300 µA
2	Normal	No Earth (Open)	No (Open)	1000 µA
3	Reverse1	No Earth (Open)	No (Open)	1000 µA
4	Reverse	No Earth (Open)	Yes (Closed)	300 µA

System ground continuity

WARNING

(If applicable) Failure to follow these instructions may pose a risk of serious injury or death. Disconnect the POAG cable from the BUB to the x-ray table and/or remove the BUB from the table rail. Do not use high current mode to perform the steps below.

1 Zero the analyzer.

WARNING

(If applicable) Failure to follow these instructions may pose a risk of serious injury or death. Any value other than an initial reading of zeroes (e.g., 0.00x) indicates that either the test leads or the analyzer are defective. Replace the test leads and repeat the zeroing process.

2 Connect the lead from the Analyzers Single Wire Test Probe (RED connector) to an exposed conductive surface of the workstation. The fan grate on the workstation's 48V power supply is a good point to use for this connection.

3 Conduct an Earth Resistance Measurement on the workstation. Limit is <0.20 Ω.

4 Remove the test lead from the workstation.

5 Connect the lead to the ground busbar of the isolation transformer (preferably where the PE wire of the C13/C14 power patch cable is connected).

6 Conduct an Earth Resistance Measurement on the isolation transformer. The limit is <0.10 Ω.

7 Remove the test lead connection from the isolation transformer's ground busbar.

8 Connect the lead to the POAG stud of the BUB.

9 Conduct an Earth Resistance Measurement on the isolation transformer. The limit is <0.20 Ω.

BUB POAG to exam table POAG resistance

NOTE ***This test only needs to be conducted when a POAG connection between the BUB and the x-ray table is required by local regulations.***

WARNING

Failure to follow these instructions may pose a risk of serious injury or death. The POAG cable must be secured to the BUB and, if applicable the BUB must be placed back on the table rail. Ensure the wingnut is strongly hand-tightened. Tightening the wingnut with tools is not allowed by regulations.

1 Plug the analyzer into an AC supply outlet as close as possible to the patient table in the exam room and power it ON.

2 Zero the analyzer for a 2-lead resistance test.

WARNING

Failure to follow these instructions may pose a risk of serious injury or death. Any value other than an initial reading of zeroes (e.g., 0.00x) indicates that either the test leads or the analyzer are defective. Replace the test leads and repeat the zeroing process.

3 Conduct a 2-lead Earth Resistance test between the POAG stud (Potential Equalization Post) on the exam table and the POAG on the back of the BUB. Limit is <0.10 Ω.

15.3 Storage disk space management

You can view the status of the system storage disk by opening the menu in the top right of the screen. A visual indication of the storage disk space used is displayed at the top of the menu.

When images and recordings are acquired, disk space is needed to store the data. The system continually monitors the available storage disk space and notifies you if there is insufficient disk space to perform studies or if the available disk space is low.

The system provides two types of disk space notifications:

- Yellow: disk space is low and you should consider taking action.
- Red: disk space is insufficient to perform the desired study and you should take action before proceeding.

To make disk space available, you must remove existing studies from the system. For more information, see:

- *12.4 Archiving studies and exporting data on page 126*
- *12.5 Deleting a study on page 127*

15.4 Activating the screensaver

For occasions when you want to blank the displays, you can activate the screensaver.

1 From the patient list or the procedure home screen on the main display, select the menu in the top right of the screen.

2 Select **Activate Screensaver**.

The screensaver is displayed. After 30 minutes, the screensaver switches off and a blank screen is displayed.

3 To deactivate the screensaver, move the mouse or press any key or mouse button.

15.5 Using remote support

The remote support function allows you to provide remote access to your system to a Philips representative. You can also schedule a remote support session for a later date and time.

Remote support allows you to give full access rights to the remote Philips representative or to provide viewing rights only. **Note:** Depending on the configuration of your system, some of these options may not be available to you.

1 From the patient list or the procedure home screen on the main display, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts. Only system administrators can access the Philips SupportConnect application.

3 Log in to Philips SupportConnect. The **System** tab is displayed.

4 Select the **Remote Service** tab.

The **Remote Connection Tool** menu is displayed.

Details of your system connection status are displayed in the **Connection Details** section of the menu. If your **Remote Connection** is **Enabled** and **Enterprise Connectivity** is **Connected**, the **Enable remote access** and **Enable remote view** buttons are enabled.

5 Do one of the following:

- To enable remote access for the remote Philips representative with the ability for them to interact with your system, select **Enable remote access**.
- To allow the remote Philips representative to view your system without the ability to interact with it, select **Enable remote view**.

A disclaimer message is displayed informing you of the risks of allowing remote support.

6 Do one of the following:

- To proceed with the remote support session, select **Accept**.
- To cancel the remote support session, select **Reject**.

A floating notification is displayed on the procedure home screen during a remote support session, indicating that remote access is enabled. You can reposition the notification by dragging it to a new position.

7 To stop the remote support session at any time, select **Disconnect** on the floating notification displayed on the procedure home screen.

15.5.1 Scheduling remote support

1 In the **Remote Access Configuration** menu, switch on **Remote support assistance**.

A disclaimer message is displayed informing you of the risks of allowing remote support.

2 Do one of the following:

- To proceed and schedule a remote support session, select **Accept**.
- To proceed without scheduling a remote support session, select **Reject**.

3 Select the start date.

4 Enter the start time.

5 Select the end date.

6 Enter the end time.

7 To automatically accept an incoming connection, select **Automatically accept incoming connections**.

If this function is enabled, the remote support session will start automatically at the selected date and time.

8 Do one of the following:

- To enable remote access for the remote Philips representative with the ability for them to interact with your system, select **Enable remote access**.
- To allow the remote Philips representative to view your system without the ability to interact with it, select **Enable remote view**.

When the selected start date and time is reached, a remote support session is initiated. If you have not selected to automatically accept incoming requests, the system displays a connection request when the scheduled start date and time is reached. The connection request includes details about the remote user and a countdown timer. If you do not accept or reject the connection request within the time indicated, the request expires and the connection request is rejected by default. You should read the remote request and note the remote user's details before accepting the request.

9 To stop the remote support session at any time, select **Disconnect** on the floating notification displayed on the procedure home screen.

15.5.2 Enabling and disabling Philips Remote Support functionality

You can enable **Philips Remote Support** to allow technical support to monitor the system, or you can disable this service to prevent remote monitoring.

1 From the patient list or the procedure home screen on the main display, select the menu in the top right of the screen.

2 Select Philips SupportConnect.

The **Philips SupportConnect** application starts. Only system administrators can access the Philips SupportConnect application.

3 Log in to Philips SupportConnect. The **System** tab is displayed.

4 Select the **Remote Service** tab.

5 Select the **Remote Connection Tool** menu.

6 Confirm that your system is connected to the PRS portal and that your system is registered.

If you do not have the appropriate license installed on your system, your system will not be registered. In your system is not registered, contact technical support.

7 Select the **Service** tab.

8 Select **Configure Remote Settings**.

The **Configure Remote Settings** menu is displayed.

9 To allow the system to send diagnostic data, set the **Log Upload** setting to **Enabled** and confirm your action by selecting **OK**.

10 To prevent the system from sending diagnostic data, set the **Log Upload** setting to **Disabled** and confirm your action by selecting **OK**.

15.5.3 Uploading service logs

To assist with remote support, you can upload service logs. You can set the time interval for log uploads and you can upload a log manually.

To allow automatic or manual upload of service logs, RADAR functionality must be enabled. For more information, see *15.5.2 Enabling and disabling Philips Remote Support functionality on page 142*.

1 From the patient list or the procedure home screen on the main display, select the menu in the top right of the screen.

2 Select **Philips SupportConnect**.

The Philips SupportConnect application starts. Only system administrators can access the Philips SupportConnect application.

3 Log in to Philips SupportConnect. The **System** tab is displayed.

4 Select the **Service** tab.

5 Select the **RADAR** menu.

6 To change the tine interval for **Periodic log upload**, select the desired **Time interval (hours)** using the **+** and **-** buttons and then select **Save**.

7 To manually upload a service log, select **Upload**.

15.6 Reporting an issue

If you encounter a problem when using the system, you can report the issue by generating a problem report which technical support can use to investigate the issue.

1 From the patient list or the procedure home screen on the main display, select the menu in the top right of the screen.

2 Select **Report an Issue**.

The **Problem Reporting** form is displayed.

3 Enter a **Title** and the **Description** of the problem.

4 To include co-registration data with the problem report, select **Include CoReg data**.

a Select the **Start date** for co-registration data to be included in the problem report.

b Select an **End date** for co-registration data to be included in the problem report.

If the co-registration option is not installed on your system, the option to include co-registration data is not available.

5 Select **Generate**.

Your problem report is stored and can be accessed by technical support.

Generating the problem report can take up to 30 minutes. During this time, you cannot use the system.

15.7 Cleaning and disinfecting

Clean and disinfect the system and equipment with common detergents, liquid chemical germicide, bactericide, and antiviral solutions, using warm water and a soft cloth.

To prevent any patient contamination, always clean and disinfect parts of the equipment which were in the patient vicinity with a bactericidal, germicidal and antiviral solution after each procedure. Ensure the solution used is active against HIV virus and hepatitis B virus.

Do not use solvents to clean any part of the system.

Do not allow liquids to enter the system openings, especially control consoles, display housings, and patient interface modules.

NOTE ***No portion of the system should be immersed in water or other fluids. Never use acetone to clean the bedside peripheral, plastic housings, or patient interface module.***

CAUTION

Never spray or otherwise apply any cleaner directly into the openings or seams of the system. Always apply the cleaner to the cloth instead.

Take care with catheter and cable connections during cleaning to avoid unnecessary bending or breaking.

CAUTION

Do not clean by inserting material into contact receptacle holes. This will break contacts and cause intermittent catheter operation.

15.7.1 Cleaning and disinfecting monitor displays

NOTE ***Switch the system off before cleaning monitor displays.***

Follow the hospital's protocol for the handling of blood and body fluids. Clean the display with a diluted mixture of mild detergent and water. Use a soft towel or swab.

Use of certain cleaning agents may cause degradation of the plastic enclosure and labels of the product. The plastic is composed of acrylonitrile, butadiene, and styrene (ABS). Consult with the manufacturer of the cleaning agent to see if the agent is compatible with ABS plastic.

CAUTION

Nex-rayver spray or otherwise apply any cleaner directly to a touch screen because leakage could cause damage to the system. Always apply the cleaner to the cloth instead.

15.7.2 Cleaning and disinfecting the patient interface module (PIM)

Clean and disinfect the PIM as needed with common detergents, liquid chemical germicide, bactericide, and antiviral solutions, using warm water and a soft cloth.

NOTE ***Never use acetone to clean the PIM or cables.***

The PIM is sealed against water ingress but you must avoid allowing liquids to enter the connector openings.

NOTE ***No portion of the PIM should be immersed in water or other fluids.***

Pay special care to the cable connections during cleaning and avoid any unnecessary bending to minimize the possibility of breaking a connection.

15.8 Inspecting cables

Check the placement of PIM cables and connectors, and ensure the cables are protected from accidental damage.

Inspect the cable connections to ensure the connections are secure and no cables are bending excessively.

Inspect open connections for corrosion or fluid contamination.

15.9 Disposing of the system

Final disposal is when the equipment or system is disposed of in such a way that it can no longer be used for its intended purpose. Philips is concerned about protecting the natural environment and ensuring continued safe and effective use of the system through proper support, maintenance and training.

The system, or any part of it, should not be disposed of with industrial or domestic waste.

NOTE ***Do not dispose of this device or its components. Improper disposal may be harmful to the environment and human health. Dispose of the device in accordance with local electronic waste regulations. Return disposables to Philips for final disposal.***

Contact the manufacturer for information about disposing of the system. For contact details, see *18.7 Contacting Philips on page 180*.

Recycling

Philips supports responsible organizations with recovery of reusable parts, recycling useful materials, and the safe and effective disposal of equipment. The WEEE Recycling passport of this product can be requested through the following website:

www.medical.philips.com/main/about/sustainability/recycling/index.wpd

Motherboard and touch screen module battery disposal

The system's motherboard and touch screen module contain batteries that must be disposed of in accordance with local, state, and federal laws and in accordance with the EU Battery Directive 2006/66/EC requirement.

15.9.1 Deleting all patient data from the system

Patient data is stored on the system storage disk. Before disposing of the system, you must perform data sanitization by deleting all patient personal data from the system storage disk. This is achieved by wiping the storage disk. For more information about data sanitization, contact technical support.

15.10 Troubleshooting

Use the information in this section to determine what action you can take if you encounter a problem.

Issue	Possible cause	Resolution actions
The workstation will not switch on.	The workstation is not connected to the electrical power supply, or the power supply is not switched on.	Ensure that the isolation transformer is switched on and then attempt to switch the workstation on again.
The system is overheating.	This may be caused by a cooling fan failure or prolonged use of the system with drapes or sterile covers.	**1** Shut the system down and allow it to cool. **2** Clear any obstructions to the workstation front and rear air vents. **3** Contact technical support if fans are not operating or if the problem persists after the other actions have been performed.
A catheter fault is detected.	An unsupported catheter is being used. A system or software failure occurred. A PIM fault occurred.	**1** Disconnect the catheter. **2** Check that the catheter is supported by the system. **3** Reset the PIM by disconnecting and reconnecting it to the PIM cable. **4** Follow the on-screen guidance. **5** If the fault reoccurs or persists, re- place the catheter and try again before contacting technical support.
The system is unable to acquire images but study data is accessible.	A hardware fault may have occurred.	Contact technical support.
Patient data or studies cannot be opened or retrieved.	A hardware or software fault may have occurred.	Contact technical support.
Recording stopped due to a data acquisition error.	Recording stopped due to data acquisition error.	If the problem persists, shut down the system and contact technical support.
Closing Philips SupportConnect takes longer than expected.	The audit trail server has not been configured or is not connected.	Configure the audit trail settings and test the audit trail server connection to ensure the connection is working. If a connection to the server does not exist, disable the configuration in Philips SupportConnect.
When a modal dialogue appears after closing Philips SupportConnect, the mouse cursor is only visible when hovering over the modal dialogue. Outside the modal dialog, the cursor is not visible, which may lead to user confusion.	This issue is caused by a software limitation in how the application renders the mouse cursor outside the modal dia- logue window.	Select an option within the modal diaogue to proceed. Once the modal dialog is dismissed, the mouse cursor will become visible across the entire screen.
User receives the following error message: “The system failed to save the IPv6 changes you made. Select ‘Try again’ to initiate another attempt or ‘Cancel’ to revert back to the old settings.”	This message appears when a user attempts to add a static IP address using the same address that was previously assigned dynamically by the operating system.	The error message is misleading. Do not select “Try again.” When manually adding a static IP address, ensure the manually added IP address is different from the one already assigned by the operating system.

Troubleshooting QCA/VE series

Issue	Possible cause	Resolution actions
QCA/VE fails to detect the vessel.	Poor image quality. The injection was performed with an inadequate amount of contrast material. An inappropriately selected frame or location to analyze was used.	Check the X-ray quality and if neces- sary, increase the radiation level. Increase the amount of contrast material used during the injection. Select an area of interest to analyze, where the vessel border is clearly visi- ble and not too close to the image border.
VE fails to enhance.	The selected location for vessel enhancement is too bright or too dark.	Select a different location for vessel enhancement where there is enough contrast in the image. Avoid enhancing areas that are too bright or too dark (opaque artifacts).
QCA calibration detection fails	The guiding catheter edges are not clear in the selected point. The guiding catheter is too close to the edge of the image.	Try to select a different location along the guiding catheter tip. Calibrate using another frame in the same x-ray image.

Troubleshooting with ChromaFlo

Issue	Possible cause	Resolution actions
Flow is not detected.	Blood flow with velocity below certain threshold (~ 4-7 cm/s) will be not detected with ChromaFlo. In addition, blood flow more than approximately 6.3 mm away from catheter mask center cannot be detected.	Carefully identify and compare the lumenal boundary based on grayscale images with those obtained from ChromaFlo images, as well as other modalities such as angiography.
The frame rate is reduced.	Due to processing speeds in ChromaFlo mode, the overall combined frame rate of grayscale and ChromaFlo of the Philips system is lowered to approxi- mately 22 frames per second for EE/ PV.014P/PioneerPlus/Reconnaissance PV .018 OTW and 20 frames per second for PV .018.	There are no actions you can take. Very fast moving structures may appear to move in a more continuous manner during standard, non-ChromaFlo imaging.
Dark regions are coded in color.	In cases of high noise floor from catheters, or stray speckle, regions showing up as black (or no signal) in grayscale imaging can present color.	Adjust the region of interest to block out the regions being coded in color. Alterna- tively, use the grayscale live mode without ChromaFlo.
Moving tissue is coded in color.	Under some specific conditions, for example, myocardial tissues that are moving very fast (similar to blood flow) could be displayed as color.	Adjust the region of interest to prevent tissue from being coded in color. Additionally, use the grayscale images to locate vessel and tissue boundaries so that tissue motion artifact is not misinterpreted.
Flow is not indicated near the transducer, resulting in a 'dead zone'.	Signal saturation near the transducer surface prevents detection of flow, therefore it would show a dark ring with a diameter of ~2 mm. For vessels smaller than ~2.5 mm in diameter, flow cannot be detected well.	There are no actions you can take. Use grayscale live mode to observe blood flow in small vessels.

Troubleshooting imaging artifacts

Issue	Possible cause	Resolution actions
Automatic distance measurements do not appear to be properly positioned.	The automatic distance (minimum and maximum diameter) measurements may not always correspond to that which a trained operator would select. This algorithm does not replace the operator, but rather assists in identifying starting distance measurements within an area boundary.	Carefully review any automatic distance measurement prior to accepting it. If the distance measurement is not properly placed, the operator should edit the measurement
Irregular artery contours	The imaging transducer at the catheter tip may not always be withdrawn from the artery in a linear manner. Motion of the catheter tip from side to side during pullback data collection appears on the sagittal view as if the artery wall is moving toward and away from the transducer axis.	There are no actions you can take. Carefully review the x-ray image to determine the vessel contours. Use the outer vessel wall boundary (media to adventitia interface) to evaluate whether luminal irregularities are due to catheter motion or actual lumen variations. (Note that vessel wall boundary or the media to adventitia interface changes slowly as catheter is moved axially.)
Catheter slack. The same image plane is presented along the artery length.	Due to mechanical slack, which can occur in a pullback system, the beginning of the pullback sequence may contain a series of identical consecutive images. This occurs because the pullback device is moving the catheter holder clamp, and the system is collecting data, but the transducer at the tip of the catheter is not moving.	Ensure that there is no excessive slack in the system. Observe the image as the pullback is started.
There is a seamline at approximately 12 o'clock on the rotational IVUS image.	The seamline artifact is caused by artery motion or pullback movement during imaging, leading to misalignment of the lumen border.	Performing pullback at a slower speed may reduce the discontinuity appearance of the image at approximately the 12 o'clock position. In a high motion region such as a coronary artery, the seamline may be unavoidable.
Image artifacts appear in the area of ringdown after the ringdown function is activated.	Image artifacts appear in the area of ringdown after the ringdown function is activated.	The ringdown function should be switched on just after the imaging catheter exits the guide catheter or sheath, as in the aorta or ostium of a coronary artery. To avoid image artifacts, it is recommended to switch the ringdown function off when the imaging catheter is retracted back inside the guide catheter or sheath or outside of the body. Switch the ringdown function on again when the catheter is re-inserted into the artery. Optimal imaging and best performance are achieved if the ringdown function is switched on in an open area where tissue structures are not in the ringdown region. Be aware of areas surrounding the catheter within 1 mm of the catheter surface as these surrounding areas may contribute to the presentations of artifacts. For example, stents, calcification, and bright tissues.

Issue	Possible cause	Resolution actions
Tissue blanking occurs or tissue is removed from the area of ringdown after the ringdown function is activate. Artifacts are present in the vessel lumen, such as a darkened concentric circle, that may appear or disappear in the image.	The ringdown function is switched on when the catheter is within 1 mm of tissue or other stationary features, like stents.	Avoid any tissues in the ringdown region when the ringdown function is switched on or off. Be aware of areas surrounding the catheter within 1 mm of the catheter surface as these surrounding areas may contribute to the presentation of artifacts. For example, stents, calcification, and bright tissues. To avoid possible tissue blanking, avoid situations where the transducer is barely moving or is wedged for a prolonged period in a heavily blocked vessel. If the catheter is wedged, an artifact representing a darkened concentric circle may appear or disappear in the image.
The image is degraded by shadowing. There is a ring artifact in image	There is air surrounding the IVUS transducer within the catheter sheath.	Flush with heparinized saline in accordance with the catheter instructions for use.
Non-Uniform Rotational Distortion (NURD)	Excessive tightening of the hemostasis valve. Excessive bending of the catheter.	Loosen the hemostasis valve. Make sure catheter is not bent between the SpinVision (PIMr) and the hemostasis valve. Flushing with heparinized saline may also help.

Troubleshooting PIMr error codes

The PIMr displays error codes at the PIMr controls if an error is detected.

PIMr error code	Definition	Resolution
E0	The PIMr completed and passed the self-test.	This code is displayed briefly after the unit is switched on and indicates that the unit is ready to use.
E1	Unable to read RFID.	The catheter may be faulty or may not be fully rotated into place. Ensure the catheter is fully rotated into place. If the catheter is fully rotated into place and the error code is still displayed, try using another catheter. If the problem persists, contact technical support.
E2	TGC memory failure.	The unit has failed. Contact technical support.
E3	Analog high voltage failure.	The unit has failed. Contact technical support.
E4	One of the pulse width control pins is stuck low.	The unit has failed. Contact technical support.
E5	Catheter motor failure. Catheter rotation has stalled.	Ensure the catheter has been prepared and flushed in accordance with the catheter instructions for use. If the problem persists, contact technical support.
E6	Pullback motor drive failed.	Ensure the pullback has not reached the end of its travel. Check the cable for binding or for excessive drag in the body. If the problem persists, contact technical support.
E7	EEPROM data error.	If the problem persists, contact technical support.

Troubleshooting iFR and FFR issues

Issue	Possible cause	Resolution actions
The system will not normalize to a value of 1.0 or pressure waveforms do not overlap after normalization.	-	Flush the guide catheter with a suitable saline solution, remove the introducer needle, and close the hemostatic valve. Repeat the normalization procedure. Contact technical support if a normalized value of 1.0 cannot be achieved after repeated attempts.
Pd is not correctly displayed. The FM-PIM does not respond	If the system does not correctly display the Pd waveform (such as a distorted display or a straight line instead of a normal waveform) or has a warning message concerning the FM-PIM pressure plug, the FM-PIM may have lost communication with the system.	With the pressure guide wire removed from the patient, disconnect the pres- sure guide wire from the FM-PIM then reconnect it. The pressure guide wire will be zero again and operation should be restored. If the waveform is not corrected, then the FM-PIM should be reinitialized by disconnecting it from the system and reconnecting it. FM-PIM communication should be automatically restored within 20 seconds.
Artifacts have caused an incorrectly recorded FFR value.	Not pressing the stop button at the end of a run. Manipulating the manifold during the recording. Injecting the hyperemic agent while recording. Flushing the guide catheter with saline while recording. Withdrawing the pressure guide wire from the measurement location while recording. The patient coughed or had an irregular heartbeat during the recording.	If an artifact is detected, the study should be reviewed to determine the correct FFR location, which should occur in the area of maximum hyperemia. The recorded FFR value can then be relocated to this position.
Recording buttons are disabled.	Absence of a proper signal on Pd.	Ensure there is a signal present on Pd. Check your connections and signal sources to verify everything is properly connected and functioning correctly. The recording buttons will be enabled only when the system detects enough cycles according to the MAP period setting. If cycles are not being detected, review the MAP period settings to ensure they are configured correctly. The MAP period setting determines how many cycles need to be detected before enabling the recording buttons. Ensure these settings align with the signal characteristics and expected cycle duration.

Troubleshooting co-registration

Issue	Possible cause	Resolution actions
The co-registration automatic pathway is incorrect.	The pressure guide wire tip is not visible during the pullback or contrast agent occludes the pressure guide wire tip. Other vessels are interfering with the view of the pullback. Poor image quality. The image contains static object interferences such as CABG, wires, or surgery clips.	Manually correct the pathway line to represent the pullback line on the vessel. Draw from the most proximal point of the guiding catheter to the most distal area of the vessel.
The **Record** button and/or **Home** button is disabled.	The software is currently processing a previous co-registration recording in the background. This prevents starting a new recording or returning to the **Home** screen.	Wait until processing is complete. When processing is complete, the buttons will be automatically re-enabled.
IVUS tomography displays black frames.	Co-registration was performed using fluoroscopic images captured at a frame rate exceeding 15 fps, which the software is unable to process.	Navigate to the IVUS frames that are correctly rendered. Co-registration measurements within these frames remain valid. Alternatively, redo the co-registration using fluoroscopic images captured at a frame rate of 15 fps or lower.
Co-registration fails.	The IVUS EEP scanner or markers or physiology wire tip could not be detected throughout the pullback due to poor image quality or bad positioning of the pullback view, or because of image interferences such as CABG, wires, or large body mass. Patient table movement, zoom, collimator, or C-arm angle changes during the pullback. During the pullback, the X-ray frame rate was lower than 7.5 fps or the pullback speed was too fast.	Repeat the co-registration, carefully following the instructions. Select a different view in which the scanner or wire tip is sufficiently visible during the pullback. Avoid moving the table or changing the zoom, collimator factor, or C-arm angle until the end of the pullback. Check the X-ray quality and if neces- sary, increase the radiation level and frame rate.
The co-registration is inaccurate or the co-registration region is too small.	The IVUS EEP scanner or markers or physiology wire tip could not be detected throughout the pullback due to poor image quality or bad positioning of the pullback view. The vessel is too straight or too curved in the pullback view. The pullback pathway was not properly drawn and does not represent the pullback path. Patient table movement, Patient table movement, zoom, colli-mator, or C-arm angle changes before or during the pullback. The guiding catheter slips out of the ostium or moves during the pullback. During the pullback, the X-ray frame rate was lower than 15 fps or the pullback speed was too fast.	Repeat the co-registration, carefully following the instructions. Select a different view in which the scanner or wire tip is sufficiently visible during the pullback. Verify that the co-registration pathway and the roadmap are suitable, before analyzing the co- registration result. Avoid moving the table or changing the zoom, collimator factor, or C-arm angle until the end of the pullback. Check the X-ray quality and if neces- sary, increase the radiation level and frame rate.
The co-registration is suboptimal due to an iFR timing difference.	A timing difference was detected between iFR data and X-ray image data.	Verify the results or perform co-registra-tion again. If the issue persists, contact technical support.

Troubleshooting device detection

Issue	Possible cause	Resolution actions
Device Detection fails to detect the device.	Poor image quality. Unclear balloon or stent markers. The specific balloon or stent may not be suitable for tracking if it has only one radiopaque marker or is longer than 35 mm.	Check the X-ray quality and if necessary, increase the radiation level. Adjust the region of interest to focus the detection in the device area.
A Device Motion Indication (DMI) image is not generated.	Poor image quality. The injection was performed with an inadequate amount of contrast material.	Check the X-ray quality and if necessary, increase the radiation level. Increase the amount of contrast material used during the injection. Ensure the device makers are visible during the injection.
A Device Detection positioning event is generated instead of an inflation event.	Injection and device inflation were performed in the same X-ray series.	After the injection is complete, end the X-ray series and start a new X-ray series for the inflation result.

Troubleshooting printer issues

Issue	Possible cause	Resolution actions
In the **Printer settings** tab of the **DI- COM printers** menu, the **Printer type** list does not contain the printer to be installed.	The required printer template is not installed.	Select a different printer initially. When the selected printer is configured, select the **Edit** icon next to the **Printer type** list, and add the new printer template file from a USB drive. Printer templates must be configuration files (.ini).

16 Security

16.1 Customer role in product security

Philips recognizes that the security of its products is an important part of your facility's in-depth security strategy. However, these benefits can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

Following industry-standard practice, your strategy should address physical security, operational security, procedural security, risk management, security policies, and contingency planning. The practical implementation of technical security elements varies by site and may employ a number of technologies, including firewalls, virus-scanning software, and authentication technologies.

As with any computer-based system, protection must be provided such that firewalls or other security devices are in place between the medical system and any externally accessible systems. The USA Veterans Administration has developed a widely used Medical Device Isolation Architecture for this purpose. Such perimeter and network defenses are essential elements in a comprehensive medical device security strategy.

The latest information on security and privacy, including recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

NOTE ***You should check the system's published cyber security status regularly on this website.***

16.2 Detecting security failures

The system is designed to handle errors, including security failures, and restricts user access to the application level only. The system provides logging capabilities for local and remote services that support diagnostics and forensics.

Security failures arising from user actions display error messages for the user and create audit events according to the IHE ATNA integration profile.

Network communication failures are audited. An error message is displayed for the user when user interaction is required.

If you experience unexpected system behavior or if other circumstances lead you to believe that a security vulnerability was potentially exploited, you should report this to Philips, to allow appropriate mitigation to be identified (see *18.7 Contacting Philips on page 180*).

System failures are handled depending on the nature and severity of the failure and may result in changes to the workflow, error messages, logging, or audit events. For example, software that is not on the whitelist is not executed and the failure is logged.

A number of security features have been implemented in this product. These features are described below.

Encryption of personal data

To protect personal data stored on the system, encryption ensures that sensitive information remains secure, even if the media is removed from the system or site. The following encryption measures are implemented:

Secure DICOM transfer

When medical images or data are transmitted over a network, this feature ensures that the data is not modified by intruders during transmission, as well as ensuring that the data cannot be read if it is intercepted and displayed.

Audit trail

Any user action involving personal data is logged to allow analysis as to whether any hostile action has been performed on the personal data.

Network time synchronization

This function ensures that every device on the network uses the same clock so that all relevant user actions and data transmissions, including audit trail actions, can be checked in chronological order.

16.3 Risks related to security

It is recommended to review the implemented security controls, as detailed further in the MDS2 (Manufacturer Disclosure Statement for Medical Device Security) form.

For more information, see *16.1 Customer role in product security on page 153* and *16.4 Malware protection on page 154*.

The assessment should be repeated whenever changes are made to the network. Such changes include:

- Changes in the network configuration
- Connection of additional items to the network
- Disconnection of items from the network
- Updates or upgrades to items that are connected to the network

16.4 Malware protection

This section contains security information for the protection of network-connected systems, including hardware, software, and data, from cyber attacks.

The operating system is protected with write protection, so any security compromise that occurs does not persist if the device is restarted.

The system maintains no backup of configuration. If a customer suspects a compromised configuration, contacting technical support is advised.

Philips installs and configures the system as required for infrastructure to permit intended operation.

Several protection methodologies are used to protect the operating system:

- The operating system disk is write-protected. No changes can persist.
- Whitelisting software is installed. Only trusted applications are allowed to run on the system.
- Firewalls are in place and only designated ports allow connection and access.
- End users do not have access to operating system tools.
- The system starts directly to Philips software applications which control how the end user interacts with the system. Only technical support personnel have direct access to the operating system.

The Windows default firewall is enabled on the system. This firewall blocks all ports from incoming communication with the following exceptions:

- ICMP (Ping) (outbound)
- Port 123 (TCP) for Network Time Protocol (NTP) is used to synchronize the clocks of all devices over a network, to ensure that all systems within a network have the same time (outbound)
- Port 443 to enable upload of the Philips logs to the internet server (outbound)
- Port 2994 (TFTP) (dynamic port)
- Port 49669 (MMTSM)
- For outbound connection, ports are limited by the configuration performed by Philips technical support . Additional ports are opened during system configuration by system administrators or service engineers to enable communication with remote DICOM nodes, including PACS, Worklist, and DICOM printers.

16.5 Security updates

This equipment incorporates protection mechanisms against the intrusion of malware such as viruses. Without proper cyber security maintenance, the effectiveness of these provisions may degrade over time, since malware is continuously altered to target newly discovered vulnerabilities.

The systematic analysis on cyber security vulnerabilities includes an assessment on the applicability and need for applying security updates taking into account mitigating circumstances in the intended use and design of this equipment.

Security updates alter the equipment's design and thus require proper validation and approval by Philips. Security updates are deployed by the Philips Service organization and are only to be installed by authorized service engineers according to Philips maintenance procedures for medical devices.

The latest information, including recommended customer actions, can be found on the following website:

www.philips.com/productsecurity

17 Technical information

17.1 Environmental requirements

CAUTION

Only operate the IntraSight Plus system and its options within the range of environmental conditions specified in the following sections.

Philips IntraSight Plus system

Item	Temperature	Relative humidity	Atmospheric pressure
Operating	50 to 86°F / 10 to 30°C	20-80% (non-condensing)	70 to 106 kPa / 20.67 to 31.30 inHg / 525 to 795 mmHg (0 to 3,000 m / 9,842 ft altitude)
Storage	0 to 140°F / -18 to 60°C	15-90% (non-condensing)	50 to 106 kPa / 14.77 to 31.30 inHg / 375 to 795 mmHg
Shipping	0 to 140°F / -18 to 60°C	15-90% (non-condensing)	50 to 106 kPa / 14.77 to 31.30 inHg / 375 to 795 mmHg

17.2 Dimensions and weights

Philips IntraSight Plus system

Item	Height	Width	Depth	Weight
Workstation	19.38 in / 49.20 cm	10.00 in / 25.40 cm	16.75 in / 42.50 cm	~46.0 lb / 29.0 kg
Touch screen module	8.09 in / 20.56 cm	11.95 in / 30.35 cm	1.45 in / 3.68 cm	~4 lb / 1.8 kg
Monitor (1920 x 1080, 16:9) Control room (at 5 degree tilt)	15.6 in / 39.6 cm	22.4 in / 56.9 cm	6.5 in / 16.5 cm	21.6 lb / 9.8 kg
Monitor (1920 x 1080, 16:9) Examination room	15.2 in / 38.7 cm	25.6 in / 64.9cm	3.4 in / 8.6 cm	19.6 lb / 8.9 kg
SA-PIM (IVUS)	1.60 in / 3.80 cm	4.00 in / 9.60 cm	7.40 in / 17.75 cm	~4.4 lb / 2.0 kg
FM-PIM	6.0 in / 15.2 cm	3.5 in / 8.9 cm	1.5 in / 3.8 cm	0.5 lb / 0.2 kg
PIM FM-PIM r	3.9 in / 9.9 cm	4.0 in / 10.2 cm	14.4 in / 36.6 cm	~3.2 lb / 1.5 kg
PIMr	3.9 in / 9.9 cm	4.0 in / 10.2 cm	14.4 in / 36.6 cm	2.9 lb / 1.3 kg

17.3 Classifications

The Philips IntraSight Plus system has the following classifications, as defined by IEC 60601-1:2005 + A1:2012 + A2:2020.

Item	Specification
Type of protection against electric shock	Class I
Degree of protection against electric shock (for parts that are used inside the sterile zone of the system)	Type CF, defibrillation proof

Item	Specification
Degree of protection against the harmful ingress of water	• PIM: IPX4 • Examination room monitor: IPX1 • Workstation: IPX0
Degree of safety of application in the presence of anesthetics	The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous operation

17.4 Power

Philips IntraSight Plus system ratings and fusing

System input configurations	Workstation input	Fusing
100-120 V~ 240 V~ 50/60 Hz, *1000 VA	100-240 V~ 50/60 Hz	100 VAC,12.5 A 120 VAC, 10 A 240 VAC, 5 A
*Maximum isolation transformer rating		

Fusing

The isolation transformer is merged with a fuse on each mains leg. The fuse values are dependent on the transformer setting for the available AC mains power from the wall. The transformer uses 5 x 20 mm time delay fuses.

The AC mains input for the workstation power supply and 48 VDC power supply are internally fused and are not serviceable parts.

The 48 VDC power supply output is protected with a 5 A, 5 x 20 mm time delay fuse.

17.5 Compatible catheters

The catheters are designed to image under physiologic conditions. The operating temperature of all solid-state array catheters used with the Philips system is <55 +/- 0.3°C in air and <41+/- 0.3°C under physiologic conditions (37°C in fluids). The operating temperature of rotational catheters used with the Philips system is 1 +/- 0.3°C above ambient temperature in air and <38 +/- 0.3°C under physiologic conditions (37°C in fluids).

Operation of the catheters in air degrades the life of the catheter, and is not recommended. Should operation of the solid-state array catheters in air occur, this results in a temperature at the distal end of up to 55°C, but the catheters thermal load (heat capacity) is negligible and the catheters may be safely touched and may feel slightly warm under these conditions. Should operation of the rotational catheters in air occur, this results in a negligible temperature rise at the distal end.

17.5.1 Imaging catheters

Transducer type:

- Piezoelectric
- 360-degree view, multi-element solid-state array transducer

The following table provides frequencies and available imaging diameters for imaging catheters.

Catheter	Frequency	Imaging diameters (mm)	Part number
Eagle Eye Platinum	20 MHz	8, 10, 12, 14, 16, 18, 20	989609002381 (formerly 809746001)
Eagle Eye Platinum Japan	20 MHz	8, 10, 12, 14, 16, 18, 20	989609001101 (formerly 400-0200.71)
Eagle Eye Platinum short tip	20 MHz	8, 10, 12, 14, 16, 18, 20	989609000481 (formerly 4400-0200.141)
Pioneer Plus	20 MHz	8, 10, 12, 14, 16, 18, 20	989609000961 (formerly 400-0200.246)
Reconnaissance PV .018 OTW	20 MHz	8, 10, 12, 14, 16, 18, 20	300000513451
Reconnaissance PV .018 OTW Japan	20 MHz	8, 10, 12, 14, 16, 18, 20	300000513461
Visions PV .014P	20 MHz	8, 10, 12, 14, 16, 18, 20	989609000951 (formerly 400-0200.233)
Visions PV .014P Japan	20 MHz	8, 10, 12, 14, 16, 18, 20	989609000941 (formerly 400-0200.230)
Visions PV .014P RX	20 MHz	8, 10, 12, 14, 16, 18, 20	989609001091 (formerly 400-0200.297)
Visions PV .014P RX short tip	20 MHz	8, 10, 12, 14, 16, 18, 20	989609001091 (formerly 400-0200.297)
Visions PV .018	20 MHz	8, 10, 12, 14, 16, 18, 20, 22, 24	989609002431 (formerly K8886700)
Visions PV .018 Japan	20 MHz	8, 10, 12, 14, 16, 18, 20, 22, 24	989609001011 (formerly 400-0200.285)
Visions PV .035	10 MHz	20, 25, 30, 35, 40, 45, 50,	989609000491 (formerly 400-0200.173)
Visions PV .035 Non-Hospital	10 MHz	20, 25, 30, 35, 40, 45, 50, 55, 60	989609000971 (formerly 400-0200.272)

NOTE ***For more information about the catheter that you are using, refer to the Instructions for Use supplied with the catheter.***

17.5.2 Rotational IVUS catheters

Catheter	Frequency	Imaging diameters (mm)	Part number
Refinity short tip	45 MHz	8, 10, 12, 14	300003738791

NOTE ***For more information about the catheter that you are using, refer to the Instructions for Use supplied with the catheter.***

Refinity Rotational IVUS imaging catheter

Item	Specification
Transducer type	Piezoelectric 360° view, single-element rotating transducer
Lumen characteristics	Coaxial, guide wire lumen
Crossing profile at transducer	3.0 Fr (1.0 mm / 0.039 in)
Maximum guide wire	0.014 in / 0.36 mm
Minimum ID guiding catheter clearance	5 Fr (1.42 mm) ≥0.056 in
Length	53.2 in / 135 cm

17.5.3 Catheter acoustic outputs

Ultrasound exposure / acoustic output power

Ultrasound exposure/acoustic output power is fixed and cannot be adjusted by the operator of this equipment. Ultrasound exposure occurs only when live imaging is enabled. When live imaging is not selected by the operator, no ultrasound exposure occurs.

The Philips IntraSight Plus system is in compliance with the Acoustic Output Display Standard and within FDA limits for ultrasound equipment.

These terms and definitions are used in the following tables:

Term	Definition
f_{awf}	Acoustic Working Frequency
$I_{pa,\ \alpha}$	Attenuated Pulse-Average Intensity
pii	Pulse-Intensity Integral
I_{spta}	Spatial-Peak Temporal-Average Intensity
$I_{spta,\ \alpha}$	Attenuated Spatial-Peak Temporal-Average Intensity
MI	Mechanical Index
n_{pps}	Number of Pulses Per Ultrasonic Scan Line
P	Output Power
P_{1x1}	Bounded-Square Output Power
$P_{r,\ \alpha}$	Attenuated Peak-Rarefactional Acoustic Pressure
P_r	Peak-Rarefactional Acoustic Pressure
prr	Pulse Repetition Rate
srr	Scan Repetition Rate
TIB	Bone Thermal Index
TIC	Cranial-Bone Thermal Index
TIS	Soft-Tissue Thermal Index
z_b	Depth for Bone Thermal Index
z_{pii}	Depth for Peak Pulse-Intensity Integral
z_{MI}	Depth for Mechanical Index
$z_{pii,\ \alpha}$	Depth for Peak Attenuated Pulse-Intensity Integral
z_{sii}	Depth for Peak Sum of Pulse-Intensity Integrals
$z_{sii,\ \alpha}$	Depth for Peak Sum of Attenuated Pulse-Intensity Integrals
z_s	Depth for TIS

Eagle Eye Platinum / Visions PV .014P / Reconnaissance PV .018 OTW

Combined acoustic output reporting table: Eagle Eye Platinum / Visions PV .014P / Reconnaissance PV .018 OTW (B-mode + ChromaFlo)

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			4.93E-02	1.58E-04	1.58E-04	1.58E-04	1.58E-0	5.26E-04
Index component value			X	1: 9.10E-05 2: 6.65E-05	1: 9.10E-05 2: 6.65E-05	1: 9.10E-05 2: 6.65E-05	1: 9.10E-05 2: 6.65E-05	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	1: 0.21	X	X	X	X	X
	P	mW	X	1: 2.12E-03 2: 1.35E-03	1: 2.12E-03 2: 1.35E-03	1: 2.12E-03 2: 1.35E-03	1: 2.12E-03 2: 1.35E-03	1: 2.12E-03 2: 1.35E-03
	P_{1x1}	mW	X	1: 1.06E-03 2: 6.74E-04	1: 1.06E-03 2: 6.74E-04	1: 1.06E-03 2: 6.74E-04	1: 1.06E-03 2: 6.74E-04	X
	z_s	cm	X	X	1: N/A 2: N/A	X	X	X
	z_b	cm	X	X	X	X	1: N/A 2: N/A	X
	z_{MI}	cm	1: 4.34E-02	X	X	X	X	X
	$z_{pii,\alpha}$	cm	1: 0.27	X	X	X	X	X
	f_{awf}	MHz	1: 18.16	1: 18.16 2: 20.67	1: 18.16 2: 20.67	1: 18.16 2: 20.67	1: 18.16 2: 20.67	1: 18.16 2: 20.67
Other Information	prr	Hz	1: 25088.0	X	X	X	X	X
	srr	Hz	1: 7.0	X	X	X	X	X
	n_{pps}		1: 14	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	1: 0.120	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/ cm²	3.69E-02	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/ cm²	5.30E-02	X	X	X	X	X
	Pr at z_{pii}	MPa	1: 7.57E-02	X	X	X	X	X
Operating Control Conditions	Component 1: 17.9MHz-15.0mm-ChromaFlo		X	X	X	X	X	X
	Component 2: 18.6MHz- 15.0mm-B-Mode		X	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: Cells containing an X do not require numerical values. All other cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
- NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Uncertainties: Power: ±17.9%; Hydrophone pressure sensitivity: ±3.6%; Intensity: ±17.8%; TI: ±17.9%; MI and pressure: ±9.0%

Acoustic output reporting table: Eagle Eye Platinum / Visions PV .014P / Reconnaissance PV .018 OTW (B-mode + ChromaFlo) - Component 2: 18.6MHz-15.0mm-B-Mode

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			1.42E-02	6.65E-05	6.65E-05	6.65E-05	6.65E-05	2.04E-04
Index component value			X	6.65E-05	6.65E-05	6.65E-05	6.65E-05	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	6.45E-02	X	X	X	X	X
	P	mW	X	1.35E-03	1.35E-03	1.35E-03	1.35E-03	1.35E-03
	P_{1x1}	mW	X	6.74E-04	6.74E-04	6.74E-04	6.74E-04	X
	z_s	cm	X	X	X	N/A	X	X
	z_b	cm	X	X	X	X	N/A	X
	z_{MI}	cm	4.47E-02	X	X	X	X	X
	$z_{pii,\alpha}$	cm	0.28	X	X	X	X	X
	f_{awf}	MHz	20.67	20.67	20.67	20.67	20.67	20.67
Other Information	prr	Hz	53760.0	X	X	X	X	X
	srr	Hz	30.0	X	X	X	X	X
	n_{pps}		7	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	0.013	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	1.31E-02	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	1.94E-02	X	X	X	X	X
	Pr at z_{pii}	MPa	3.91E-02	X	X	X	X	X
Operating Control Conditions	18.6MHz-15.0mm-B-Mode		X	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: Cells containing an X do not require numerical values. All other cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
- NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.
- **Uncertainties:** Power: ±17.9%; Hydrophone pressure sensitivity: ±3.6%; Intensity: ±17.8%; TI: ±17.9%; MI and pressure: ±9.0%

Pioneer Plus

Combined acoustic output reporting table: Pioneer Plus (B-mode + ChromaFlo)

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			5.10E-02	1.90E-04	1.90E-04	1.90E-04	1.90E-04	6.45E-04
Index component value			X	1: 3.73E-05 2: 1.53E-04	1: 3.73E-05 2: 1.53E-04	1: 3.73E-05 2: 1.53E-04	11: 3.73E-05 2: 1.53E-04	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	2: 0.22	X	X	X	X	X
	P	mW	X	1: 7.65E-04 2: 3.49E-03	1: 7.65E-04 2: 3.49E-03	1: 7.65E-04 2: 3.49E-03	1: 7.65E-04 2: 3.49E-03	1: 7.65E-04 2: 3.49E-03
	P_{1x1}	mW	X	1: 3.83E-04 2: 1.74E-03	1: 3.83E-04 2: 1.74E-03	1: 3.83E-04 2: 1.74E-03	1: 3.83E-04 2: 1.74E-03	X
	z_s	cm	X	X	1: N/A 2: N/A	X	X	X
	z_b	cm	X	X	X	X	1: N/A 2: N/A	X
	z_{MI}	cm	1: 4.02E-02	X	X	X	X	X
	$z_{pii,\alpha}$	cm	2: 0.34	X	X	X	X	X
	f_{awf}	MHz	2: 18.33	1: 20.47 2: 18.33	1: 20.47 2: 18.33	1: 20.47 2: 18.33	1: 18.16 2: 20.67	1: 20.47 2: 18.33
Other Information	prr	Hz	2: 25088.0	X	X	X	X	X
	srr	Hz	2: 7.0	X	X	X	X	X
	n_{pps}		2: 14	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	2: 0.186	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	4.92E-02	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	7.03E-02	X	X	X	X	X
	Pr at z_{pii}	MPa	2: 0.10	X	X	X	X	X
Operating Control Conditions	Component 1: 19.6MHz-15.0mm-B-Mode		X	X	X	X	X	X
	Component 2: 19.6MHz-15.0mm-ChromaFlo		X	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: Cells containing an X do not require numerical values. All other cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
- NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Uncertainties: Power: ±17.9%; Hydrophone pressure sensitivity: ±3.6%; Intensity: ±17.8%; TI: ±17.9%; MIand pressure: ±9.0%

Acoustic output reporting table: Pioneer Plus (B-mode) - Component 1: 19.6MHz-15.0mm-B-Mode

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			1.09E-02	3.73E-05	3.73E-05	3.73E-05	3.73E-05	1.16E-04
Index component value			X	3.73E-05	3.73E-05	3.73E-05	3.73E-05	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	4.91E-02	X	X	X	X	X
	P	mW	X	7.65E-04	7.65E-04	7.65E-04	7.65E-04	7.65E-04
	P_{1x1}	mW	X	3.83E-04	3.83E-04	3.83E-04	3.83E-04	X
	z_s	cm	X	X	N/A	X	X	X
	z_b	cm	X	X	X	X	N/A	X
	z_{MI}	cm	4.66E-02	X	X	X	X	X
	$z_{pii,\alpha}$	cm	0.25	X	X	X	X	X
	f_{awf}	MHz	20.47	20.47	20.47	20.47	20.47	20.47
Other Information	prr	Hz	53760.0	X	X	X	X	X
	srr	Hz	30.0	X	X	X	X	X
	n_{pps}		7	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	0.019	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	1.07E-02	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	1.52E-02	X	X	X	X	X
	Pr at z_{pii}	MPa	3.47E-02	X	X	X	X	X
Operating Control Conditions	19.6MHz-15.0mm-B-MODE		X	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.

- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: Cells containing an X do not require numerical values. All other cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
- NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Uncertainties: Power: ±17.9%; Hydrophone pressure sensitivity: ±3.6%; Intensity: ±17.8%; TI: ±17.9%; MI and pressure: ±9.0%

Visions PV .018

Acoustic output reporting table: Visions PV .018 (B-mode)

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			4.17E-3	7.88E-6	7.88E-6	7.34E-5	7.34E-5	(3)
Index component value			X	7.88E-6	7.88E-6	7.34E-5	7.88E-6	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	0.0188	X	X	X	X	X
	P	mW	X	1.62E-4	1.62E-4	1.62E-4	1.62E-4	X
	P_{1x1}	mW	X	8.11E-5	8.11E-5	8.11E-5	8.11E-5	X
	z_s	cm	X	X	0.05	X	X	X
	z_b	cm	X	X	X	X	0.05	X
	z_{MI}	cm	0.05	X	X	X	X	X
	$z_{pii,\alpha}$	cm	0.05	X	X	X	X	X
	f_{awf}	MHz	20.2	20.2	20.2	20.2	20.2	X
Other Information	prr	Hz	43008	X	X	X	X	X
	srr	Hz	24	X	X	X	X	X
	n_{pps}		28	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	1.20E-2	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	5.29E-3	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	5.68E-3	X	X	X	X	X
	Pr at z_{pii}	MPa	0.0194	X	X	X	X	X
Operating Control Conditions	B-Mode		applicable	applicable	applicable	applicable	applicable	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.
- NOTE 7: Cells containing an X do not require numerical values. All other cells should have a numerical value or a checkmark.

Uncertainties: Power: ±30.2%; Hydrophone pressure sensitivity: ±5.6%; Intensity: ±30.2%; TI: ±30.2%; MI and pressure: ±15.1%

Acoustic output reporting table :Visions PV .018 (B-mode + ChromaFlo)

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			1.94E-2	2.35E-4	2.35E-4	2.52E-3	2.52E-3	(3)
Index component value			X	2.35E-4	2.35E-4	2.52E-3	2.35E-4	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	8.14E-2	X	X	X	X	X
	P	mW	X	5.58E-3	5.58E-3	5.58E-3	5.58E-3	X
	P_{1x1}	mW	X	2.79E-3	2.79E-3	2.79E-3	2.79E-3	X
	z_s	cm	X	X	0.05	X	X	X
	z_b	cm	X	X	X	X	0.05	X
	z_{MI}	cm	0.05	X	X	X	X	X
	$z_{pii,\alpha}$	cm	0.05	X	X	X	X	X
	f_{awf}	MHz	17.7	20.2/17.7	20.2/17.7	20.2/17.7	20.2/17.7	X
Other Information	prr	Hz	70175	X	X	X	X	X
	srr	Hz	10	X	X	X	X	X
	n_{pps}		110	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	2.21E-1	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	1.89E-1	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	2.01E-1	X	X	X	X	X
	Pr at z_{pii}	MPa	8.49E-2	X	X	X	X	X
Operating Control Conditions	B-Mode + Chroma- Flo		X	applicable	applicable	applicable	applicable	X
	ChromaFlo only		applicable	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.

- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.
- NOTE 7: Cells containing an X do not require numerical values. All other cells should have a numerical value or an asterisk.

Uncertainties: Power: ±30.2%; Hydrophone pressure sensitivity: ±5.6%; Intensity: ±30.2%; TI: ±30.2%; MI and pressure: ±15.1%

Visions PV .035

Acoustic output reporting table: Visions PV .035 (B-mode)

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			2.45E-02	7.29E-04	7.29E-04	7.29E-04	7.29E-04	2.12E-03
Index component value			X	7.29E-04	7.29E-04	7.29E-04	7.29E-04	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	7.44E-02	X	X	X	X	X
	P	mW	X	3.31E-02	3.31E-02	3.31E-02	3.31E-02	3.31E-02
	P_{1x1}	mW	X	1.66E-02	1.66E-02	1.66E-02	1.66E-02	X
	z_s	cm	X	X	N/A	X	X	X
	z_b	cm	X	X	X	X	N/A	X
	z_{MI}	cm	0.47	X	X	X	X	X
	$z_{pii,\alpha}$	cm	0.67	X	X	X	X	X
	f_{awf}	MHz	9.27	9.27	9.27	9.27	9.27	9.27
Other Information	prr	Hz	20966.4	X	X	X	X	X
	srr	Hz	11.7	X	X	X	X	X
	n_{pps}		7	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	0.11	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	6.30E-02	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	9.14E-02	X	X	X	X	X
	Pr at z_{pii}	MPa	7.20E-02	X	X	X	X	X
Operating Control Conditions	11.7MHz-8.0mm-B-MODE		X	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.

- NOTE 6: Cells containing an X do not require numerical values. All other cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.
- NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Uncertainties: Power: ±17.9%; Hydrophone pressure sensitivity: ±3.6%; Intensity: ±17.8%; TI: ±17.9%; MI and pressure: ±9.0%

Refinity

Acoustic output reporting table: Refinity (B-mode)

Index label			MI	TIS At surface	TIS Below surface	TIB At surface	TIB Below surface	TIC
Maximum index value			7.83E-02	6.10E-04	6.10E-04	6.10E-04	6.10E-04	3.44E-03
Index component value			X	6.10E-04	6.10E-04	6.10E-04	6.10E-04	X
Acoustic Parameters	$P_{r,\alpha}$ at z_{MI}	MPa	0.43	X	X	X	X	X
	P	mW	X	8.65E-03	8.65E-03	8.65E-03	8.65E-03	8.65E-03
	P_{1x1}	mW	X	4.32E-03	4.32E-03	4.32E-03	4.32E-03	X
	z_s	cm	X	X	N/A	X	X	X
	z_b	cm	X	X	X	X	N/A	X
	z_{MI}	cm	0.22	X	X	X	X	X
	$z_{pii,\alpha}$	cm	0.31	X	X	X	X	X
	f_{awf}	MHz	29.89	29.89	29.89	29.89	29.89	29.89
Other Information	prr	Hz	15360.0	X	X	X	X	X
	srr	Hz	30.0	X	X	X	X	X
	n_{pps}		1	X	X	X	X	X
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	W/cm²	2.9	X	X	X	X	X
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	mW/cm²	0.10	X	X	X	X	X
	Ispta, $_{\alpha}$ at zpii or zsii	mW/cm²	0.19	X	X	X	X	X
	Pr at z_{pii}	MPa	0.44	X	X	X	X	X
Operating Control Conditions	42.1 MHz-5.0mm-B-Mode		X	X	X	X	X	X

Notes: See IEC 60601-2-37 for additional details.

- NOTE 1: Only one operating condition per index.
- NOTE 2: Data should be entered for “at surface” and “below surface” both in the columns related to TIS or TIB.
- NOTE 3: Information need not be provided regarding TIC for a TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
- NOTE 4: If the requirements of 201.12.4.2a are met, it is not required to enter any data in the columns related to TIS, TIB, or TIC.
- NOTE 5: If the requirements of 201.12.4.2b are met, it is not required to enter any data in the column related to MI.
- NOTE 6: Cells containing an X do not require numerical values. All other cells should have a numerical value. The equipment setting related to the index has to be entered in the operating control section.

- NOTE 7: The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{pii,\alpha}$ apply to SCANNING MODES.

Uncertainties: Power: ±17.9%; Hydrophone pressure sensitivity: ±3.6%; Intensity: ±17.8%; TI: ±17.9%; MI and pressure: ±9.0%

17.6 Compatible guide wires

The IntraSight Plus is compatible with the following Philips pressure measurement guide wires:

Compatible Philips guide wires	Model numbers
OmniWire pressure guide wire 185 cm straight tip	300000252871 (formerly 89185)
OmniWire pressure guide wire 185 cm J-tip	300000252891 (formerly 89185J)

Not all models are available in all locations.

17.7 PIM compatibility

NOTE ***If a catheter is not recognized, the catheter version may not be compatible with the system. Contact technical support for assistance.***

17.7.1 Intravascular Ultrasound (IVUS)

Synthetic Aperture (SA PIM)

The Synthetic Aperture PIM (SA PIM) is compatible with the following catheters:

- Eagle Eye Platinum
- Eagle Eye Platinum Japan
- Eagle Eye Platinum short tip
- Visions PV .014P
- Visions PV .014P Japan
- Visions PV .014P RX
- Visions PV .014P RX short tip
- Visions PV .018
- Visions PV .018 Japan
- Visions PV .035
- Visions PV .035 Non-Hospital
- Reconnaissance PV .018 OTW
- Reconnaissance PV .018 OTW Japan
- Pioneer Plus

For more information about these catheters, see *17.5.1 Imaging catheters on page 157*.

Rotational IVUS PIM (PIMr)

The rotational IVUS PIM (PIMr) is compatible with the Refinity short tip catheter.

For more information about these catheters, see *17.5.2 Rotational IVUS catheters on page 158*.

17.7.2 Functional Measurement (FM)

The Functional Measurement PIM (FM PIM) is compatible with the following guide wires:

- OmniWire Pressure Guide Wire 185 cm straight tip
- OmniWire Pressure Guide Wire 185 cm J-tip

For more information about these catheters, see *17.6 Compatible guide wires on page 169*.

17.8 Video

System video display format:

- Adapters available for DisplayPort, DVI and VGA output.
- 1920 x 1080 pixel resolution, 16:9 aspect ratio / 1280 x 1024 pixel resolution, 5:4 aspect ratio
- 60 Hz refresh rate

Image properties:

- Live/Still modes
- Variable frame rate
- 360-degree image
- Multiple depth scaling

17.8.1 Image sizes

Main display

Image mode	Viewing mode	Image area (in pixels)
IVUS tomography	IVUS live mode IVUS recording mode IVUS single frame review mode Freeze	832 x 832
	IVUS pullback review mode	768 x 768

Touch screen module

Image mode	Viewing mode	Image area (in pixels)
IVUS tomography	IVUS live mode IVUS recording mode IVUS single frame review mode Freeze	616 x 616
	IVUS pullback review mode	576 x 576

Control room display

Image mode	Viewing mode	Image area (in pixels)
IVUS tomography	IVUS live mode IVUS recording mode IVUS review mode	768 x 768

17.8.2 Video outputs

A DisplayPort connector is available on the rear side of the IntraSight Plus system, which supports connectivity to an external display using a Philips adaptor. External displays must support one of the following video modes:

- 1920 x 1080 60 Hz (138.5 MHz) via VESA-timing CVT 2.07M9-R (CVR1960H)
- 1280 x 1024 60 Hz (108 MHz) via VESA-timing DMT ID 23h (DMT1260G)

17.8.3 Third party monitors

If your IntraSight Plus system is configured to use a monitor not supplied by Philips , it is critical that the monitor complies with the following specifications to ensure image quality for accurate IVUS clinical diagnosis:

- Digital video connection: DVI-D
- Brightness: minimum 300 cd/m2
- Brightness uniformity: minimum 75%
- Brightness stabilization: automatic or maintained through specific preventative measures
- Grayscale curve: must comply with DICOM PS 3
- Color depth: 8 bits per sub-pixel
- Contrast ratio: minimum 600:1
- Anti-glare surface treatment
- Typical viewing angle: minimum 170 degrees (horizontal and vertical)
- The combination of the system and the connected third party monitor (not supplied by Philips) must comply with IEC 60601-1 requirements for medical electrical systems.

Failure to meet these requirements may result in sub-optimal image quality, which can compromise clinical diagnostics. Philips cannot be held responsible for any issues arising from the use of third-party monitors that do not meet these specifications.

For general usage (e.g., presentations), other standard specifications apply, such as:

- Color and grayscale display capability
- Must support VESA timing CVT 2.07M9-R (CVR1960H) for 1920x1080 (16:9), or DMT ID 23h (DMT1260G) for 1280x1024 (5:4)

17.9 Recording devices

- Hardcopy digital photo printer
- DVD and Blu-ray optical writer
- USB storage device

17.10 DICOM image storage

Saving patient cases to USN, DVD or Blu-ray: The archived images are stored in DICOM format with the Philips system acting as a File Set Creator (FSC), following the guidelines in the DICOM specification.

Warning: Studies archived to DVD or Blu-ray are not encrypted. For enhanced security, it is recommended to export data to media such as USB drives, which support encryption.

The Local AE supports the RWA - Create File-SET for the STD-GEN-CD and STD-GEN-DVD-JPEG , STD-GEN-USB-JPEG , and STD-GEN-BD-JPEG Application Profiles.

Information Object Definition	SOP Class UID	Transfer Syntax UID
DICOM Media Storage Directory	1.2.840.10008.1.3.10	1.2.840.10008.1.2.1
Ultrasound Multi-frame Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.3.1	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50
Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7	1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50
X-ray Angiographic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.1	1.2.840.10008.1.2.4.57 1.2.840.10008.1.2.4.70

Sending patient cases to a DICOM server: The Philips system supports the ultrasound multi-frame image storage SOP Class as an SCU (Service Class User) or SCP. The SOP Classes supported by the Philips system are categorized in the following table.

Information Object Definition	SOP Class UID	Transfer Syntax UID
Verification SOP Class	1.2.840.10008.1.1	1.2.840.10008.1.2
Ultrasound Multi-frame Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.3.1	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50
Secondary Capture Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.7	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.50
X-Ray Angiographic Image Storage SOP Class	1.2.840.10008.5.1.4.1.1.12.1	1.2.840.10008.1.2 1.2.840.10008.1.2.1 1.2.840.10008.1.2.4.57 1.2.840.10008.1.2.4.70
Patient Root QR Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.1.1	
Patient Root QR Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.1.2	
Study Root QR Information Model - FIND SOP Class	1.2.840.10008.5.1.4.1.2.2.1	
Study Root QR Information Model - MOVE SOP Class	1.2.840.10008.5.1.4.1.2.2.2	
Modality Worklist Information Model - FIND SOP Class	1.2.840.10008.5.1.4.31	

DICOM printing

Information Object Definition	SOP Class UID
Basic Grayscale Print Management Meta SOP Class	1.2.840.10008.5.1.1.9
- Basic Film Session SOP Class	1.2.840.10008.5.1.1.1
- Basic Film Box SOP Class	1.2.840.10008.5.1.1.2
- Basic Grayscale Image Box SOP Class	1.2.840.10008.5.1.1.4

Information Object Definition	SOP Class UID
- Printer SOP Class	1.2.840.10008.5.1.1.16
Basic Color Print Management Meta SOP Class	1.2.840.10008.5.1.1.18
- Basic Film Session SOP Class	1.2.840.10008.5.1.1.1
- Basic Film Box SOP Class	1.2.840.10008.5.1.1.2
- Basic Color Image Box SOP Class	1.2.840.10008.5.1.1.4.1
- Printer SOP Class	1.2.840.10008.5.1.1.16

17.11 Accessories and replacement parts

The following accessories and replacement parts are compliant with the Philips IntraSight Plus system IEC 60601-1-2 EMC certification.

Part Number	Description
30000757291x	Philips IntraSight Plus Instructions for use
30000757306x	Philips IntraSight Plus Instructions for use multilanguage (USB)
60000000044x	Printer, medical grade, USB, A6 color
	A6 paper for Sony UP-D25MD 4 packs of 50 sheets
	A6 paper for Sony UP-D25MD 3 packs of 80 sheets
60000000401x	PIM cable (3 meters)
60000000401x	PIM cable (5 meters)
	DVI-D interconnect cable (3 meters)
45360102282x	FM-PIM extension cable (5 ft)
45360102209x	Synthetic PIM holder assembly
60000000321x	DICOM network connection cable (10 ft)
30000191709x	FM-PIM
98960900165x 30000519510x	IVUS SA-PIM
30000331186x	PIMr option kit (SpinVision)
30000063428x	Touch screen module to connection box interface cable
30000201810x	Multi-modality touch screen module
60000000121x	BNC, connector dust cap
60000000717x	BNC, male dust cap with cord

18 Regulatory information

The system complies with current international and national standards and laws.

18.1 Frequently used functions

The system provides the following frequently used functions:

- Logging in and out of the system
- Searching and selection of existing studies
- Functional measurement setup guidance
- Intravascular ultrasound (IVUS) setup guidance
- Vessel quantitative analysis
- Vessel image enhancement
- Aortic pressure balancing
- Pressure normalization
- iFR spot measurement
- iFR pullback measurements (with and without co-registration)
- FFR measurement
- Recording of IVUS images (IVUS and rotational IVUS, with and without co-registration)
- Creating measurements and annotations
- Reviewing of procedures (all applications)
- Device detection and image enhancement
- ·Archiving studies and snapshots

18.2 Electromagnetic compatibility (EMC)

We declare that the Philips System Family of Image Guided Therapy systems meets the requirements for Electromagnetic Compatibility (EMC) through the use of International Standard IEC/60601-1-2 and complies with the following standards:

Guidance and Manufacturer's declaration - electromagnetic emissions Philips System Family		
The Philips System Family is intended for use in the electromagnetic environment specified below. The customer or the user of the Philips System Family should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	Philips systems use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	Philips systems are suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Caution: This equipment is not intended for use in residential environments and might not provide adequate protection to radio reception in such environments.

NOTE ***The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio- frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.***

Guidance and Manufacturer's declaration - electromagnetic immunity Philips System Series

IntraSight Plus Vascular System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntraSight Plus Vascular System should assure that it is used in such an environment.

During immunity testing the IntraSight Plus Vascular System was exercised by placing the system in a simulated imaging mode with normal operation indicated by an active image portrayed on the display.

During and after immunity testing the system shall continue to function and accept the commands given by user. It can temporarily lose communication but must return to normal operation without being disconnected.

Immunity Test	Test Level	Compliance Level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz 3 V/m 80 MHz to 2.7 GHz Proximity Fields [a] (see below table for proximity field characteristics)	3 Vrms b 6 Vrms 3 V/m [b] Proximity Fields (see below table for proximity field characteristics)	**WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the IntraSight Plus Integrated system, including cables specified by the manufacturer. Otherwise, degradation of the perfomance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Philips systems are used exceeds the applicable RF compliance level above, the Philips systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Philips systems.

[b] Over the frequency range 5 MHz to 150 MHz, image degradation may be encountered but complies with IEC 60601-2-37.

Guidance and manufacturer's declaration - electromagnetic immunity

The Philips System Family Image Intensifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Philips System Family should assure that it is used in such an environment.

Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air [a] ± 4 kV contact ± 8 kV air [b] [a] all system parts with exception of keyboard and mouse [b] keyboard and mouse		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5, ± 1 kV line(s) to line(s) ±0.5, ±1, ±2 kV line(s) to earth	± 0.5, ± 1 kV differential mode ±0.5, ±1, ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT ; 0.5 Cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315° 0% U T ; 1 Cycle 70% UT ; 25/30 Cycles Single Phase: at 0° 0% UT ; 250/300 Cycle	0% UT ; 0.5 Cycle At 0° , 45° , 90° , 135° , 180° , 225° , 270° , and 315° 0% UT ; 1 Cycle 70% U T ; 25/30 Cycles Single Phase: at 0o 0% UT ; 250/300 Cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Vascular System requires continued operation during power mains interruptions, it is recommended that the Vascular System be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels typical for commercial or hospital environments.
Proximity Magnetic Field IEC 61000-4-39	65 A/m [a] at 134.2 kHz. Pulse modulation b 2,1 kHz 7.5 A/m [a] at 13.56 MHz. Pulse modulation b 50 kHz a r.m.s., before modulation is applied [b] The carrier shall be modulated using a 50 % duty cy- cle square wave signal.	65 A/m [a] at 134.2 kHz. Pulse modulation b 2,1 kHz 7.5 A/m a at 13.56 MHz. Pulse modulation [b] 50 kHz	Proximity Magnetic fields should be at levels typical for commercial or hospital environments.

NOTE: UT is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's declaration – electromagnetic immunity to RF proximity fields					
Test Frequency (MHz)	**Band (MHz)**	**Modulation**	**Maximum Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	Pulse Modulation [a] 18 Hz	1.8	0.3	27
450	430-470	FM +/- 5 kHz deviation [b] 1 kHz sine	2	0.3	28
710 745 780	704-787	Pulse Modulation [a] 18 Hz	0.2	0.3	9
810 870 930	800-960	Pulse Modulation [a] 217 Hz	2	0.3	28
1720 1845 1970	1700-1990	Pulse Modulation [a] 217 Hz	2	0.3	28
2450	2400-2570	Pulse Modulation [a] 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	Pulse Modulation [a] 217 Hz	0.2	0.3	9

[a] The carrier shall be modulated using a 50 % duty cycle square wave signal

[b] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used.

RFID Transmitter Specifications		
Frequency	**Frequency Modulation**	**Radiated Power**
13.56 MHz ± 7 kHz	100%ASK	300 mW

18.3 Measurement accuracy and essential performance

Measurement accuracy

Measurements obtained with the Philips system are subject to the following measurement inaccuracies due to variations in tissue speed of sound and display limitations. The measurement precision is limited in both relative and absolute ranges.

IVUS accuracy

- Area measurements with an accuracy of +/- (0.1 mm2 + 5% of measurement value).
- Diameter measurements with an accuracy of +/- (0.1 mm + 1% of measurement value).
- ILD length measurement for rotational catheters with an accuracy of +/- (0.1 mm + 4% of measurement value).

FM accuracy

- Pressure with an accuracy of +/- 3 mmHg over the range of -30 to 100 mmHg.
- Measure pressure with an accuracy of +/- 3 % over the range of 100 to 330 mmHg.

Co-registration/tri-registration accuracy

- Provide location of the iFR value on the Roadmap with an accuracy of +/-2.8 mm in FM Review Mode when co-registration is enabled.
- Length of segments with an accuracy of ≤ +/-1.6 mm, precision ≤ 2.0 mm, when reviewing an iFR co-registration pullback in the FM Review Mode.
- Location of the IVUS frame on the Roadmap with an accuracy of +/-2.3 mm in IVUS Review Mode when co-registration is enabled.
- Length measurement on ILD and Roadmap with an accuracy of ≤ +/-1.0 mm, precision ≤ 1.0 mm in IVUS Review Mode when co-registration is enabled.

QCA accuracy

- MLD accuracy of +/- 0.2 mm, precision 0.15 mm.
- Percent stenosis accuracy of +/- 5%, precision 5%.
- Narrowing Length accuracy of +/- 1.0 mm, precision 0.5 mm.

NOTE ***A slight difference in total pullback length displayed on SpinVision (PIMr) and ILD may exist due to the latent response in initiation/termination of the pullback relative to recording. This discrepancy only exists in the most proximal and distal 1 mm of the video loop.***

Essential performance

The following items detail the essential performance of the system:

- The system shall provide area measurements with an accuracy of ±(0.1 mm2 + 5% of measurement value) in IVUS review mode.
- The system shall provide diameter measurements with an accuracy of ±(0.1 mm + 1% of measurement value) in IVUS review mode.
- The system shall measure pressure with an accuracy of ±3 mmHg over the range of -30 to 100 mmHg in functional measurement live and recording modes. Note: Functional management live and recording modes are equivalent in the acquisition of pressure data.
- The system shall measure pressure with an accuracy of ±3 % over the range of 100 to 330 mmHg in functional measurement live and recording modes. Note: Functional management live and recording modes are equivalent in the acquisition of pressure data.
- The system shall provide measurements with the following accuracy in QCA/VE mode:
  - MLD accuracy of ±0.2 mm
  - Percent stenosis accuracy of ±5%
  - Narrowing length accuracy of ±1 mm

18.4 Applied parts

The following parts are regarded as applied parts:

- Disposables (catheters and pressure guide wires)

The following parts can come into contact with the patient or are connected to an applied part, and are therefore treated as applied parts:

- Patient interface modules (PIM) and their associated cables
- Touch screen module

18.5 Third party software

This product uses other software, including open-source software. Details of this software can be found in the **3rd_party_sw folder** on the release notes USB medium.

18.6 Installation and equipment connections

WARNING

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 62368-1 for data processing equipment and IEC 60601-1:2005 + A1:2012 + A2:2020 for medical equipment). Furthermore all configurations shall comply with system requirements in accordance with IEC 60601, Clause 16. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for system complying with the requirements of IEC 60601-1, Clause 16. If in doubt, consult the technical services department or your local representative. In specific, AC mains powered devices are not recommended unless approved and installed by Philips.

Bedside utility box connections

Use caution when unplugging a cable from the bedside utility box. Do not disconnect a connection by pulling the cable. Always ensure that the dust cap covers provided are fitted to any unused connectors.

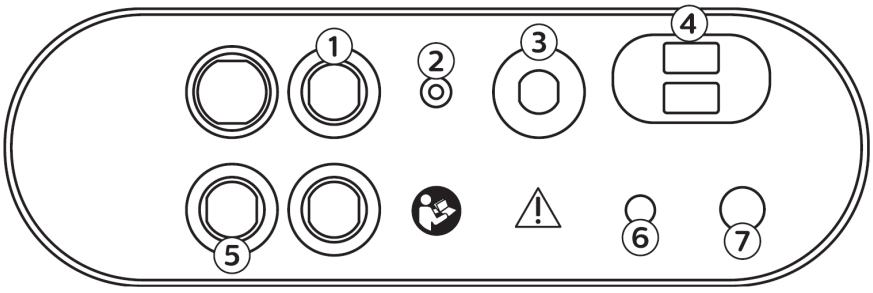


Figure 87 Bedside utility box front panel

Legend	Connection	Function	Connection type
1		IVUS SA-PIM and SpinVision (PIMr)	Twist lock
2		Power indicator light	Not applicable

Legend	Connection	Function	Connection type
3		FM-PIM	Push or pull
4		Dual USB (not used)	Push or pull
5		This connector may be used to accommodate future system upgrades	Push or pull
6		24 V DC power supply	Screw lock
7		ECG/Aortic input connection	Twist lock
Connections which are not listed in the table are not used.			

18.7 Contacting Philips

You can contact Philips by post, by telephone, by email, or using the Philips website.

Manufacturer's address	
Postal address	Philips Image Guided Therapy Corporation 9965 Federal Drive Colorado Springs, CO 80921 USA
European authorized representative:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands
UK Responsible Person:	Philips Electronics UK Limited Ascent 1, Aerospace Boulevard Farnborough GU14 6XW United Kingdom
Australian sponsor:	Philips Electronics Australia Ltd 65 Epping Road North Ryde, NSW Australia 2113
Email address	USA, Canada, and Mexico: IGTD.CustomerInquiry@philips.com International: IGTDCustomerService-Int@philips.com
Telephone	USA and Canada: (800) 722-9377 Option 1 International: + 525515001184
Website address	www.philips.com/IGTdevices

19 Glossary

Term	Definition
Angiogram	An exposure (cine) series acquired with contrast to emphasize vessel structure.
ATNA	Audit Trail and Node Authentication
B-mode	Brightness mode: the displaying of an ultrasound image in which the intensity of the echo is represented by modulation of the brightness within the image and in which the position of the echo is determined from the position of the transducer and the transit time of the acoustic pulse.
CABG	Coronary Artery Bypass Graft
DICOM	Digital Imaging and Communications in Medicine
EMC	Electromagnetic Compatibility
EUDAMED	European Database of Medical Devices
FFR	Fractional Flow Reserve
FM-PIM	Patient interface module for functional measurements (iFR and FFR)
IEC	International Electrotechnical Commission
iFR	instantaneous wave-Free Ratio
IHE	Integrating the Healthcare Enterprise
ILD	Inline display (IVUS)
IVUS	Intravascular ultrasound
MAP	Mean Arterial Pressure
MLD	Minimum Lumen Diameter
MPPS	Modality Performed Procedure Step manager
Pa	Mean aortic pressure
PACS	Picture Archiving and Communication System
Pd	Measured pressure distal to the stenosis
PIMr	Patient interface module for rotational IVUS (also referred to as SpinVision)
QCA	Quantitative Coronary Analysis
REACH	Registration, Evaluation, Authorization, and Restriction of Chemicals
Roadmap	A single image (frame) from an angiogram used for co-registration, showing the vessel of interest.
SA-PIM	Patient interface module for IVUS
UPS	Uninterruptible Power Supply
VE	Vessel Enhancement
WEEE	Waste Electrical and Electronic Equipment
Whitelist	The list of software applications that are allowed to execute on the system.
WLM	Worklist Management

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D001088282.D Revision Date: 2025-12