



Operator's Manual

English

IntraSight

IntraSight for use with Philips Integrated System

Software Version 1.1.X

PHILIPS



Complies with the Council Directive 93/42/EEC.



Philips system product meets TUV's safety requirements.



Attention: Read Operator's Manual and Instructions For Use prior to using this device. Please contact your local Philips representative for translated versions.



Do not dispose of this device or its components. Improper disposal may be harmful to the environment and human health. Dispose device per local electronic waste regulations.



Manufactured by:

Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670 USA
Phone: 916.638.8008
Phone: 800.228.4728 (USA and Canada)
Fax: 916.638.8112
www.philips.com/IGTdevices



Authorized European Representative:

Volcano Europe BVBA/SPRL
Excelsiorlaan 41
B-1930 Zaventem, Belgium
Phone: +32.2.679.1076
Fax: +32.2.679.1079

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Warranty

NOTICE: Manufacturer's Specifications and Policies 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.

LIMITED WARRANTY

Subject to the conditions and limitations on liability stated herein, Philips ("PHILIPS") warrants that the Philips Image Guided Therapy System (IGTS) (the "System") as so delivered, shall materially conform to Philips's then current specifications for the System, for a period of one year from the date of delivery. ANY LIABILITY OF PHILIPS WITH RESPECT TO THE SYSTEM OR THE PERFORMANCE THEREOF UNDER ANY WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY WILL BE LIMITED EXCLUSIVELY TO SYSTEM 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 SYSTEM. EXCEPT FOR THE FOREGOING, THE SYSTEM 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 SYSTEM 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 System is operated in other than a manner prescribed by Philips in the Operator's Manual, and/or supplements.
- 2 The System is operated in a manner that is not in conformance with purchase specifications and specifications contained in the Operator's Manual, and/or supplements.
- 3 The System is not maintained in accordance with procedures in the Operator's Manual, and/or supplements.
- 4 The System 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 System or components of the System are to be returned. The System or components will not be accepted for warranty purposes unless the return has been authorized by Philips.

System 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. System 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.

Patents and Trademarks

Refer to www.ip.philips.com/patentmarking to view a comprehensive list of Philips patents.

Trademarks

Trademarks are the property of Koninklijke Philips N.V. or their respective owners.

Warnings and Precautions

Read and Review Manual before Operation

Carefully read and review the entire Philips System Operator's Manual before attempting to operate the system.

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.

WARNINGS are used to indicate the possibility of severe personal injury. Follow the instruction or procedure correctly to avoid injury to the operator, patient, or other personnel.

The warnings are identified by the exclamation symbol.



CAUTIONS are used to indicate the possibility of damage to the equipment. Follow the instruction or procedure correctly to avoid damage to the equipment.

REACH Declaration

REACH requires Philips Healthcare (PH) 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:

<http://www.philips.com/about/sustainability/reach.page>

For Use only by Trained Medical Personnel

Federal (U.S.A.) 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 insertion procedures should use the Philips 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 at least on 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.

System Use Cautions and Warnings

- The Philips system supplies diagnostic information when used in conjunction with Philips imaging catheters during ultrasonic imaging (IVUS) of peripheral and coronary vasculature, and functional measurement (FM). It is intended to be used as an adjunct to conventional angiographic procedures or interventional therapies such as balloon angioplasty.
- **CAUTION:** Although the Components are spill-resistant, avoid spilling or dropping any foreign material onto components. It is important to be especially careful with the keyboard, controller, workstation, and monitor.
- The Philips bedside mounted equipment complies with the fluid ingress requirements of IEC60529 (IPX0 for control panel, IPX4 for all other bedside peripherals) when configured for normal use. The bedside mounted Philips system equipment should be located under a sterile drape when configured for normal use.



- **WARNING:** Do not place the isolation transformer on the floor. The unit must remain on an elevated surface.
- **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.
- **CAUTION:** Do not obstruct mains AC cord.



- **WARNING:** To prevent compromising patient isolation, the system operator must not simultaneously touch the patient and/or any implanted catheter or guide wire and any part of the system mobile cart or computer chassis or connector interface.

NOTE: Within the U.S.A., a hospital-grade receptacle *must* be used.

- **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 Philips systems are protected against the voltages of defibrillation; still, it is recommended that the catheter be disconnected from the patient interface module prior to defibrillation.
- For cardiac catheterization applications, the Philips system must be connected to the potential equalization system of the hospital room.
- **CAUTION:** The Philips system is intended to be installed into diagnostic and interventional catheter 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+A1:2012, 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.

System has to be installed to 60601-1:2005+A1:2012, Clause 16 (Medical Systems)

Including the use of an isolation transformer and potential equalization  on control console system and other peripheral devices

- **CAUTION:** The Philips system is a high-gain wide-band patient connected intravascular ultrasound (IVUS) and functional management (FM) systems intended for use during diagnostic or interventional percutaneous coronary or peripheral 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:** The Philips system should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it is used.
- **WARNING:** Portable and mobile RF communications equipment can affect medical electrical equipment. See Technical Specifications chapter for the recommended separation distances between portable and mobile RF communications equipment and the Philips system equipment.
- **WARNING:** The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the system as replacement parts for internal components, may result in increased emissions or decreased immunity of the system.
- **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:** Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1:Edition 3 2005 for medical equipment). Furthermore all configurations shall comply with the system



standard IEC 60601-1, 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 60601-1-1:2000. 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.



- **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.
- **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.

PIM Use Cautions and Warnings

- **CAUTION:** The patient interface module (PIM) magnetic strip, which allows it to be attached to various surfaces during use, can damage audiotapes, computer tapes, computer disks, and other magnetically sensitive components. Do not place the PIM near these items.
- **CAUTION:** Do not damage the PIM's cable by rolling equipment on it or using excessive force when disconnecting it.
- **CAUTION:** If the PIM is dropped, permanent damage to the external packaging and internal electronics may occur. Do not use the system if the outer case of the module appears damaged.
- **CAUTION:** The PIM should not be placed below the IV pole where liquids may drip into the catheter connector and cause damage.
- **CAUTION:** The PIM cable is susceptible to damage if not stored properly. Never let the PIM cable lay on the floor. Store the PIM cable in a manner where the connector end cannot be damaged by personnel, gurneys or table movements. There must be sufficient slack in the cable when stored on the table to avoid binding during table movements.
- **CAUTION:** All bedside mounted peripherals should be securely placed to avoid injury to the user or patient.

Catheter and Wire Use Cautions and Warnings

NOTE: See the package insert for a complete description of product usage, warnings, and precautions.

Conventions

The IntraSight system includes Main Monitor and Bedside Controller screens. The Bedside Controller uses touch-screen technology, which makes it convenient for the doctor, technician, or operator at the patient table to conveniently select menu options, vessel images, make measurements, save and archive image frames and video loops.

Entering patient information, selecting menu options/functions, displaying images, and creating measurements, and saving views can be performed several ways. To perform tasks, you may use:

- Touch screen (Bedside Controller)
- Keyboard/mouse (Main Monitor)

Consequently, action verbs used in describing following workflows will include a generic word such as “select” (for example, select option, tool, view, menu, etc.), which will cover use of either touch-screen or keyboard/mouse in performing procedures.

Contact Information

United States:

Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670 USA
Phone: 916.638.8008
Phone: 800.228.4728 (USA and Canada)
Fax: 916.638.8112
www.philips.com/IGTdevices

Authorized European Representative:

Volcano Europe BVBA/SPRL
Excelsiorlaan 41
B-1930 Zaventem, Belgium
Phone: +32.2.679.1076
Fax: +32.2.679.1079

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Chapter 1. Overview

Introduction

The Philips IntraSight Vascular system provides qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

Intravascular ultrasound (IVUS) utilizes 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.

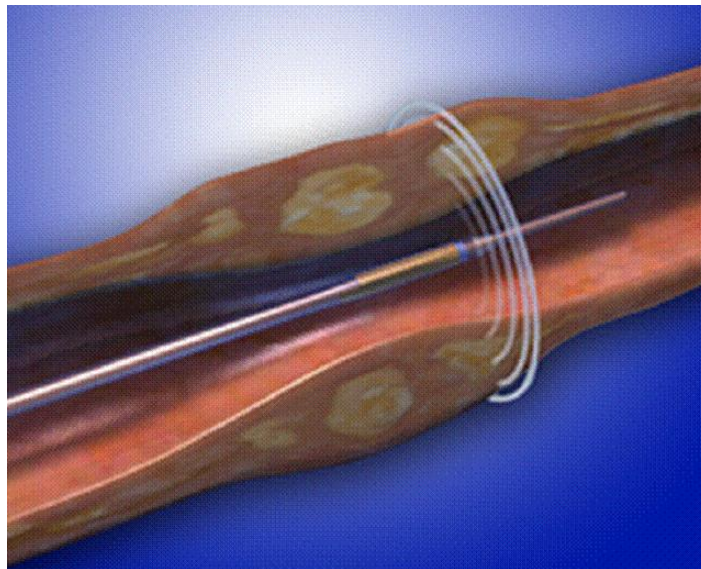


Figure 1: IVUS Catheter in Vessel

The system is then able to analyze the signal that is received by the transducer to differentiate between vessel structures to produce a 360° cross sectional image.

Overview

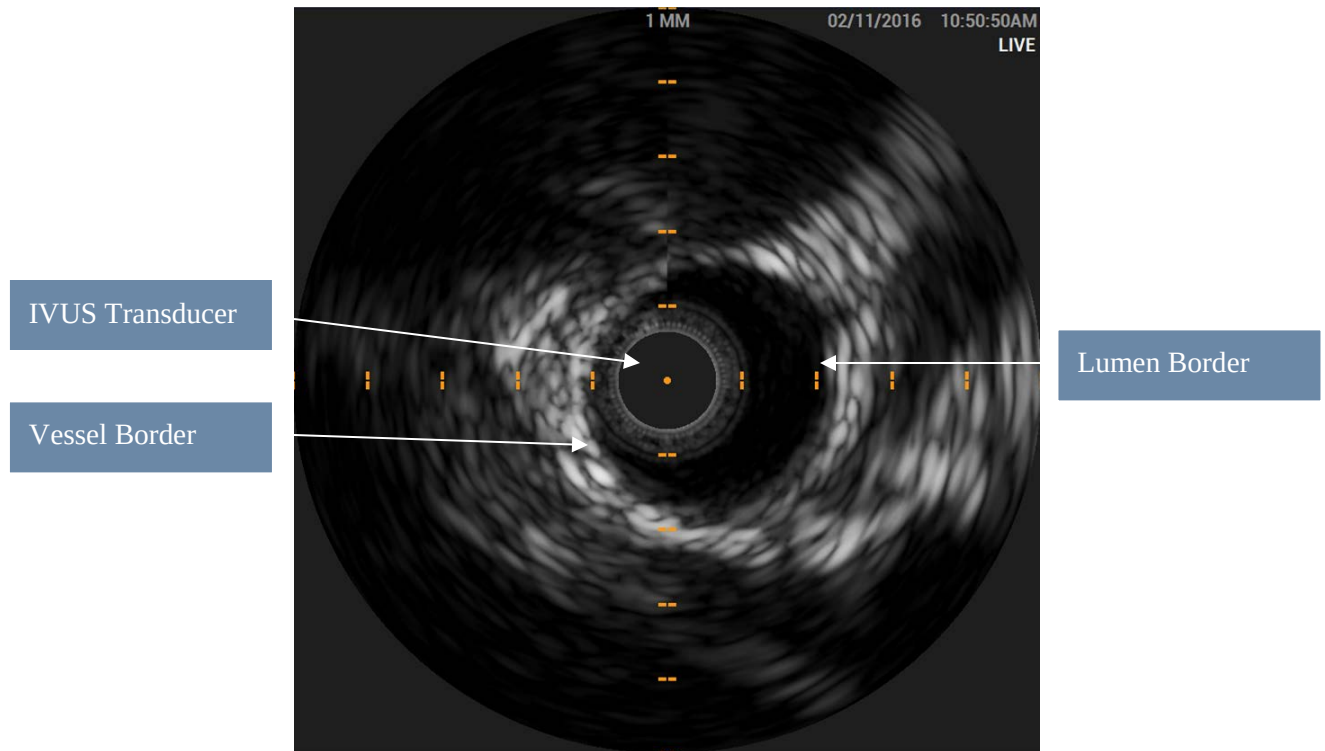


Figure 2: Grayscale IVUS image

Blood Flow

The ChromaFlo option uses patented technology to provide a visual depiction of blood flow through the vessel. This is accomplished by overlaying a two-dimensional color mapping of relative blood flow velocity onto the grayscale ultrasound image.

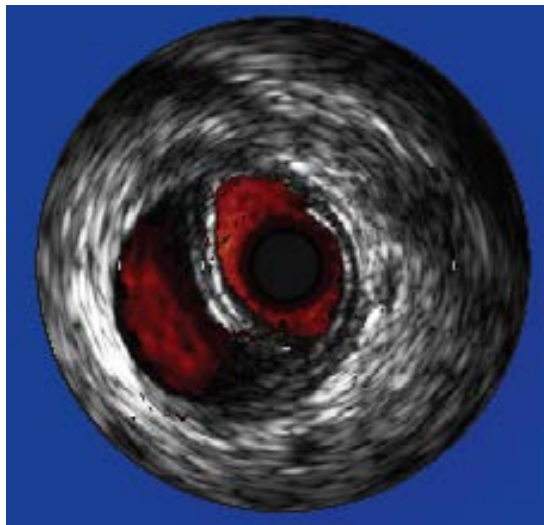


Figure 3: False Lumen, Right Iliac using ChromaFlo feature

Indications for Use

The IntraSight System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vasculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

The pressure feature is intended for use in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

Rotational 45MHz feature is intended for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vasculature as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and the wall structures. The Pullback feature of the PIMr withdraws the imaging core within the protective sheath for a maximum of 15 cm.

The FFR modality of the IntraSight system is indicated in all blood vessels, including coronary and peripheral arteries, to measure intravascular blood pressure during diagnostic angiography and/or interventional procedures.

The iFR Modality is intended to be used in conjunction with currently marketed Volcano pressure wires. In the coronary anatomy, the iFR modality has a diagnostic cut-point of 0.89 which represents an ischemic threshold and can reliably guide revascularization decisions during diagnostic catheterization procedure. When used for a pullback assessment, the iFR modality is intended as a visual aid in decision making by indicating the relative location and severity of the stenoses such as, multiple lesions or diffuse disease.

Clinical Applications

The system is used to evaluate vascular morphology.

Contraindications

Use of the Philips system is contraindicated wherever tissue or organ damage is a reasonable probability.

Possible Adverse Reactions

The use of the Philips Imaging Catheter—or any percutaneous intravascular catheter—could result in adverse reactions, including, but not limited to:

- Bleeding at the entry puncture site
- Injury to vascular wall
- Thrombosis of the vessel
- Peripheral embolization

Overview

NOTE: See the label provided with the imaging catheter for specific indications, contraindications, and possible adverse reactions.

Chapter 2. System Description

This chapter describes the main components of the Philips system and available options.

System Overview

The Philips system consists of the following main components. Each component is described in more detail in the following sections. The arrangement can be customized to suit the needs of the lab.

- Monitors: Main Monitor located in control room, with monitor boom; Bedside Controller located at patient table (see Monitors chapter)
- Central Processing Unit (CPU) or workstation: located in the control room
- Patient Interface Module (PIM): catheter connection point at the patient table
- Printer: high quality photo printer, located in the control room
- Connection Box: located in exam room

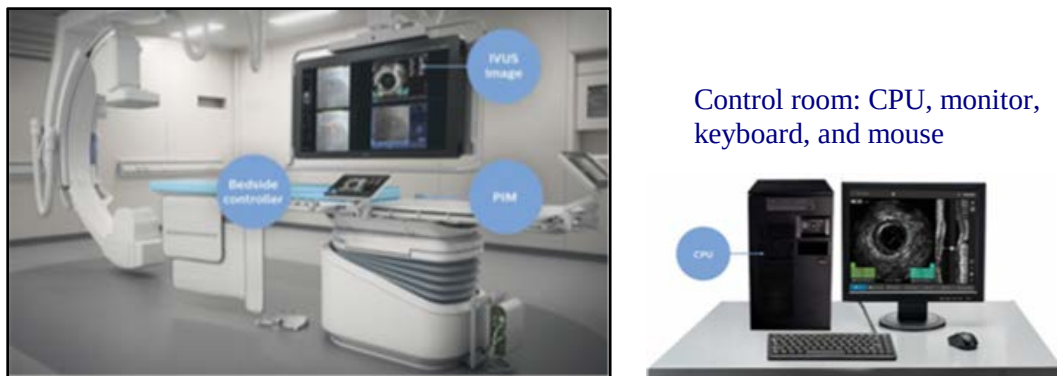


Figure 4: Typical Philips System Configuration

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.

Monitor(s)

Available options for monitors include:

- non-medical grade Main Monitor for use outside the patient environment (control room)
- medical grade monitor for use within the patient environment (examination room), Main Monitor boom and/or Bedside Controller (see Monitors chapter)

The Philips system utilizes the SXGA (1280 x 1024 @ 60Hz) computer video standard to insure maximum compatibility with the majority of catheter laboratory monitors. Philips provides both medical and non-medical-grade monitors for use with the Philips system.

System Description

The non-medical grade monitor is required to be connected to the isolation transformer and is restricted to use outside the patient environment (beyond 1.5 meters of the patient table). Medical grade monitors are not required to be connected to the isolation transformer and is allowed to be used within the patient environment. The monitor's settings can be optimized for viewing via the menu buttons located on the monitor front panel. The medical grade monitors include factory calibrated gray scale settings compliant to the DICOM 3.14 standard.

When it is not practical to interface the Philips system video to the existing boom mounted monitors in the exam room, Philips provides a small format medical grade monitor or bedside controller for installation directly onto the patient table. The bedside controller is mounted to an articulating arm. The arm provides the flexibility to position the monitor for optimal viewing angle or into a convenient storage position.

For monitor control information, consult the monitor user manual.



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 60601-1-1 Edition 3 2005 for further information.

CAUTION: Improper adjustment of the monitor may result in image problems.

Workstation (Central Processing Unit)

The workstation or CPU (central processing unit) contains the main system electronics as well as the inputs and outputs for all the peripheral devices.

NOTE 1: The isolation transformer should remain on and plugged into an AC wall outlet when it is not in use.

NOTE 2: The workstation model number and electrical ratings are labeled on the inside door panel of the workstation. The workstation model numbers are listed as applicable throughout the manual.

System Inputs and Outputs

Workstation Connections – System Model 797403

***NOTE:** Philips Field Service personnel install the system, workstation console with the ATX power supply and 48V power switch settings ON. Switches should remain ON.

System Description

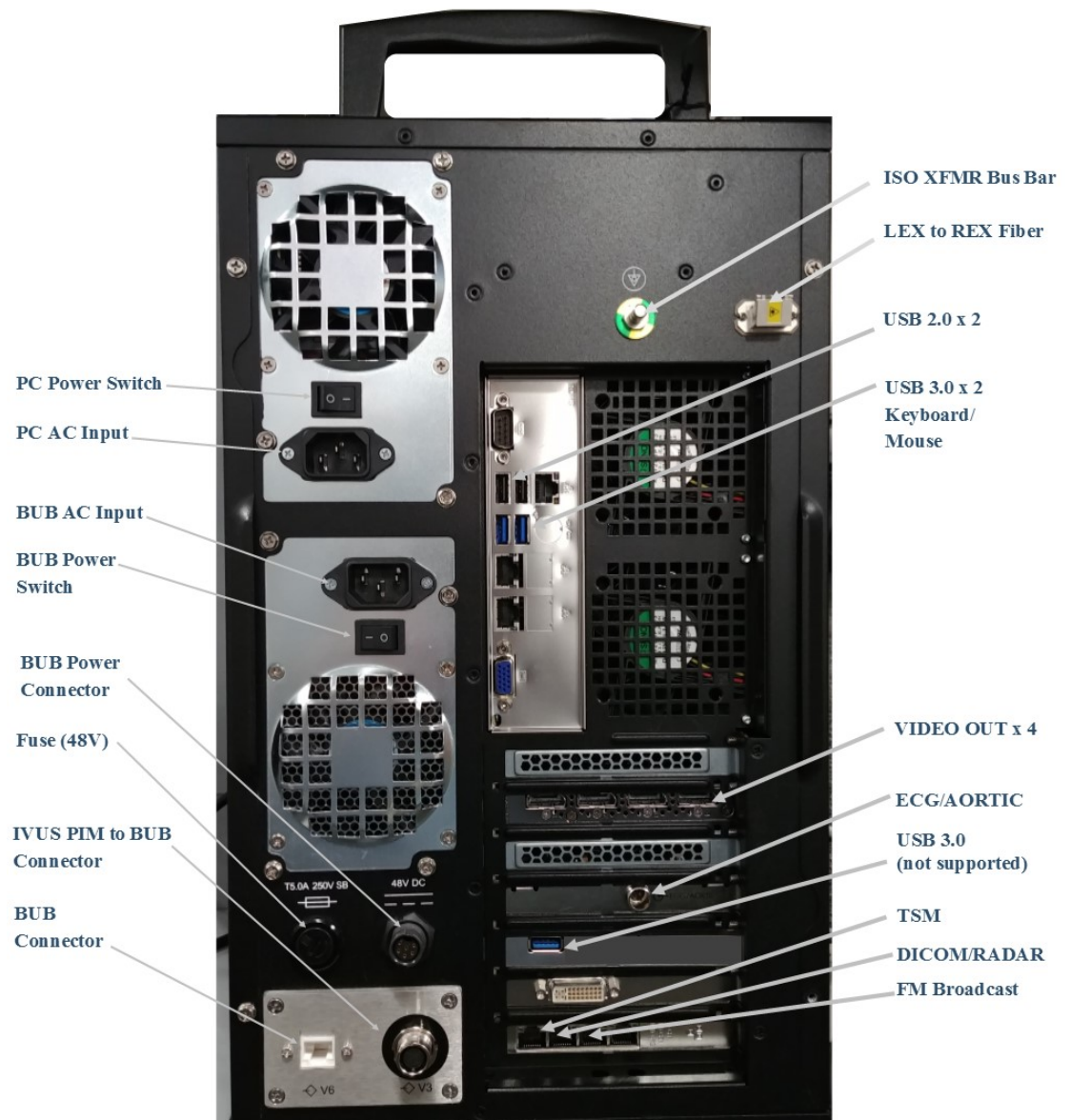


Figure 5: Philips System, Workstation (797403), Rear View

- **PC Power Switch:** Power switch for 12VDC PC
- **PC AC Input:** Power supply for 12VDC PC
- **BUB AC Input:** Power for 48V bedside utility box (BUB)
- **BUB Power Switch:** Power switch for 48V BUB
- **BUB Power Connector:** Supports BUB cable connection
- **Fuse:** For 48V BUB
- **IVUS PIM to BUB Connector:** Supports PIM to BUB cable connection
- **BUB connection:** Reserved for future system feature
- **ISO XFMR Bus Bar:** Support isolation transformer connection
- **USB Ports:** Supports USB devices located in exam room connected to the Remote USB Extender; other USB connectors can be used for local peripheral devices such as the Philips Panel or USB printer

- **DICOM/RADAR:** Supports image data archiving for image sharing on a common computer network, RADAR, and CWIS
- **FM Broadcast:** Supports FM communication to integrated Philips labs with FM data output
- **Fiber optic MPO connector (LEX to REX):** fiber optic cable supports USB devices (such as FM-PM connection to BUB) located in exam room connected to the Remote USB Extender
- **Video Out:** Supports 4 video port connections

****NOTE:** Graphics card controller prioritizes monitor displays depending on specific connection to ports. For example, from left to right, ports 1 through 4 are prioritized as the following :

Port 1	Port 2	Port 3	Port 4
3	4	1	2

Port 3 is for primary monitor, Port 4, secondary monitor, and so on. Failure to follow this port connection sequence may introduce odd display behavior.

- **Aortic Input:** Pressure input from hemodynamic system. Required for FFR measurements
- **ECG Input:** ECG input from hemodynamic system option
- **TSM:** Supports bedside controller connection



WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1:2006/A1:2013 Edition 3.1 for medical equipment). Furthermore all configurations shall comply with the system standard IEC 60601-1, Clause 16. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of IEC 60601-1-1:2000. 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.

Printer

A color printer is available as an option for the system. The printer provides high quality color printouts for patients' records. Replacement ink cartridges can be ordered through Philips or most major office supply stores.

Isolation Transformer

The Isolation Transformer is the main power distribution for the system and accessories. The main system power switch is located on the front panel of the transformer and may be used to turn the entire system On or Off. The transformer is used to reduce noise, suppress electrical spikes, and help prevent leakage currents that can occur between modality/power line connections in the Workstation Console System and Connection Box, plug specified peripheral device (modality) lines into the Isolation Transformer.

System Description

Isolation Transformers contain primary and secondary windings that are physically separated from each other. The separated windings provide medical grade, console insulation for each line to meet IEC60601-1 electrical safety leakage current requirements. System ground is passed through this device at the potential equalization connector. For electrical safety, this ground must be made equivalent to the patient table in the exam room per IEC60601-1.

Isolation Transformer must be medical grade, Subclause 7.9.2.7.

NOTE: The system model number and electrical ratings are located on top of transformer.

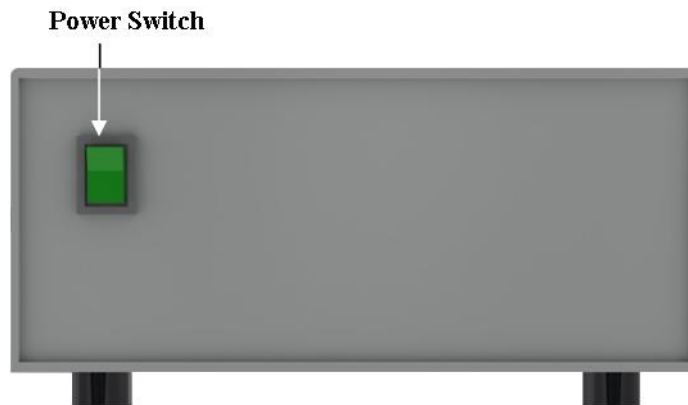


Figure 6: Isolation Transformer, Front View

Connection Box

The Connection Box or Bedside Utility Box (BUB) is designed to provide a flexible intermediary connection platform for Philips's integrated multi-modality system. It offers a manageable interface panel for connecting bedside peripherals and patient interface modules. There are flexible mounting schemes to allow adapting the installation to various environments and needs.

Use caution when unplugging a cable from the connection box. See connector types in the table below. Do not unplug by pulling on the cable. For any unused connectors, please make sure that the provided cap covers are on the connectors.

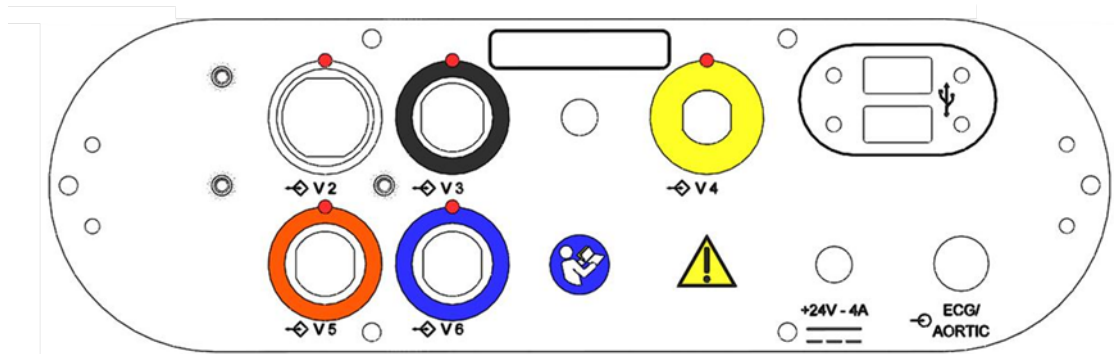
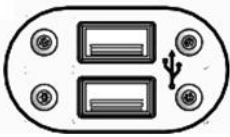


Figure 7: Connection Box (connectors on front connector panel)

System Description

Connection Box Connectors	Function	Connect Type
	Not used	
	IVUS SA PIM and SpinVision (PIMr)	Twist lock
	INTRASIGHT FM	Push/Pull
	Power ON LED(not a connector)	(Not applicable)
	Dual USB (Bedside Monitors)	Push/Pull
	24 V DC Power Supply (Bedside Controller and/or LoMap power)*	Screw lock
	ECG/Aortic input connection	Twist lock
	Connector may be used to accommodate future system upgrades	Push/Pull

***NOTE:** If connecting both Bedside Controller and LoMap cables, using same connection in Connection Box, use 'Y' cable.

Patient Interface Module

The imaging catheter connects to the patient interface module (also referred to as the PIM), which excites the catheter's transducer elements to transmit ultrasonic energy to the surrounding tissue. The PIM, shown below amplifies and processes the resultant echo signals from the transducer, sending them to the console through its connection on the rear panel of the console. Additionally, the PIM provides patient electrical isolation.



Figure 8: Patient Interface Module



WARNING: The PIM's cable may be damaged if equipment is rolled on it. Do not pull on the cable, place it where there is any traffic, or use extensive force; the strain relief ends may be damaged. Do not use the system if the outer case or wires appear damaged.

Catheters

IVUS imaging catheters are sold separately. Please contact Philips for more information. The Philips system is compatible with the following Philips IVUS catheters:

- Eagle Eye *Gold*
- Eagle Eye *Platinum*
- Pioneer Plus
- Rotational 45MHz
 - Refinity
 - Revolution
- Visions PV .014P
- Visions PV .018
- Visions PV .035

Available Options

Available options for the Philips System include:

System Description

- **Rotational IVUS:** Includes the rotational patient interface module and pullback device SpinVision (PIMr) used to drive both Refinity and Revolution 45MHz rotational catheters
- **iFR/FFR:** Includes patient interface module specific for Philips's pressure wires
- **Philips System-vid:** Scan converter offering composite and svideo outputs in PAL or NTSC
- **Video Switch:** Provides functionality to alternate video input sources to a single monitor
- **Two or Four Channel Video Amplifier:** Provides a source for alternate monitor displays

Please contact the local Philips representative for more information on these options.

Chapter 3. Monitors

NOTE: The IntraSight system includes Main Monitor and Bedside Controller. The Bedside Controller uses touch screen technology that makes it convenient for the doctor, technician, or operator at the patient table to conveniently select menu options, vessel images, make measurements, save, archive, and retrieve image frames and video loops.

Entering patient information, selecting menu options/functions, displaying images, and creating measurements, and saving views can be performed several ways. To perform tasks, you may use:

- Keyboard/mouse (Main Monitor)
- Touch Screen (Bedside Controller)

NOTE 1: Generally actions to be performed will be prefaced with ‘select’ tool, view, measurement, etc.

NOTE 2: Patient information is entered from the Main Monitor only, not Touch Screen.

The Main Monitor and Bedside Controller, are included with the IntraSight system. The larger Main Monitor is located on the monitor boom, inside control room.

The smaller Bedside Controller (touchscreen) is located in operating room, attached to the bedside rail of patient table, for the convenience of doctor and/or technician.

Both monitor screens are synchronized, mimicking the other, that is, they display matching screen states in real time. Screen display options and functions can be selected by touching the Bedside Controller screen in examination room (or using keyboard and/or mouse for the Main Monitor in control room).

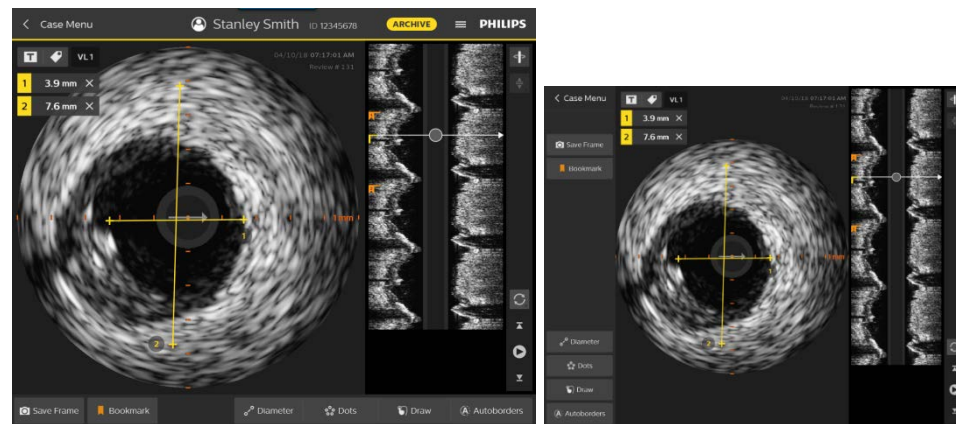


Figure 9: Main Monitor /Bedside Controller Screens, Respectively

However, the smaller Bedside Controller is limited to quantity of information presented on the screen due to smaller screen.

For example, the Main Monitor screen’s information header including Patient Name/ID, System Setting drop down menu, and Philips logo are not displayed on the Bedside Controller screen.

Additionally, the Main Monitor screen displays menu ribbon horizontally; the Bedside Controller screen displays menu ribbon vertically.

Monitors

All screen displays, showing IntraSight features/functions, in this manual will be taken from the Main Monitor.

Action verbs used in describing following workflows will include a generic word such as “select” (for example, select option, tool, view, menu, etc.), which will cover use of either touch-screen or keyboard/mouse in performing procedures.

NOTE: For more information regarding the Bedside Controller, please refer to the Philips TSM (Touch Screen Module) User Manual.

Chapter 4. System Setup

Overview

The system can be customized to suit the workflow of a practice. Please work with the local Philips representative to establish the desired settings. Once set, these settings are maintained for each use. Change settings at any time by following the instructions in this chapter.

Installation

The Philips system should only be installed by a qualified Philips representative.

To obtain any operational training information contact a local Philips Representative at one of the following regions:

USA and Canada

Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670
United States of America
Phone: 800-228-4728 (USA and Canada)
Phone: 916-861-0230
Fax: 916-861-0266

Europe

Volcano Europe BVBA/SPRL
Excelsiorlaan 41
B-1930 Zaventem
Belgium
Phone: 32.2.679.1076
Fax: 32.2.679.1079

Japan

Philips Japan, Ltd.
Philips Building, 13-37
Kohnan 2-chome,
Minato-ku, Tokyo 108-
8507 Japan
Phone: 81-3-5767-7430
Fax: 81-3-6414-8701

System/Service Settings

NOTE 1: Before logging into the system, Philips Field Service enters system in “Service” mode (not displayed) and assigns system administrator temporary username/password. The system administrator is required to change his/her username/password at next login session. To add new users to the system, the system administrator assigns usernames/passwords in System/Service Settings, User Account Management.

NOTE 2: Login passwords must be alphanumeric and a maximum of 8 characters long.

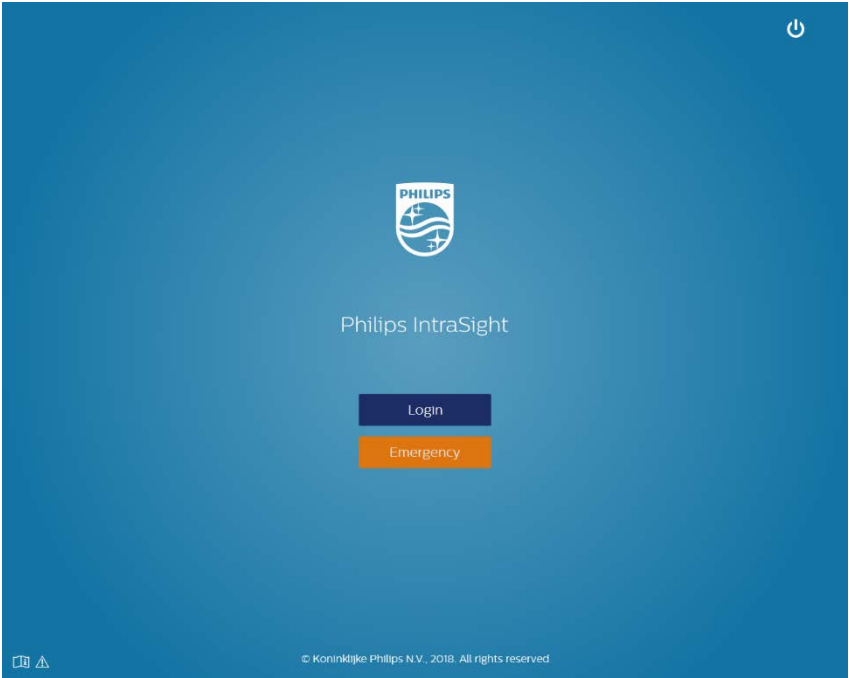


Figure 10: Initial Login

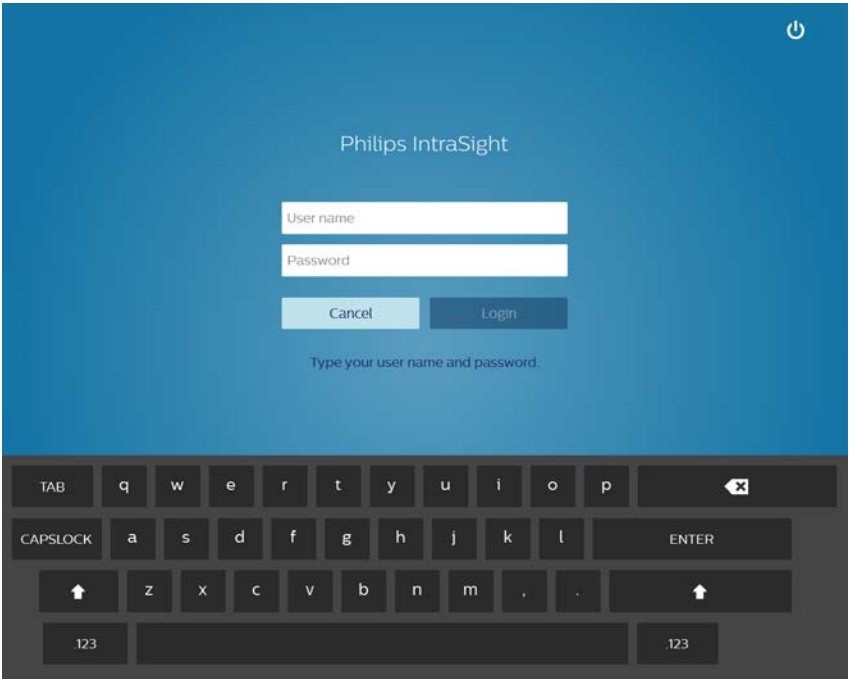


Figure 11: Administrator Login

System Setup

To display general system/service settings, the system administrator selects the three horizontal line grouping icon, located on upper right hand corner (next to Shutdown button icon) of the Philips Welcome screen.

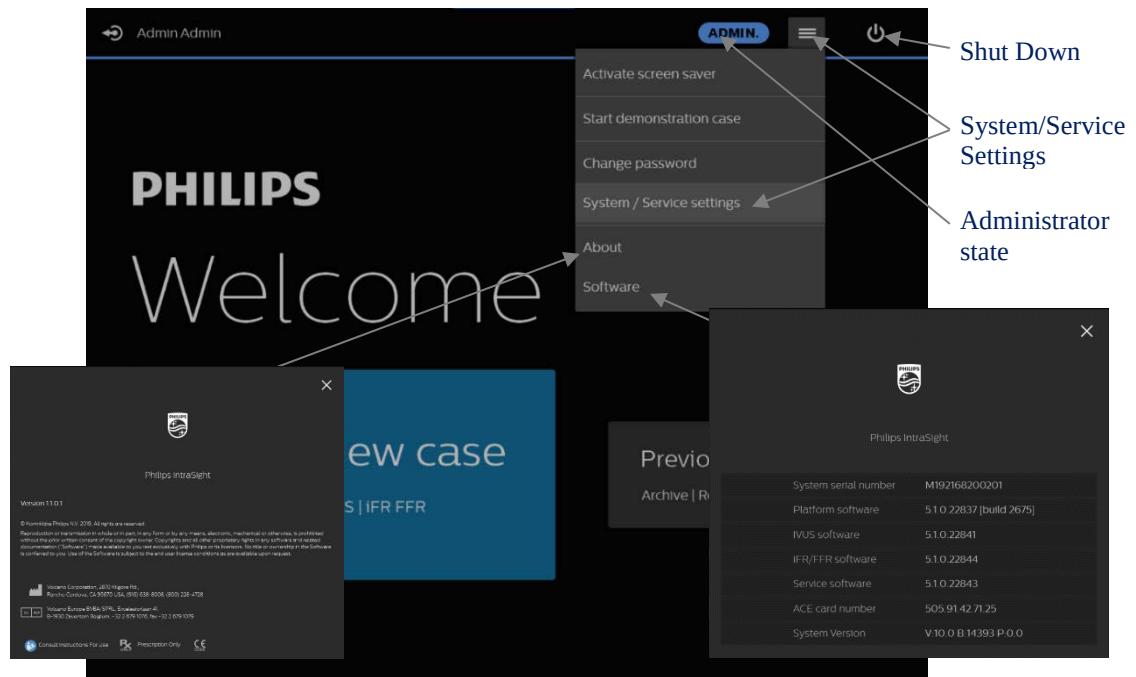


Figure 12: Administrator – System/Service Settings Option

From the drop down tab options, select System/Service Settings to display system/service setting screens.

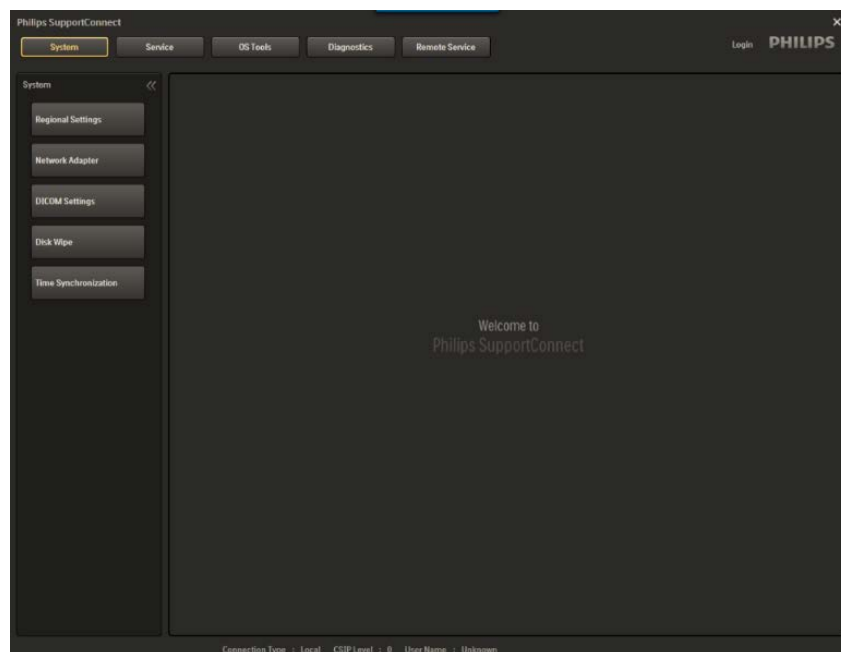


Figure 13: System/Service Settings

The System/Service Settings screen displays, containing the following tab/option descriptions.

System Setup

System

The System tab is used by the System Administrator only to configure basic system settings, regional settings, DICOM network settings, disk maintenance, and time synchronization.

NOTE: The Service tab is used by the Philips Field Service Representative only for user account management, licenses, security, Cath Lab ID, RADAR, IVUS, iFR/FFR, and X-ray admittance settings, which will be discussed after System section.

Regional Settings

Set desired language for vessel image displays, time format (12/24 hour), date format (mm/dd/yyyy), and number format (nnn,nnn.dd).

- To choose a local language for the system, select Language drop down box.
- To set time format, 12 or 24 hour, select a radio button in Time format.
- To set date format, select Date format drop down box.
- To set a number format, select Number format drop down box.

Settings are saved automatically. Select 'X' tab to close dialog box.

NOTE 1: After saving settings, restart system to activate settings.

NOTE 2: Data entered in following fields of System settings are examples only.

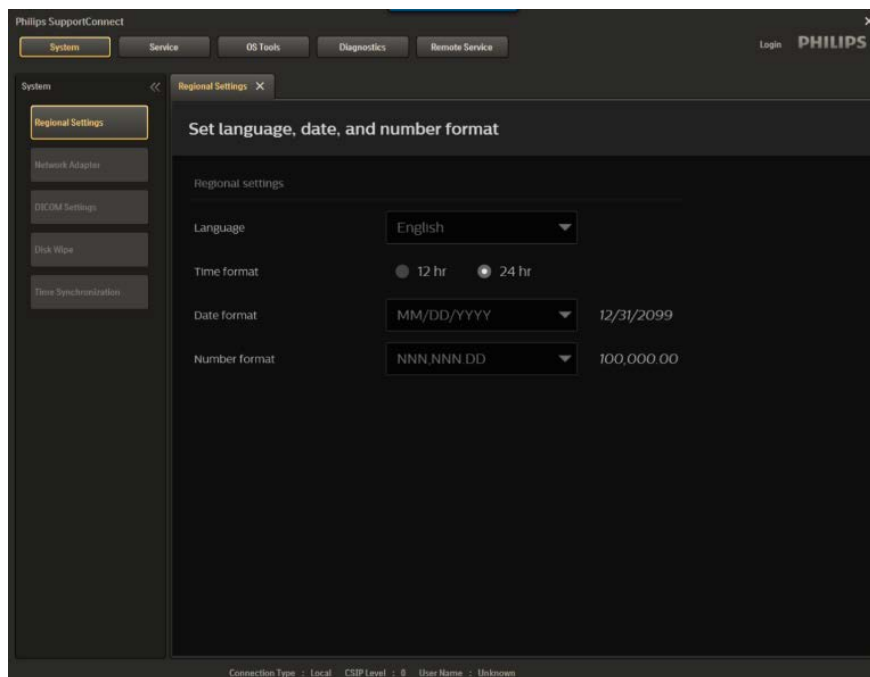


Figure 14: Regional Settings

Network Adapter

Configure IP address assignment as either manual or automatic (DHCP), depending on the configuration of the associated network. Enable or disable the DNS IP address assignment according to the associated network configuration. Please contact the

network administrator or IT department for details on configuring DHCP and DNS details for the network to which the system is connected.

- Use the 'Obtain an IP address' slider to enable or disable DHCP (automatic assignment of IP address vs. manual IP address assignment). The slider turns green indicating DHCP is being enabled (automatic assignment), and gray indicating disabled (manual assignment).
- IP address, Subnet mask, and Default gateway fields will populate automatically when DHCP is enabled. The fields can be filled manually when DHCP is disabled.
- Use the 'Get DNS server IP address from DHCP server' slider to enable or disable DNS (Dynamic Name Server IP address resolution). The slider turns green indicating DNS is being enabled (automatic assignment), and gray indicating disabled (manual assignment)..
- The preferred and/or alternate DNS server IP address assignment is done automatically if the DNS assignment slide is set to enabled. DNS server IP addresses may be entered manually if the DNS assignment slider is set to disabled. Please contact the network administrator or IT department for details on configuring DHCP and DNS details for the network to which the system is connected.

Select Save to save local network settings. Selecting the Save button is required to save these settings.

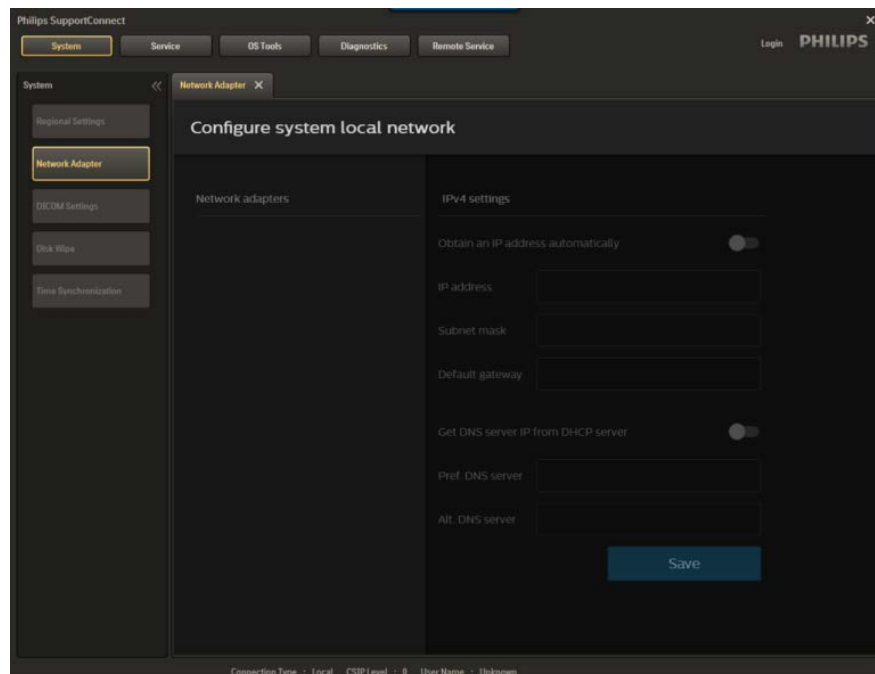


Figure 15: Network Adapter

System Setup

DICOM Settings

CAUTION: Launch DICOM viewer by accessing Show_Studies.exe from root location of DICOM DVD. Do not launch viewer using the Viewer.exe file from viewer folder.

NOTE: The specific medical institution's local IT department and system operator is responsible for configuring site DICOM/network.

Local System

1. View local system IPv4 address, enter application entity (AE) title, and network timeout.
2. The IPv4 address is filled in automatically. Enter an AE title per network administrator or IT directions. The Network timeout is prefilled with a 15 second value, as a recommended value. Please contact your network administrator or IT department for optimal values for the network attached to the system.
3. Select Save to save local network settings. Selecting the Save button is required to save these settings.

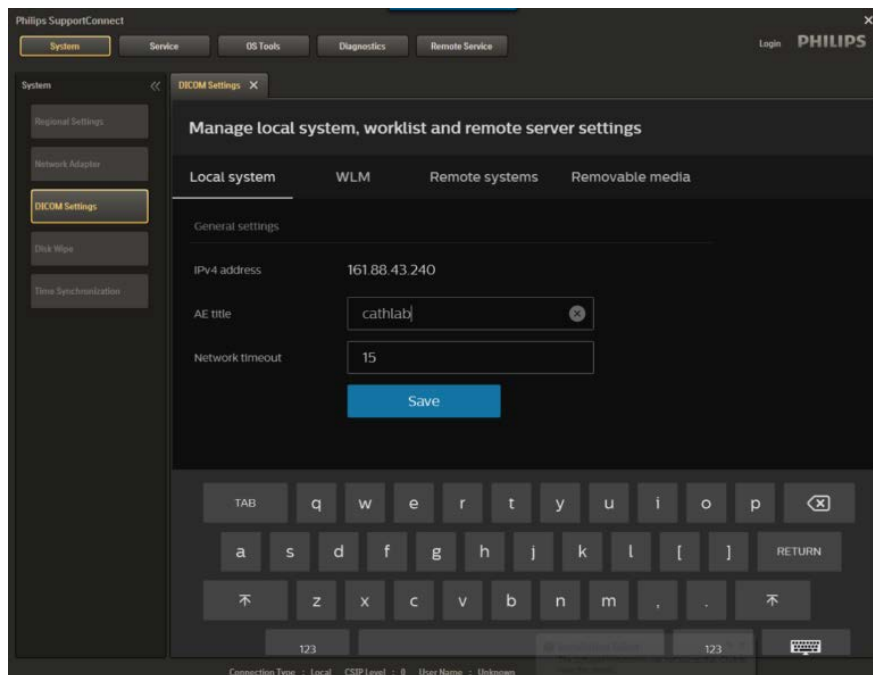


Figure 16: DICOM Local System

WLM

Use the Worklist slider, located above title bar to enable or disable the worklist server functionality. The slider turns green indicating enabled and gray indicating disabled.

If the Worklist is enabled, complete the following fields, using network administrator or IT recommendations for network associated values:

- AE title
- Host name/IP address
- Port number
- Network timeout
- Default modality
- Auto query scheduled date
- Scheduled – this system only
- Max SPS results

To verify if the worklist server connection is working as expected, select the ‘Test Connection’ bar at bottom of screen. If connection is enabled, select Save. If connection is not established, confirm remote server settings, and re-test connection.

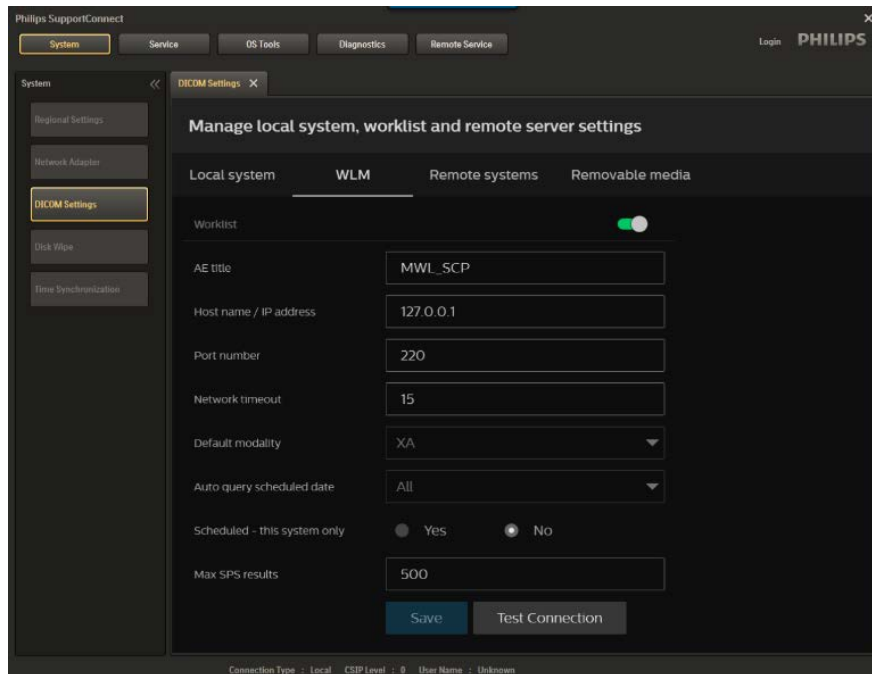


Figure 17: Worklist Manager

System Setup

Remote Systems

Configure remote systems.

- If no remote systems are configured, select the '+ Add' button to add a new DICOM archive server.
- All fields are required, though the Quality, US modality and Default systems have default values.
- Enter values in all fields depending on network administrator or IT department requirements.
- Set the Quality to the desired setting. The High quality setting allows no compression of data, provides the highest quality imaging, but takes up the most storage space.
- The Low quality setting uses the highest compression, takes up the least space, but reduces image quality. The Medium setting balances the need for quality and storage space, and uses a lower compression setting. The Medium setting is recommended.
- Use the US modality setting for compatibility with older PACS (DICOM archiving) servers that do not support the IVUS modality. The recommended setting is to use the IVUS modality (US modality deselected) setting. This is the default setting. Note that the US modality setting applies only to IVUS modality data, and not to iFR/FFR modality data.

Select save to save settings. Selecting the Save button is required to save these settings.

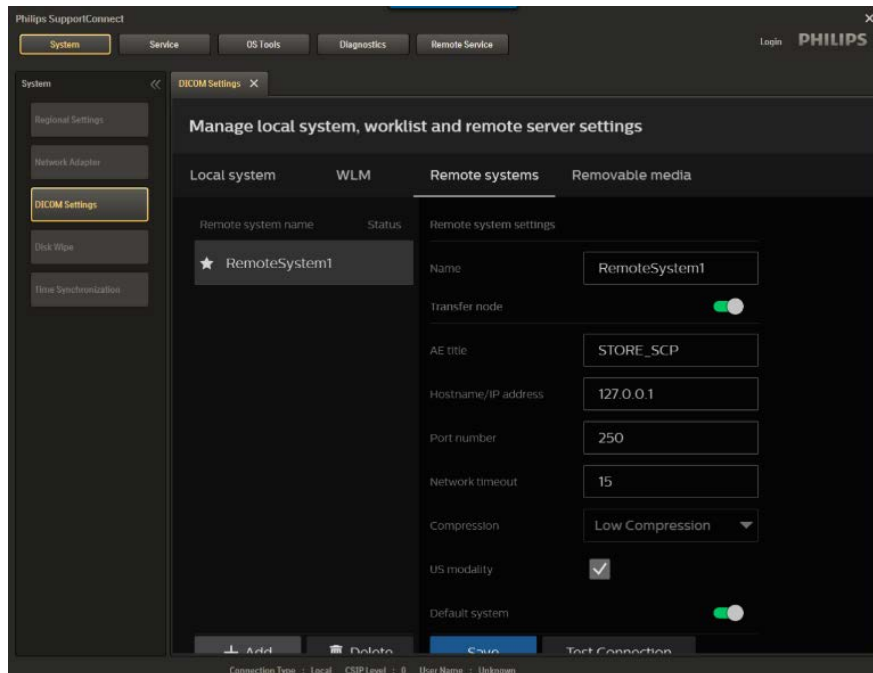


Figure 18: Remote Systems

Removable Media

The removable media settings, Archive settings, allows the following settings to be set for desired functionality of the system.

- **Media Write Speed:** The Faster setting is the default, allowing highest possible optical media drive speed setting. The Slower setting allows slower optical media drive speed setting to accommodate lesser quality media while minimizing optical drive write speed impact.
- **Verify DVD / Blu-ray:** This setting allows enabling or disabling or verification during optical media archiving. Verifying optical media is recommended to ensure data is recorded accurately to the optical media. Verification of the optical media does impact optical media archive time, but disabling it does not guarantee the content of the archived content when archiving to optical media.
- **Auto delete case:** This setting allows the automatic deletion of archived cases when the maximum case limit (40) has been reached. The default is disabled, which requires manual deletion of cases when reaching the maximum case limit.
- **Set the Quality to the desired setting.** The High (restorable) quality setting disallows compression of data, allows retrieval of a case from optical media, provides the highest quality imaging, but takes up the most storage space. The High quality setting uses the same settings as High (restorable) but does not allow retrieval of data from the optical media.
- The Low quality setting uses the highest compression, takes up the least space, but reduces image quality. The Medium setting balances the need for quality and storage space, and uses a lower compression setting. The Medium setting is recommended.
- Use the US modality setting for compatibility with older PACS (DICOM archiving) servers that do not support the IVUS modality. The recommended setting is to use the IVUS modality (US modality deselected) setting. This is the default setting. Note that the US modality setting applies only to IVUS modality data, and not to iFR/FFR modality data

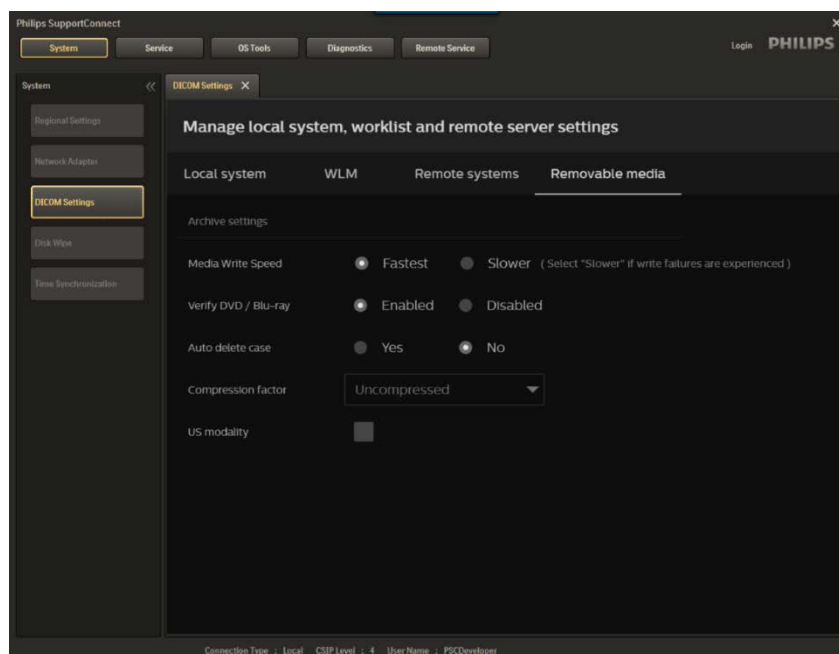


Figure 19: Removable Media

System Setup

Disk Wipe

Disk wipe permanently deletes all patient data, user configuration data, user configuration data, and disk logs, and cannot be undone. (Not accessible by administrative users.)

NOTE: If Disk Wipe operation returns an error and system is unusable (e.g., Ao Calibration screen is not accessible in FFR modality), Field Service needs to reinstall software.

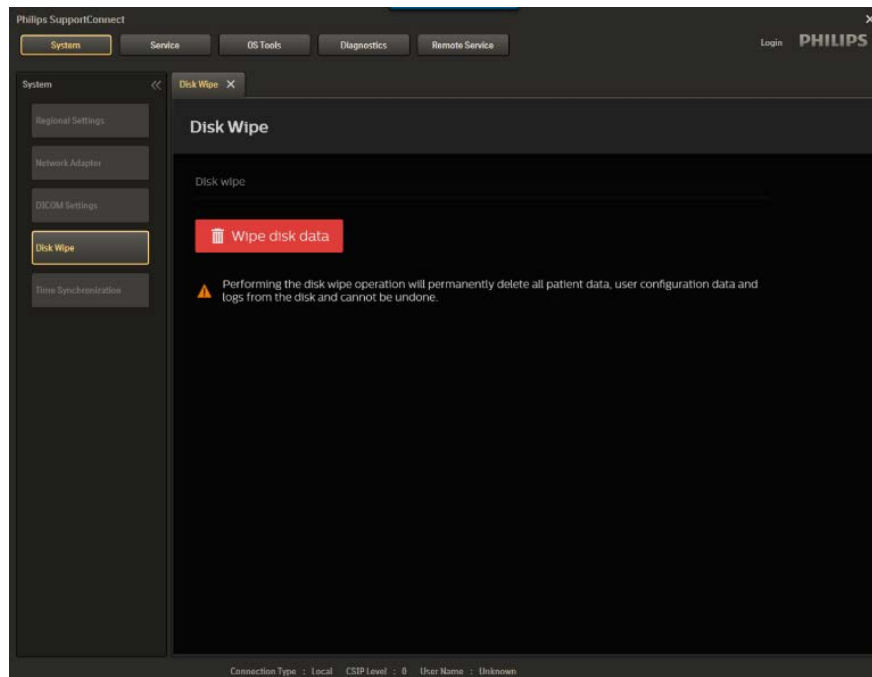


Figure 20: Disk Wipe

Time Synchronization

- Enable or disable the time server, if a time server is accessible on the network to which the system is attached. Please see the network administrator or IT department for time server availability on the available network. If unavailable, disable the Time server.
- Set the time zone for the area in which the system is located.
- If the Time server is set to disabled, set the local time and date for the system in the applicable fields (System time and System date).
- Select save to save settings. Selecting the Save button is required to save these settings.

The screenshot shows the Philips SupportConnect interface for Time Synchronization. The main window is titled "Set system time and date". It features a sidebar on the left with navigation options: Regional Settings, Network Adapter, DICOM Settings, Disk Wipe, and Time Synchronization (which is highlighted). The main content area has a "Time server" section with radio buttons for "Enabled" (selected) and "Disabled". Below this is a "Host name or IP address" field containing "19216801120" and a "Test" button. The "System time and date" section includes a "Timezone" dropdown menu set to "(UTC-08:00) Pacific Time (US & Canada)". Below the dropdown are fields for "System time" (06 : 28 AM) and "System date" (03 / 29 / 2018). A "Save" button is located at the bottom right of the form. At the very bottom of the window, a status bar displays "Connection Type : Local CSIP Level : 0 User Name : Unknown".

Figure 21: Time Synchronization

System Setup

Service

User account management, licenses, security, Cath Lab ID, RADAR, IVUS, iFR/FFR, and X-ray admittance settings can be managed from the Service tab and is for Philips Field Service Representative use only. However, system administrators can access User Account Management and Security tools only.

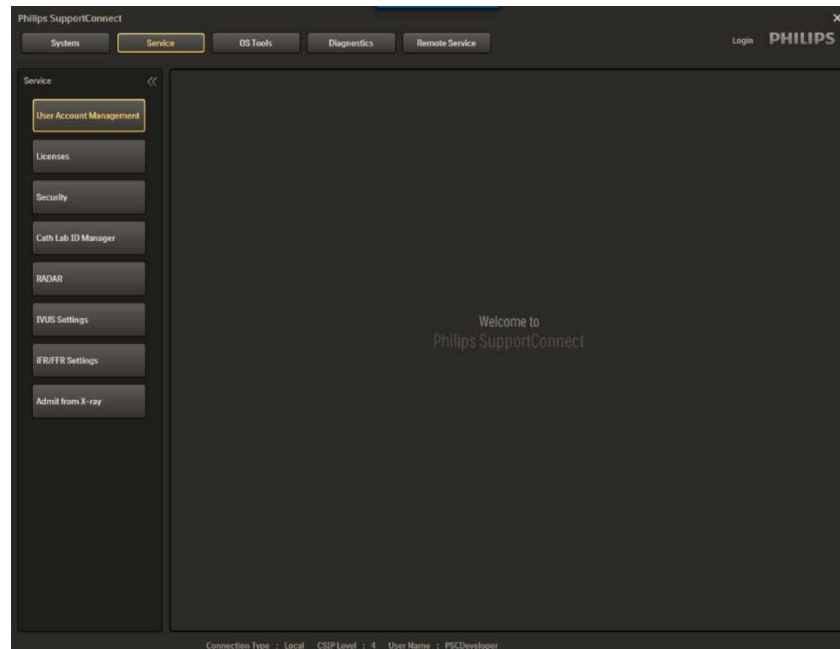


Figure 22: Service Settings

User Account Management

Add, edit, or delete user accounts and reset passwords from User Account Management tab.

1. To add a new user account, select '+New user account' bar.
2. Select Account – Enable/Disabled radio buttons to add/modify user details.
3. Select User group drop down box, to assign user groups, i.e., clinical, administrative, etc.
4. Enter Last/First name of user in respective fields.
5. Assign Username and Password (using quality password management) for each user.

6. Select 'X' tab to close dialog box.

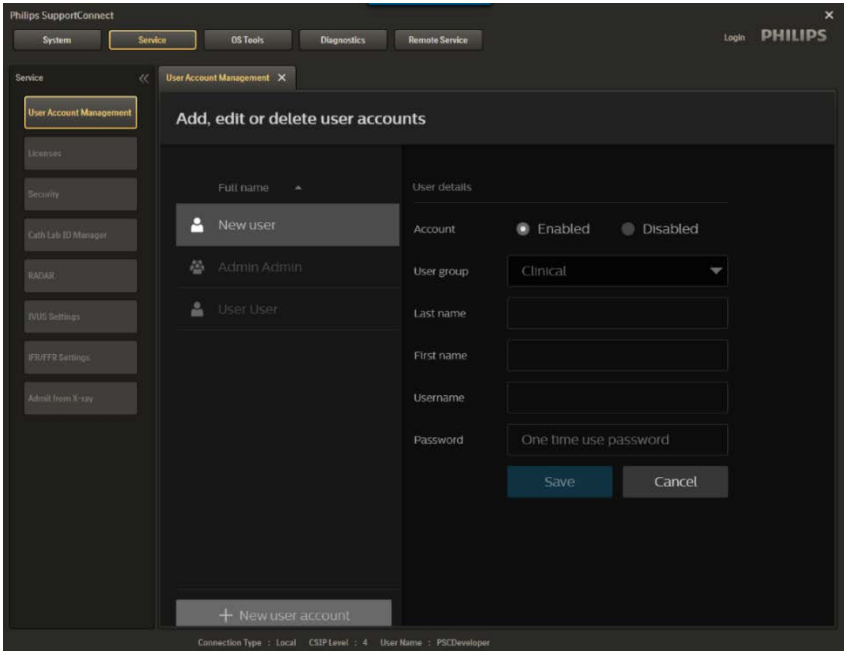


Figure 23: User Account Management

System Setup

Licenses

Manage system licenses by searching/opening listed license files. Select ‘X’ tab to close dialog box. (Not accessible by administrative users.)

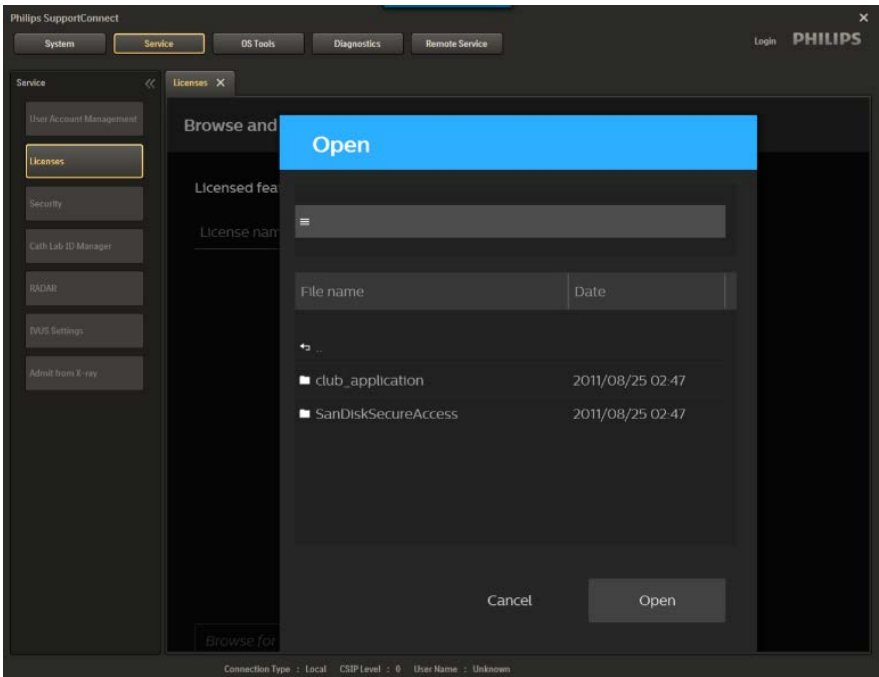


Figure 24: Licenses

Security

Access

Manage automatic/logout/screen blanking, emergency procedure access, timeout periods, and password unlock configuration.

1. To enable/disable automatic login, slide bar (enable is green state).
2. To enable/disable emergency access, slide bar.
3. To enable/disable automatic logout for a given timeout period, slide bar to green state and specify timeout period in minutes.
4. To enable/disable screen blanking, slide bar to green state and specify timeout period in minutes.
5. To require password to unlock screen blanking, select Yes radio button.
6. Select 'X' tab to close dialog box.

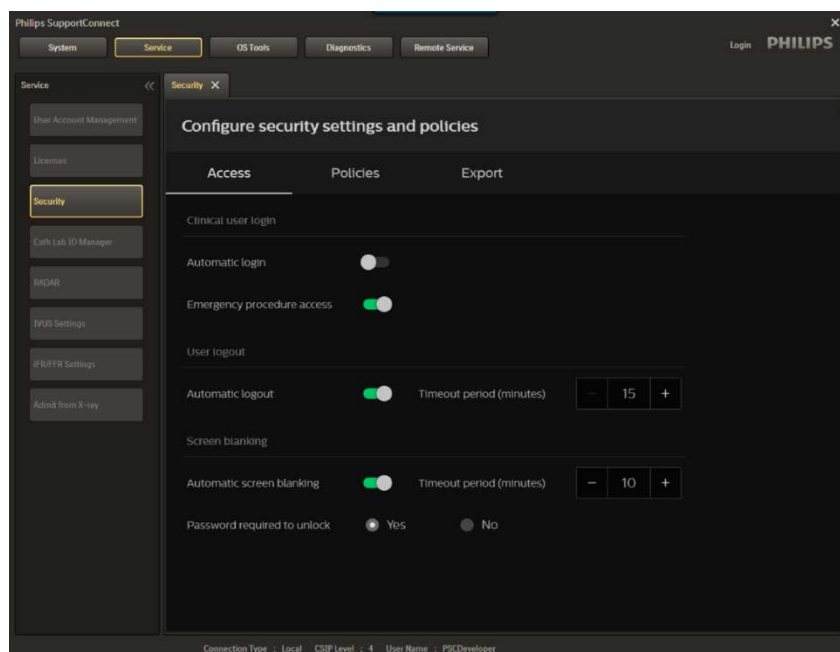


Figure 25: Security Access

System Setup

Policies

Configure security settings/policies, i.e., minimum password length/expiration; lockout policies, i.e., allowed login attempts, duration. Select ‘X’ tab to close dialog box.

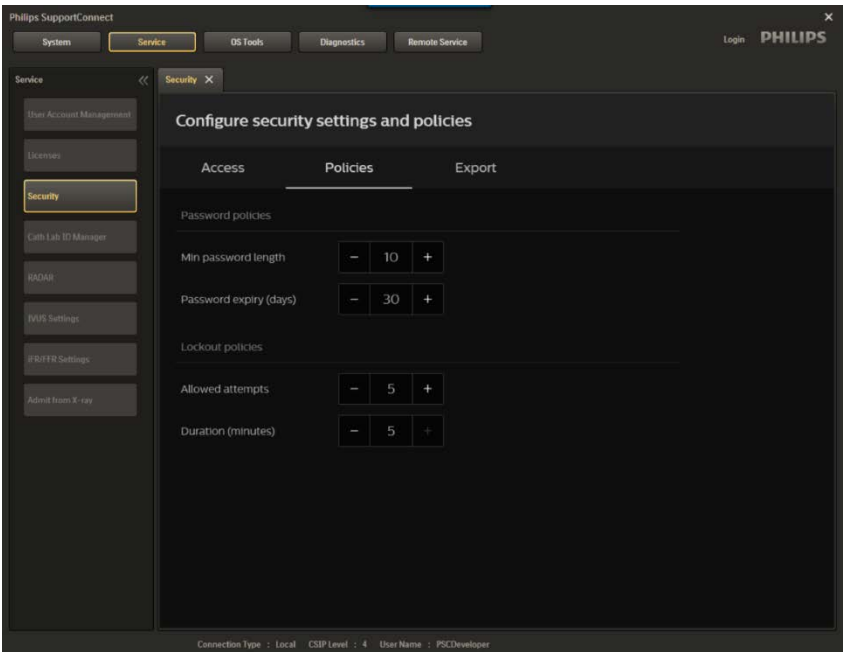


Figure 26: Security Policies

Export

Manage data export media options, setting Enabled/Disabled radio buttons RADAR, Optical and USB media. Select ‘X’ tab to close dialog box.

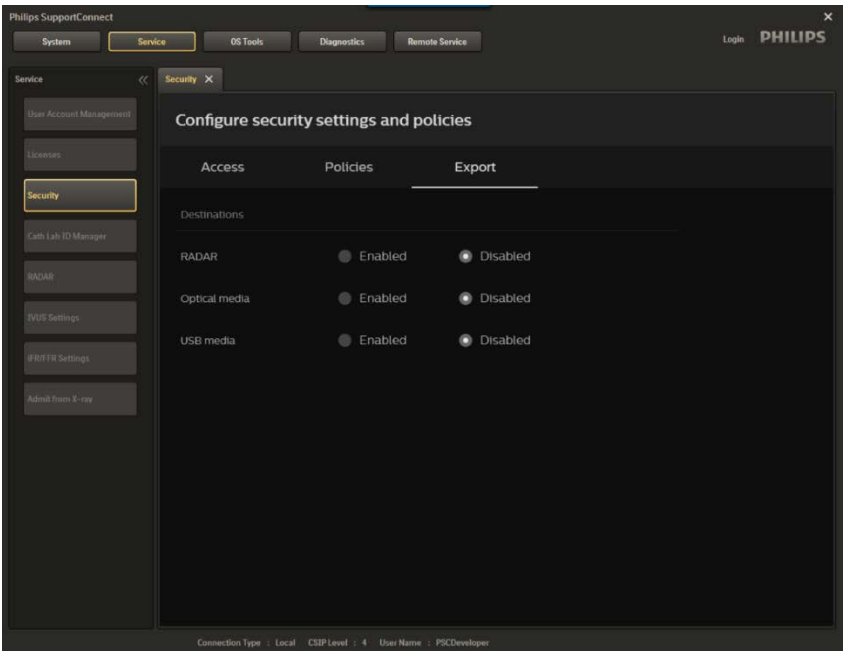


Figure 27: Security Export

Cath Lab ID Manager

Configure system modality availability (mobile/integrated) and manage Cath Lab IDs, i.e., add/delete Cath Lab IDs. (Not accessible by administrative users.)

Select '+ Cath Lab ID' option to add new Cath Lab name. Select checkmark in blue box to save. Select 'X' tab to close dialog box.

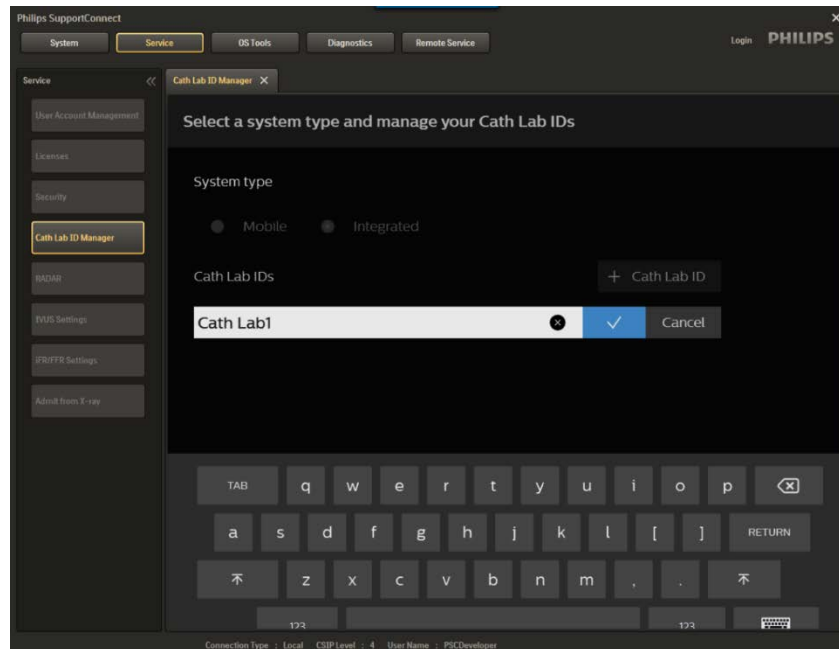


Figure 28: Cath Lab ID Manager

System Setup

RADAR

Manage periodic upload of process event logs including time interval and log upload.
(Not accessible by administrative users.)

NOTE: Initially, RADAR needs to be enabled in Service/Security export settings.

Select 'X' tab to close dialog box.

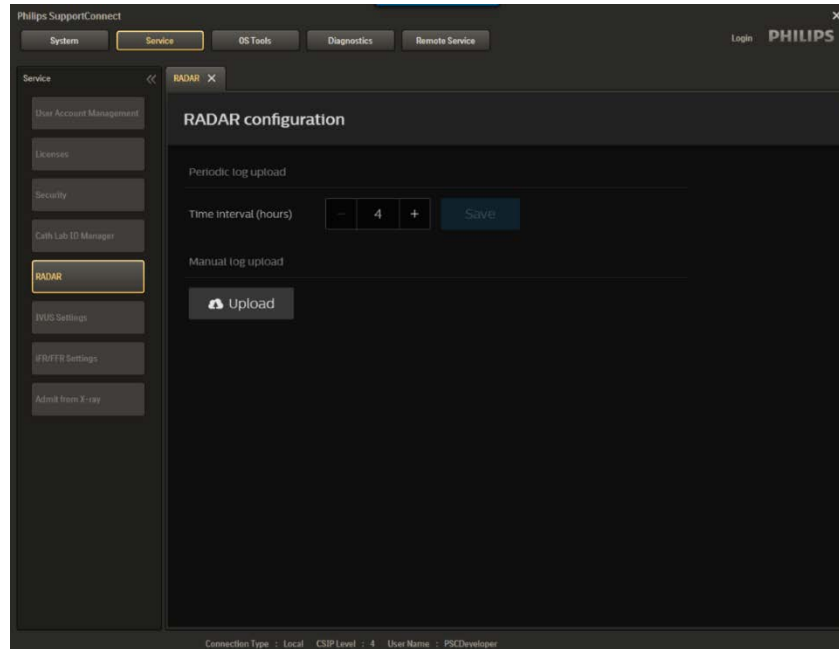


Figure 29: RADAR

IVUS Settings

Configure IVUS settings including PIM cable length. (Not accessible by administrative users.)

NOTE 1: Measurement selection should match actual PIM cable length, otherwise measurement will be incorrect.

NOTE 2: Envelope data is used by Philips personnel only.

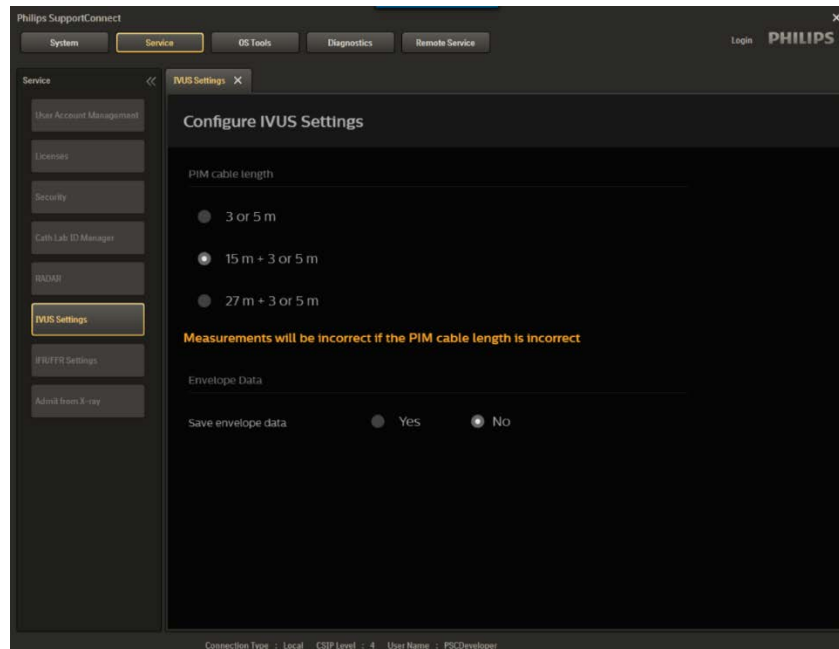


Figure 30: IVUS Settings

System Setup

Admit from X-ray

Configure admit from X-ray settings including enabling/disabling X-ray data admittance, turning IP security on/off, and selecting Cath Lab IP address/port number. (Not accessible by administrative users.)

1. To configure X-ray data admittance, select Enabled/Disabled radio buttons.
2. To enable IP security, slide IP security bar to green state.
3. To choose a configured Cath Lab, select Cath Lab names from 'Select a configured Cath Lab' drop down box.
4. Enter host name/IP address in 'Host name or IP address' field.
5. Enter port number in 'Port number' field.
6. Select 'X' tab to close dialog box.

NOTE: A valid host name or IP address is required for 'Admit from X-ray' to work.

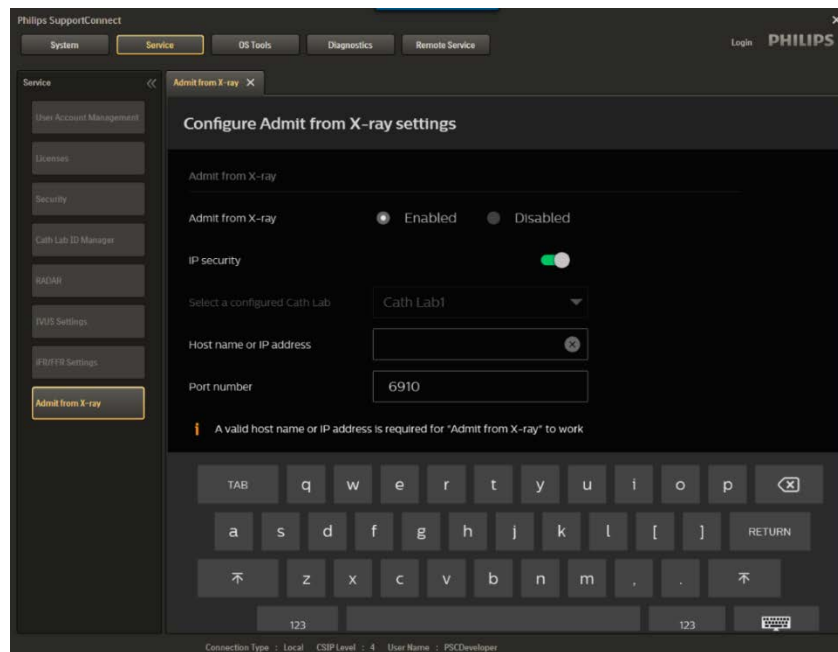


Figure 31: Admit from X-ray

OS Tools

Control operating system applications by accessing resident OS system Task Manager, Windows Explorer, and command prompt. (Not accessible by administrative users.)

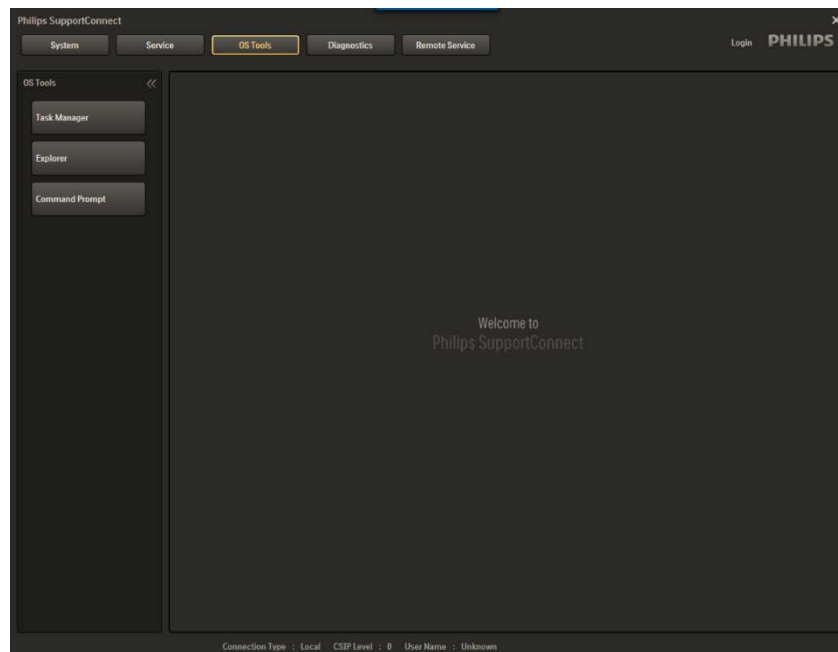


Figure 32: OS Tools

System Setup

Diagnostics

Troubleshoot system issues through Log Viewer. (Not accessible by administrative users.)

- Perform general Event search using Repository drop down box, setting specific time period for a Search, and entering search criteria in 'magnifying glass' field.
- Export log(s) to system folders using 'Export log...' option, located next to magnifying glass icon.
- Add bookmark icon (blue flag) to an Event ID, category, time stamp, description, etc. by selecting 'Bookmarks...' option, located next to 'Export log...'.
- Manage automatic presets by using the 'Presets' option, located next to 'Bookmarks...' option.
- Additionally, column headings are searchable by event ID, event category, and time stamp.
- Select 'X' tab to close dialog box.

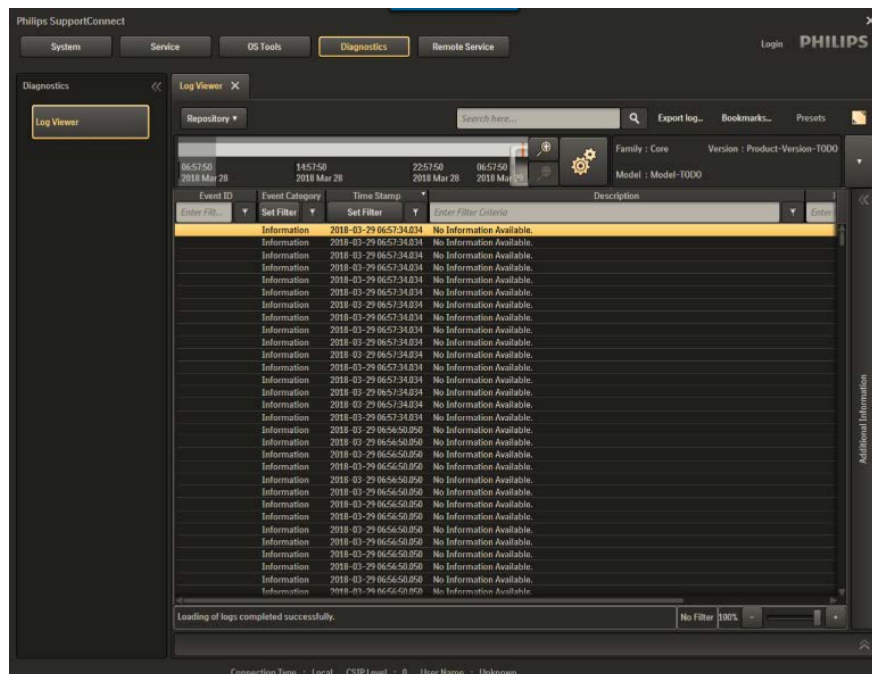


Figure 33: Diagnostics

Remote Service

Manage remote service access. (Not accessible by administrative users.)

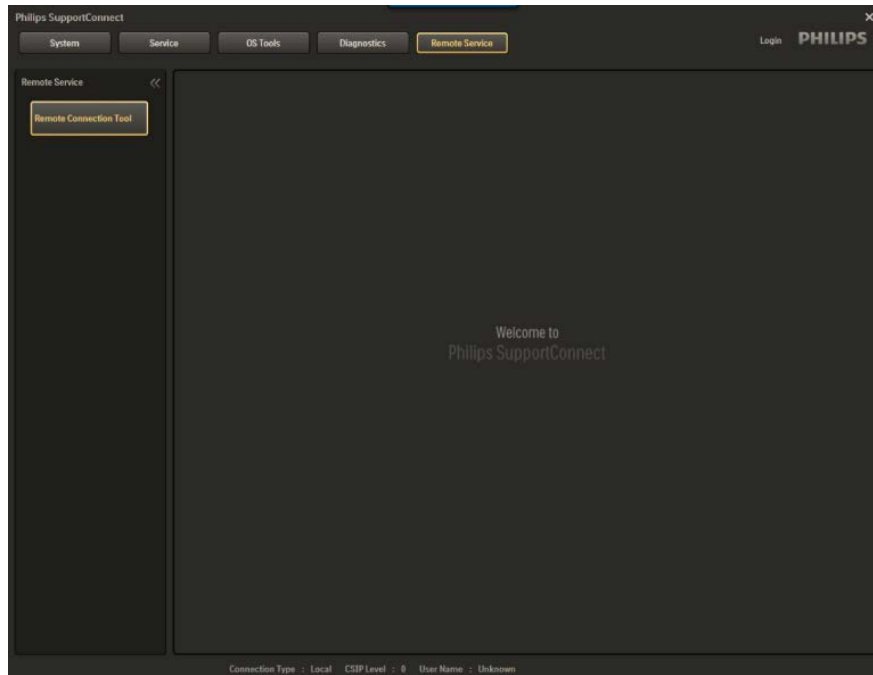


Figure 34: Remote Connection Tool

If the administrator forgets their password or an administrator is not available, contact:

Philips Technical Support:

US - Technical Support

1-800-228-4728, option 5

technicalsupport@Philipscorp.com

European Technical Support:

Phone: +32.2.679.1076

Philips Japan Technical Support:

Phone: +81-3-5767-7340

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Chapter 5. Selecting Modalities

Overview

This chapter describes how to switch between available modalities, IVUS and iFR/FFR. Select a modality from the Case Menu screen.

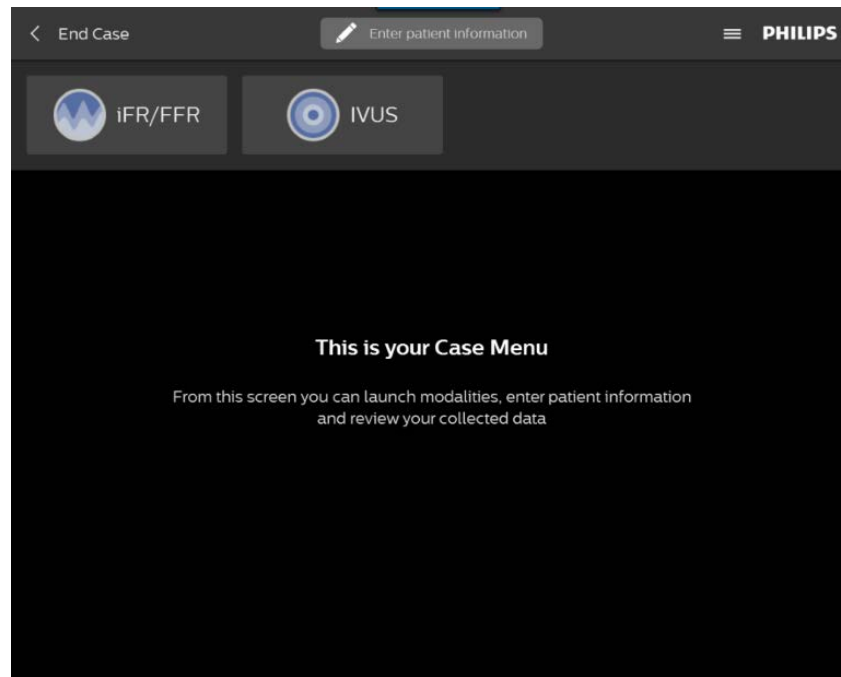


Figure 35: Case Menu

Selecting Modalities

Selecting Previous Cases displays a list of automatically archived cases, which can be retrieved for review.

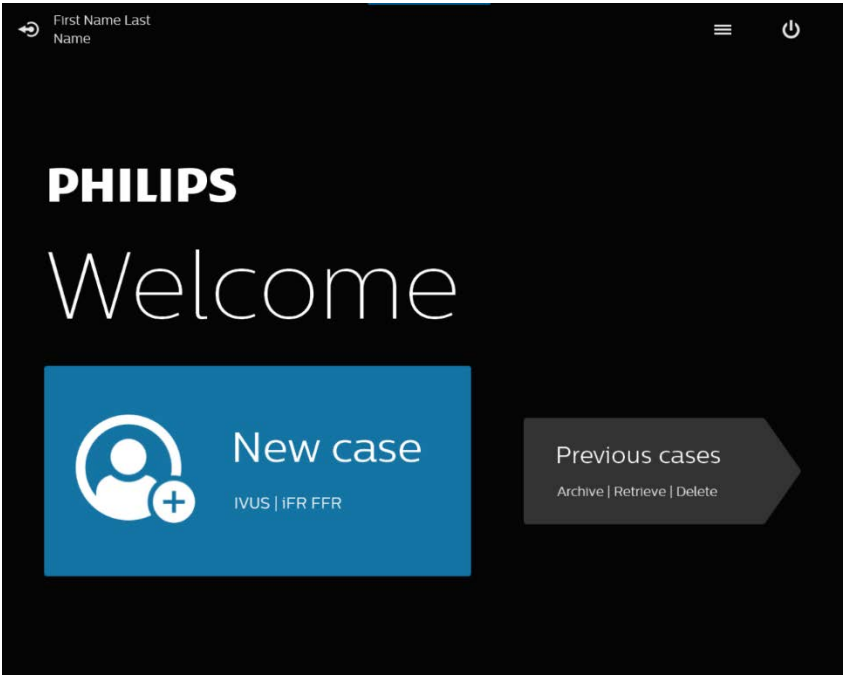


Figure 36: Selecting Previous Cases

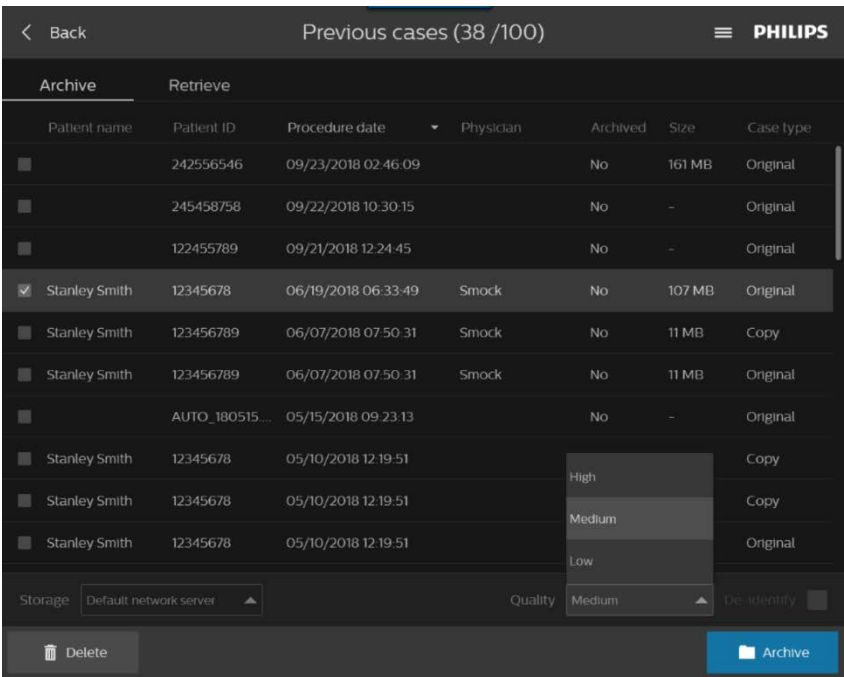


Figure 37: Archive/Retrieve Cases

Chapter 6. Preparing for a Case

This chapter describes the steps to prepare the system for use. This procedure should be followed prior to each case. Please refer to the previous chapter for system settings.

Overview

The following should be performed in preparation prior to each IVUS case:

- Turn system power on
- Ensure PIM is attached to PIM extension cable
- Prepare the catheter
- Connect catheter to PIM
- Enter patient information
- Have DVD-R ready

Ensure System Power is On

The system power for the Philips system should be turned on at the beginning of each day and turned off at the end. Turn the system on by using the power button located on the front of the workstation. The monitor displays several messages regarding initialization. If an error occurs during initialization, an information box provides detailed information about the problem to expedite service. Please contact Philips technical support if an error is encountered.



- **Equipotentiality:** This symbol on the system rear electrical panel identifies the connector where the hospital room's potential equalization system can be connected during intracardiac applications. This connector on the Isolation Transformer is connected by an 8AWG green and yellow striped wire to the bus bar in the X-Ray equipment cabinets that serves the potential equalization ground for the patient table in the exam room. (Equipotentiality cords are available from Philips Service: PN 804768001 singled ended, PN 804769001 double ended.)
- **Power cord:** Can be detached from the system by loosening the screw on the cord retainer and unplugging the cord from the system.

NOTE: Leave the power on during the case unless there is an emergency.

Preparing for a Case

System Login

At the system login screen, click/press Login to enter appropriate user name and password credentials. If login credentials are unavailable, you can click on Emergency to access system and record a new case. However, previous cases cannot be reviewed.

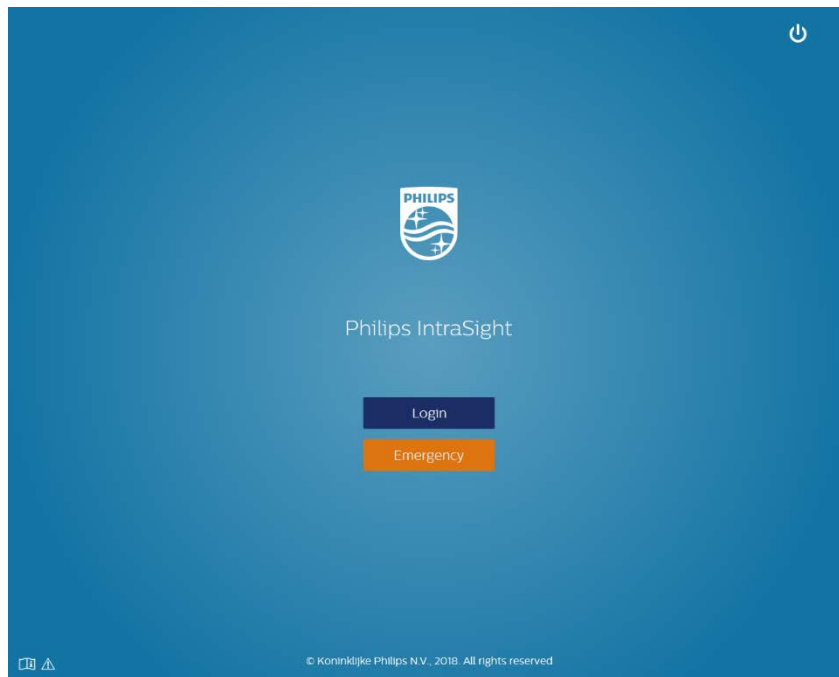


Figure 38: Login Screen

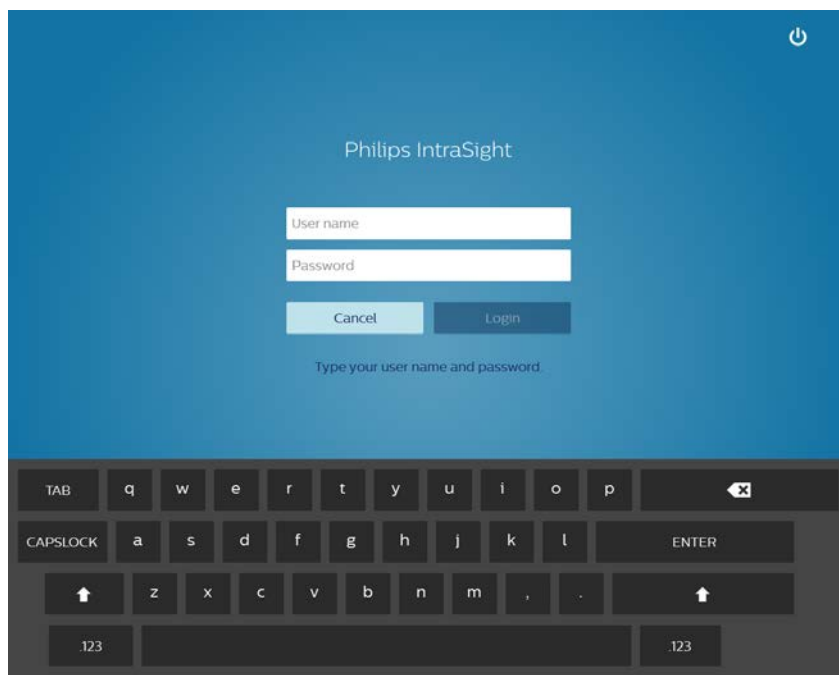


Figure 39: User Name/Password

If username and password are entered incorrectly, the following screen displays with error message.

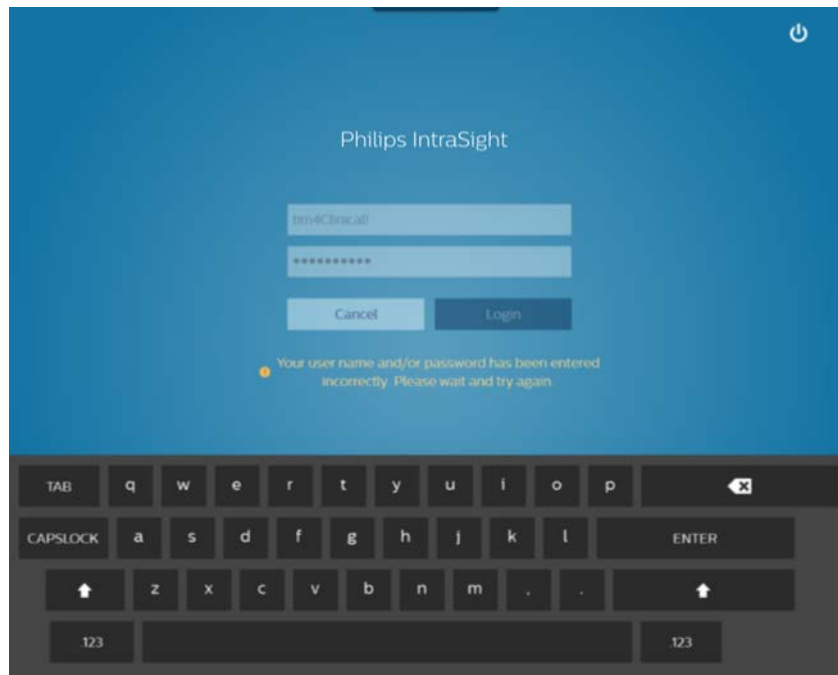


Figure 40: Incorrect Login

If after several attempts to re-login are unsuccessful, the account may become locked, and user is required to wait a specific period of time until subsequent re-login.

After successful login, the user is prompted to change password per password strength requirements.

Preparing for a Case

Welcome Screen

To start a new case, select rectangular blue box, New Case, from the Welcome screen below.

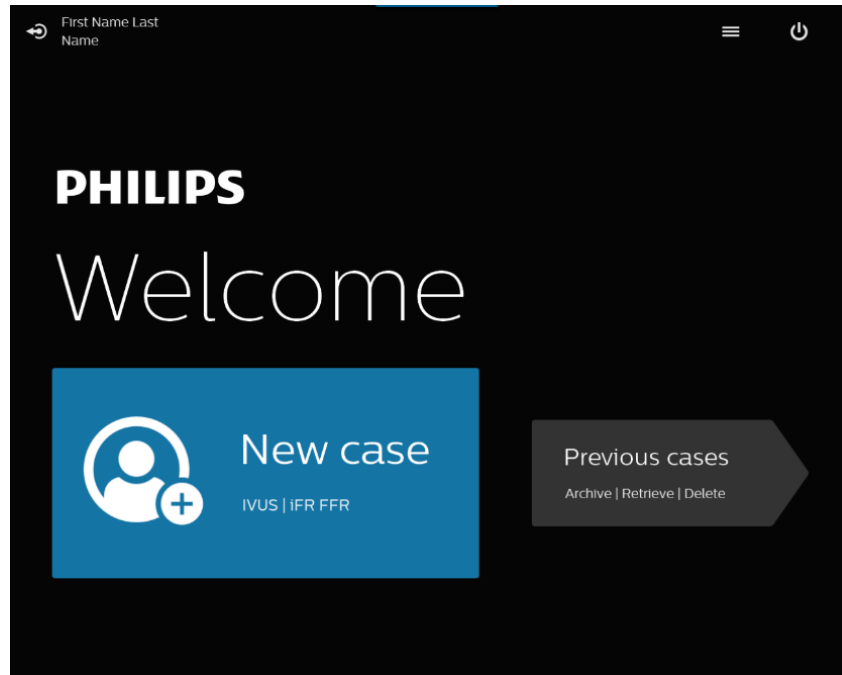


Figure 41: Welcome Screen

Enter Patient Information

NOTE: Three methods of entering patient information can be used: manually (as shown in this section), Worklist (if configured), and Admit from X-ray (if configured), previously discussed in System Setup section.

To enter patient information, select Enter Patient Information (pencil icon), located in the header of Case Menu screen shown below. Later, after completing patient information, return to the Case Menu to launch desired modality, that is, either iFR/FFR and/or IVUS depending on modality licensing privileges.

NOTE: Modalities shown in Case Menu screen will display either iFR/FFR and/or IVUS modalities depending on customer licensing.

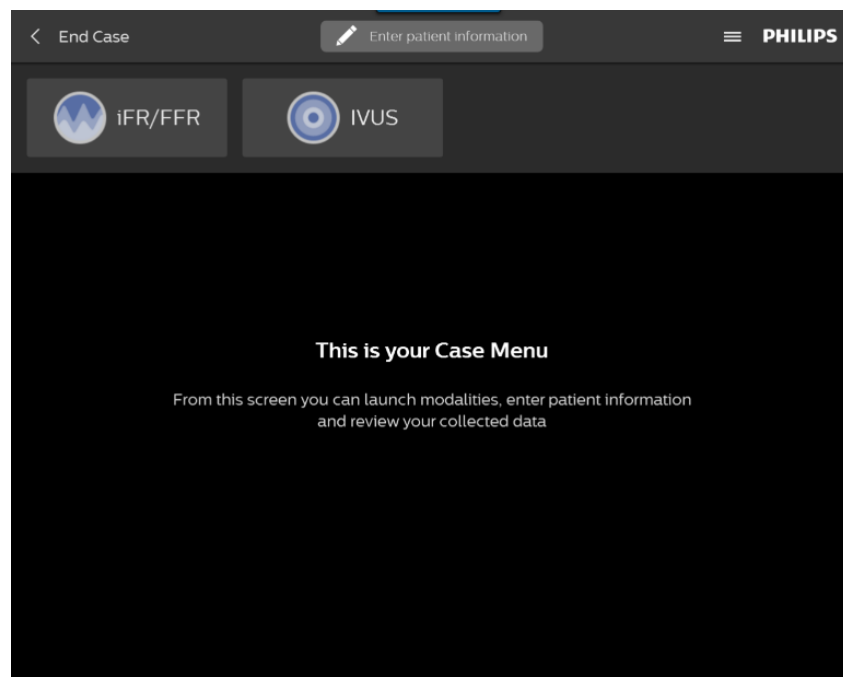


Figure 42: Select Enter Patient Information

Preparing for a Case

The Patient Information dialog screen displays.

The screenshot shows the 'Patient Information' dialog box. On the left, a list of fields (Patient Name, Patient ID *, Sex, Date of Birth, Accession #, Procedure ID, Procedure, Physician) each has a small downward arrow. On the right, there are text input fields for 'Patient Name', 'Last name', 'First name', and 'Middle name'. At the bottom, there are three buttons: 'Clear Patient Info', 'Worklist', and 'Save & Close'. Below these buttons is a virtual QWERTY keyboard. The 'PHILIPS' logo is in the top right corner.

Figure 43: Patient Information

To display as worklist of patients, select rectangular gray box, Worklist, located on lower left corner of screen.

The Worklist dialog screen displays from which patient searches can be performed by using patient attributes such as patient name, procedure ID, date, accession number, and modality.

Preparing for a Case

Search fields allow user to narrow searches by using the aforementioned patient attribute filters. After entering patient attribute(s) using one of the six search filters, select Search to begin patient search. A list of search matches displays.

Highlight a patient record (row) and press Select to display specific patient information. The Search This System Only option limits search to current system or all systems. Additionally, patient attribute columns can be sorted in ascending/descending order.

The screenshot shows a 'Worklist' dialog box with a search filter section and a table of patient records. The search filter section includes fields for Patient Name, Procedure ID, All dates, Patient ID, Accession #, and XA, along with a Search button and a checkbox for 'Search this system only'. The table below lists patient information with columns for Patient Name, Patient ID, Procedure ID, Procedure Date/Time, and Accession #.

Patient Name	Patient ID	Procedure ID	Procedure Date/Time	Accession #
XperIMTest, Patient	AV35674	RP454G234	05/08/2018 10:46:32	00000
XA modality	Pat6	D	05/08/2018 10:46:32	Q0V2
Balasubramanian, George Taj	99000	RP488M9439	05/08/2018 10:46:32	00099
Franklin, Rosalind	RF-004	RP2812308	05/08/2018 10:46:32	0033
Newgirl, Randy	23096-4324	RP488M9439	05/08/2018 10:46:32	00046
Carson, Rachel	RC-003	RP2812307	05/08/2018 10:46:32	0033
Goeppert-Mayer, Maria	MG-002	RP2812306	05/08/2018 10:46:32	0033

At the bottom of the dialog, there is a status bar showing 'Latest: 05/08/2018 10:52:31', '38 Results', and buttons for 'Close Worklist' and 'Select'.

Figure 44: Worklist

Returning to the Patient Information dialog screen, either manually complete entering patient information or use Worklist. If selecting Worklist, a confirmation dialog box displays showing patient information with populated fields, which cannot be changed.

Information can be entered in each attribute field, either by using keyboard or virtual keyboard display, which fills the bottom half of the screen. Patient information can be erased or cleared by selecting the Clear Patient Info box, located on the lower left corner of the screen.

Preparing for a Case

The screenshot shows a mobile application interface for 'Patient Information'. At the top, there is a header bar with a back arrow, the title 'Patient Information', and the Philips logo. Below the header, the patient details are listed in a table-like format. The 'Case Notes' section is on the right, showing a text area with 'AB264'. At the bottom, there are three buttons: 'Clear Patient Info', 'Worklist', and 'Save & Close'.

Patient Information	
Patient Name	Stanley Smith
Patient ID *	12345678
Sex	Male
Date of Birth	11/15/1960
Accession #	1234
Procedure ID	27184919
Procedure	Post Right LAD Lesion
Physician	Smock
Institution	St. Johns
Case Notes	AB264
* Mandatory	
Clear Patient Info	Worklist
Save & Close	

Figure 45: Completing Patient Information

NOTE: To display numbers on keyboard, press on the “.123” key; press again to return to letter display.

1. Select TAB key on regular keyboard to move between fields.
2. Press keyboard icon on lower right corner of keyboard to close keyboard display.
3. After completing patient attribute fields, select Save & Close, located on the lower right corner of screen.
4. The following Case Menu screen displays, showing patient name and ID in the header.

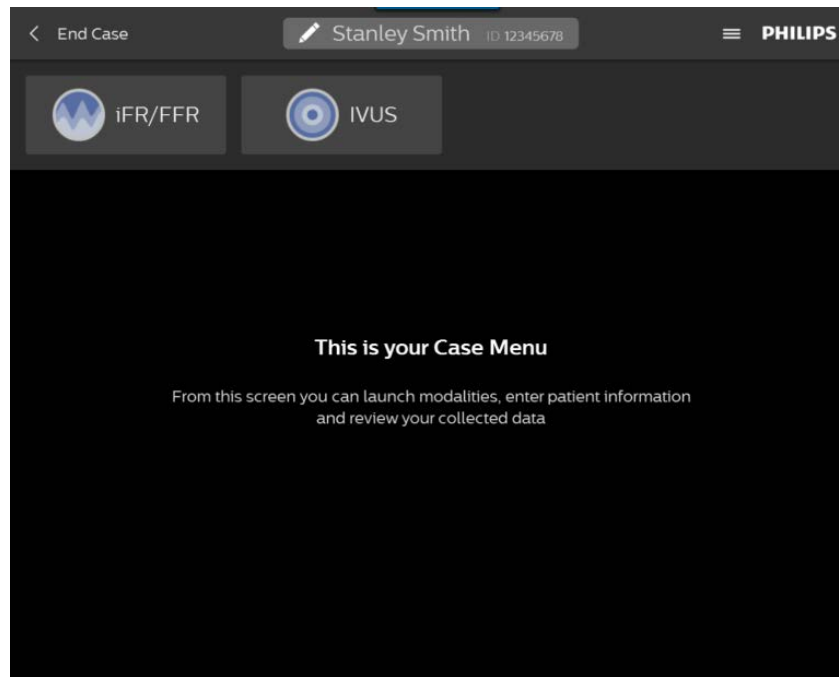


Figure 46: Case Menu/Select Mode Screen

Connect PIM

The IVUS catheter connects to the system via the patient interface module (PIM). The PIM is typically left connected to the Connection Box between cases, but may need to be reconnected if removed after the prior case.

CAUTION: Use care when handling the PIM to avoid accidental dropping, especially when a catheter is connected.

Prepare Catheter

The IVUS catheter should be selected based on the needs of the procedure. Proper handling and preparation of the catheter is critical to successful imaging. Prepare the catheter in accordance with the Instructions for Use included with each catheter.

CAUTION: Do not re-sterilize a catheter or reuse a catheter.

NOTE 1: See the catheter label for specific insertion instructions. Consult package insert for full description of warnings, precautions, and use instructions.

NOTE 2: Imaging does not start until the catheter is connected to the PIM.

Connect PIM to System

Connect the patient side of the PIM cable to the short cable length from the Connection Box. Orient the marker on the cable connector to align with the indicator on the PIM and

Preparing for a Case

slide the connector in. Verify that the PIM connection is secure by gently pulling on the catheter. To remove the cable from the PIM, rotate the collar on the PIM cable connector counterclockwise a quarter turn and then pull back.

NOTE 1: Refer to the catheter Instructions for Use for directions on use before and during the procedure.

NOTE 2: Once the catheter type is configured and connected to the system, a live vessel image displays, after selecting a new or previous case, without showing sequential PIM connection screens (as shown below). Installing a new catheter results in the following PIM connection (IVUS selected), screen sequence shown below.

NOTE 3: The screen sequence below is based on PIM connection. Screen sequence for PIMr is similar, but will vary slightly.

1. Connect PIM to IntraSight Vascular System. The following screen shows SpinVision rotational PIM (left) and digital PIM (right).

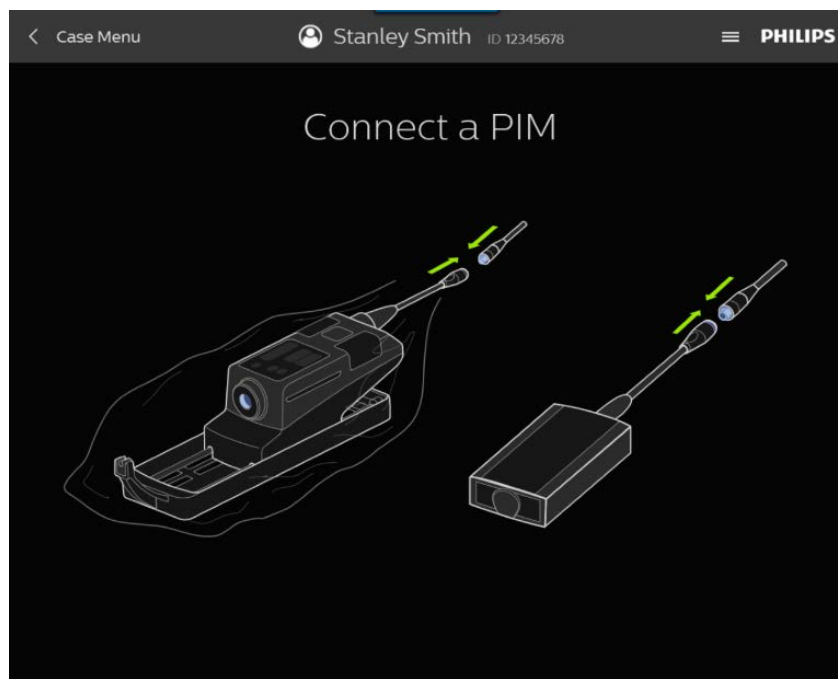


Figure 47: Connect PIM

2. Prepare and connect catheter to PIM.

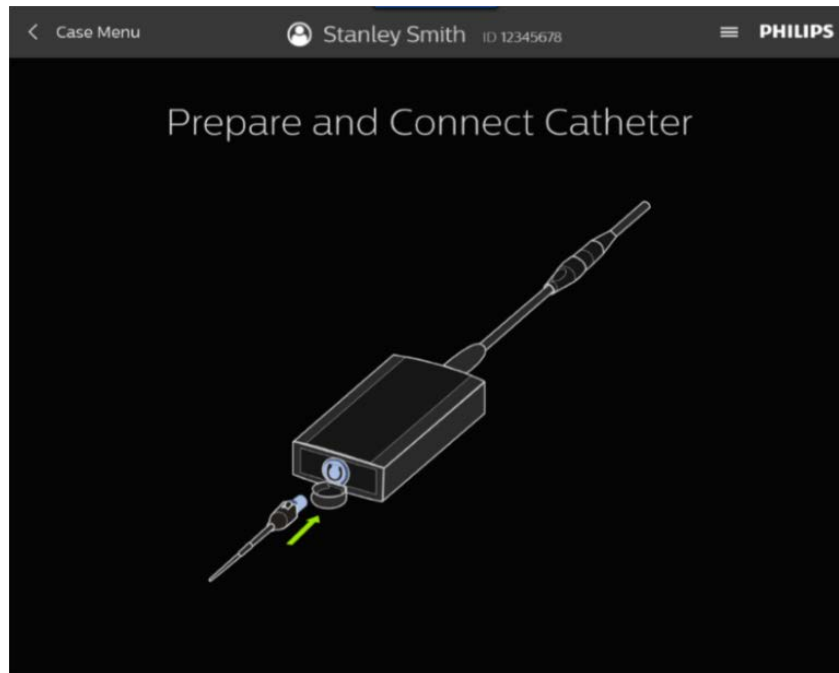


Figure 48: Connecting Catheter

3. Once connected, the catheter is initialized.

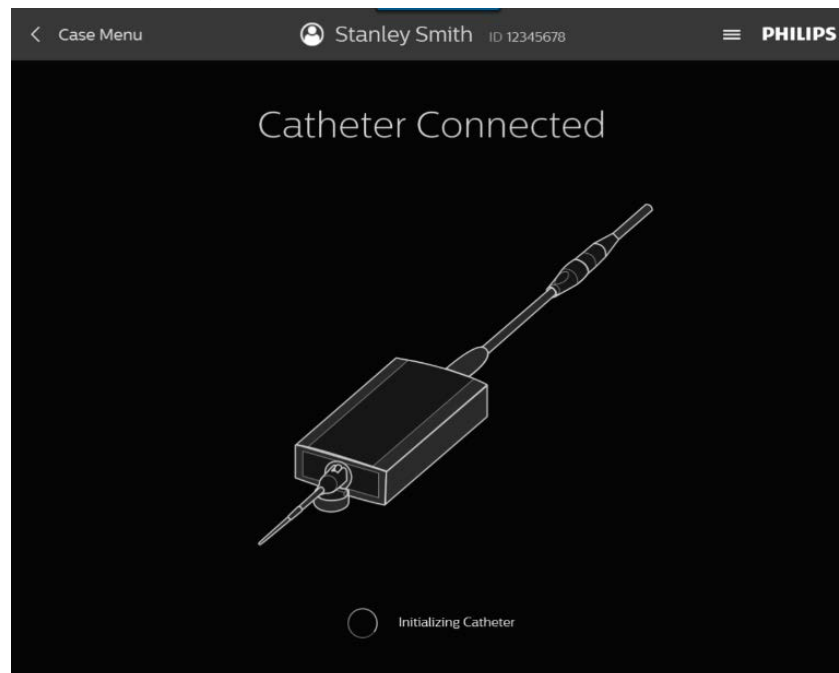


Figure 49: Catheter Connection/Initializing

Preparing for a Case

NOTE: The catheter type persists for successive imaging sessions or cases, i.e., the system recognizes the installed catheter for each case until a new catheter is installed. However, user-defined values are reset to default values at the beginning of each case and need to be redefined by the user.

The following section describes how to acquire IVUS images.

Chapter 7. Acquiring IVUS Images

This chapter describes the steps that should be followed for imaging during an IVUS case. Please refer to the previous chapters for instructions on preparing the system using the IVUS Settings option (selected from System/Service Settings, located in the three line icon drop down of the Welcome screen) and performing catheter setup procedures.

Overview

The following should be performed during each IVUS case, prior to recording images:

- Insert the catheter
- Adjust the image (if desired)

Insert Catheter

The Philips Vascular System imaging catheters are designed for placement using standard intra-operative or percutaneous techniques by suitably trained physicians. The frequency and duration of administration is subject to the discretion of the physician and depends upon the procedure and information required.

1. Prepare the patient according to local standard operating procedures.
2. After selecting the IVUS modality and connecting the catheter, introduce the catheter into target vessel, placing it onto the previously positioned intravascular guide wire.
3. Advance the imaging catheter distal to target region.

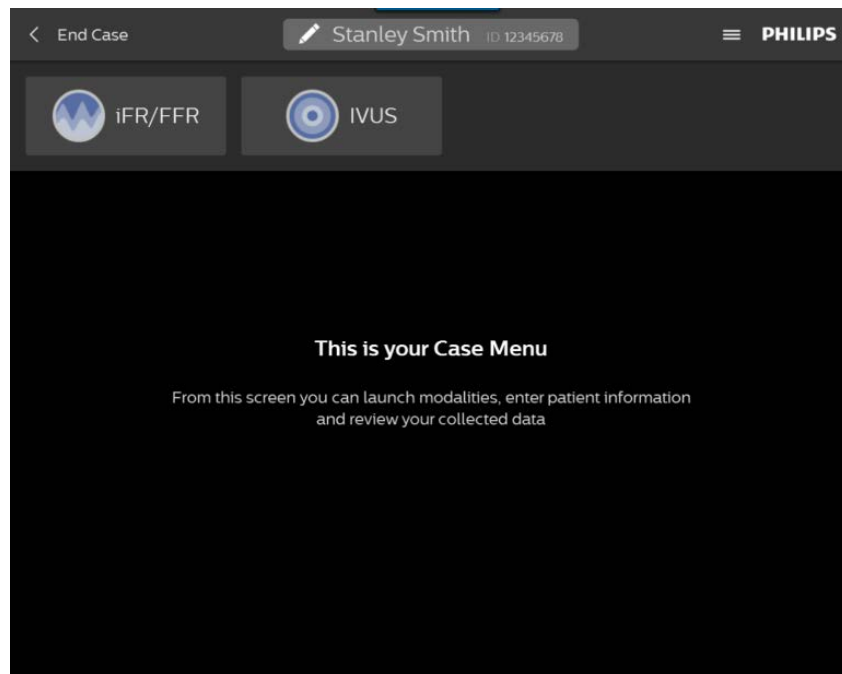


Figure 50: Select IVUS Mode

Acquiring IVUS Images

NOTE: ChromaFlo images are displayed in ChromaFlo section. Generally, most image displays are shown in grayscale throughout manual.

Adjust the Image (if desired)

Your system's image settings will be set to the default values recommended by the manufacturer. These settings can be adjusted based on your preferences. Once set, specific values persist until changed.

To change the settings, use the slider bars located under Adjust Image to adjust Gain (brightness) and Diameter (field of view).

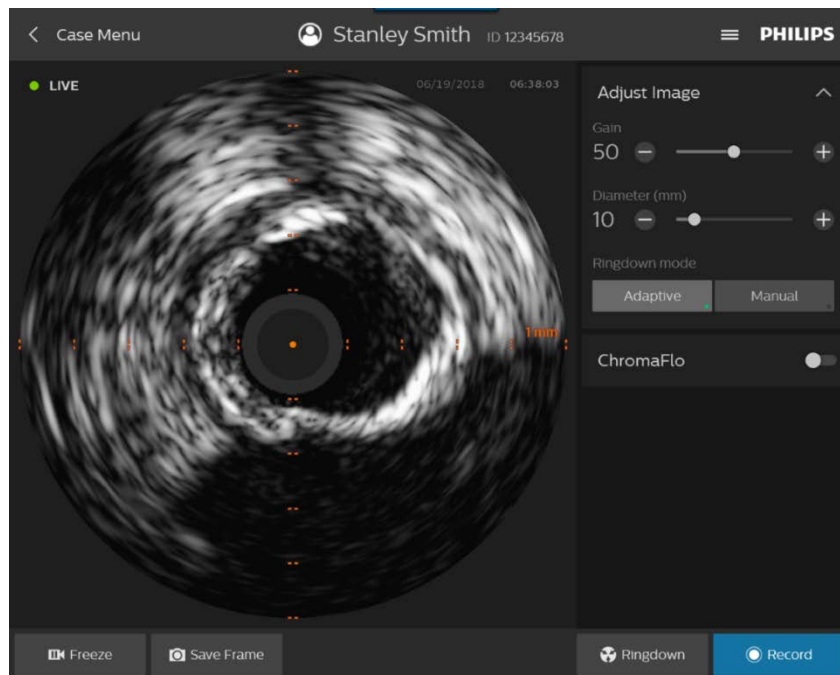


Figure 51: Image Adjustment

NOTE 1: Gain and Diameter do not persist; user-defined values are reset to default values at the beginning of each case and need to be redefined by the user.

NOTE 2: Ensure that the image is configured properly before recording; gain values cannot be changed during video loop recording process.

Activating ChromaFlo

The ChromaFlo option provides a visual depiction 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.

NOTE: ChromaFlo must be turned on before recording IVUS loop.

Enable ChromaFlo on live image screen by moving slider to the right, green state. Additionally, the gain (brightness) and diameter settings of the image can be adjusted

Acquiring IVUS Images

similarly, moving slider between minus/plus signs including adjustment of ChromaFlo sensitivity, selecting options Low, Medium, or High.

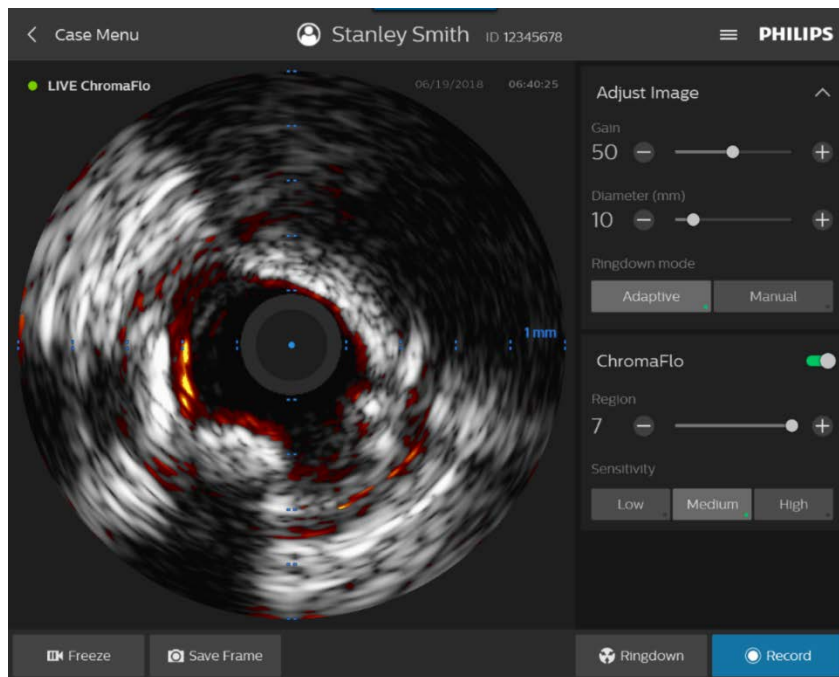


Figure 52: ChromaFlo Image View

Acquiring IVUS Images

Printing

To print a screen image, first ensure a printer is connected to the system.

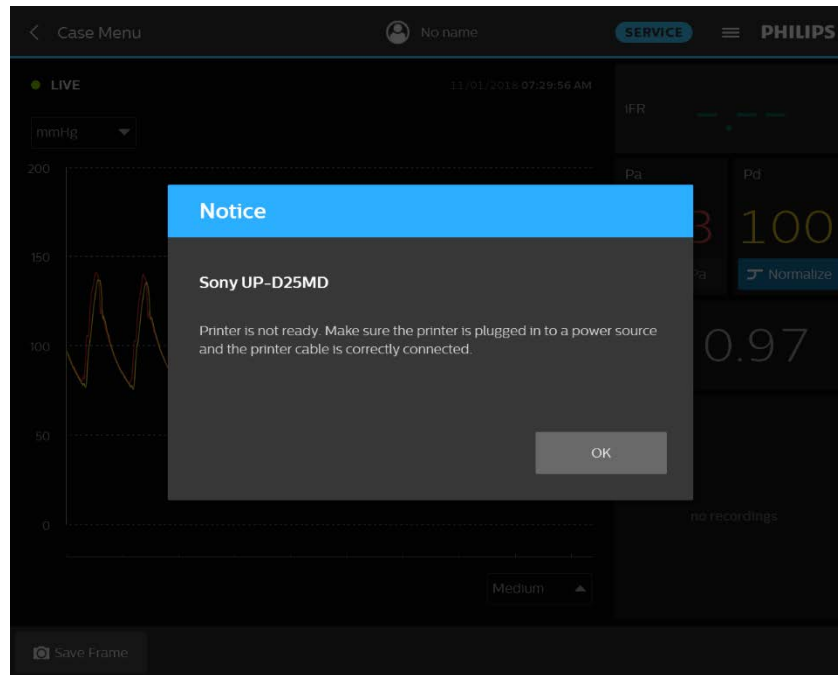


Figure 53: Printer Not Ready

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

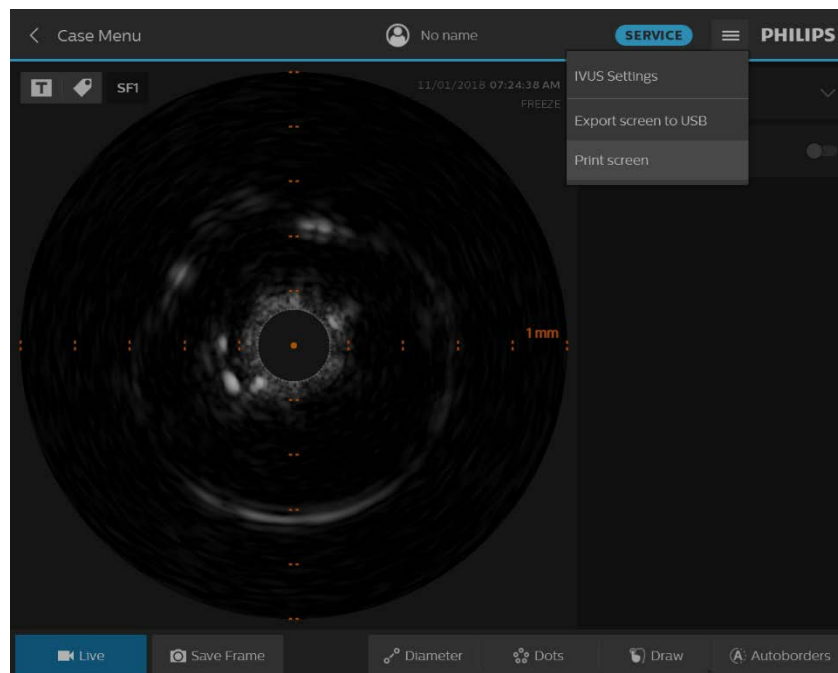


Figure 54: Print option

Chapter 8. Recording IVUS Images

This chapter describes the methods of recording images. Please refer to the previous chapter for information on inserting the catheter and adjusting the image settings.

Overview

Images can be recorded by either saving a single frame (Save Frame) or recording a video loop of multiple frames.

Recording a Video Loop

1. Position the catheter distal to the area to be imaged.
2. For PV.014, Eagle Eye Platinum, and PioneerPlus catheter images, Adaptive/Manual Ringdown (which mitigates appearance of ultrasound artifacts on image) modes are included. Default value is adaptive.
3. To perform manual ringdown on a desired catheter location, manipulate catheter to a desired vessel location. Select Ringdown with Manual option selected.

NOTE: The transducer (catheter) emits a burst of 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 contains one reference point from which subsequent manual ringdowns are calculated. Adaptive ringdown contains several reference points, updated continuously.

4. To perform adaptive ringdown on another image location, select Ringdown with Adaptive option selected.
5. From the live imaging screen, select either Adaptive or Manual Ringdown mode.

Recording IVUS Images

6. To start recording, select Record button, rectangular blue box, located on lower right corner of screen.

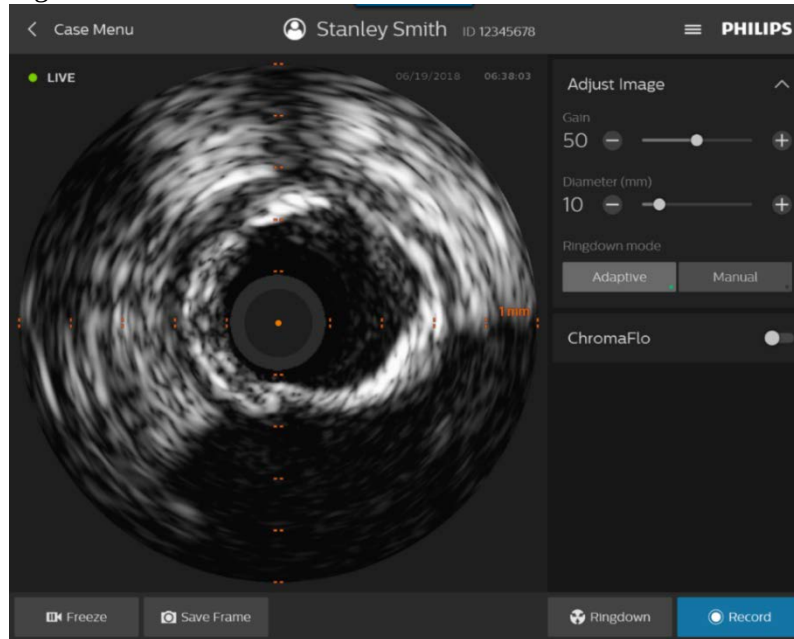


Figure 55: Press Record Button

7. After selecting Record button, collected image data is displayed in the ILD on the right side of the screen.

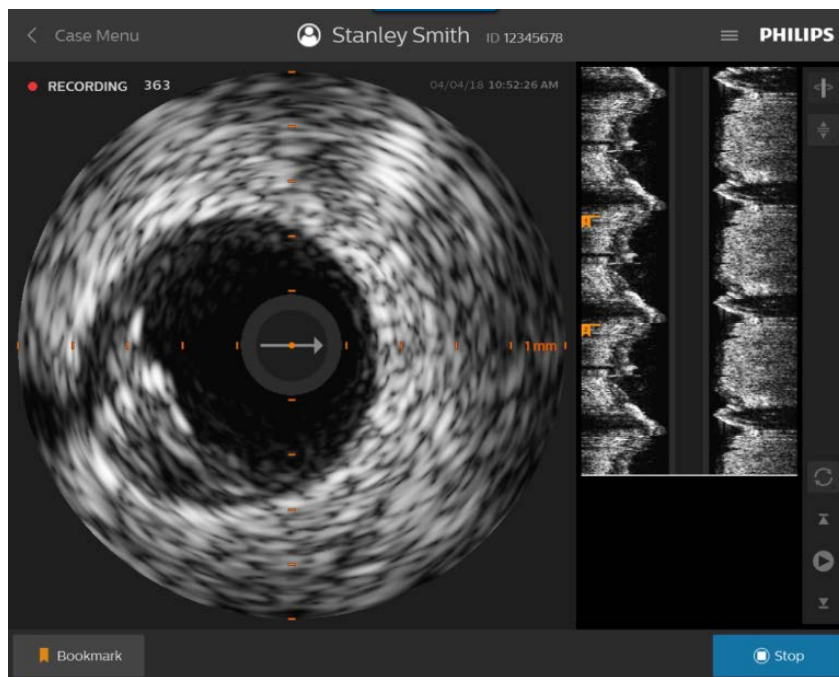


Figure 56: Record Video Loop

8. After the region of interest has been imaged and bookmarks positioned on ILD regions of interest, stop recording by selecting the Stop rectangular blue option, located on lower right corner of screen.

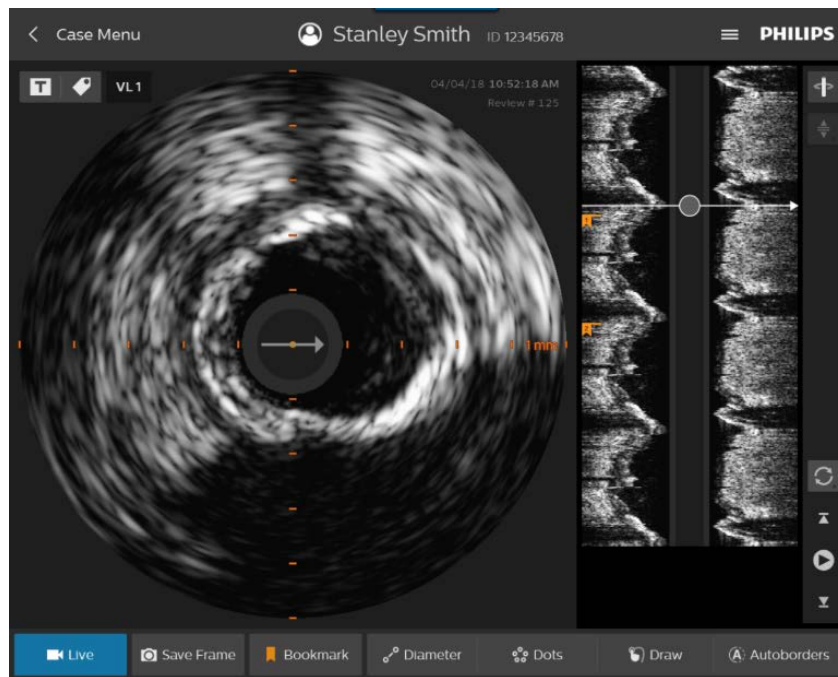


Figure 57: Record Stop

9. After selecting Stop button, the ILD review displays on the right side of vessel image where the user can review or playback current recording.
10. Use navigation ribbon, located to the right of the ILD to review or replay current recording. Review modes include performing a 360 degree view of a specific vessel cross-section, tomographic view. Additionally play/pause icons are used to review vessel lumen/wall navigate ILD, designating bookmarks, noting areas of interest.

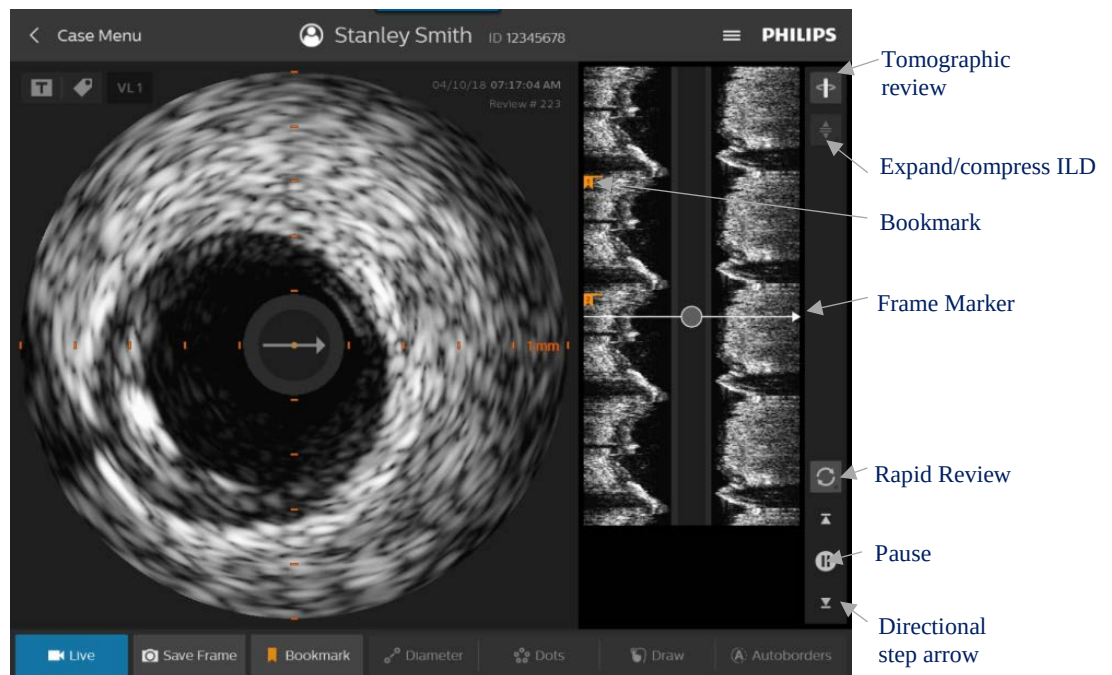


Figure 58: ILD Review

Recording IVUS Images

Other ILD features include the ability to expand/compress ILD view and perform Rapid Review (enabling 3 frame view at each desired point along ILD). For more information on ILD function, see Reviewing IVUS Images chapter.

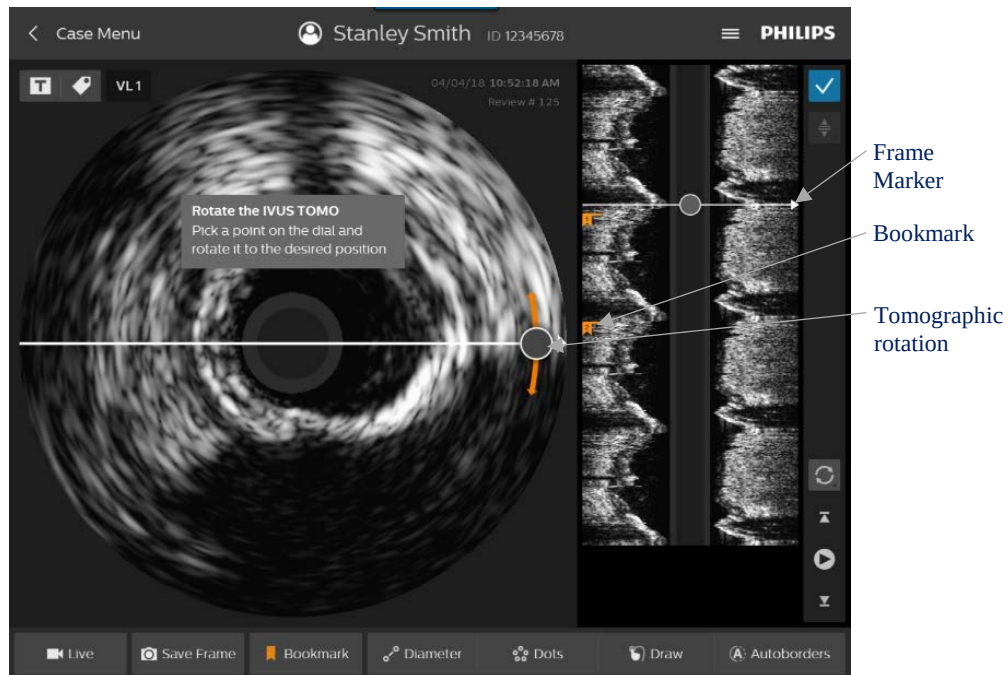


Figure 59: Tomographic Section, 360° Review

As mentioned above, bookmarks (color-coded icons located along ILD) can be set along ILD, noting areas of interest. A maximum of 99 bookmarks can be stored within a video loop.

Additionally, the frame marker, noted above, helps navigate ILD with complementary tomographic image, and tomographic rotation feature, located to the left of ILD. Features of ILD are discussed further in following Reviewing IVUS Images chapter.

A new video loop can be recorded by repeating the steps above. A maximum of 30 video loops may be recorded within a single case.

Saving a Frame

The Philips Vascular System can store up to 99 frame images from a live view or a video loop. Saved frames are labeled automatically and numbered SF1, SF2, etc.

To save a frame:

1. Select Save Frame option, located on the bottom menu ribbon of the screen. The current real-time image is stored and labeled, starting with F1.
2. Select Save Frame again to store another image as SF2, and so on.

NOTE: Frames can be saved while playing a video loop or displaying a frame. To save a frame:

Displaying Image Measurement Elements

Measurement display elements can be shown or hidden on an image by selecting the three horizontal line icon, located in the upper right corner of the image frame, next to the Philips name. Select the IVUS Setting option.

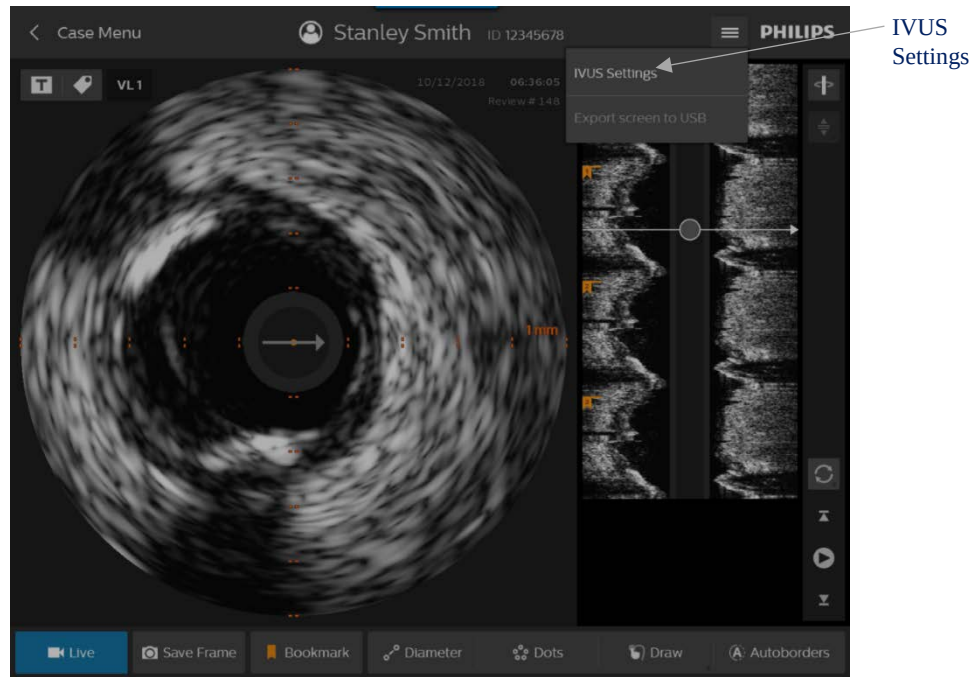


Figure 60: IVUS Settings

When performing measurements on vessel diameter, vessel border, or lumen, selecting the IVUS Settings option allows the user to set the display of diameter lines, graticules (calibration grid/lines), or lumen and/or vessel autoborders on a vessel image.

NOTE: Vessel area measurements are discussed in the following chapter, Creating Measurements and Annotations.

The IVUS Settings menu first displays the Area diameter lines option, which is used to Show or Hide minimum/maximum diameter lines of area measurements.

Recording IVUS Images

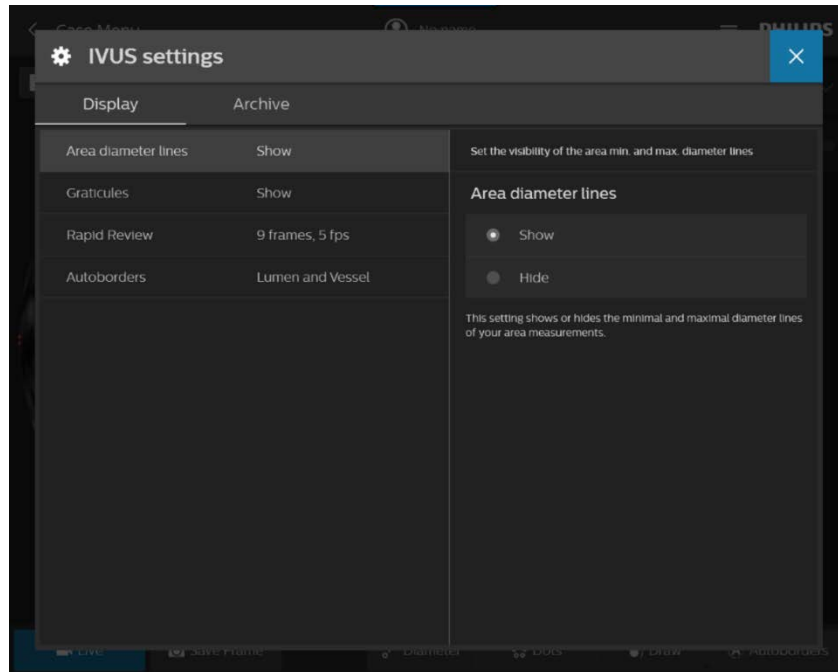


Figure 61: Area Diameter Line Display

Selecting the Graticules option Shows or Hides graticules or calibration grid/lines, laid on top of a tomographic image.

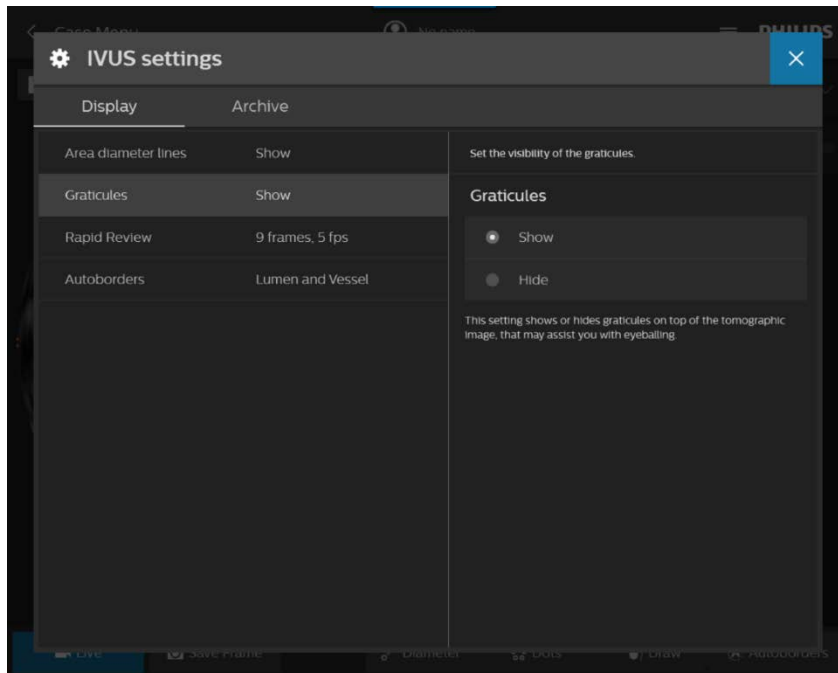


Figure 62: Graticule Display

The Autoborders option is used to display autoborder measurements, showing lumen and vessel, lumen only, or vessel border only on a tomographic or vessel image, using the autoborders measurement feature.

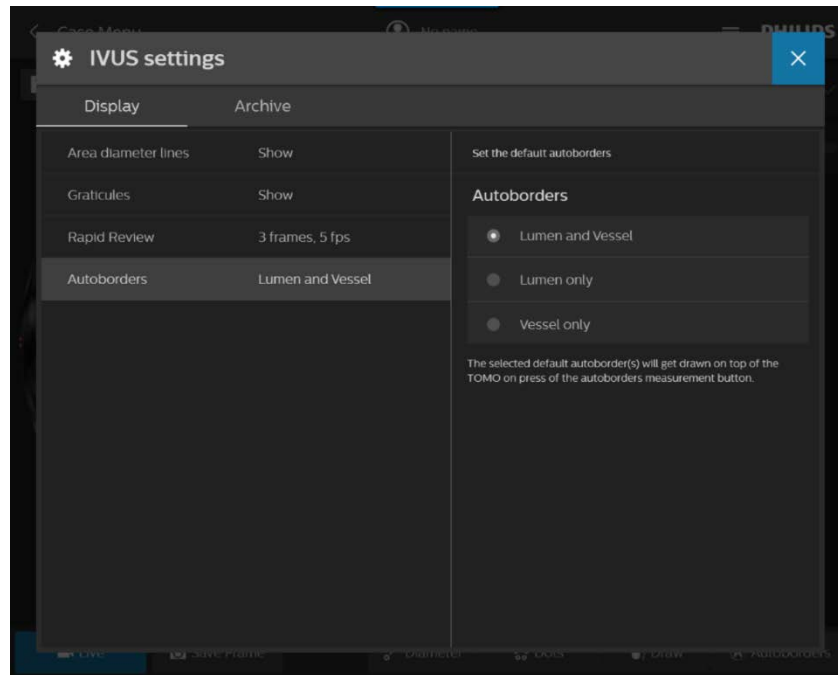


Figure 63: Autoborder Display

Additionally, when navigating an ILD vessel section, the Rapid Review feature allows the user to determine loop size or iterative frame cycle of a specific view. Rapid Review is a playback or quick review of areas of interest along the lumen or vessel wall.

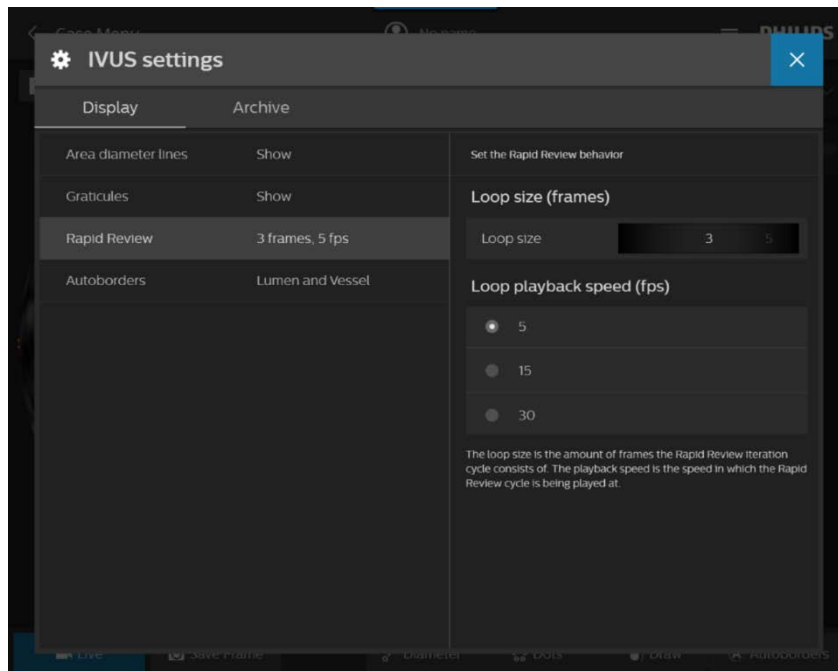


Figure 64: Rapid Review

Another feature, regarding the archiving of saved frames (SF) and video loops (VL), includes the ability to embed graticule, measurement, and/or annotation elements on clinical images.

Recording IVUS Images

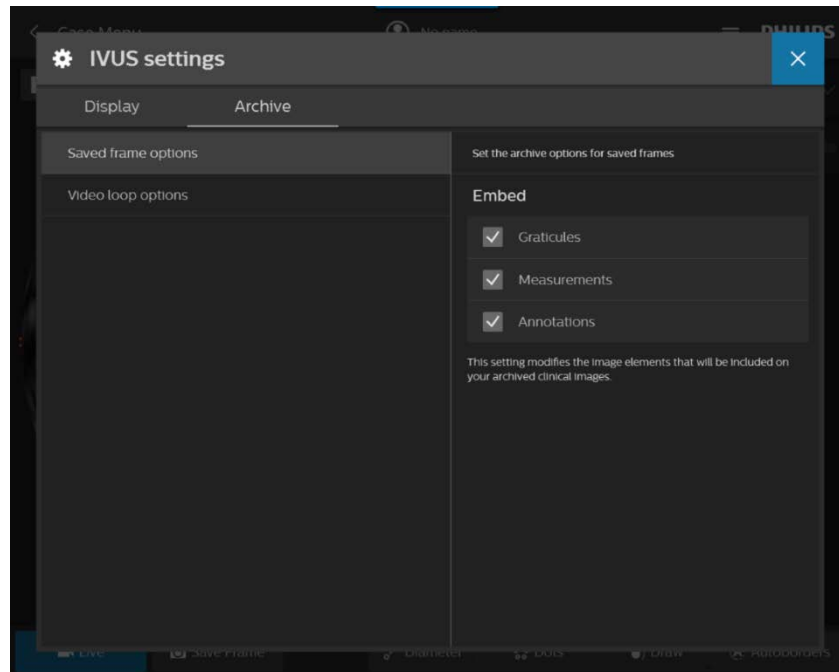


Figure 65: Archiving Images – SF Options

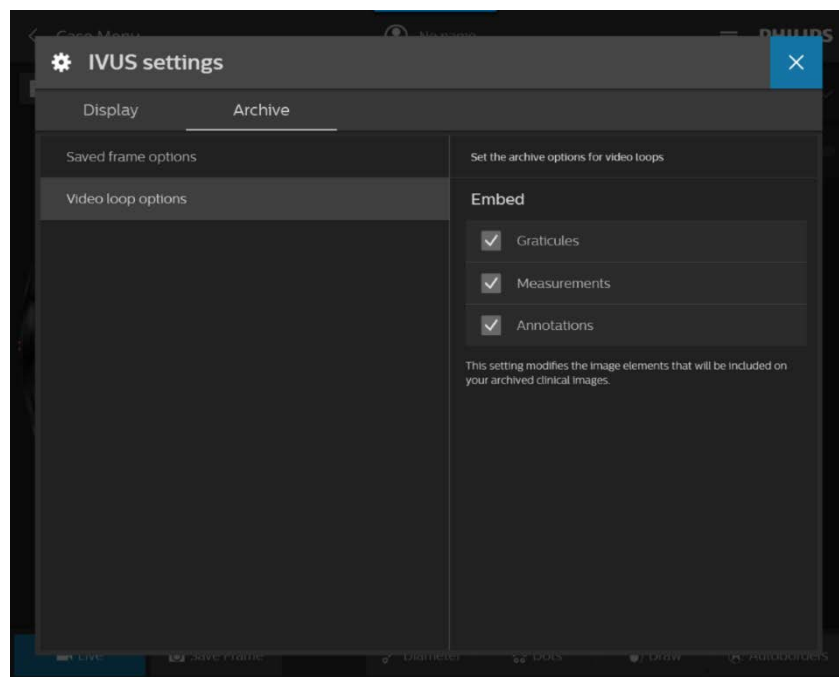


Figure 66: Archiving Images – VL Options

Chapter 9. Creating Measurements and Annotations

This chapter describes the measurement and annotation tools that are available on your system.

NOTE: Measurement accuracy is dependent on operator's familiarity with specified measurements and interpretation of ultrasound images.

Making Measurements

The following measurements can be made on any single grayscale frame:

- Distance/Diameter
- Area (Dots or Draw)
- Autoborders

NOTE 1: ILD display/measurement only applies to IVUS rotational catheters. See Rotational Option Manual for more information on IVUS rotational catheters.

NOTE 2: The following measurement examples are taken from the Main Monitor screens, in which keyboard/mouse are used to make measurements. For Bedside Controller, the touchscreen can be used to make measurements, e.g., creating a starting point by touching desired starting point on image, dragging line to end point, and releasing mouse button to complete line segment. Or, touching desired starting and ending points on image to complete line segment.

To Enter Measurement Mode:

1. Navigate to desired screen image.
2. Locate the frame of interest, for example:
 - Saved Frame
 - Frame within a video loop (loop must be stopped)
 - Frozen image from Live mode

NOTE 1: Measurements are saved automatically. Freeze frames are saved by pressing Save Frame. When reviewing video loop, measurements display on the frame.

NOTE 2: Measurements cannot be made on live frames.

Measuring Vessel Diameter

To measure vessel diameter from the touchscreen, place a point at each opposing end by using mouse to create a measurement, adding successive measurements as necessary.

1. Select the Diameter icon, located at the bottom icon ribbon of the screen.
2. Click on a desired starting point on the vessel image. The starting point appears.
3. To create an end point, click on a desired end point on the screen.

Creating Measurements and Annotations

4. To create a second diameter measurement, repeat Steps 1 – 2.

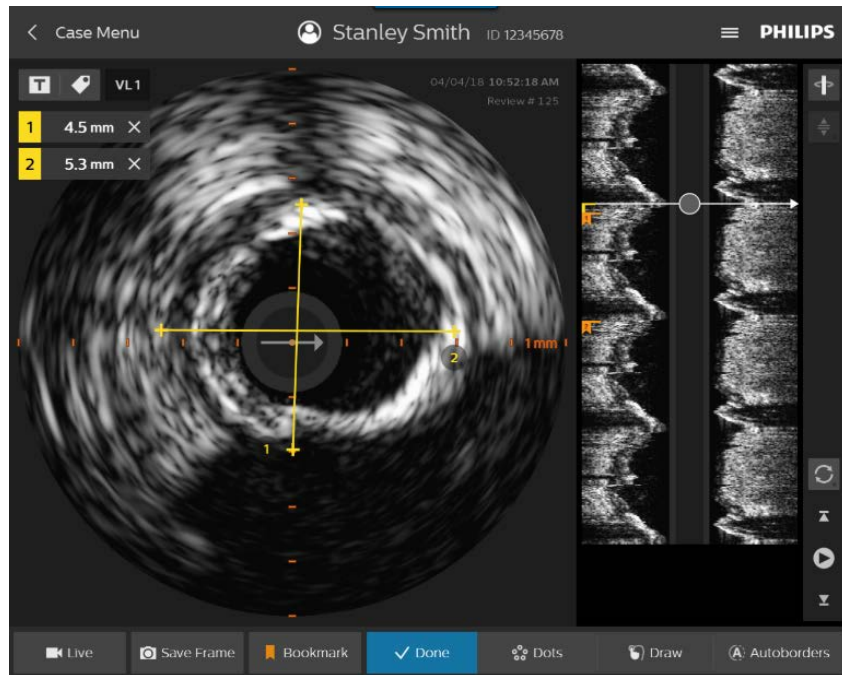


Figure 67: Measuring Vessel Diameter

NOTE: Alternatively, you can create a diameter measurement by selecting a diameter starting point. Hold down the left mouse button (or maintain contact on touchscreen), and drag the diameter measurement to an end point.

5. To edit a diameter, select an end point of the diameter (becomes dashed line) and drag to desired location.

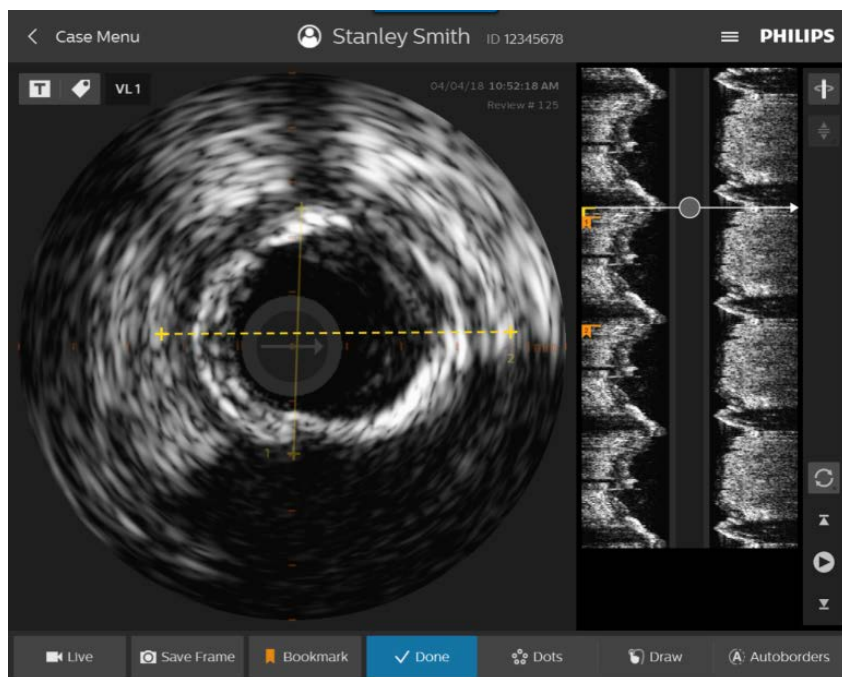


Figure 68: Editing Vessel Diameter

Measuring Vessel Area - Draw

1. Select Draw option from bottom icon ribbon.
2. Select a desired location on the screen to create a starting point.
3. Draw (drag) an area measurement with mouse. The area measurement completes after releasing mouse button.

To create a second area measurement, repeat Steps 2 – 3. Note the data difference between first and second measurements in the figure below. The measurement difference is located between the two color-coded measurements.

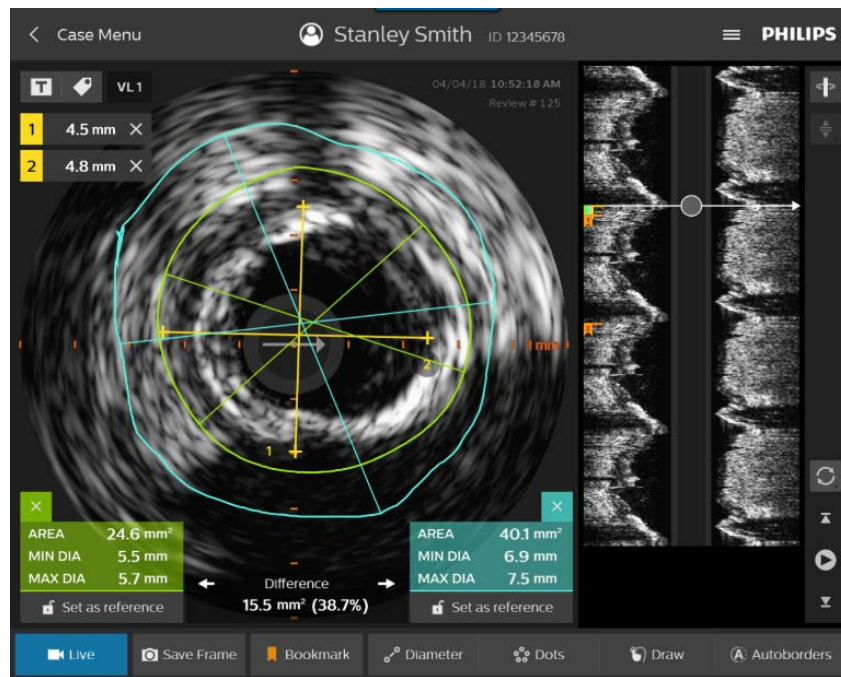


Figure 69: Drawing Vessel Area

To create a drawing reference or base point, select the Set as Reference, unlocked icon.

Editing Measurement

To edit an area measurement, three methods are provided. Select an area measurement and:

- Drag measurement with mouse in or out from central point of image using cursor.
- Redraw by dragging cursor along desired path.
- Click on desired screen location to move line segment.

Creating Measurements and Annotations

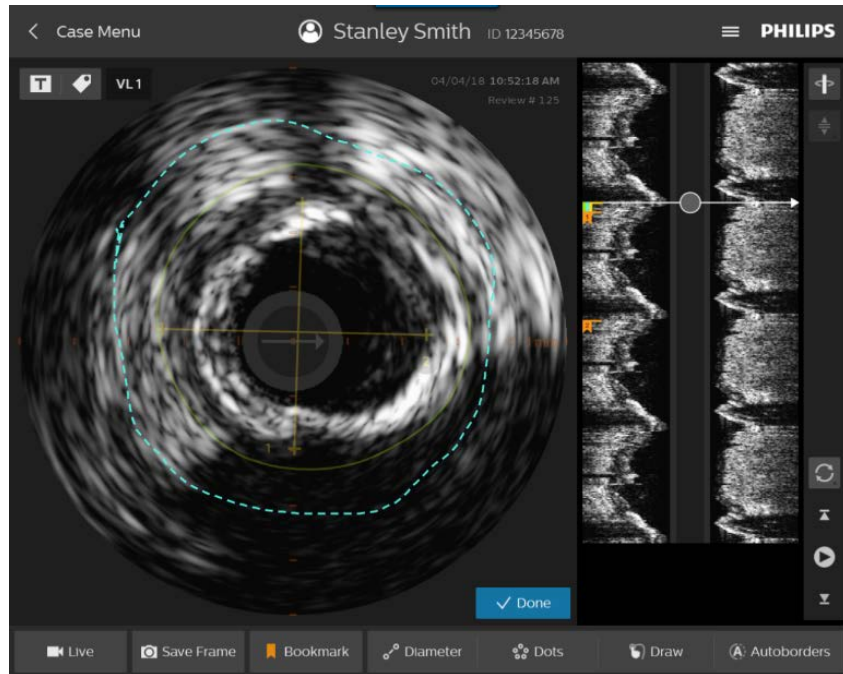


Figure 70: Editing Vessel Drawing

To save the frame, select Save Frame option from the bottom icon ribbon.

Measuring Vessel Area - Dots

1. Select Dots option from bottom icon ribbon.
2. Select a desired location with mouse on the image to create a starting point.
3. Continue placing dots on desired vessel locations.

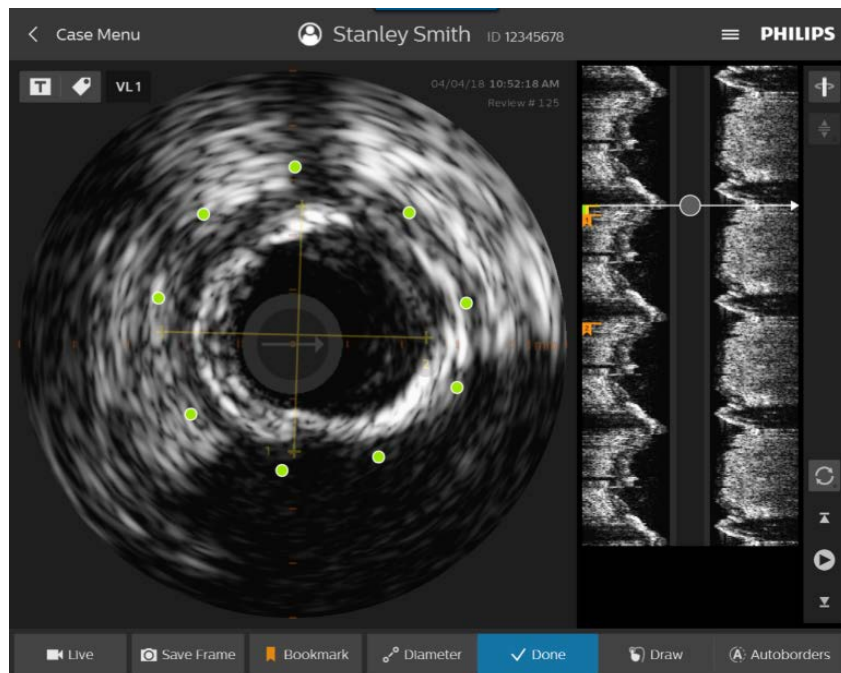


Figure 71: Creating Dots Measurement

Creating Measurements and Annotations

4. Select Done to complete area measurement.

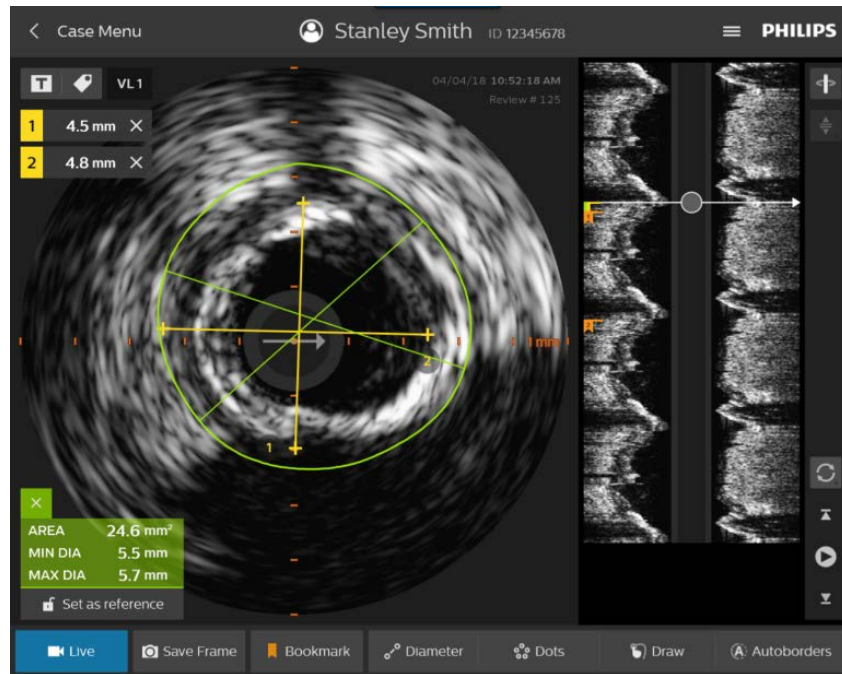


Figure 72: Dots Area Measurement

5. To create a second measurement, repeat Steps 1 – 4.

Up to two area measurements can be made for each frame. The area measurements are displayed in color-coded boxes, located in lower left and right corners of the image. Displayed in each box is the area measurement (mm^2) and the maximum and minimum diameters (mm). The image measurements are color coded, complementing color-coded box measurements.

Creating Measurements and Annotations

Autoborders

To automatically measure vessel wall and lumen areas of interest, select Autoborders option from the bottom icon ribbon.

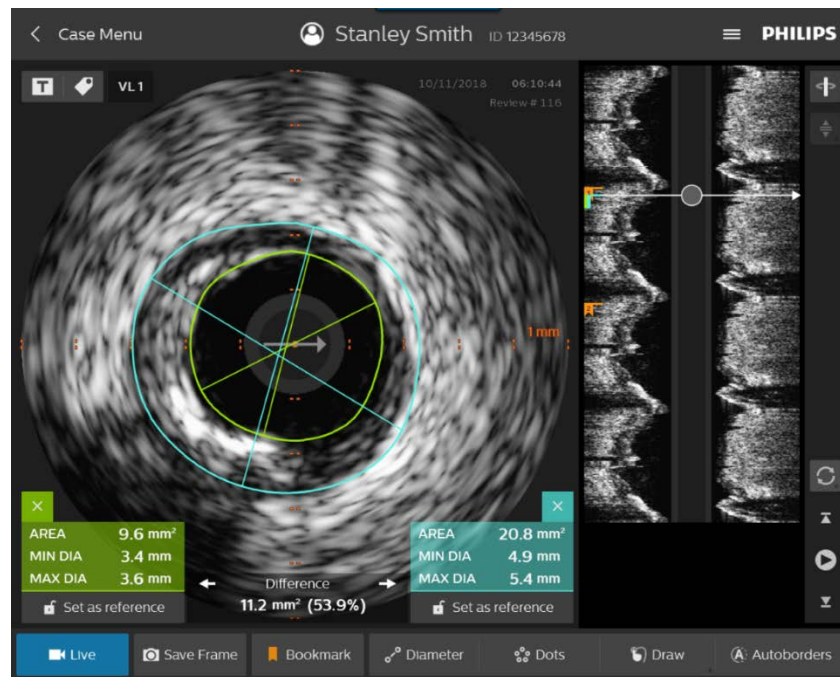


Figure 73: Autoborders

Lock Measurement

To create another measurement at another vessel area of interest along the ILD, and compare data between the two vessel image measurements in the same video loop, lock the first or initial, vessel image measurement to set as reference.

1. Create a measurement on a vessel image and select Done.
2. Lock the measurement by clicking on the open lock, located next to Set as Reference. A complementary color-coded box is displayed on the upper right corner of the vessel image as the reference measurement, complementing the other measurement shown below.

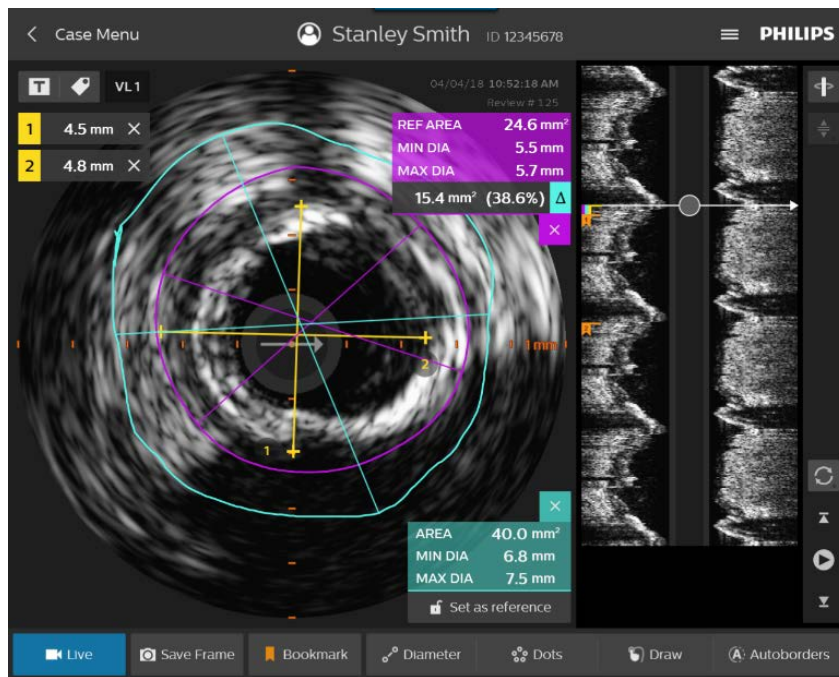


Figure 74: Measurement Locked for Reference

3. Move the ILD Frame Marker to another area of interest along the vessel image.
4. Create another measurement on the vessel image and select Done. This measurement references the initial measurement.
5. The difference between initial and subsequent measurements is displayed in a box, located between initial and subsequent measurement boxes. Additionally, note the difference between measurements in complementary color coding in vessel image.

Deleting Measurement

To delete an area measurement, select “X” located next to a measurement.

NOTE: There is no “undo” for deleting an area measurement.

Making Annotations

Creating Video Loop Titles/Image Annotations

Create video loop titles and/or image frame annotations for saved video loops and frames, respectively.

Adding Video Loop Title

1. Add a *title* to a video loop by selecting the label icon, located on the upper left corner of vessel image (video loop 1 or VL1 displays next to label icon).

Creating Measurements and Annotations

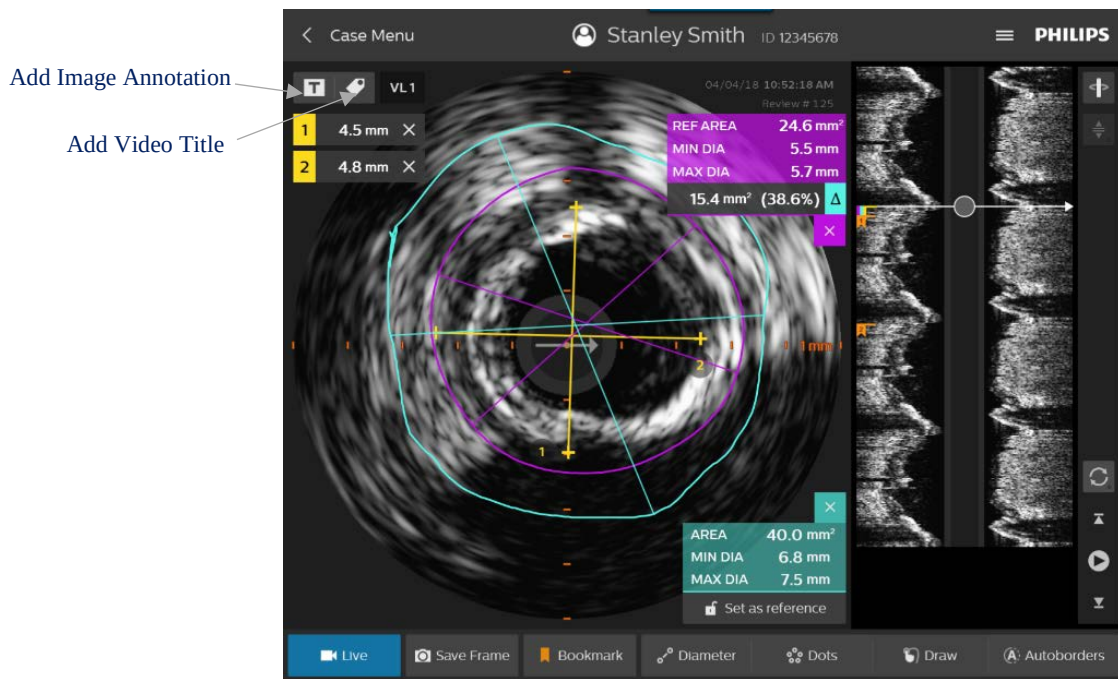


Figure 75: Video Loop Title/Image Annotation Options

2. Select Add Video Title icon (label) from the screen. The Title Video Loop dialog box displays.

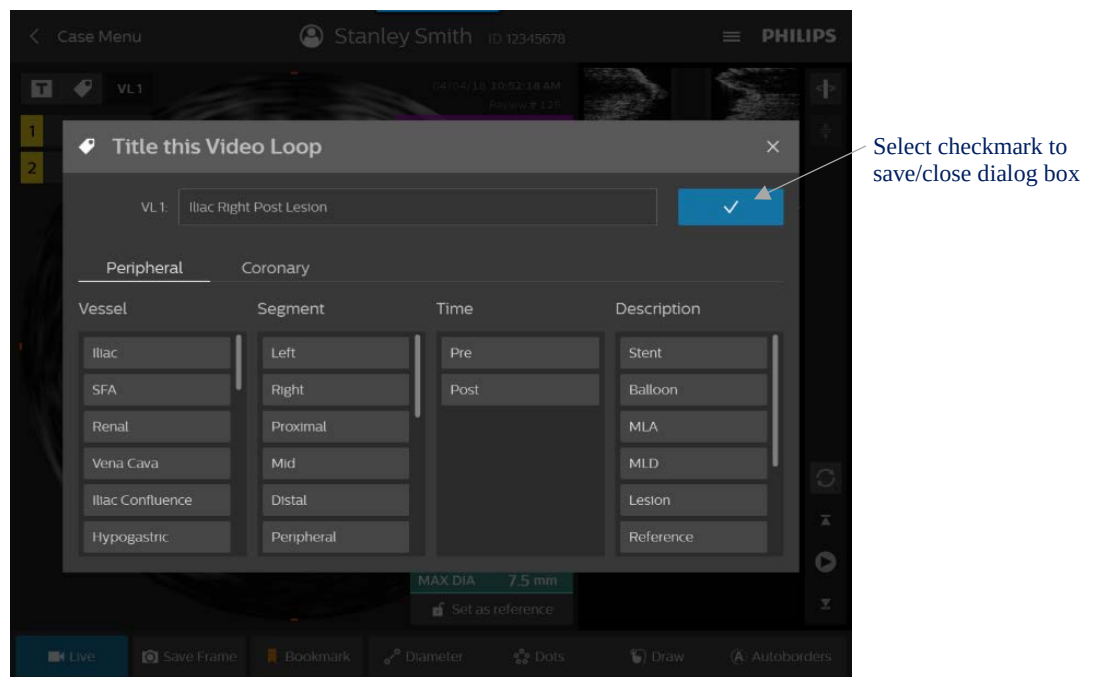


Figure 76: Title Video Loop Dialog Box

3. Predefined title elements can be selected for the coronary and peripheral vasculatures, including vessel, segment, time, and description.
4. After title is entered in VL field, select blue checkmark box to save/close dialog box. The video loop title displays on screen image.

Creating Measurements and Annotations

- To delete a title, perform the steps above and re-enter desired title in the VL field of video loop dialog box, or clear text and select blue checkbox button.

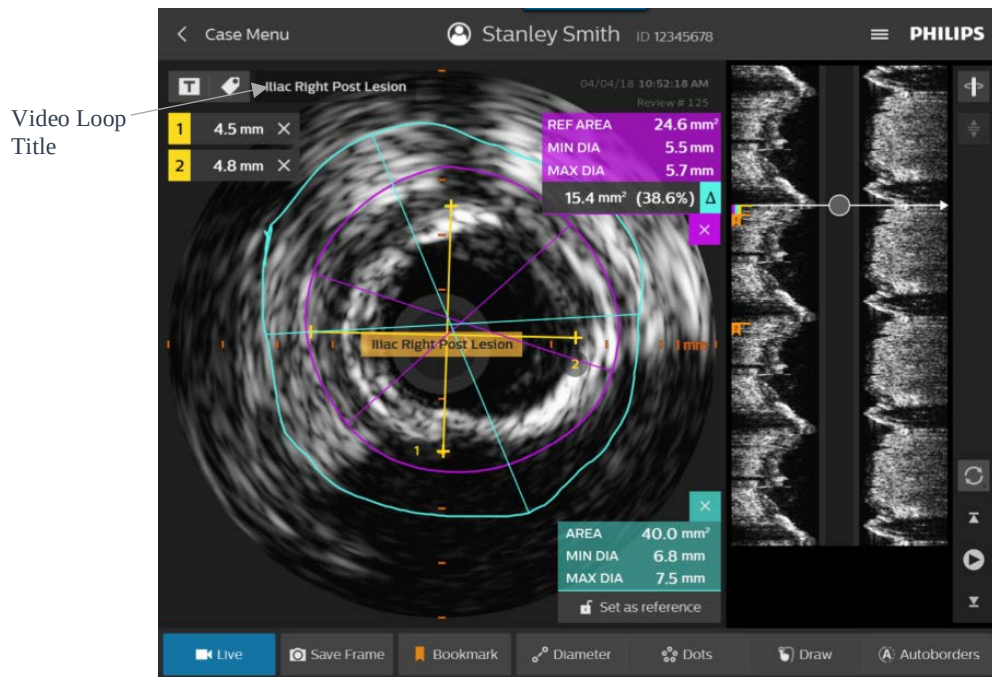


Figure 77: Video Loop Title

NOTE: PV .035 catheter has peripheral labeling options only.

Adding Image Frame Annotation

- Add an annotation to a frame by selecting the 'T' in a box icon, located next to the label icon. The Add Annotation dialog box displays.

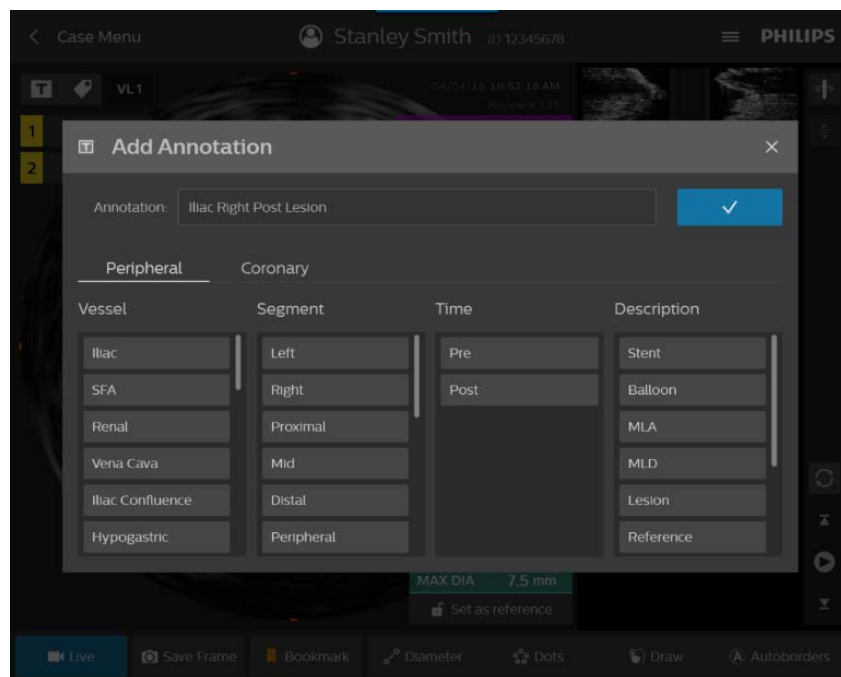


Figure 78: Image Annotation Dialog Box

Creating Measurements and Annotations

2. Predefined annotation elements can be selected for the coronary and peripheral vasculatures, including vessel, segment, time, and description.
3. After annotation is entered in annotation field, select blue checkmark box to save/close dialog box. The annotation displays on screen image.

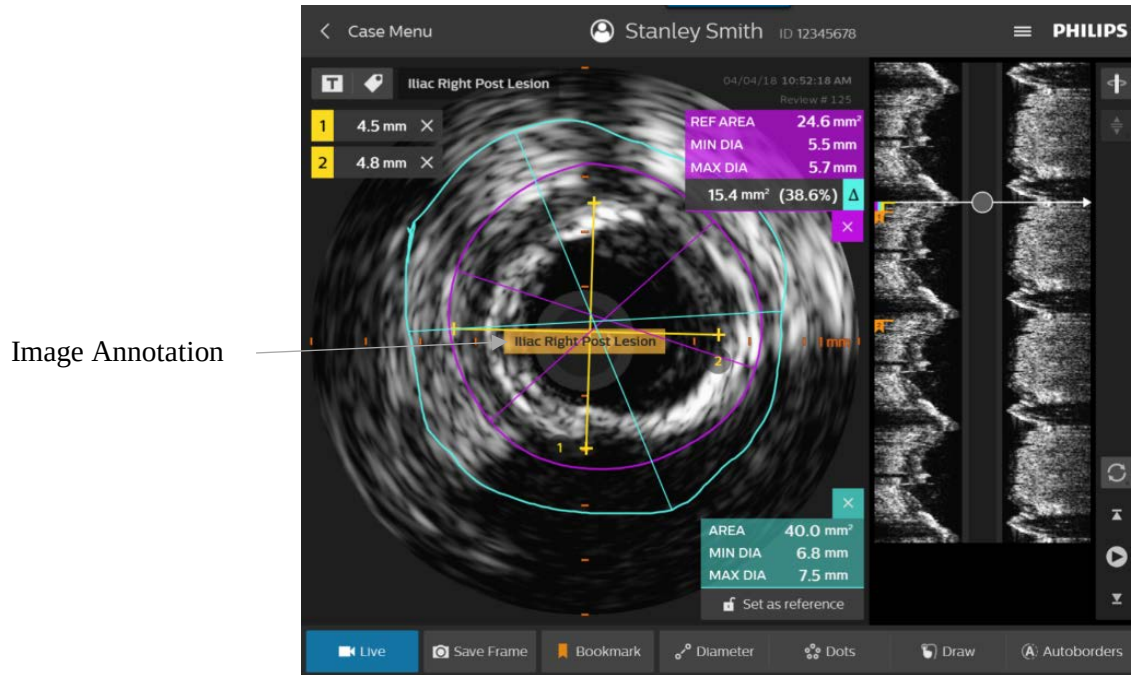


Figure 79: Create Image Annotation

4. To reposition an annotation on an image, select annotation and drag it to another desired location.
5. To correct an annotation, perform the steps above and re-enter desired annotation in the annotation field of annotation dialog box.

Chapter 10. Using ChromaFlo Feature

Overview

The ChromaFlo option provides a visual depiction 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 in which there is no or little presence of flow are presented as clear or non-colored overlay. These regions appear gray in the standard display. Regions in images contain red-yellow overlay based on the strength of the flow detected. In general, red means slower flow, yellow faster flow.

The ChromaFlo processor detects 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. This is possible by utilizing ultra-high speed electronics and Philips's proprietary algorithms.

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

NOTE 1: ChromaFlo displays targeted region of interest (ROI) and may not include entire vessel diameter. To help ensure optimal focal area, adjust ROI on vessel of interest as necessary. Beyond ROI, any clinical phenomena can be identified using grayscale mode (i.e., ChromaFlo turned off).

NOTE 2: Available on Eagle Eye Platinum, Pioneer Plus, Visions PV .014P and Visions PV .018 catheters.

NOTE 3: The ChromaFlo feature cannot be activated while recording and therefore has to be activated prior to recording.

Using ChromaFlo Feature

NOTE 4: In ChromaFlo mode, the frame rate is 22 frames per second for EE/PioneerPlus/Visions PV.014P catheters and is 20 frames per second for Visions PV .018 catheter.

Activating the ChromaFlo Feature

Open the Adjust Image dialog box in Live mode and toggle the ChromaFlo On (green state).

Controlling the Sensitivity

The Sensitivity setting can be increased to intensify the brightness of flow overlay, or it can be decreased to diminish the brightness of blood flow overlay. Select from Low, Medium and High settings to change the Sensitivity.

NOTE: Decreasing ChromaFlo Sensitivity may diminish brightness of slow moving blood.

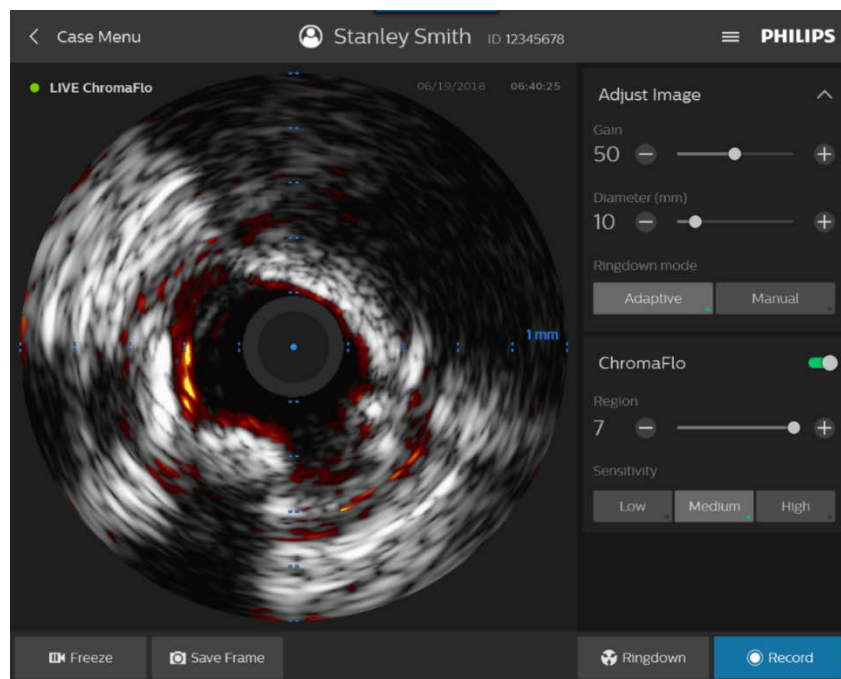


Figure 80: ChromaFlo Image View

Setting the Region of Interest

Setting the Region of Interest restricts the flow display to a particular area of the ultrasound image concentric to the catheter. Change the Region of Interest setting by sliding the control toward either end. The Region of Interest circle (displayed during adjustment of this setting) on the screen image will be adjusted to correspond to your selection.

Value mappings for the Region of Interest range from:

Using ChromaFlo Feature

- Setting 1, corresponds to a Region of Interest diameter of 2 mm, i.e., ChromaFlo is not displayed beyond 1mm radius from the center of the catheter mask.
- Setting 7, corresponds to a Region of Interest diameter of 14 mm, i.e., ChromaFlo is not displayed beyond approximately 6.3 mm radius from the center of the catheter mask.

Each increment changes the diameter by approximately 2 mm.

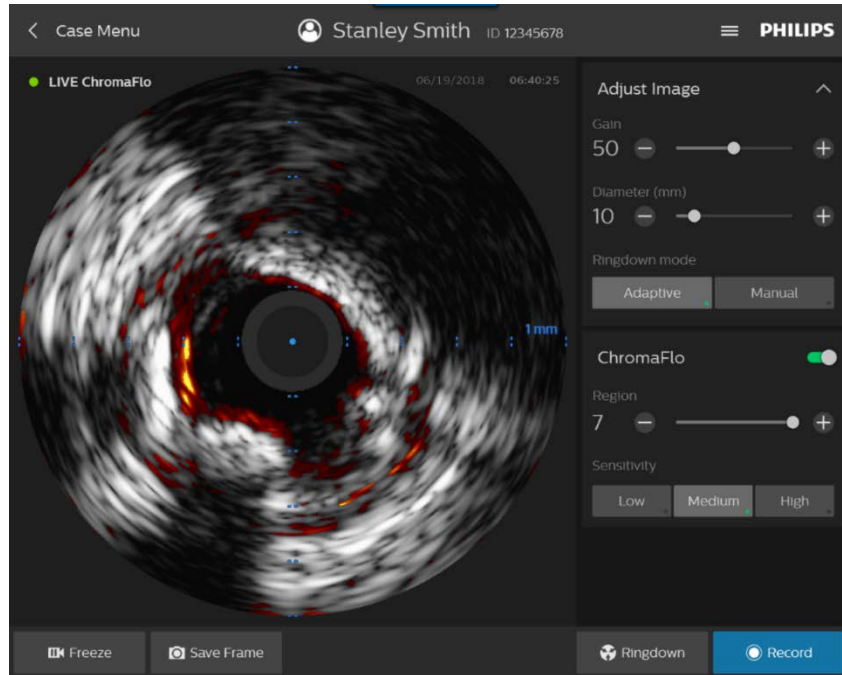


Figure 81: ChromaFlo Mode

Deactivating the ChromaFlo Feature

To deactivate the ChromaFlo feature, toggle the ChromaFlo On (green state) to ChromaFlo Off (gray state).

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Chapter 11. Reviewing IVUS Images

This chapter describes the process for reviewing IVUS images and the tools available for analysis.

Overview

The Case Menu provides a list of all the video loops and saved frames for the open case. Use this list to select the video loops or images to be reviewed.

Select Previous Cases at the Welcome screen to access Case Menu.

Use Case Menu to display the following:

- Video loops
 - Bookmarks within each video loop
- Saved frames
 - List of video loops and saved frames have parent/child relationships, that is, saved frames are indented under associated video loops for ease of reference

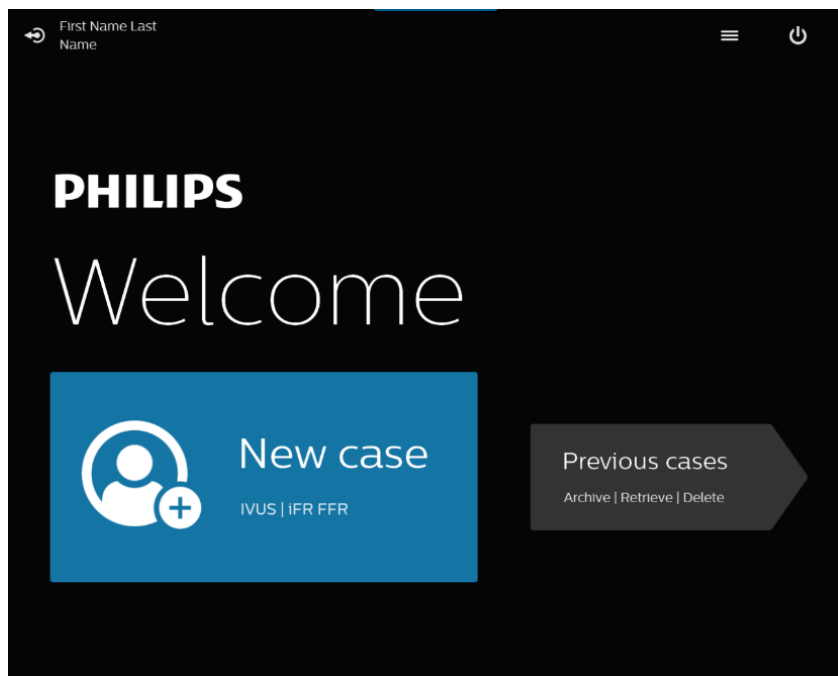


Figure 82: Select Previous Cases

Reviewing IVUS Images

Displaying Images

To view an image listed in the Case Log, select the desired image/video loop, which displays in Preview pane, located to the right of case list.

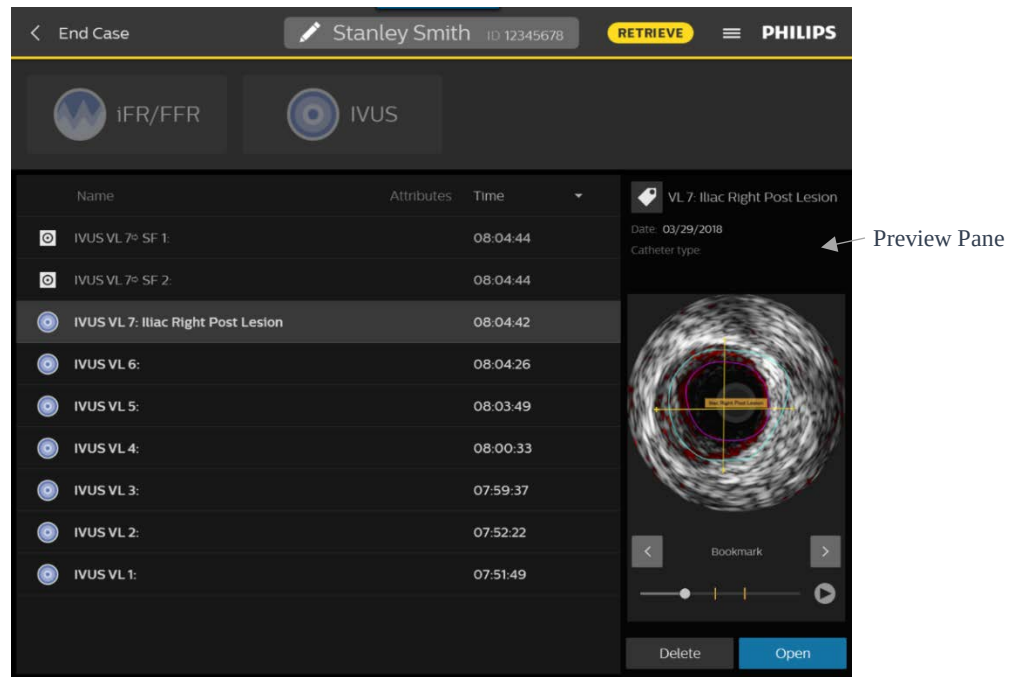


Figure 83: Case Menu

Image Menu

Various options associated with images may be accessed in the image preview pane including the following:

- To retile video loop (or frame), select the label icon, located above image. Note that date of video loop and catheter type are shown also.
- To display full view of video loop, select Open.
- To increment through image bookmarks (orange lines) and measurements (blue lines) along the video loop run, select forward and back arrows. Also, the video bar (video loop marker) can be manipulated for fine tuning.
- To view full video loop run, toggle play/pause (black arrow) button.
- To delete video loop, select Delete.

Reviewing IVUS Images

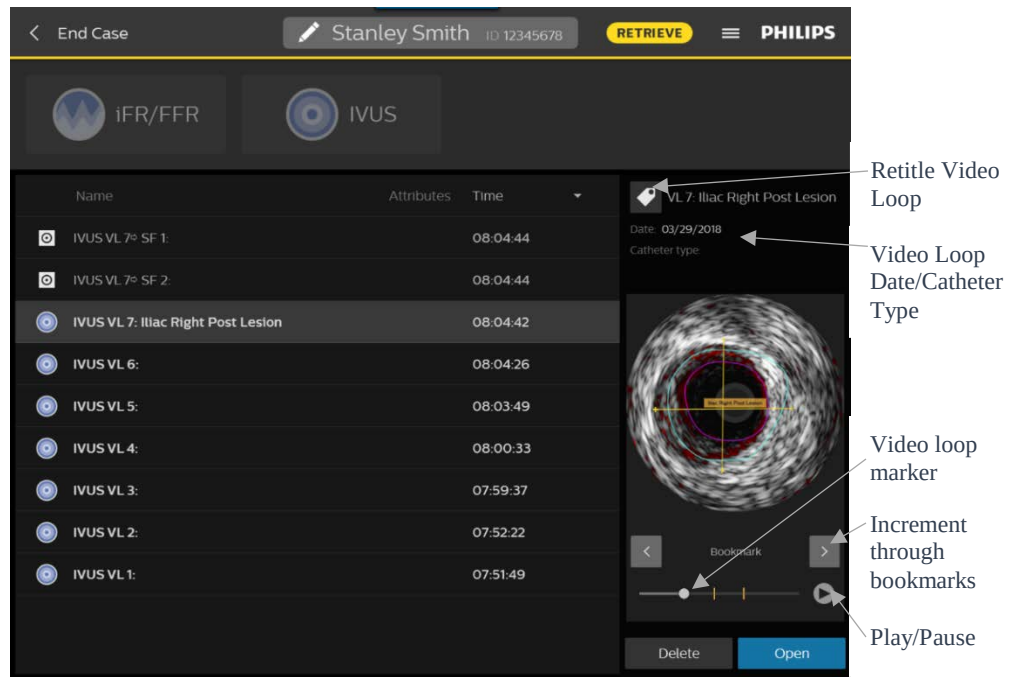


Figure 84: Image Preview

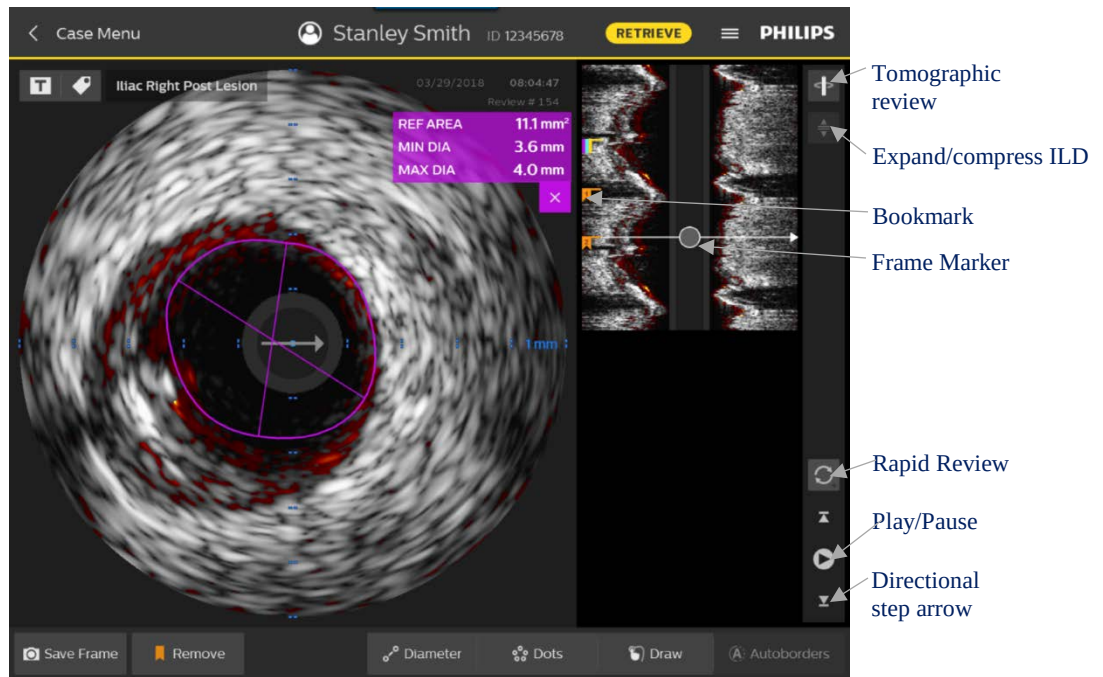


Figure 85: Image Full View

Reviewing IVUS Images

Reviewing Saved Frames

To review a Saved Frame:

1. Select desired saved frame from case list in Case Menu.
2. Make measurements and annotations in saved frames, when viewing them in grayscale mode, which can be found in the Making Measurements and Annotations chapter.

Reviewing Video Loops

To play back a video loop:

1. Select desired video loop from case list in Case Menu.
2. The video loop will begin playback.

Creating/Reviewing Bookmarks

Bookmarks can be created during playback of a video loop by selecting Bookmark option, located on the bottom icon ribbon. A bookmark will be created for the frame that is currently displayed at the time that the button is pressed.

Bookmarks can be reviewed, selecting marked frames from preview pane in the case list screen.

In-Line Digital (ILD) Display

The In-Line Digital (ILD) displays a sagittal view of the blood vessel.

NOTE: ILD display/measurement only applies to IVUS rotational catheters. See Rotational Option Manual for more information on IVUS rotational catheters.

Navigating the ILD

Methods of scrolling through frames in the ILD include the following:

- Select Frame Marker to navigate the ILD. The cross-section, tomographic view on the left moves in concert with the Frame Marker and vice versa. Selecting Revolve performs a 360° review of the cross-section, tomographic image.
- Select directional up/down arrows to step through video loop. Select Pause/Play icon to replay video.

Reviewing IVUS Images

When the video loop is playing, a white frame marker moves downward to represent movement through the frames captured when the loop was recorded. The tomographic image changes to correspond to the location of the frame marker in sagittal view. When the frame marker reaches the end of the video loop, it starts at the first frame and continues until the user stops playback. Use the scroll bar to scroll through the image.

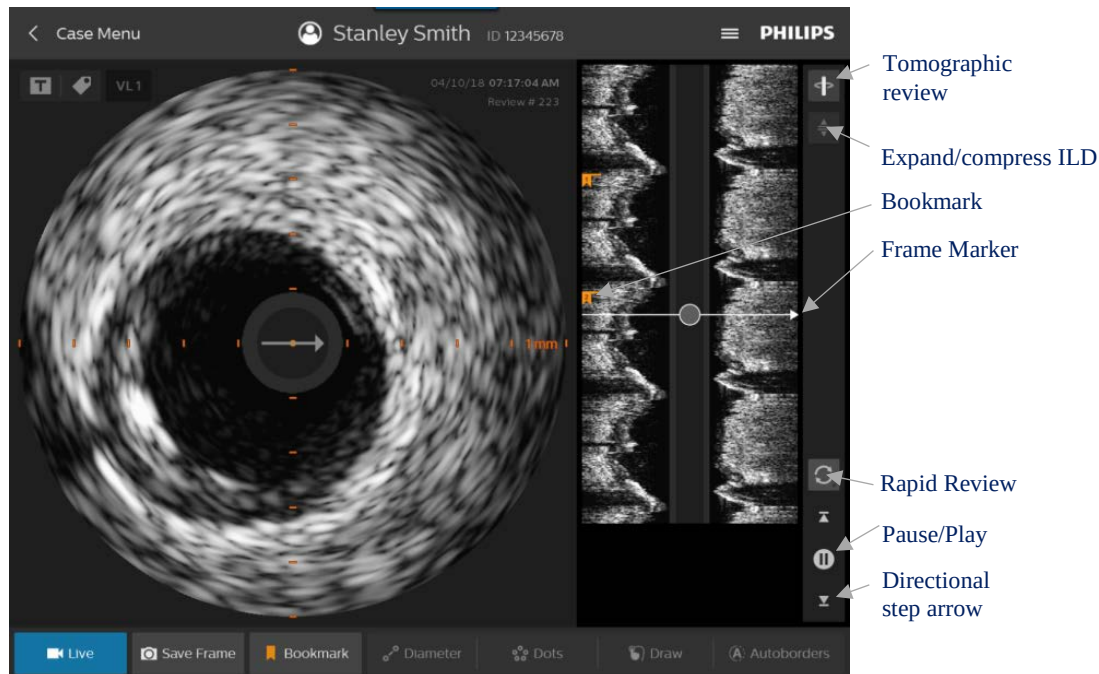


Figure 86: ILD Navigation

NOTE 1: The markers in the ILD are active only when a video loop is paused.

NOTE 2: The scroll bar is active only when the video loop exceeds the viewing area in the ILD.

NOTE 3: There are up to 5400 image frames in a loop. The scroll bar represents a 347-frame section of the video loop; it is sized proportionally to the size of the entire video loop. For example, if all 5400 frames were captured, the scroll bar would be quite small, but if only 600 frames were captured the scroll bar would be larger than half the scroll box.

Rotating the ILD

The 360° rotation of the ILD allows for complete vessel visualization. An arrow on the cross-sectional tomographic image corresponds to the angle represented by the straight line arrow cursor in the ILD. The default position of the arrow is at 90 degrees (the 3 o'clock position). See figures below for a graphical representation that describes how the ILD displays the tomographic view.

Reviewing IVUS Images

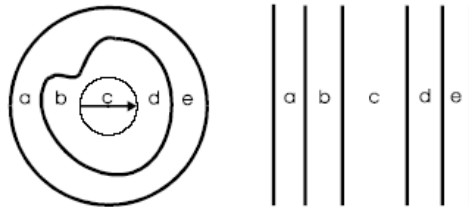


Figure 87: ILD Display of Tomographic View

To rotate the vessel:

1. Press the Rotate icon, located on the upper right corner of ILD (see figure below).
2. Or, press on a desired location along diameter line and drag the line (rotating vessel image) to a desired point. The sagittal ILD image moves in concert with the cross-sectional tomographic image.

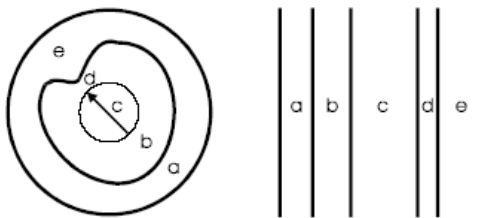


Figure 88: Rotated ILD Display of Tomographic Image



Figure 89: Rotate Tomographic Image

Chapter 12. Ending an IVUS Case

Overview

An open case exists after the patient information and/or image data is collected. Once the case is complete, you must end the case before starting a new one. Ending a case is equivalent to saving the case to the system’s hard drive. Alternatively, you may choose to end the case.

NOTE: If power is shut off before ending a case, restart the system. When the system restarts, the interrupted case (along with other cases) displays in the Archive and Retrieve screens.

Ending a Case

To end the current case:

- 1. Verify patient data is correct or perform edits as needed.
- 2. Select End Case, located on upper left corner of Case Menu screen.

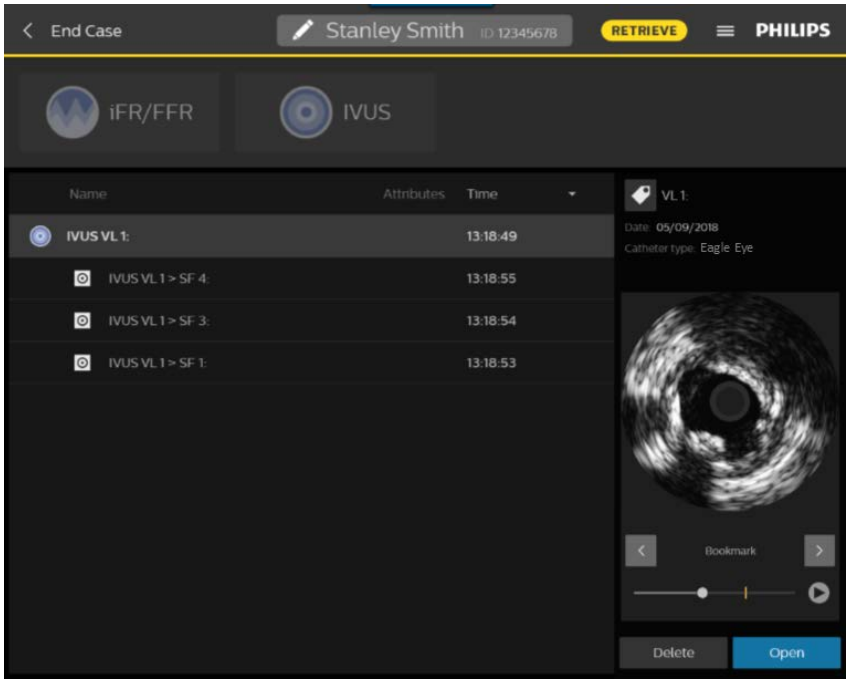


Figure 90: End Case

Ending an IVUS Case

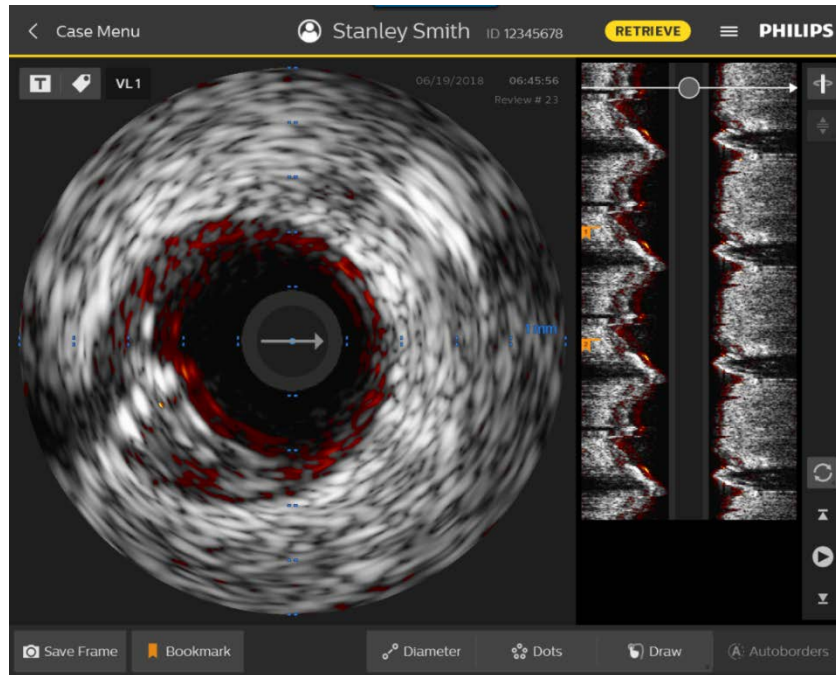


Figure 91: Open Case

3. The case is automatically saved to the hard drive and appears in the archive with a Case Type, labeled Original.

NOTE: Only 40 cases are allowed on the system's hard drive at one time.

If attempting to end a case, with an exceeded limit of 35 cases on the system, a prompt displays, requiring user to delete unneeded cases. If a case ends with 40 cases on the system, a prompt displays, requiring user to delete a case to accommodate the next procedure.

Deleting a Case

To delete the current case, do the following:

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

Chapter 13. Archiving a Case

Overview

A maximum of 40 patient cases can be stored on the system's hard drive. Saving to a hard drive is faster than saving to a DVD or optical media.

However, archiving a case to a DVD allows for viewing or exporting of images or video loops on other PCs.

Patient data is archived in Read-Only format. Archive patient data regularly.

NOTE: Since archiving can expose patient names unintentionally, the qualified user is highly encouraged to perform archival process in a safe location, under appropriate supervision to avoid comprising patient information, potentially posing a security and privacy risk.

Archiving Options

Cases can be archived using any of the following:

- Recordable DVD, Blu-ray drive
- DICOM Network Interface Port

What Data is Archived

The data you entered in the Patient screen is archived, as well as the video loops, saved frames and measurements.

CAUTION: A maximum of 40 cases can reside on the system's hard drive. Once this limit is reached, archive and delete a case. To free up more hard disk space, configure the system to delete the oldest archived case. Archive cases to a DVD on a regular basis to prevent exceeding 40 case limit.

Removing Patient Information/Archived DVD/Blu-ray

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

Archiving Using DVD/Blu-ray Disk

When a case is saved to DVD or Blu-ray disk, a DICOM Viewer is automatically installed on the disk as well. This allows viewing cases on a PC at a later time. Additionally, to view archived cases on a PC/laptop, a DVD (Blu-ray) driver needs to be installed. To begin archiving the case:

1. Select Archive tab. The Archive Case screen displays.
2. Select a case, checking case box.
3. Insert DVD.

Archiving a Case

4. Select Archive button.

The system first checks to be sure a disk is in the DVD drive. If no DVD/BR drive is in place, or if the disk in place does not have enough storage space, a message alert will display. If the disk contains adequate storage space for the current case, the system will save that case to the disk in DICOM format. A progress bar on the screen and accompanying messages indicate how much data has been transferred and how much data remains to be transferred.

NOTE: Multiple cases can be archived and deleted at one time.

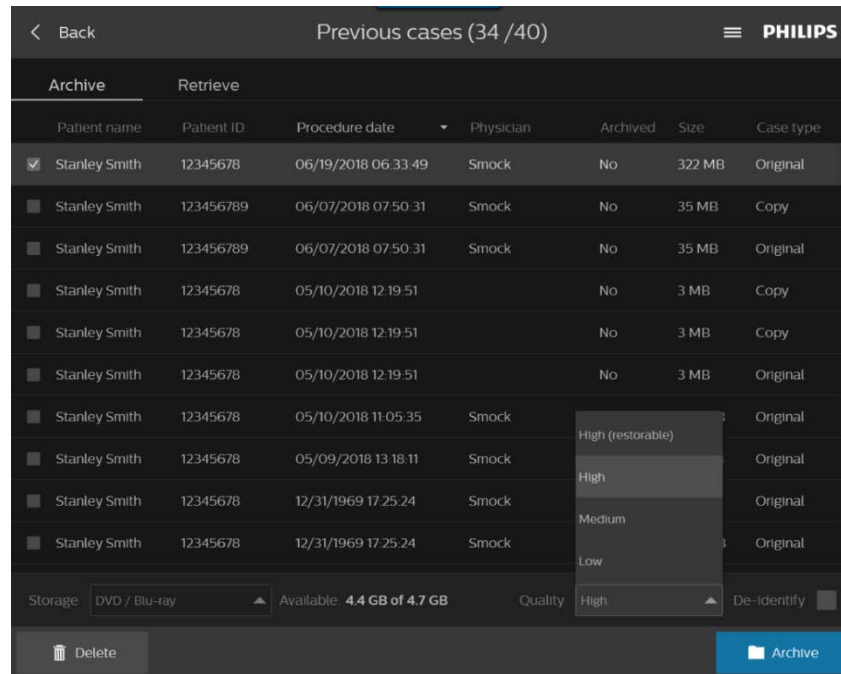


Figure 92: Archiving a Case

DVD/BR quality options are High (restorable) meaning data can be restored from the disk onto an IntraSight system for review. High quality increases file size, low quality decreases file size.

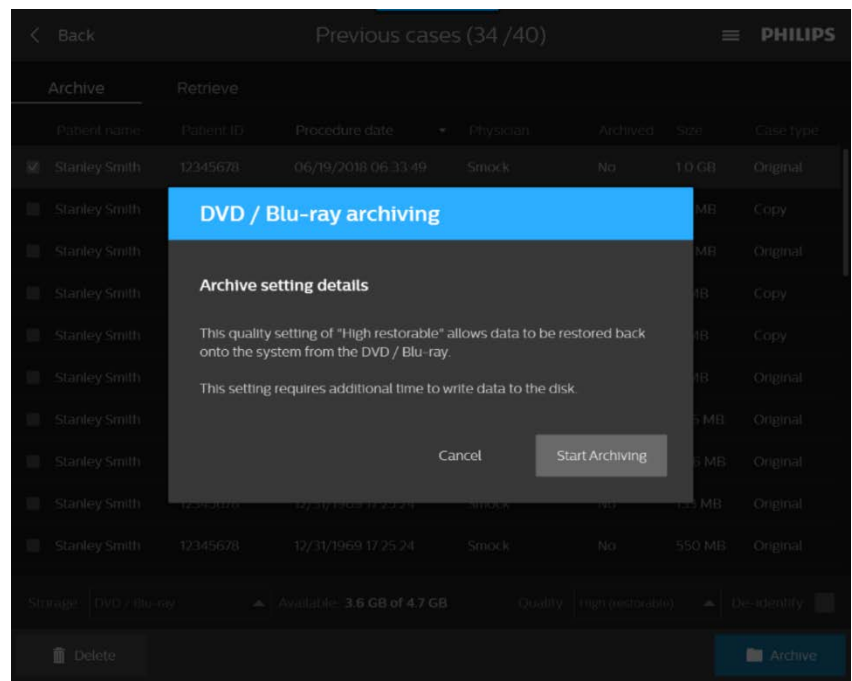


Figure 93: Archive to DVD – High Restorable

Additionally, archiving to DVD/BR using High quality setting increases archiving speed and file size as shown in figure below.

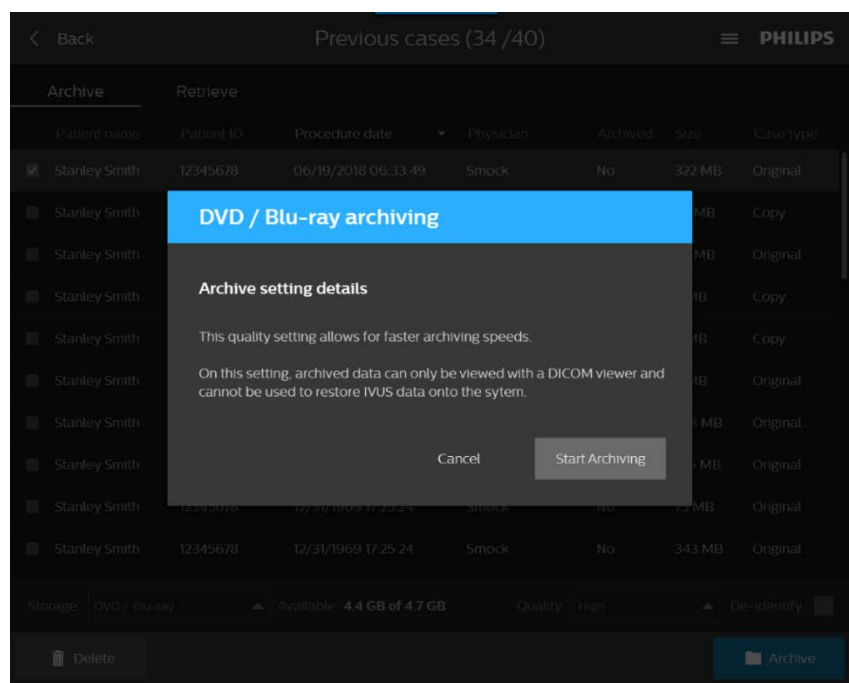


Figure 94: Archive to DVD – High Quality

Archiving a Case

CAUTION: If the system power is turned off while data is being written to the DVD/BR, you could damage the DVD/BR directory structure. DVD/BR archived cases may be inaccessible by both standard DVD/BR readers and DVD/BR drives. Avoid turning 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.

DVD/Blu-ray Use Cautions and Warnings

- The DVD/BR drive may not initialize if there is a disk inserted in the drive when the system is started. If this occurs, a message will appear after the hardware initialization phase. Remove disk and reboot the system. Allow the system to fully initialize before reinserting the DVD/BR.
- You can set the DVD/BR drive to perform a verification pass when data is written. However, the potential exists that a defective DVD can be created without your knowledge. After storing a case to a DVD/BR, do not delete it from the hard drive before verifying that it was properly archived by first retrieving the case from the DVD/BR and then reviewing it.
- To prevent the potential loss of data, always use a new DVD/BR when archiving patient cases to the DVD/BR.
- Do not share DVDs from other non-IntraSight Vascular System or computers with the Vascular System; instead keep a separate supply of DVDs just for the system. If you save cases to DVDs that were created on a different system or computer, the potential for data corruption exists.

Archiving Using DICOM

DICOM stands for Digital Imaging and Communications in Medicine. It is an image format for medical images that has been standardized so that images from different types of medical electronic equipment can be shared on a common computer network. The intravascular ultrasound images from your Philips system can be sent to a network within a hospital or clinic, or to a network of health care providers. Sending images to a remote computer using a standardized format may be able to provide physicians with quicker access to medical information for more rapid diagnoses and treatment decisions.

The DICOM Settings should be set up by either a Philips Field Service representative or the Information Systems manager or network administrator at your facility.

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

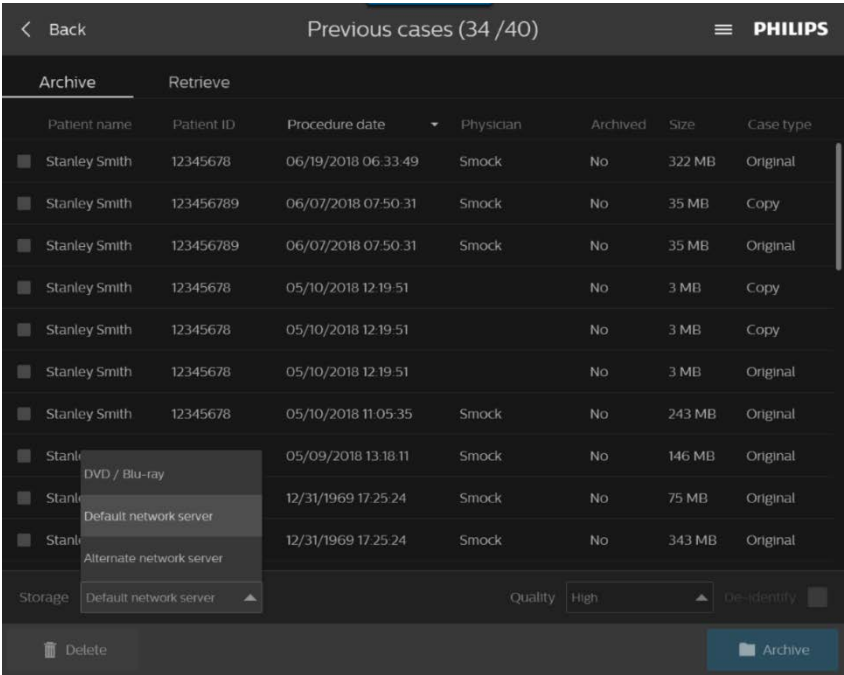


Figure 95: Archive to DICOM Network

Archive to alternate server, by selecting Alternate Network Server option from Storage option list. The following screen displays, allowing user to select alternate server by highlighting desired server (in this case, only one) and pressing Select blue box.

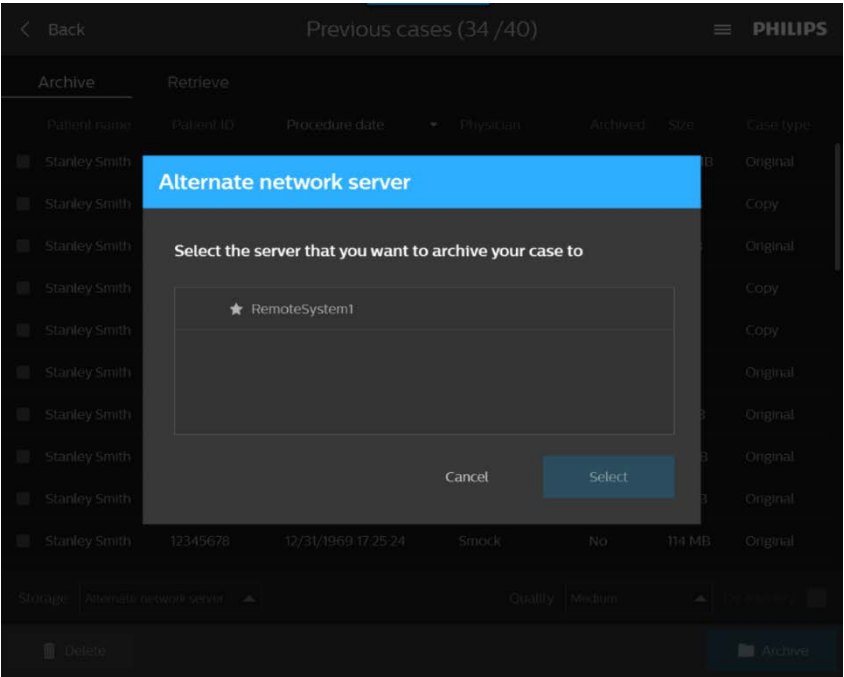


Figure 96: Archive - Alternate Network Server

Archiving a Case

Case file size can be manipulated using Archive compression feature, located above the Archive button. High quality denotes maximum file size, low quality denotes reduced file size.

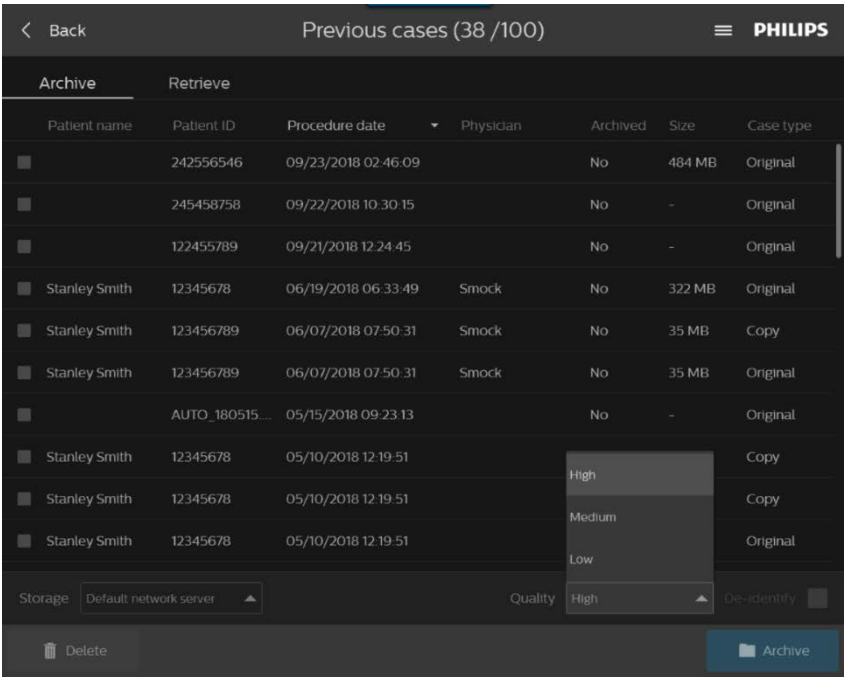


Figure 97: Archive Compression

Exporting Screen to USB

To export a desired screen image to a USB memory stick, enable export by checking the USB media radio button, located in Service, Security Export settings. (This is performed by an administrator or Philips Field Representative.)

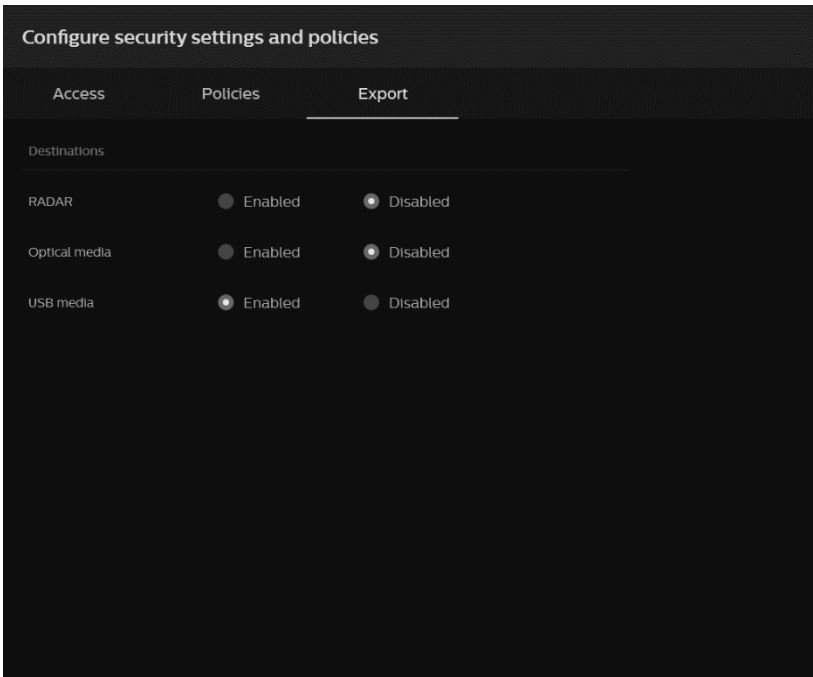


Figure 98: Export USB Media Setting

At a screen image, select Export screen to USB option from the three line icon, located next to the Philips logo.

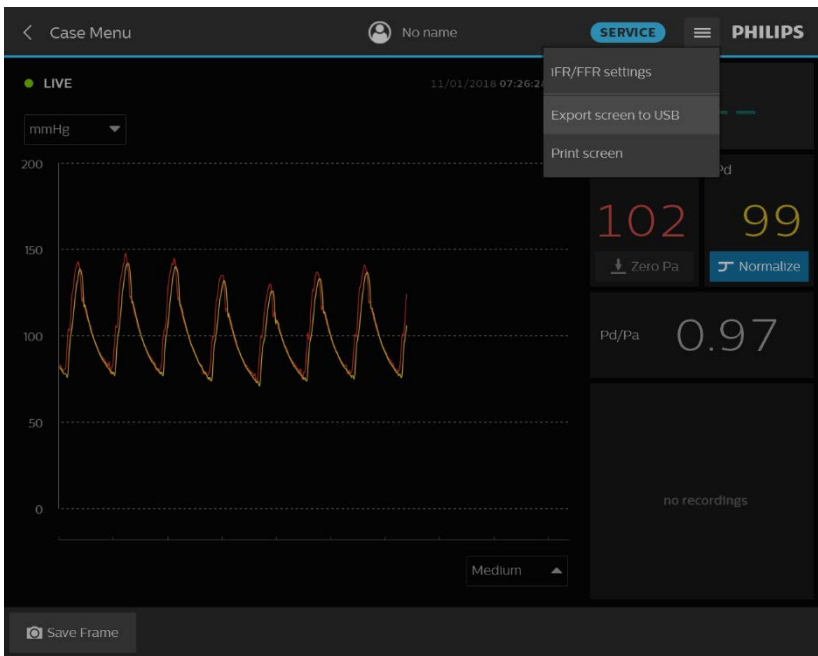


Figure 99: Export screen to USB

Archiving a Case

USB screen export is successful.

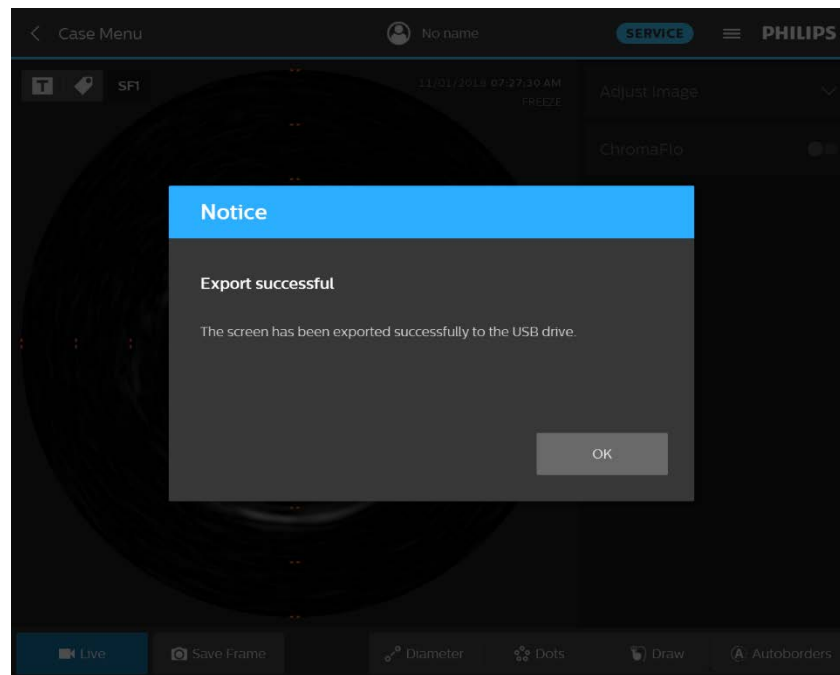


Figure 100: USB Screen Export Successful

Protecting Patient Information

CAUTION: Use caution in exporting or saving patient information to local hard disks or USB memory sticks.

To safeguard a patient’s name when downloading patient information to a USB memory stick, the patient name can be aliased or de-identified.

- 1. First, check box, located to the left of a patient’s name in Archive.
- 2. Check the De-identify blue box, located on the lower right corner of the screen.
- 3. Select Archive.

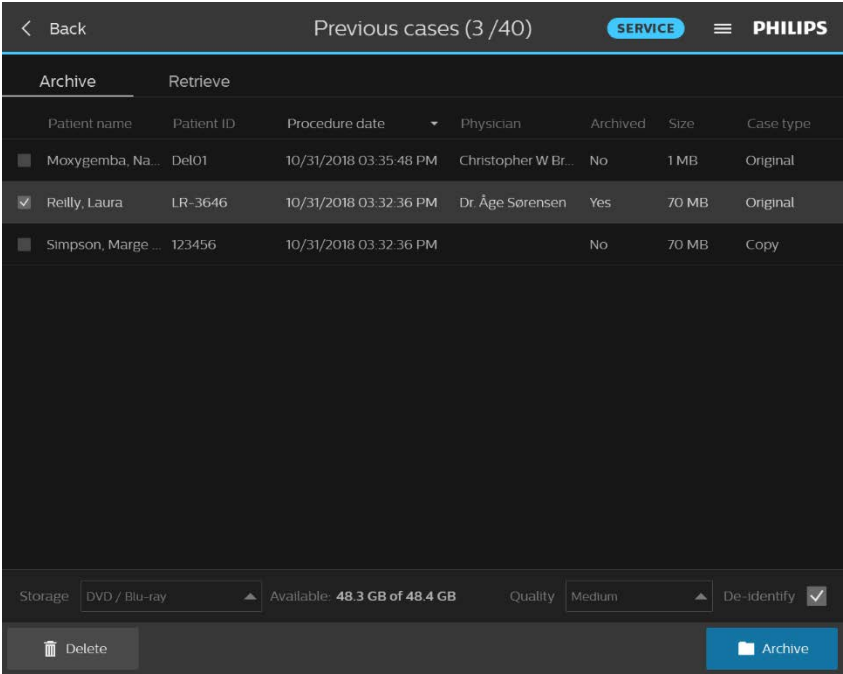


Figure 101: De-identify Patient Name

A dialog box displays, allowing the user to create an alias or a short note in place of the patient’s name. When the archived case is redisplayed, the de-identified case displays the alias or short note instead of patient name.

Archiving a Case

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Chapter 14. Retrieving and Deleting Cases

Overview

This chapter provides the instructions for retrieving a case that has previously been ended to review and/or edit case data. Cases can be retrieved from the system hard drive and optical media.

In addition, instructions are provided for deleting an IVUS case from the hard drive.

Retrieving and Deleting Cases

Select Previous Case

To select a previous case to view archive, retrieve or delete cases, select the Previous Cases.

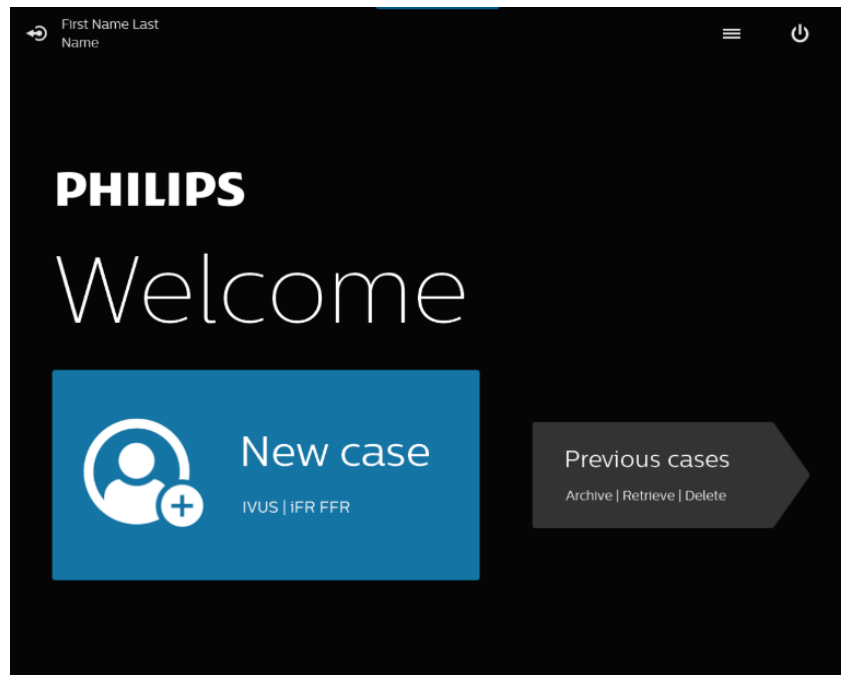
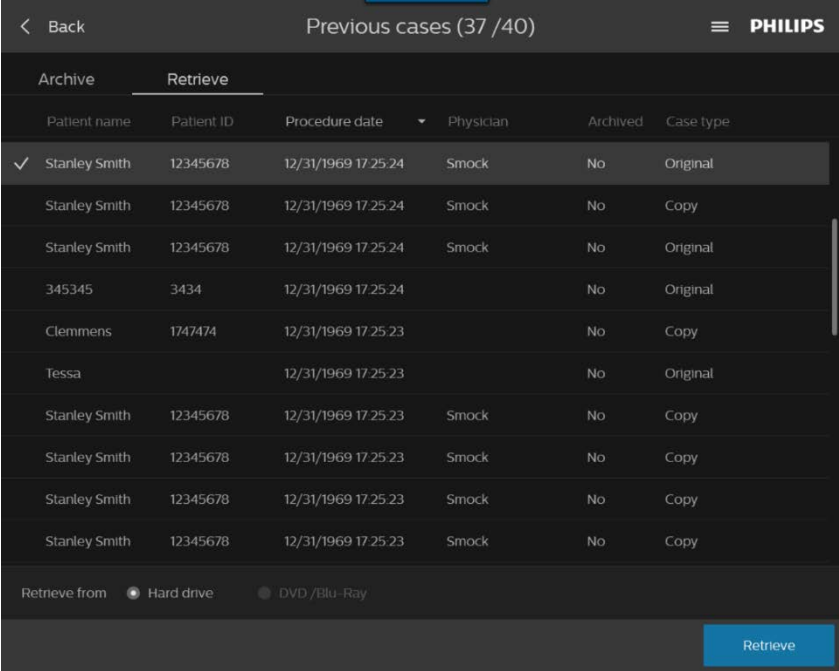


Figure 102: Welcome Screen – Previous Cases Option

From the Previous Cases screen, the Retrieve tab allows viewing of cases, stored on the system, or retrieval of cases from an appropriately archived DVD or Blu-ray disk.

Sort cases by pressing on title of each column. Additionally, if field does not display the full field content, and ellipsis (...) displays more cases can be viewed, scrolling down.

Retrieving and Deleting Cases



Previous cases (37 / 40)						
PHILIPS						
Archive Retrieve						
	Patient name	Patient ID	Procedure date	Physician	Archived	Case type
✓	Stanley Smith	12345678	12/31/1969 17:25:24	Smock	No	Original
	Stanley Smith	12345678	12/31/1969 17:25:24	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:24	Smock	No	Original
	345345	3434	12/31/1969 17:25:24		No	Original
	Clemmens	1747474	12/31/1969 17:25:23		No	Copy
	Tessa		12/31/1969 17:25:23		No	Original
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
Retrieve from ☒ Hard drive ☐ DVD /Blu-Ray						
						Retrieve

Figure 103: Previous Cases – Retrieve Option

Cases can be retrieved from hard drive or DVD/Blu-ray.

Retrieving and Deleting Cases

Retrieve a Case

To retrieve a case:

1. Select Retrieve tab.

Back

Previous cases (37 / 40)

PHILIPS

Archive

Retrieve

	Patient name	Patient ID	Procedure date	Physician	Archived	Case type
✓	Stanley Smith	12345678	12/31/1969 17:25:24	Smock	No	Original
	Stanley Smith	12345678	12/31/1969 17:25:24	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:24	Smock	No	Original
	345345	3434	12/31/1969 17:25:24		No	Original
	Clemmens	1747474	12/31/1969 17:25:23		No	Copy
	Tessa		12/31/1969 17:25:23		No	Original
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy
	Stanley Smith	12345678	12/31/1969 17:25:23	Smock	No	Copy

Retrieve from

Hard drive

DVD /Blu-Ray

Retrieve

Figure 104: Retrieve Tab

2. To retrieve a case from hard drive or media, select Hard drive or DBD/Blu-ray option
3. Enter a checkmark to the left of desired case.
4. Select Retrieve box, located on lower right corner of case list screen. The retrieved case is then displayed as shown in following figure.

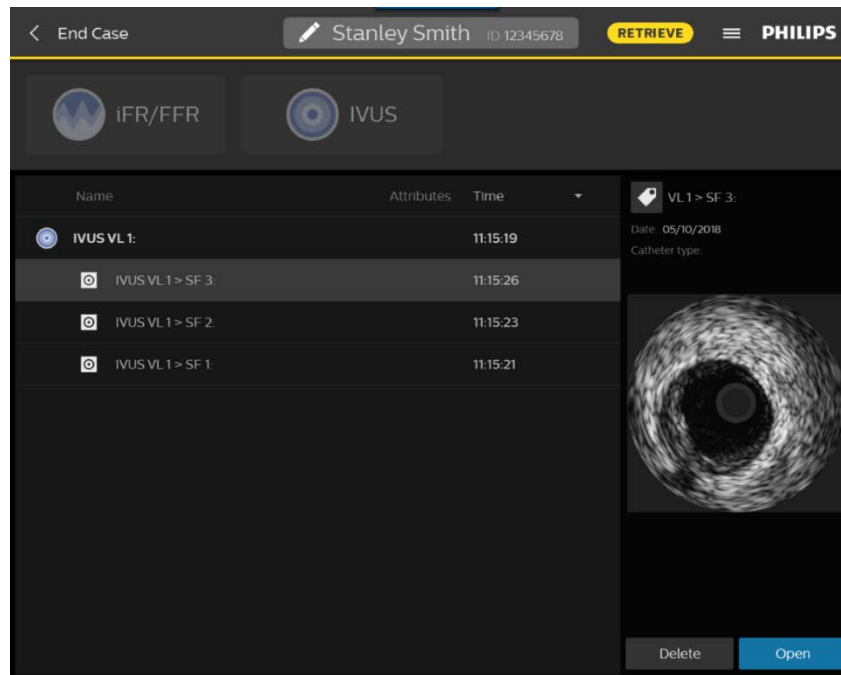


Figure 105: Retrieved VL/SF

Delete a Case

Patient cases can be deleted from the hard drive, but not from the DVD/BR. To delete a case from the hard drive, first select one or multiple cases from the list, and choose Delete button, located on the lower left corner of the screen.

Retrieving and Deleting Cases

A Delete Case dialog prompt displays requesting the user to confirm deletion.

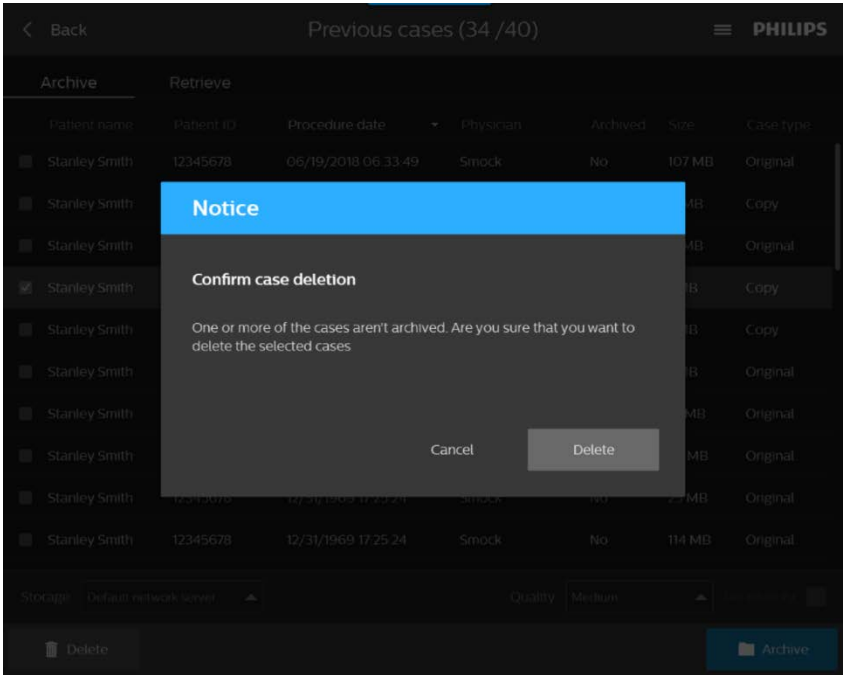


Figure 106: Delete Case Confirmation

Chapter 15. Troubleshooting

Message Alerts

Message	Reason	Resolution
The system is overheating. Please shutdown the system.	Cooling fan failure. Also, may occur with prolonged use when draped.	1. Shutdown system and allow to cool. 2. Clear any obstruction to rear air vents. 3. Contact Technical Support if fans not operating or if problem re-occurs after Steps 1 & 2 above are completed.
PIM Busy – unable to start imaging. Please wait and try again.	PIM connection process stalls.	See above.
Case limit reached. Please remove archived cases before continuing.	Case limit exceeded.	Remove archived cases.
A maximum of 4 diameter measurements is allowed. Do you want to delete diameter measurement 1?	The maximum limit of 4 diameter measurements has been reached.	To perform a new diameter measurement, select Delete on warning notification to delete diameter measurement #1.
A maximum of 2 measurement curves is allowed. Do you want to delete measurement curve 1?	The maximum limit of 2 curve measurements has been reached.	To perform a new curve measurement, select Delete on the warning notification to delete curve measurement #1.
Locking this measurement will replace the existing locked measurement. Are you sure you want to lock this measurement?	A curve measurement is already locked and is a reference for the Video Loop.	To change the reference curve measurement for the video loop to the selected one, select Lock Measurement on warning notification.
Catheter Fault <ERROR CODE> detected. Please replace the catheter.	Catheter fault IVACEPI0008' : 'Catheter Initialization Timeout'	1. Disconnect catheter. 2. Reset PIM by disconnecting/reconnecting to PIM cable. 3. Follow screen commands.

Troubleshooting

	'TVACEPI0020' : 'Catheter Not Supported' (Example: Unsupported Catheter Avamar is used for the IntraSight system) 'TVACEPI4080' : 'Catheter Current Failed' 'TVACEPI4090' : 'PIM Current Failed' 'TVACEPI6010' : 'Catheter Failed' 'TVACEPI6020' : 'Catheter Eeprom Checksum Failed' 'TVACEPI6030' : 'Catheter Eeprom Read Failed' 'TVACEPI6090' : 'Catheter Eeprom Read Failed' 'TVACEPI6100' : 'Catheter Eeprom Read Timeout' 'TVACEPI6110' : 'Channel Match Set Fail' 'TVACEPI6120' : 'Catheter Map Set Failed' 'TVACEPI6130' : 'Firmware FPGA Reconfig Request Failed' 'TVACEPI6140' : 'Firmware Config File Parse Failed' 'TVACEPI6150' : 'FPGA Reconfig Failed' 'TVACEPI6160' : 'RGC Write Failed'	4. If fault re-occurs or persists, replace catheter and try again before contacting Technical Support.
Catheter <NAME> not supported. Please replace the catheter.	Catheter supported by hardware. However, not supported by IntraSight software.	Use PV.014, PV.018, PV.035, Pioneer Plus, and Eagle Eye Platinum catheter family with IntraSight software only.
PIM Fault <ERROR CODE> detected. Please disconnect and reconnect the PIM. If the problem persists, shut down the system and contact Technical Support.	PIM fault 'TVACEPI0007' : 'PIM Initialization Timeout'. PIM failed to initialize within 5 seconds.	1. Disconnect catheter. 2. Reset PIM by disconnecting/reconnecting to PIM cable. 3. Follow screen commands. 4. If fault re-occurs or persists, replace catheter and try again before contacting Technical Support.
Recording has stopped. Maximum video frame limit has been reached.	Video recording limit reached. The limit is 5400 frames.	Dismiss the displayed warning notification.

Troubleshooting

Video Loop storage is almost full. Please delete video loop(s) to free up space.	- The remaining number of IVUS video loops possible in the case is less than or equal to 2 (permissible limit is 30), i.e., there are 28 or more video loops in current case. - The remaining space available in the case is less than 7.91 GB of the permissible 16.76 GB.	Delete video loops from the Case Log.
Video Loop storage is full. Please delete a video loop to record a new image.	- IVUS video loops in the case have reached maximum limit of 30. - The remaining space available in the case is less than 5.27 GB of the permissible 16.76 GB.	Delete video loops from the Case Log to continue acquiring new pullbacks.
Frame storage is almost full. Please delete saved frame(s) to free up space.	- The remaining number of IVUS save frames possible in current case is less than or equal to 2 - permissible limit is 99, i.e., there are 97 or more saved frames in case. - The remaining space available in the case is less than 7.91 GB of the permissible 16.76 GB.	Delete saved frames from the Case Log to continue saving new frames.
Frame storage is full. Please delete a frame to save a new image	- IVUS saved frames in the current case have reached the maximum limit of 99. - The remaining space available in the case is less than 1 MB of the permissible 16.76 GB.	Delete saved frames from the Case Log to continue acquiring new pullbacks.
Error recording the video loop. No data was acquired. Please try again.	A very short video loop was acquired - 0 frames available to store.	Dismiss the displayed warning notification and perform a new pullback if necessary.
Shutting down the system will abort the case archiving.	Pressing the power button while archiving.	Selecting yes will turn off the application.
Hardware Fault (ERROR CODE> detected. Please contact Philips Field Service.	Hardware fault. The system can't image, but case data is still accessible 'IVACEPI0001' : 'ACE card driver failure' - driver failure 'IVACEPI0008' : 'Catheter Initialization Timeout' 'IVACEPI0004' : 'Invalid ACE card Mode detected' 'IVACEPI0010' : 'ACE Plugin Initialization Failed' (exception)	Contact Technical Support.

Troubleshooting

	'TVACEPI0011' : 'Recovery Image FPGA detected.' 'TVACEPI0012' : 'Recovery Focus FPGA detected.' 'TVACEPI0014' : 'Recovery MCU detected.' 'TVACEPI0016' : 'No VPIP Connection with the MCU' (firmware crash) 'TVACEPI0018' : 'Program Error: Structured Exception' 'TVACEPI0021' : 'THERMAL SHUTDOWN' 'TVACEPI1100' : 'FPGA Temperature High' 'TVACEPI1110' : 'FPGA Temperature Low' 'TVACEPI1120' : 'FPGA IntraSight Voltage High' 'TVACEPI1130' : 'FPGA IntraSight Voltage Low' 'TVACEPI1140' : 'FPGA Auxiliary Voltage High' 'TVACEPI1150' : 'FPGA Auxiliary Voltage Low' 'TVACEPI1160' : 'System Flash Test Failed' 'TVACEPI1170' : 'System Flash Cache Test Failed' 'TVACEPI1180' : 'Nand Flash Test Failed' 'TVACEPI1240' : 'ACE Card File System Failed' 'TVACEPI7030' : 'FPGA Temperature Low' 'TVACEPI7040' : 'FPGA IntraSight Voltage High' 'TVACEPI7050' : 'FPGA IntraSight Voltage Low' 'TVACEPI7060' : 'FPGA Auxiliary Voltage High' 'TVACEPI7070' : 'FPGA Auxiliary Voltage Low' 'TVACEPI7080' : 'FPGA Config File missing in Firmware' 'TVACEPIW0012' : 'Imaging Start Failed. Try restarting imaging'	
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Troubleshooting

	'IVACEPIW0013' : 'Image Frame Data not detected' 'IVACEPIW0014' : 'Get Pullback Rate Failed' 'IVACEPIW0015' : 'Set Pullback Rate Failed' 'IVACEPIW0017' : 'Imaging Stop Failed. Disconnect the catheter' 'IVACEPIW0018' : 'Set Pullback Mode Failed' 'IVACEPIW0019' : 'Pullback Start Failed' 'IVACEPIW0020' : 'Pullback Stop Failed' 'IVACEPIW0021' : 'Missing Image Frame' 'IVACEPIW0024' : 'Frame out of order' 'IVACEPIW0025' : 'Bad Frame Number' 'IVACEPIW0026' : 'Streaming DMA Descriptor Error' 'IVACEPIW0027' : 'Streaming DMA Hardware Short' 'IVACEPIW0028' : 'Streaming DMA Software Short' 'IVACEPIW0038' : 'ChromaFlo Data All Zeroes'	
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Error retrieving patient case.	There is a problem with the hard drive.	Contact Technical Support.
The DVD/Blu-ray drive is empty. Please insert a new blank DVD or Blu-ray disk and try again.	DVD/Blu-ray drive is empty.	Insert disk.
The DVD/Blu-ray disk inserted in the drive is not blank. Please insert a new blank DVD or Blu-ray disk and try again.	Disk is not blank.	Insert blank disk.
Incorrect media type is inserted in the DVD/Blu-ray drive. Insert a new blank DVD or Blu-ray disk and try again.	DVD/Blu-ray drive does not recognize disk media type.	Re-insert disk.

Troubleshooting

There is insufficient space on the DVD/Blu-ray disc to burn the selected cases(s). Please adjust compression or decrease the number of cases.	Data size exceeds DVD storage limit.	Adjust compression or decrease number of cases.
Are you sure you want to cancel the archiving? The current DVD will be invalid.	User confirmation notification of a cancel archive request.	To cancel archive, press Confirm on the notification. To continue the archive, press Cancel on the notification.
Previous case automatically saved. Please ensure patient information was entered correctly.	System shutdown prematurely before case was ended.	Dismiss notification by pressing on Close button. Validate patient information was entered correctly in previous cases.
The retrieved case is already a copy of the original case. Would you like to overwrite the existing copy? Press Yes to overwrite the copy. Press No to create an additional copy.	An End Case is performed for a retrieved copy case.	To overwrite the retrieved case, press Yes button on notification. To create an additional copy, press No on notification.
Case limit reached. Please remove archived cases before continuing.	Case count has reached the maximum limit of 40.	To continue, press Previous Cases button on notification to navigate to the Previous Cases screen and delete cases. Or, If already on Previous Cases screen, press the Close button to dismiss dialog and delete cases.
Insufficient disk space available. Please archive and remove some cases.	The remaining space available on disk is less than 16.76 GB), maximum for 1 case.	To continue press the Previous Cases button on notification to navigate to the Previous Cases screen and delete cases. Or, If already on Previous Cases screen, press Close button to dismiss dialog and delete cases.

Troubleshooting

The hard drive is becoming full. Please archive and remove some cases.	The remaining space available on disk is less than or equal to 33.52 GB (size of two cases)	Press the Previous Cases button on notification to navigate to Previous Cases screen and delete cases. Or, Press Close button on notification to Dismiss dialog.
The DVD/Blu-ray is removed, archiving is cancelled.	DVD/Blu-ray is removed during an archive in progress.	Press Close button to dismiss notification and redo archiving if desired.
Currently writing to DVD/Blu-ray, shut down will cancel this archiving procedure. Do you wish to continue with shut down?	System Shutdown is requested during archiving.	A user confirmation shuts down system.
Recording stopped due to a data acquisition error. If the problem persists, shut down the system and contact Technical Support.	Recording stopped due to data acquisition error.	If problem persists, shut down system and contact Technical Support.
Cannot archive patient case(s) because of missing or corrupted data error.	Case data is corrupt and cannot be archived.	To cancel archive, press CLOSE on the notification.
The selected data element has been corrupted and cannot be recovered. Please select Case Menu to return to Case Log.	The selected case contained corrupted data, was unrecoverable, and has been deleted.	Press OK on the notification to return to the Case Log.
One or more of the selected case(s) has not been archived. Are you sure you want to delete?	User confirmation notification to delete a case that has not been archived to DVD/Blu-ray or Network.	Press DELETE button to continue with case deletion. Or, Press CANCEL button to Dismiss dialog.
One of the selected cases contains data larger than allowed for archive using No Compression. Please choose to archive using one of the provided compression levels.	The case size exceeds 2 GB capacity limitation associated with 32-bit Windows operating systems. To ensure compatibility with 32-bit windows applications the application prevents archiving with the No Compression setting.	To continue, press CLOSE on the notification. Select an alternate compression setting to archive the case.

Troubleshooting

The [...] settings are incomplete or invalid and will not be saved. Do you wish to leave settings anyway?	User confirmation notification to exit settings with incomplete configuration.	Press LEAVE button to continue with invalid settings. Or, Press CONTINUE SETUP button to Dismiss dialog and continue setup.
Server Setup is incomplete. Do you wish to continue with the server setup or leave without saving?	User confirmation notification to exit DICOM server setup with incomplete configuration.	Press LEAVE button to continue with invalid settings. Or, Press CONTINUE SETUP button to Dismiss dialog and continue setup.
Are you sure you want to delete the settings for archive server [...]?	User confirmation notification to delete DICOM server settings.	Press CANCEL button to continue with invalid settings. Or, Press DELETE to remove the archive server and all the archive server settings associated with it.
The system detected an IP address conflict with another system on the network. Please confirm the IP address in the Network tab of the System Settings menu.	Notification of IP address conflict on the network to which the system is attached.	Press CLOSE on the notification to return Settings dialog.
System restart required for new language settings to take effect.	Notification to restart system after changing the language selection.	Press the CLOSE button to close the dialog. Select restart or shut down to have language changes take effect. Alternately, select the original language and no language changes will occur following a system restart.

Potential Imaging Artifacts – the ChromaFlo Feature

Artifact	Cause	Resolution
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	Carefully identify and compare the luminal boundary

Troubleshooting

	approximately 6.3 mm away from catheter mask center cannot be detected.	based on grayscale images with those obtained from ChromaFlo images, as well as other modalities such as angiography.
Reduced frame rate	Due to processing speeds in ChromaFlo mode, the overall combined frame rate of grayscale and ChromaFlo of the Philips system is lowered to approximately 22 frames per second for EE/PV.014P/PioneerPlus and 20 frames per second for PV.018.	None. Very fast moving structures may appear to move in a more continuous manner during standard, non-ChromaFlo imaging.
Dark regions coded as 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 region of interest as necessary to block out these regions being coded as color. Alternately, use grayscale live mode without ChromaFlo.
Moving tissue coded as color	Understand some specific conditions, e.g., myocardial tissues that are moving very fast (similar to blood flow) could be displayed as color.	Adjust the region of interest as necessary to prevent tissue from being coded as color. Additionally use the grayscale images to locate vessel and tissue boundaries so that tissue motion artifact would not be misinterpreted.
Missing ChromaFlo/Dead zone near transducer	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.	None. Use grayscale live mode to observe blood flow in small vessels.

Potential Imaging Artifacts – Automatic Distance Measurement

Artifact	Cause	Resolution
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Troubleshooting

Automatic Distance Measurement is not proper	The automatic distance (minimum/maximum diameter) measurements may not always correspond to that which a trained operator will 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.
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Potential Imaging Artifacts

NOTE: Due to potentially significant inaccuracies, the user should carefully review any computer generated boundary before proceeding with a measurement.

IntraSight Vascular System	Cause	Resolution
Irregular Artery Contours	The imaging transducer at catheter tip may not always be withdrawn from the artery in a linear manner. Motion of catheter tip from side to side during a pullback data collection appears on the sagittal view as if the artery wall is moving towards and away from transducer axis.	None possible. Carefully review angiogram to determine vessel contours. Also, use 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, same image plane presented along artery length	Due to mechanical slack, which can occur in pull-back system, the beginning of pullback sequence may contain a series of images in which the image does not change for several frames. This occurs because the pullback device is moving catheter holder clamp, and the system is collecting data, but transducer at tip of catheter is not moving.	Ensure that there is no excessive slack in the system. Observe image as pull-back is started. If image remains unchanged for several images, use longitudinal editing feature to remove beginning of pullback sequence.
Seamline at approximately 12 o'clock on the B-mode image	The seamline artifact is caused by artery motion or pull-back movement during imaging, leading to misalignment of lumen border.	Performing pull-back at slower speed may reduce discontinuity appearance of image at approximately 12 o'clock. In high motion region such as coronary artery, seamline may be unavoidable.

Troubleshooting

Image Artifacts appear in area of ringdown after Ringdown function is activated	Artifacts may appear immediately after toggling Ringdown function On/Off.	▪ Ringdown function should be turned on just after imaging catheter exits guide catheter/sheath, as in aorta or ostium of coronary artery. ▪ To avoid image artifacts, it is recommended to turn Ringdown function off when imaging catheter is retracted back inside guide catheter/sheath or outside of body. Switch on Ringdown function again when catheter is re-inserted into artery. ▪ Optimal imaging and best performance are achieved if Ringdown function is toggled on in an open area where tissue structures are not in the ringdown region. Be aware of areas surrounding catheter within 1 mm of the catheter surface as these surrounding areas may contribute to the presentations of artifacts – e.g., stents, calcification, bright tissues, etc.
• Tissue blanking occurs in or Tissue is removed from area of ringdown after Ringdown function is activated • Artifacts presenting in vessel lumen, such as a Darkened concentric circle, that may appear/disappear in the image	Ringdown function is turned on when catheter is within 1 mm from tissue or other stationary features (like stents).	▪ Avoid any tissues in the ringdown region when Ringdown function is toggled. Be aware of areas surrounding the catheter within 1 mm of catheter surface as these surrounding areas may contribute to presentation of artifacts – e.g., stents, calcification, bright tissues, etc. ▪ To avoid possible tissue blanking, avoid situations where transducer is barely moving and completely wedged for a prolonged period in a heavily blocked vessel. If catheter is wedged, an artifact representing a darkened concentric circle may appear/disappear in image.

The IntraSight Vascular System software is designed to minimize artifacts and errors. As with any imaging modality, however, some artifacts may occur. Images or features may be presented on the screen which do not directly represent a physical structure or which may cause image defects.

Chapter 16. Maintenance

Service

The IntraSight Vascular 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, turn the system off, unplug the system from the power receptacle, and contact a Philips-certified service person and/or Philips Technical Support.

As part of the hospital's maintenance program, routine safety inspections and testing should be conducted annually. Trained hospital technicians should inspect and safety test all isolated connections and the system's power supply.

CAUTION: The IntraSight Vascular System must be serviced only by Philips Service personnel or by Philips-certified technical representative.

Philips Technical Service Centers

USA and Canada

Volcano Corporation
2870 Kilgore Road
Rancho Cordova, CA 95670
United States of America
Phone: 800-228-4728 (USA and Canada)
Phone: 916-861-0230
Fax: 916-861-0266

Europe

Volcano Europe BVBA/SPRL
Excelsiorlaan 41
B-1930 Zaventem
Belgium
Phone: 32.2.679.1076
Fax: 32.2.679.1079

Japan

Philips Japan, Ltd.
Philips Building, 13-37
Kohnan 2-chome,
Minato-ku, Tokyo 108-
8507 Japan
Phone: 81-3-5767-7430
Fax: 81-3-6414-8701

Maintenance Frequency

User-Performed Maintenance	Frequency
Archive patient cases	Daily as used
Clean components in patient vicinity	Daily as used
Clean system and monitor	As needed
PIM cables inspection and placement	Daily as used
Inspect and clean as needed, contrast and contaminating fluids from PIM catheter connectors* (See Note/Warning below.)	Daily as used
Verify cable connections	Monthly
Inspect and safety test all isolated connections and system power supply	Annually
Philips-Certified Maintenance	Frequency
A comprehensive preventive maintenance procedure performed by Philips-certified service engineers only	Annually, starting 18 months post-installation

Maintenance

***NOTE:** The catheter connector is sealed in back; using syringe containing water and alcohol mixture to flush is acceptable. However, unit must be set aside to dry (or high-pressure air flushed) thoroughly before re-use.



***WARNING:** Do not clean by inserting material into contact receptacle holes. This will break contacts and cause intermittent catheter operation.

NOTE: As part of the hospital's maintenance program, routine safety inspections and testing should be performed annually. Trained hospital technicians should inspect and safety-test all isolated connections.

NOTE: Do not dispose of this device or its components. Improper disposal may be harmful to the environment and human health. Dispose device per local electronic waste regulations. Return disposables to Philips for disposition.

Philips-Certified Maintenance

Philips-certified maintenance is performed by Philips-certified service engineers only.

A comprehensive preventive maintenance procedure needs to be done annually, starting approximately 18 months post-installation.

User-Performed Maintenance

Archive Patient Cases

See **Archiving an IVUS Case** chapter.

Cleaning and Disinfecting the IntraSight Vascular System

- Clean and disinfect the system, patient interface module, and other parts of the equipment as needed with common detergents, liquid chemical germicide, bactericide, and antiviral solutions such as morning mist among others, using warm water and a soft cloth.
- To prevent any patient contamination, always clean and disinfect parts of the equipment which were in 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 portion of the system.
- Avoid allowing liquids to enter the system openings, especially control console, monitor housing, and patient interface module.

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.

- Pay special care to the catheter/cable connections during cleaning to avoid unnecessary bending or breaking.

Monitor Care

NOTE: Power off system prior to cleaning monitor.

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 cleanser manufacturer to see if agent is compatible with ABS.

CAUTION: Never spray or otherwise apply any cleaner directly to the touch screen because leakage could cause damage to the system. Always apply the cleaner to the cloth instead.

Cable Inspection

- Check placement of PIM cables and connectors, and ensure cables are protected from accidental damage
- Inspect cable connections to ensure secure connections

EU Battery Directive, 2006/66/EC Requirements

When decommissioning IntraSight Vascular System unit for disposal, power down and unplug unit. Remove plastic cover and sheet metal cover from Panel PC back. Battery is located on motherboard.

Dispose of internal battery according to state/local laws per EU Battery Directive 2006/66/EC requirement. The remainder of unit is disposed of in like manner.

Maintenance

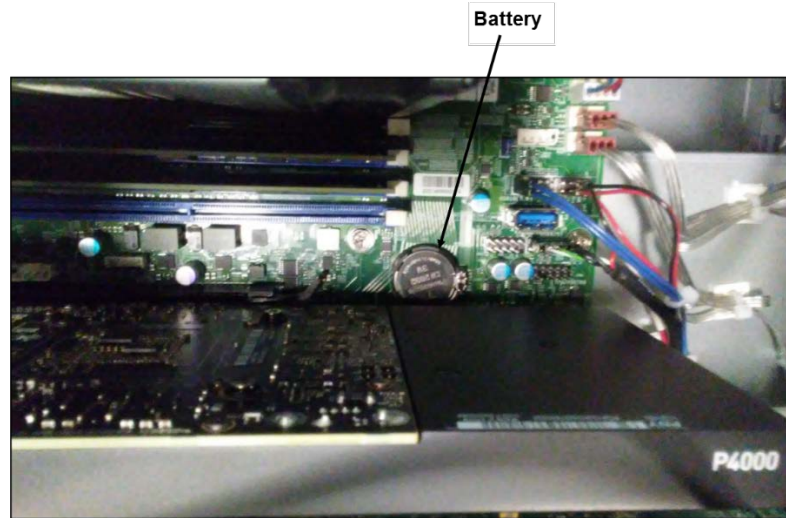


Figure 107: Motherboard Battery

Philips-Certified Maintenance

Philips-certified maintenance is performed by Philips-certified service engineers only.

A comprehensive inspection, operational check, entire system test, and check of any installed options are required.

Chapter 17. Technical Specifications

Imaging Catheters

Transducer type: Piezoelectric

360° view, multi-element solid state array transducer (except Revolution)

360° view, single-element rotational transducer (Revolution)

Frequency and available imaging diameters are noted in the table below.

Catheter	Frequency	Imaging Diameters (mm)
Eagle Eye Platinum Family	20 MHz	8, 10, 12, 14, 16, 18, 20
Pioneer Plus	20 MHz	8, 10, 12, 14, 16, 18, 20
Refinity	45 MHz	8, 10, 12, 14
Revolution	45 MHz	8, 10, 12, 14
Visions PV .014P	20 MHz	8, 10, 12, 14, 16, 18, 20
Visions PV .018	20 MHz	8, 10, 12, 14, 16, 18, 20, 22, 24
Visions PV .035	10 MHz	20, 25, 30, 35, 40, 45, 50, 55, 60

NOTE 1: Additional information is available in the Physicians Guide and Instructions for Use that accompanies each catheter.

NOTE 2: Information about the technical specification for the Revolution catheter, refer to the Philips Rotational Option Operator's Manual.

Video

External Video Support (Only applicable with the Scan converter option)

	Video Format	Frequency	Lines
USA	NTSC	60 Hz interlaced	525
Europe	PAL	50 Hz interlaced	625

System Video Display Format

- Display port and DVI/HDMI/VGA adaptors are available

Technical Specifications

- 1280 x 1024 pixel resolution
- 60 to 75 Hz refresh

Image

- Live/Still modes
- Variable frame rate
- 360° image
- Multiple depth scaling

Image Sizes

Image Mode	Image Area (in pixels)
Max IVUS	750 x 750
Normal Imaging Mode	500 x 500

Video Inputs and Outputs

One DVI and one Display Port adaptor are provided to connect Display Port to DVI-D. Adaptors are available from Philips for converting the Display Port to DVI, VGA, or HDMI.

System Dimensions and Weights

Philips System

	Height, in	Width, in	Depth, in	Weight, lb
Workstation	19.38	10	16.75	~46
Controller	5.0	15.0	10.0	~6.6
Monitor	17.5	18.0	10.0	~35
Patient Interface Module	1.6	4.0	7.4	~4.4

	Height, cm	Width, cm	Depth, cm	Weight, kg
Workstation	49.2	25.4	42.5	~29
Controller	12	36	24	~3
Monitor	42	43.2	24	~15
Patient Interface Module	3.8	9.6	17.75	~2

Power

Philips System Ratings and Fusing

System Model	System Input Configurations	Workstation Input	Fusing
797403	100-120V~ 240V~ 50/60Hz, *1000VA	100-240V~ 50/60Hz	100VAC, 12.5A 120VAC, 10A 240VAC, 5A

*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 5x20mm time delay fuses.

The AC mains input for the workstation power supply and 48VDC power supply are internally fused and are not serviceable parts.

The 48VDC power supply output is protected with a 5A, 5x20mm time delay fuse.

Technical Specifications

Recording Devices

- Hardcopy Digital Photo printer
- DVD and Blu-ray optical writers

Classifications

Per IEC 60601-1:2005, the Philips system has these classifications:

Type of Protection against Electric Shock	Class I
Degree of Protection against Electric Shock	Type CF, defibrillation proof
Degree of Protection against the Harmful Ingress of Water	Ordinary
Degree of Safety of Application in the Presence of Anesthetics	Equipment 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

EMC Statement



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 and Medical Device Directive 93/42/ EEC as amended by 2007/47/EC. 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.

Electrical Safety



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

System has to be installed to IEC 60601-1, including the use of an isolation transformer and potential equalization ⚡ on control console and workstation.

System Essential Performance for Electrical Safety

Patient leakage current < 10μA

System leakage current < 300μA

Patient attached input: Defibrillation proof 4.5kV AC (maximum for 1 minute)

System chassis inputs: 1.5kV AC (maximum for 1 minute)

Environmental Conditions

	Temperature, °F	Temperature, °C	Relative Humidity, % non-condensing	Altitude, ft	Altitude, m
Operating	50 to 95	10 to 35	10-95	10,000	3,048
Storage*	-0 to 140	-18 to 60	15-90	—	—
Shipping*	60 to 140	16 to 60	10-90	35,000	10,668

*As per IEC 60601-1, section 7.2.17.

DICOM Image Storage

Saving patient cases to DVD: The archived images are stored in DICOM format with the Philips system acting as a File Set Creator (FSC), following the guidelines in the 2004 DICOM 3.0 specification.

The DICOM images are stored using the Ultrasound Application Profile STD-US-SC-MF-DVD, using the UIDs in the following table.

Information Object Definition	SOP CLASS UID	Transfer Syntax UID
DICOMDIR	1.2.840.10008.1.3.10	1.2.840.10008.1.2.1
Ultrasound Multi-frame Image Storage	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

Technical Specifications

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). The SOP Classes supported by the Philips system are categorized in the following table.

Information Object Definition	SOP CLASS UID	Transfer Syntax UID
Verification	1.2.840.10008.1.1	1.2.840.10008.1.2
Ultrasound Multi-frame Image Storage	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

Essential Performance, Catheter Operating Temperatures

The catheters are designed to image under physiologic conditions. Operating Temperature of all solid-state array catheters used with the Philips system is $<55 \pm 0.3$ °C in air and $<41 \pm 0.3$ °C under physiologic conditions (37 °C in fluids). Operating Temperature of rotational catheters used with the Philips system is 1 ± 0.3 °C above ambient temperature in air and $<38 \pm 0.3$ °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.

Essential Performance, System

The essential performance of the Philips system when operating with Philips catheters is specified below:

- The rotation of the Refinity and Revolution imaging transducer at the distal tip of the catheter is automatically maintained at a predetermined speed during live imaging operations
- If present, any signal distortion leading to errors of diagnostically relevant parameters is visually evident to the operator
- The ultrasound (acoustic) output and heating of the catheter transducer is maintained within safe levels
- Ultrasound (acoustic) output of the Eagle Eye and PV catheters imaging transducer is active when an active moving image is displayed
- Ultrasound (acoustic) output of the Refinity and Revolution catheter imaging transducer is active in imaging mode only
- System control of movement of the catheter imaging transducer is limited to the following operator actions:
 - Push and pull motion of the catheter imaging transducer can be initiated through manual manipulation of catheter body by the operator

- Motorized pullback of the Refinity and Revolution catheter is manually controlled by the operator. Motorized push motion of Revolution catheter is not possible.
- Changes in Refinity and Revolution catheters, ultrasound imaging operation from off to on and from on to off occur only when initiated by the operator
- Ultrasound output power settings are automatically maintained at preset and safe levels during imaging operations
- Electrical safety is maintained in all operational modes

Catheter Acoustic Outputs

Ultrasound Exposure Maxima

Ultrasound Exposure/ Acoustic output power is fixed and cannot be adjusted by the operator of this equipment. Ultrasound exposure only when LIVE imaging is enabled. When LIVE imaging is not selected by the operator, no ultrasound exposure occurs. The Philips system is in compliance with the Acoustic Output Display Standard and within FDA limits for Ultrasound equipment.

Eagle Eye *Platinum*

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm ²)*	4.8×10^{-3}	91.3×10^{-3}
$I_{SPPA.3}$ (W/cm ²) *	9.1×10^{-3}	192.0×10^{-3}
$P_{r.3}$ (MPa)	20.0×10^{-3}	81.5×10^{-3}
PD (μs)	177.0×10^{-3}	137.0×10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)	19.9	17.6
MI**	4.5×10^{-3}	19.2×10^{-3}
TI**	6.76×10^{-6}	211.0×10^{-6}

* Maximum uncertainty +33.9%/-30.5%

** As estimated in tissue

Visions PV .014P

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA.3}$ (mW/cm ²)*	4.8×10^{-3}	91.3×10^{-3}
$I_{SPPA.3}$ (W/cm ²) *	9.1×10^{-3}	192.0×10^{-3}
$P_{r.3}$ (MPa)	20.0×10^{-3}	81.5×10^{-3}
PD (μs)	177.0×10^{-3}	137.0×10^{-3}
PRF (Hz)	53760	75368
Center Freq (MHz)	19.9	17.6
MI**	4.5×10^{-3}	19.2×10^{-3}
TI**	6.76×10^{-6}	211.0×10^{-6}

* Maximum uncertainty +33.9%/-30.5%

** As estimated in tissue

Technical Specifications

Pioneer Plus

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA,3}$ (mW/cm ²)*	2.683	20.800
$I_{SPPA,3}$ (W/cm ²) *	248×10^{-3}	1.870
$P_{r,3}$ (MPa)	137.1×10^{-3}	315.3×10^{-3}
PD (μs)	201.2×10^{-3}	125.0×10^{-3}
PRF (Hz)	53760	88320
Center Freq (MHz)	20	20
MI**	31.31×10^{-3}	60.0×10^{-3}
TI**	278.1×10^{-6}	571.6×10^{-6}

* Maximum uncertainty +33.9%/-30.5%

** As estimated in tissue

Visions PV .018

Acoustic Output Parameter	B-Mode	ChromaFlo
$I_{SPTA,3}$ (mW/cm ²)*	2.087	13.950
$I_{SPPA,3}$ (W/cm ²) *	296.3×10^{-3}	1.709
$P_{r,3}$ (MPa)	132.3×10^{-3}	267.7×10^{-3}
PD (μs)	168.3×10^{-3}	113.8×10^{-3}
PRF (Hz)	43008	70656
Center Freq (MHz)	20	20
MI**	30.6×10^{-3}	53.06×10^{-3}
TI**	269.8×10^{-6}	474.8×10^{-6}

* Maximum uncertainty +33.9%/-30.5%

** As estimated in tissue

Visions PV .035F

Acoustic Output Parameter	B-Mode
$I_{SPTA.3}$ (mW/cm ²)	67.7×10^{-3}
$I_{SPPA.3}$ (W/cm ²)	97.1×10^{-3}
$P_{r.3}$ (MPa)	58.8×10^{-3}
PD (μs)	321.0×10^{-3}
PRF (Hz)	19712
Center Freq (MHz)	9.08
MI*	19.5×10^{-3}
TI*	68.7×10^{-6}

Maximum overall uncertainty $\pm 30.2\%$

* As estimated in tissue

Refinity

Acoustic Output Parameter	B-Mode
$I_{SPTA.3}$ (mW/cm ²)*	608.0×10^{-3}
$I_{SPPA.3}$ (W/cm ²) *	13.3
$P_{r.3}$ (MPa)	548.0×10^{-3}
PD (μs)	39.5×10^{-3}
PRF (Hz)	15400
Center Freq (MHz)	42.1
MI**	90.3×10^{-3}
TI**	1.4×10^{-3}

*Maximum overall uncertainty $\pm 30.2\%$

**As estimated in tissue

Revolution

Acoustic Output Parameter	B-Mode
$I_{SPTA.3}$ (mW/cm ²)*	70.8
$I_{SPPA.3}$ (W/cm ²) *	95.5
$P_{r.3}$ (MPa)	1.901
PD (μs)	48.0×10^{-3}
PRF (Hz)	15360
Center Freq (MHz)	42.3
MI**	281.0×10^{-3}
TI*	10.0×10^{-3}

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*Uncertainty $\pm 29.1\%$

** Uncertainty $\pm 14.6\%$

TI: Thermal Index defined as $TI = \frac{W_{01x1} f_c}{210}$

where:

W_{01x1} is the bounded-square output in milliwatts

f_c is the Center Frequency in MHz

MI: Mechanical Index $MI = Pr.3 / (f_c^{1/2})$

$I_{SPPA.3}$: Derated Intensity. Spatial Peak Pulse Average (mW/cm²)

$I_{SPTA.3}$: Derated Intensity. Spatial Peak Temporal Average (mW/cm²)

Pr.3: Derated Peak Negative Pressure at a location of the maximum derated pulse intensity integral (MPa)

W_0 : Total Power (mW)

PD: Pulse Duration (μ s)

PRF: Pulse Repetition Frequency (Hz)

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:

Distance Measurement: $-4.5\%, +7.0\%$ of measured value $\pm 0.10\text{mm}$

Area Measurement: $-9\%, +14\%$ of measured value $\pm 0.10\text{mm}^2$

These uncertainties apply to the entire range of measurement achievable with the Philips system. These are worst case measurement uncertainties and represent situations where the ultrasound signals are entirely within tissue, such as muscle, which has a very different speed of sound than blood. For measurement of luminal boundaries, where the ultrasound only traverses through blood, the inaccuracy is:

Distance Measurement: $\pm 1\%$ of the measurement $\pm 0.10\text{mm}$

Area Measurement: $\pm 5\%$ of the measurement $\pm 0.10\text{mm}^2$

NOTE: For more information about the measurement accuracy of the Refinity IVUS Imaging and Revolution 45MHz Rotational IVUS Imaging Catheters, refer to the Philips System, Rotational Option manual.

In-Line Digital Measurement Accuracy

- Two distance measurements on the longitudinal display (ILD)
- Maximum Loop Distance (Z axis length) 2700 Frames @ 30 fps & 0.5 mm/sec pull back = 45 mm

PIM Compatibility

Intravascular Ultrasound (IVUS)	Synthetic Aperture (SA PIM)	Eagle Eye Platinum	Eagle Eye Platinum
			Eagle Eye Platinum, Japan
			Eagle Eye Platinum, Short Tip
		Visions	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
		Pioneer Plus	Pioneer Plus
	Revolution (PIMr)	Revolution	Revolution
		Refinity	Refinity
			Refinity, Short Tip
Functional Measurement (FM)	FM PIM	Verrata	Verrata 185 cm Straight Tip
			Verrata 185 cm J-tip
			Verrata 300 cm Straight Tip
			Verrata 300 cm J-tip
		Verrata Plus	Verrata Plus 185 cm Straight Tip
			Verrata Plus 185 cm J-tip
			Verrata Plus 300 cm Straight Tip
			Verrata Plus 300 cm J-tip

NOTE: If catheter is not recognized, catheter version may not be compatible with system. Please contact Philip Customer Service for support.

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Accessories and Replacement Parts

The following accessories and replacement parts are compliant with Philips system IEC 60601-1-2 EMC certification.

System Model Number 797403		
Part Number	Description	Maximum length
300002104362 OM 300002104432 CD	Philips IntraSight Operator's Manual Philips IntraSight OM Multilanguage CD	N/A
804390001	A6 Paper for Sony UP 25MD 4 packs of 50 sheets	N/A
431-0100.01	A6 Paper for Sony UP 25MD 3 packs of 80 sheets	N/A
806452004	3m PIM cable	3 meters
806452009	5m PIM cable	5 meters
806395001	VGA interconnect cable	3 meters
804290001	DVI-D interconnect cable	3 meters
300001679281	'Y' cable (for both Bedside Controller and LoMap simultaneous operation)	
421-1202.12	USB Cable Type A to Type B	3 meters
806327001	Control Panel ground cable	30 cm
S5800061	AC Power cable workstation to isolation transformer	1 meter

Catheters

Visions PV .035	88901
Visions PV .018	86700
Visions PV .014P	85900P, 85900PJ
Eagle Eye <i>Gold F/X</i>	85900
Eagle Eye <i>Platinum</i>	85900P, 85900PJ
Pioneer Plus	PPLUS120
Refinity	89800, 89900
Revolution	89000

Standards and Regulations

The Philips Family of Image Guided Therapy Systems (IGTS) complies with the requirements of these standards and requirements:

Medical electrical equipment – General requirements for safety

EN 60601-1:2006/A1:2013

EN 60601-2-37:2008

Medical electrical equipment – Electromagnetic compatibility

EN 60601-1-2:2015 4th Edition
IEC 60601-1-2:2014 4th Edition

SYMBOL: Declaration of Conformity:

We declare that the Philips System Family of Image Guided Therapy Systems (IGTS) meets the requirements of the Medical Device Directive 2007/42/EC for Electromagnetic Compatibility (EMC) through the use of International Standard IEC/EN 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	

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

Technical Specifications

IntraSight Vascular System is intended for use in the electromagnetic environment specified below. The customer or the user of the IntraSight Vascular System should assure that it is used in such an environment.

During immunity testing the IntraSight 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	3 Vrms 150 kHz to 80 MHz	3 Vrms ^c	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 Integrated system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	6V in ISM bands between 150 kHz and 80 MHz 80% AM at 1 kHz	6 Vrms	
	3 V/m 80 MHz to 2.7 GHz Proximity Fields (see below table for proximity field characteristics)	3 V/m ^c Proximity Fields (see below table for proximity field characteristics)	

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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observed, additional measures may be necessary, such as re-orienting or relocating the Philips systems. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. c 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	±8 kV contact ±15 kV air	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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T ; 0.5 Cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T ; 1 Cycle 70% U_T ; 25/30 Cycles Single Phase: at 0° 0% U_T ; 250/300 Cycle	0% U_T ; 0.5 Cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T ; 1 Cycle 70% U_T ; 25/30 Cycles Single Phase: at 0° 0% U_T ; 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.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

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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	100%ASK	0.1mW

Cybersecurity

This section contains security information for the protection of network-connected systems, including hardware, software, and data, from cyberattacks.

The system/device is setup using App Locker, which prohibits any unauthorized executable file from running. The firewall is enabled, and only certified applications use specific ports. Any other access or connections are denied.

The system/device's operating system is protected with write protection; any security compromise that occurs does not persist to the next boot up of device.

The system maintains no backup of configuration. If a customer suspects a compromised configuration, contacting customer support is advised.

Philips Field Service installs and configures system as required for infrastructure to permit intended operation.

Several protection methodologies are used to protect the operating system (OS):

- The OS disk is write-protected; no changes can persist.
- App Locker is used for white listing; only signed applications can run.
- Firewalls are in place, and only designated ports allow connection and access.
- End users do not have access to OS tools such as Windows explorer.
- The system boots directly into Philips's software applications, which control how the end user interacts with the system. Only Philips personnel have direct access to the OS via a smartcard-protected field service account.

The Windows default firewall (Windows 10) is enabled on the system. This firewall blocks all ports from incoming communication with the following exceptions:

- ICMP (Ping)
- Port 1919 on IP address 192.68.32.242 for iFR/FFR Roadmap feature
- Port 123 (TCP) for Network Time Protocol (NTP) to enable time synchronization for the secondary controller
- Port 443 to enable RADAR to upload the Philips logs to the internet server
- For outbound connection, ports are limited by the configuration performed by Philips Field Service (for PACS, etc.)

The system does not permit downloads of any software updates.

All changes to configurations and log-in attempts are logged and can be viewed by Philips Field Service.

All events are logged to the event log and can be inspected by Philips Field Service.

Only Philips Field Service can directly manipulate system configuration files.

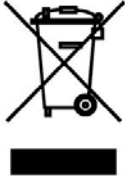
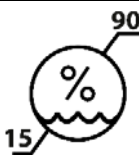
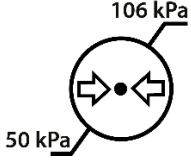
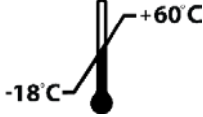
For instructions on secure network deployment, servicing, and detection of cybersecurity vulnerabilities or incidents, contact Philips Field Service.

Symbols

This chapter lists symbols used on the Philips system and their meanings.

Symbol	Description
	Power On/Off (standby mode)
	Warning, Attention, Consult Accompanying Documents
	Bi-directional digital signal
	Bi-directional analog signal
	Analog output signal
	Equipotentiality
	Indicates a strong magnetic field is present
	This device is protected against the voltages of defibrillation
	Input for the catheter connector
	Follow User Manual
	Consult Instructions for Use
	The IntraSight Vascular System product meets TÜV's safety requirements.

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	Do not dispose of this device or its components. Improper disposal may be harmful to the environment and human health. Dispose device per local electronic waste regulations.
	Recycle
	UL Classified. See complete marking on product.
	Attention: Observe precautions for handling electrostatic discharge sensitive devices.
	CAUTION: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).
	Manufacturer
	Date of Manufacture
	Authorized European Representative
	Serial Number
	Humidity Limitation
	Atmospheric Pressure Limitation
	Temperature Limitation

Technical Specifications

	Philips Logo
	Complies with the Council Directive 93/42/EEC
	Authorized European Representative
	Serial Number
	Catalog Number
	Part Number

Glossary

ChromaFlo: Provides a visual depiction of blood flow through the vessel by overlaying a two-dimensional color mapping of relative blood flow velocity onto the grayscale ultrasound image.

Diameter: The depth of field to which the ultrasound image data is acquired.

DICOM (Digital Imaging and Communications in Medicine): A format for storing images on DVD and transferring images and patient data over a network. The DICOM standard facilitates the exchange of patient images and data among different pieces and types of medical imaging equipment.

Gain: The intensity of the ultrasound echoes; a higher gain setting results in a brighter image with more intense echoes.

ILD = In-Line Digital: Two-dimensional, 360° rotation, real-time longitudinal view generated by visually stacking hundreds of cross-sectional intravascular ultrasound images.

PIM = Patient Interface Module: The imaging catheter connects to the Patient Interface Module which 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.

Post-processing: Any operation conducted on a stored ultrasound image. Measurements, annotations, and retrieving and clearing data are examples of post-processing.

Ringdown Artifact: Ringdown artifact is a result of multiple phenomena such as acoustic and RF signal crosstalk between neighboring acoustic elements on synthetic aperture catheters and the innate physical properties of ultrasound crystals and catheter tips. In addition, the operating frequency, temperature, and the size and geometry of the ultrasound elements contribute to the magnitude and appearance of the artifact.

Sensitivity: During ChromaFlo imaging, blood/ luminal flow rates can vary from 4 cm/sec up to 110 cm/sec. The Philips system is equipped to display, in color, 5 viewable flow ranges. This capability is accessed via the Sensitivity control which is available on the Adjust Image menu. There are 5 selections: Sensitivity 1 for high flow rate vessels and Sensitivity 5 for low flow rate vessels. Typically Sensitivity 3 through 5 provides the best visualization of coronary vessel flow rates.

For any given sensitivity setting, areas where the relative blood/ luminal flow rates are higher are more yellow; areas where they are slower are redder. By increasing the sensitivity setting to a higher value, one can shift towards yellow the color of slower moving areas of blood flow; by decreasing the sensitivity setting to a lower value, one can shift towards red the color of faster moving areas of blood flow.

Appendix A: OSS Libraries

The LIBICONV library is used in this product and the use of this library is covered by the following license(s).

LIBICONV

GNU Lesser General Public License - <http://www.gnu.org/copyleft/lesser.html>

GNU License - <http://www.gnu.org/licenses/gpl.html>

JPEG Library

This software is based in part on the work of the Independent JPEG Group

JSON Library

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LIBXML++

GNU Lesser General Public License - <http://www.gnu.org/copyleft/lesser.html>

GNU License - <http://www.gnu.org/licenses/gpl.html>

LIBXML2

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Log4cplus

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