



HyperVue Imaging System - Integrated Operator's Manual

R_x Only

About This Manual

This manual describes the HyperVue™ Imaging System - Integrated and provides instructions for performing DeepOCT™ – Near Infrared Spectroscopy (NIRS) procedures.

NOTE: The details of the HyperVue Software are provided in the HyperVue Software Operator's Manual and are not covered in this manual.

NOTE: The details of the Starlight™ Imaging Catheter Instructions for Use are provided with the catheter and are not covered in this manual.

NOTE: Pictures shown are for example only.

Indications for Use

The HyperVue™ Imaging System – Integrated with compatible HyperVue™ Software and Starlight™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures.

The Starlight Imaging Catheter is intended for use in vessels 2.0 to 5.2 mm in diameter.

The Starlight Imaging Catheter is not intended for use in a target vessel which has undergone a previous bypass procedure.

The NIRS capability of the HyperVue Imaging System - Integrated is intended for the detection of lipid core containing plaques of interest.

The NIRS capability of the HyperVue Imaging System - Integrated is intended for the assessment of coronary artery lipid core burden.

The NIRS capability of the HyperVue Imaging System - Integrated is intended for the identification of patients and plaques at increased risk of major adverse cardiac events.

Contraindications

Use of the Starlight Imaging Catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. Contraindications include:

- Acute renal failure
- Bacteremia or sepsis
- Inability to tolerate systemic anticoagulation
- Large thrombus
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for coronary artery bypass graft surgery
- Patients disqualified for percutaneous transluminal coronary angioplasty
- Severe hemodynamic instability or shock
- Total occlusion

Warnings

- Never look directly into the laser beam coming from the catheter or reflected from a surface.
- No modification of this equipment is allowed.
- The printed manual is recyclable. Dispose of all packaging materials appropriately.
- Class 1M laser present when in use. Invisible Laser Radiation – Do not stare into the beam or view the beam directly with optical instruments. Doing so may cause serious eye damage and hazardous radiation exposure. Viewing the laser output

with certain optical instruments (for example eye loupes, magnifiers, and microscopes) may pose an eye hazard.

Precautions

- Ensure that all ventilation holes in the HyperVue Integrated Console are not obstructed during use.
- For optimal imaging, use 100% contrast media.
- When using saline, heparinized saline is recommended.
- The system has no patient alarm functions - Do not use for cardiac monitoring.
- When used in the patient environment, all equipment connected to the HyperVue Imaging System - Integrated must meet the requirements for medical isolation according to the IEC 60601-1 safety standards.
- To obtain accurate measurements, ensure the selection for Flush media is the same as the medium in which you are imaging.

Complications

The following may occur as a consequence of intravascular imaging and catheterization procedure:

- Abnormal heart rhythm or arrhythmia
- Acute myocardial infarction
- Allergic reaction to the contrast media or drug administered for the procedure
- Arterial dissection, injury, or perforation
- Bleeding
- Catheter access side reactions; sterile inflammation or granuloma or tissue necrosis
- Coronary artery spasm
- Death
- Embolism
- Myocardial ischemia
- Repeat vascularization
- Renal insufficiency or failure from contrast media use
- Thrombus formation, abrupt closure, or total occlusion
- Unstable angina

Intended User

The HyperVue Imaging System - Integrated is intended to be used by medical professional personnel including physicians, nurses, and technologists that have been trained in percutaneous coronary interventions, both complex and non-complex.

Intended Patient Population and Tissue

The HyperVue Imaging System - Integrated is intended to be used in patients who are candidates for transluminal interventional procedures, in coronary arteries including left main, right coronary, left circumflex, left anterior descending, ramus if present, and major branches.

Training

This manual describes the basic operation of the HyperVue Imaging System - Integrated. This document is not a substitute for the required training on the clinical application of the system. To obtain the required training, please contact a SpectraWAVE representative.

Safety Information

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these instructions; otherwise, complications may occur.

Although the HyperVue Imaging System – Integrated conforms to laser emission standards and electromagnetic compatibility standards, the system is intended for use only by medical personnel who are knowledgeable in DeepOCT and NIRS procedures. Only a knowledgeable operator can determine if HyperVue Imaging System - Integrated use is appropriate. An awareness of system limitations is essential to making that determination and ensuring safe operation for both operator and patient.

Always use controls, make adjustments, and perform procedures as specified in these Instructions for Use.

To avoid any potential hazards, follow the precautions outlined in this manual.



WARNING: Failure to follow the guidelines in this manual and in the Instructions for Use provided may result in injury to users or patients and/or damage to equipment.



CAUTION: Only a qualified SpectraWAVE representative can perform installation and maintenance of the system. Do not open Console or Controller. If Controller or Console enclosures are damaged, do not use the system, and please contact a SpectraWAVE representative.

Considerations for Optimal Vessel Imaging

The HyperVue Imaging System - Integrated can be used to image through vessels or to image the inner surface of certain vessels. Since the diameter of the Starlight Imaging Catheter is smaller than the diameter of the vessel being imaged, the position of the catheter in the vessel has an effect on the portion of the vessel that can be imaged.

NOTE: Imaging range is greatest when the imaging catheter is centered in the lumen.

NOTE: Imaging range is least when the imaging catheter is placed off-center in the lumen, against the wall of the vessel.

System Overview

The HyperVue Imaging System - Integrated is an imaging platform that uses light to create high-resolution DeepOCT images and NIRS spectroscopic analysis of coronary vessels. The system uses a Starlight optical imaging catheter that emits and collects near-infrared light to produce high-resolution images. The software includes automatic detection of vessel components using artificial intelligence. In addition, the system incorporates angiographic co-registration, which allows the user to visualize the position of DeepOCT-NIRS image data on angiography images.

Table of Contents

1. Getting Started.....	8
Introduction	8
Major System Components	8
HyperVue Integrated Console	10
Console and Component Positioning	11
HyperVue Controller (Controller)	11
Controller Bag	13
Bed Mounted Controller Cradle	13
Angiography Input (Optional)	14
Auxiliary Display Output(s) (Optional)	14
System Startup.....	14
System Shutdown	14
Starlight Imaging Catheter.....	15
Deploying the Imaging Catheter	15
Removing and Disposal of the Imaging Catheter	15
2. Hazards	16
Optical Hazards.....	16
Electrical and Mechanical Hazards	16
Chemical and Fire Hazards.....	23
Liquids and Moisture	23
3. Labels and Symbols	24
4. Cleaning, Disinfecting, and Disposal.....	27
Introduction	27
Console & Controller	27
Monitors	28
System Disposal at End of Life	29
5. Maintenance and Installation.....	30
Maintenance.....	30
Installation	31
6. Troubleshooting	32
7. Theory of Operation	33
8. Specifications	34
FCC Statement	36

1. Getting Started

Introduction

This manual applies to the following model:

- HyperVue Imaging System – Integrated – P/N 933

This chapter describes:

- The major components of the HyperVue Imaging System - Integrated
 - The HyperVue Integrated Console
 - The HyperVue Integrated Controller (Controller)
- System positioning, power and optional connections
- System startup and shutdown
- Connection of optional inputs and outputs
- Starlight Imaging Catheter Connection/Disconnection

Major System Components

Table 1-1 summarizes the systems components.

Table 1-1. Major Components of the HyperVue Imaging System - Integrated

<i>Component</i>	<i>Description</i>
HyperVue Integrated Console	A state-of-the-art workstation with an integrated computer, control systems, optics for DeepOCT and NIRS, and two touch-screen interfaces.
HyperVue Integrated Controller (Controller)	A reusable unit tethered to the Console allowing direct control of image acquisition and image review.

Table 1-2. Accessory Components of the HyperVue Imaging System - Integrated

<i>Accessory</i>	<i>Description</i>
HyperVue Bed Mounted Controller Cradle	Storage location for Controller when not in use. The user can slide the Controller into the cradle to secure it in place.
Bed Touchscreen Monitor	Touchscreen and mount for the patient bed rail for software control of the system
Cath Lab Touchscreen Monitor	Touchscreen installed within the catheterization laboratory for software control of the system



CAUTION: The above components are integral parts of the HyperVue Imaging System - Integrated. The hardware and software must not be modified in any way by the customer. Making such modifications may interfere with the correct operation of the system. Contact a SpectraWAVE representative for more information.



CAUTION: Never use a converter adapter to plug the three-pronged AC plug into a two-pronged, ungrounded wall outlet. Doing so may result in an electric shock to the patient or operator and may damage the equipment.

HyperVue Integrated Console

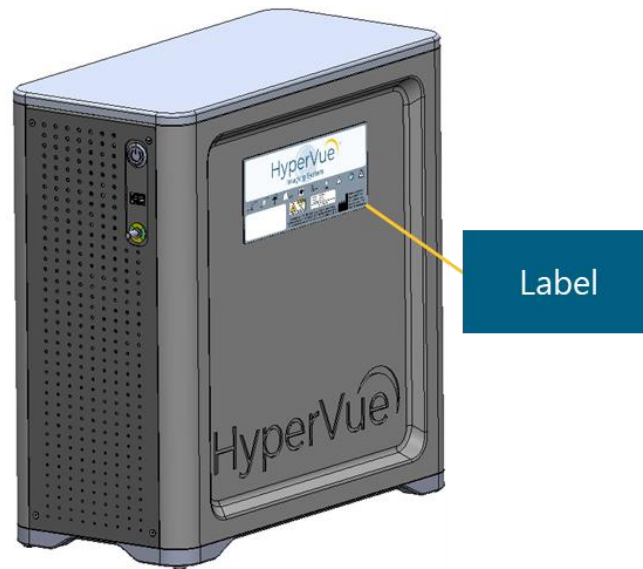


Figure 1-1. HyperVue Integrated Console and Label

Figure 1-1 shows the HyperVue Integrated Console and side label. Figure 1-2 shows the Power and Communication panel. Further details of the input/output ports can be found in Table 8-1.

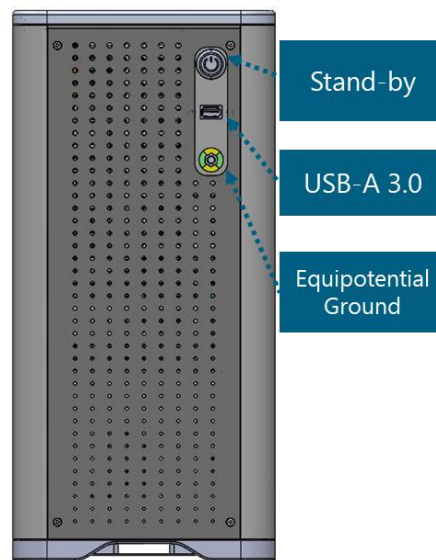


Figure 1-2. Power and Communication Panel found on the HyperVue Integrated Console

The HyperVue Integrated Console should be positioned such that the Power and Communication Panel (Figure 1-2) is easily accessible.

NOTE: The Console should have space around it so that air can circulate and cool the chassis.

NOTE: Ensure the power cord and any other connections are routed to prevent a tripping hazard. Ensure that the stand-by button and power cord can be accessed at any time during the procedure.

Console and Component Positioning

The HyperVue Integrated Console and Accessory Components should be positioned by trained SpectraWAVE personnel. Ensure the system has space around it so that air can circulate to cool the console and the Power and Communication Panel (Figure 1-2) should be easily accessible

Drape the bed mounted touchscreen monitor to maintain sterile technique.

HyperVue Controller (Controller)

The Controller's main function is initiating a pullback, controlling image review, and disconnecting a catheter. Figure 1-3 shows the Controller, with components and details of functionality listed in Table 1-3. If a button serves different purposes while acquiring a pullback or during image review, it is labeled as such in Table 1-3.

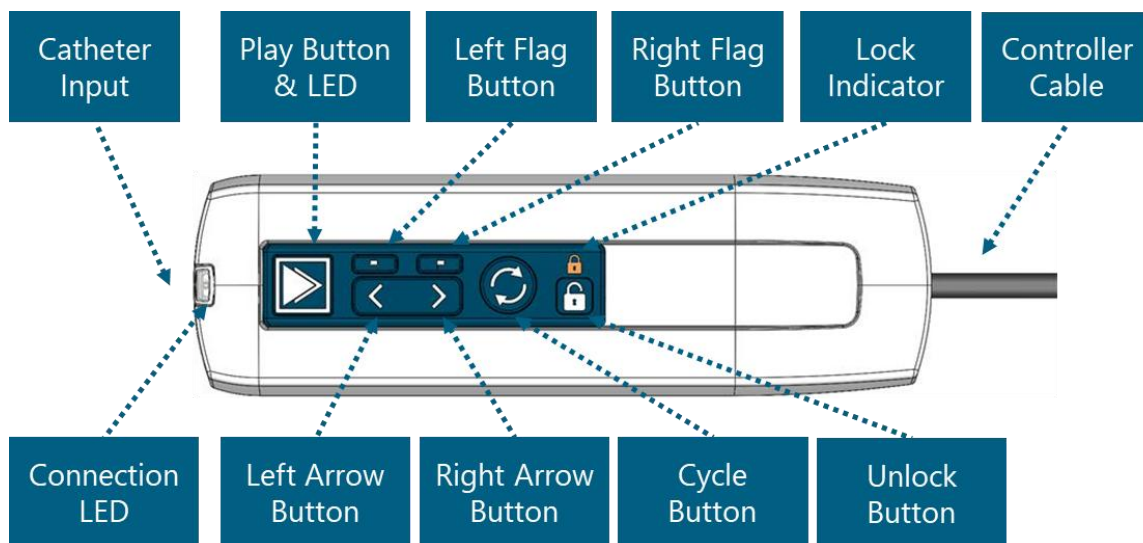


Figure 1-3. HyperVue Controller (Controller)

Table 1-3. Controller Components and Button Functionality

<i>Component</i>	<i>Description</i>
Catheter Input	Location to attach Imaging Catheter handle prior to initiating pullbacks.
Connection LED	Solid green while Catheter is locked and calibrated in the Controller Blinks green while Catheter is locking, calibrating, or unlocking No light when the catheter is not connected or has completed unlocking
PLAY Button	Begin (press and hold) and Proceed (press or press and hold) through pullback workflow
Play Button LED	Solid white while live imaging prior to acquiring a pullback No light otherwise
LEFT FLAG Button	Pullback Workflow: Select Automatic pullback initiation option Image Review: Set proximal (left) reference marker
RIGHT FLAG Button	Pullback Workflow: Select Physician pullback initiation option Image Review: Set distal (right) reference marker
LEFT ARROW Button	Pullback Workflow: Select 60 mm/s pullback speed Image Review: Move longitudinal position cursor to the left
RIGHT ARROW Button	Pullback Workflow: Select 120 mm/s pullback speed Image Review: Move longitudinal position cursor to the right
CYCLE Button	Pullback Workflow: Return to the previous screen Image Review: Swap longitudinal viewport (press) or twist longitudinal DeepOCT image cut-slice clockwise (press and hold)
UNLOCK Button	Unlock Catheter for removal from the Controller

<i>Component</i>	<i>Description</i>
Lock Indicator LED	Solid orange while the Catheter is locked in the Controller Blinks orange when the unlock button has been pressed once and waiting for user to confirm unlock or locking/unlocking is in progress No light when the catheter is unlocked
Controller Cable	Cable that connects Controller to Console

Controller Bag

Each Imaging Catheter includes a sterile Controller Bag to cover the Controller and its cable and to allow for the Controller to be operated from within the sterile field. For further instructions, please refer to the Starlight Imaging Catheter Instructions for Use.

Bed Mounted Controller Cradle

When not in-use, place the Controller in the cradle (Figure 1-4) and secure the cable. The Integrated Controller Cradle are custom fit during installation. If the Cradle is not clamped securely, contact SpectraWAVE Service.

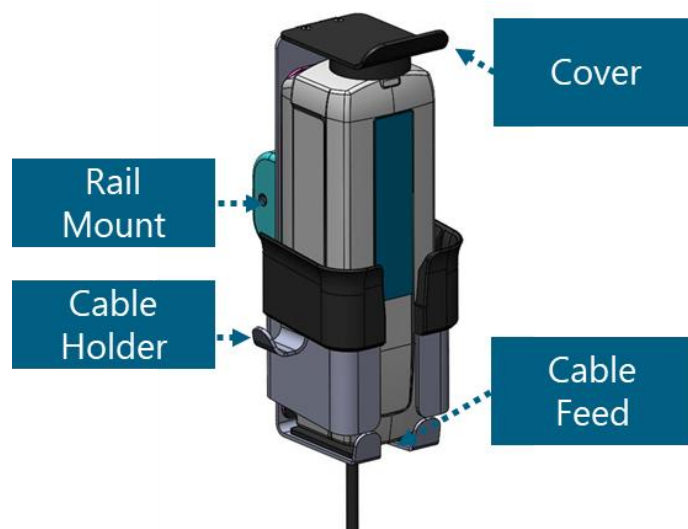


Figure 1-4. Integrated Controller Cradle

NOTE: Do not use the Controller cable to move the Controller.

NOTE: Do not pinch or excessively bend the cables while moving the Controller.

Angiography Input (Optional)

An optional live angiography feed can be connected to the HyperVue Integrated Console at installation by SpectraWAVE personnel.

Auxiliary Display Output(s) (Optional)

An optional auxiliary display can be connected to the HyperVue Imaging System - Integrated at installation by SpectraWAVE personnel.

System Startup

Make sure the power cord is plugged into a grounded electrical outlet.

To power up the system, press the stand-by button located on the Power and Communication panel side of the HyperVue Integrated Console.

After system startup is complete, the user login screen appears. Enter the appropriate login information for the system and the HyperVue Software will launch.

NOTE: The details of the HyperVue Software are provided in the HyperVue Software Operator's Manual and are not covered in this manual.

System Shutdown

To power down the system, press the power button located on the Home Screen of the HyperVue Software via one of the touch-screen monitors. Confirm shutdown when prompted.

NOTE: The details of the HyperVue Software are provided in the HyperVue Software Operator's Manual and are not covered in this manual.

After shutdown, screens will turn black and stand-by button will no longer be illuminated, confirming shutdown is complete.



CAUTION: Do not unplug the system from AC power until the shutdown is complete. Disconnecting from AC power before the shutdown is complete may damage the system.

Starlight Imaging Catheter

The Starlight Imaging Catheter is a single-use disposable device and a Type CF applied part. The Starlight Imaging Catheter connects to the HyperVue Controller (Controller) and is advanced through the guide catheter via a steerable guidewire during transluminal interventional procedures.

Please review the Instructions for Use supplied with the Starlight Imaging Catheter for more information on preparing the Controller and Imaging Catheter.

Deploying the Imaging Catheter

Please review the Instructions for Use supplied with the Starlight Imaging Catheter for more information on deploying the Imaging Catheter.

Removing and Disposal of the Imaging Catheter

Please see the Starlight Imaging Catheter Instructions for Use for more information on removal and disposal of the Imaging Catheter.

2. Hazards

Optical Hazards

The HyperVue Imaging System - Integrated contains a Class 1M laser system for imaging.

Warning: Inadvertent Exposure to Laser Light

Light energy emitted by the HyperVue Imaging System – Integrated lies in the invisible, near-infrared region of the electromagnetic spectrum. It cannot be seen with the naked eye.

Please take precautions to avoid inadvertent exposure as inadvertent exposure to laser light may cause skin or eye damage. Laser energy can be transmitted during calibration and pullbacks.

Viewing the laser output with certain optical instruments (for example eye loupes, magnifiers, and microscopes) may pose an eye hazard.

The laser aperture of the HyperVue Imaging System – Integrated is at the connection between the Imaging Catheter and Controller. The second aperture is at the distal end of the Imaging Catheter.

Safety Precautions for Lasers

During imaging, laser safety eyewear is not required.

Caution: Unauthorized Adjustments or Procedures

Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure. There are no user serviceable parts nor is any user performed maintenance required for the HyperVue Imaging System – Integrated. All adjustments are made at the factory before shipment to customers or on site by trained SpectraWAVE personnel. Tampering with or any attempt to modify the HyperVue Imaging System – Integrated may result in improper operation of the system and possibly user or patient injury.

Electrical and Mechanical Hazards

The HyperVue Imaging System – Integrated is not design to be moved without SpectraWAVE personnel.

Powering on the System

To reduce the risk of electric shock, do not connect the system's input power connection to equipment that is not protectively earth grounded.

If HyperVue Imaging System – Integrated does not power on when stand-by button is pressed; i.e. button does not illuminate; ensure power cord is plugged into an operating power source.

If HyperVue Imaging System – Integrated experiences an inadvertent power loss during use, wait 10 seconds and restart the instrument by pressing the stand-by button. Repeat if necessary.

WARNINGS

To avoid the risk of electric shock, this equipment must only be connected to supply mains with protective earth.

The system power cord plug is the primary means of isolating the system from AC Mains Voltage, do not reposition the system in such a way that it would be difficult to access and remove the plug from the wall.

DO NOT reposition the HyperVue Imaging System – Integrated in such a way where the power cord cannot be easily accessed; i.e. device pushed up against wall, power cord blocked by adjacent materials, devices.

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

The use of accessories, transducers and/or cables other than those specified, with the exception of those sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

The equipment or system should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

Table 2-1. IEC 60601 Guidance and Manufacturer's Declaration - Emissions

Guidance and Manufacturer's Declaration - Emissions		
The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The HyperVue Imaging System - Integrated uses 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	The emissions characteristics of the HyperVue Imaging System - Integrated 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.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	The HyperVue Imaging System - Integrated is suitable for use in a professional medical environment.

Table 2-2. IEC 60601 Guidance and Manufacturer's Declaration - Immunity

Guidance and Manufacturer's Declaration – Immunity			
The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact	

Guidance and Manufacturer's Declaration – Immunity			
The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	
EFT IEC 61000-4-4	± 2 kV ± 1 kV I/Os 100 kHz repetition frequency	± 2 kV ± 1 kV I/Os 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV Line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV Line-to-ground	± 0.5 kV, ± 1 kV Line-to-line ± 0.5 kV, ± 1 kV, ± 2 kV Line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycles 230 VAC 50Hz Dip: 0 % residual voltage for 0.5 cycle, Dip: 0 % residual voltage for 1 cycle, Dip: 70 % residual voltage for 25 cycles,	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HyperVue Imaging System - Integrated requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or battery.

Guidance and Manufacturer's Declaration – Immunity			
The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
	Interruption: 0 % residual voltage for 250 cycles 220 VAC 60Hz Dip: 0 % residual voltage for 0.5 cycle, Dip: 0 % residual voltage for 1 cycle, Dip: 70 % residual voltage for 30 cycles, Interruption: 0 % residual voltage for 300 cycles	230 VAC 50Hz Dip: 0 % residual voltage for 0.5 cycle, Dip: 0 % residual voltage for 1 cycle,	
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and Amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and Amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	
Radiated RF	3 V/m	3 V/m	

Guidance and Manufacturer's Declaration – Immunity			
The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
IEC 61000-4-3	80 MHz – 2,7 GHz 80 % AM at 1 kHz	80 MHz – 2,7 GHz 80 % AM at 1 kHz	

Table 2-3 – IEC Guidance and Manufacturer's Declaration - Immunity

Guidance and Manufacturer's Declaration – IMMUNITY to proximity fields from RF wireless communications equipment						
The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.						
Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN,	Pulse modulation b) 217 Hz	2	0,3	28

Guidance and Manufacturer's Declaration – IMMUNITY to proximity fields from RF wireless communications equipment

The HyperVue Imaging System - Integrated is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment. Use outside this environment could result in loss of essential performance of core workflow, image quality, catheter durability and deliverability, and user notifications.

Test frequency (MHz)	Band a) (MHz)	Service a)	Modulation b)	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
		802.11 b/g/n, RFID 2450, LTE Band 7				
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Chemical and Fire Hazards

There are no known chemical hazards associated with the HyperVue Imaging System - Integrated. To maintain protection against fire hazard the system is protected with manufacturer replaceable fuses per Section 8. Avoid flammable anesthetics and gases during use. Allow all solvents and cleaning solutions to evaporate prior to use to avoid flammable situations.

Liquids and Moisture

The HyperVue Imaging Console and Controller are not waterproof. Be careful not to expose to excessive moisture. Take care to prevent any liquid leaking or dripping onto the console or controller.

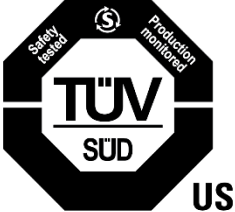
3. Labels and Symbols

Before using the HyperVue Imaging System – Integrated read this operating manual carefully, including the identification of symbols used on the equipment.

Table 3-1. Symbols

<i>Text Symbol</i>	<i>Symbol Illustration</i>	<i>Definition</i>	<i>Reference</i>
"I" in a Circle		"Stand-by"	IEC 60417-5009
Bold 'Rx Only'		Prescription Required. Restricted to sale by or on order of a physician.	
Blue man		Consult instructions for use	ISO 7010-M002
Heart in box		Defibrillation-proof type CF applied part	IEC 60417-5336
IPX0		Degree of Protection against Water Ingress for Console – No Protection	IEC 60529
"X" Over trash barrel		Waste Electrical and Electrical Equipment (WEEE)	2012/19/EU
Fuse symbol		Fuse	
AC symbol		Alternating current	IEC 60417-5032

<i>Text Symbol</i>	<i>Symbol Illustration</i>	<i>Definition</i>	<i>Reference</i>
Arrow pointing down		Equipotential (for use by service)	IEC 60417-5021
Triangle with lightning bolt		Dangerous Voltage	IEC 60878/ ISO 7010-W012
! in a Triangle		Specific caution in operator's manual	ISO 7000-0434A
Net Weight (kgs) Gross Weight (kgs)	NW GW	Weight	
Wine glass with crack on it		Contents are fragile, handle with care	
Temperature limits		Temperature limits	ISO 7000-0632
Relative Humidity		Relative humidity limits	ISO 7000-2620
Serial Number		Unique serial number of the instrument	ISO 7000-2493
Reference		Catalog Reference Number	ISO 7000-2493
Manufacturer		Name and address of the manufacturer	ISO 7000-3082
Date of Manufacture		Date Instrument was manufactured	ISO 7000-2497

<i>Text Symbol</i>	<i>Symbol Illustration</i>	<i>Definition</i>	<i>Reference</i>
Warning label		Imaging Laser Classification Label	IEC 60825-1:2014 Ed. 3
TUV		TUV Certification Mark	AAMI ES60601-1:2005+A1 IEC 60601-1-6:2010Ed.5+A1 IEC 60825-1:2014 Ed.3.0
FCC		Federal Communications Commission	

4. Cleaning, Disinfecting, and Disposal

Introduction

This chapter provides guidelines for cleaning of the console, monitors, and Controller and disinfecting of the Controller (as applicable), as well as disposal of the system components.

The Console, Controller, and monitors should be cleaned following the facility's standard protocols and cleaning schedule. If the operator suspects soiling or contamination of the Controller, the following cleaning and disinfection is recommended.

Console & Controller

The Integrated Console, Controller cable are rated at IPX0. Cleaning / disinfection instructions are as below:

- Turn off the system and unplug the power cord.
- **Cleaning:**
 - Use a Caviwipe™ to remove visible soil from the entire surface of the Console and Controller. Additional Caviwipes™ may be used if one Caviwipe™ is unable to remove the soil. Use a clean Caviwipe™ wipe and thoroughly wipe the surface.
 - Inspect the surface for visible soil. If there is any visible contamination, remove the visible contamination and wipe as many times as necessary until no visible soil is detected. Allow to air dry.
- **Disinfection:**
 - Ensure the Controller is cleaned as per the steps above before performing disinfection.

-
-
- Use a Caviwipe™ to remove visible soil from the entire surface of the Controller. To disinfect, use a Caviwipe™ and thoroughly wipe the surface. The surface should remain wet for a full three (3) minutes to disinfect.
 - If necessary, additional wipes can be used to ensure that the surface remains continuously wet for 3 minutes.
 - Allow to air dry.
 - Do not allow any cleaning fluid to leak into the HyperVue Integrated Console or Controller.
 - Allow all solvents and cleaning solutions to evaporate before using the Console and Controller.
 - If the Controller optical connectors are soiled, do not try to clean them. Instead, contact SpectraWAVE for further instructions.

NOTE: External surfaces of the Console and Controller may become discolored if subjected to cleaning agents for extended periods.

Monitors

Follow these guidelines to clean the monitors:

- Use a solution of 50% isopropyl alcohol and 50% water or any standard glass cleaner to clean the monitors. Avoid products containing ammonia or vinegar.
- Use a clean, lint-free cloth or towel.
- Spray the cleaner on the cloth, not directly on the monitor. Glass cleaner sprayed directly on the monitor can leak inside and cause damage.
- Carefully wipe the monitor to clean it.
- Always check for debris in the bezel. Clean the bezel in the same manner and with the same materials as the touchscreen, if necessary.

System Disposal at End of Life

It is the responsibility of the equipment owner to dispose of the system in a manner that conforms with local and country regulations. This normally requires the equipment to be collected separately from the municipal waste.

The equipment may have resale value on the market or as parts. Your distributor or SpectraWAVE should be contacted before disposal for potential assistance and to determine if the parts can be recycled. In the event that you choose to dispose of the system, locally, to reduce risk to the environment and to the persons discarding the equipment, a service engineer trained on maintenance and installation of the HyperVue Imaging System - Integrated may be contacted to assist in safe decommissioning of the system.

All components are RoHS compliant.

5. Maintenance and Installation

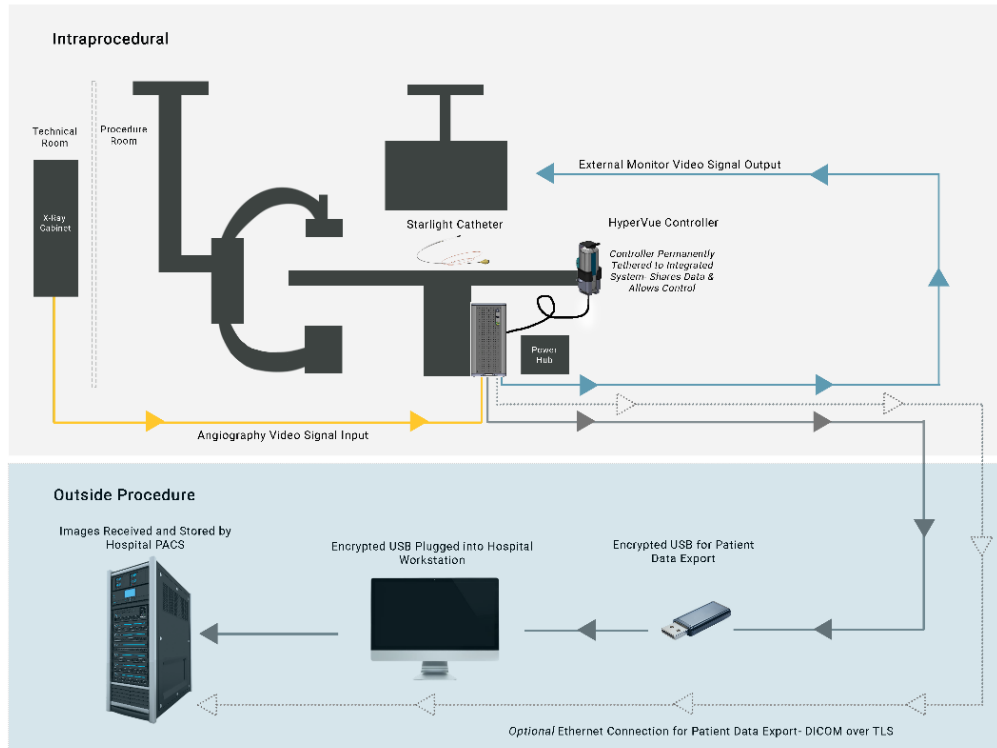


Figure 5-1. System Overview

Maintenance

There are no user serviceable parts in the HyperVue Imaging System - Integrated.

The HyperVue Integrated Console requires an annual preventive maintenance to verify calibration over time. Due to the complexity of the console and the specialized equipment required to measure the power without damaging the sensitive optics inside the console, all maintenance and service must be performed by a SpectraWAVE service representative. Contact SpectraWAVE for Service Contract options or to purchase a preventive maintenance visit.

Installation and service of the system must be performed by a SpectraWAVE representative.

SpectraWAVE will provide circuit diagrams, component part lists, descriptions, calibrations instructions to service personnel to assist in maintenance and parts repair.

Installation

Installation should be performed by trained SpectraWAVE personnel.



WARNINGS

- Do not reposition the system up against a wall.
- Do not allow adjacent materials and devices to block the power cord.

The system can run continuously.

The system incorporates a potential equalization conductor lug, adjacent to the power supply cord. This secondary grounding connection can be used by the facility to ensure equipotential grounding. Its use is optional but if needed by the room or facility, it may be utilized per IEC 60601-1 subclause 8.6.7

Table 5-1 lists the system's power requirements.

Table 5-1. Power Requirements

<i>Voltage</i>	<i>Amperage</i>	<i>Frequency</i>
100-240 VAC	6 A	50/60 Hz

6. Troubleshooting

The HyperVue Software Operator's Manual should be consulted for a full list of messages and software trouble shooting steps.

Table 6-1 - Troubleshooting

<i>Error Title and Message</i>	<i>Potential Cause</i>	<i>Potential Action</i>
System unresponsive	A rare fault condition has occurred and the system must be restarted to correct.	Press and hold the stand-by button on the side of the console until the system has been to powered down. Press the stand-by button again to power the system backup.

7. Theory of Operation

The HyperVue Imaging System - Integrated uses optical sensing to assess coronary vessel structure and content – DeepOCT™ and near infrared spectroscopy (NIRS).

DeepOCT is used to generate high resolution, cross sectional images of tissue microstructures. DeepOCT imaging is analogous to ultrasound in that the time delay and magnitude of echoes or back reflections are detected from the tissue of interest.

NIRS analyzes reflected light from tissue then determines whether lipid has been encountered at each angular and longitudinal position of the catheter.

8. Specifications

Table 8-1. Specifications

Specification	Description
Electrical	Line voltages 100-240 VAC 50/60 Hz
User accessible Fuses	None
Service accessible Fuses	L and N Input Lines Fuse type: T6.3AH 250V 5X20
Power Cable	18AWG NEMA 5-15P to IEC 320-C13, 10'
Accessories	1920 x 1080 15.6-inch Touchscreen 16:9 Controller Bed Mount Cradle Touchscreen Bed-rail Mount
External Interfaces	USB 3.0 – data export Equipotential Ground
Internal Interfaces	HDMI/DVI - angiography input HDMI – auxiliary display output DVI – auxiliary display output DVI – auxiliary display output 10/100/1000 Ethernet
Physical Dimensions	16"H x 7.5"W x 16" L
Weight	34 lbs. (15.5 Kg)
Laser Specifications (Class 1M Accessible Laser Output per IEC 60825-1:2014)	
Maximum Laser Power (Measured at Controller Aperture)	24 mW

Specification				Description			
Wavelength				1255-1365 nm			
Pulse Duration				Sweep rate: 100 kHz; duty cycle: 50%			
Environmental Operating Conditions				The system operates under the following atmospheric conditions (no condensation).			
Ambient temperature				15 °C to 30 °C			
Relative humidity				5% to 80%			
Atmospheric Pressure				≤≤≥ 70 kPa			
Transport and Storage Conditions				The instrument withstands the following transport and storage conditions without damage or performance deterioration.			
Ambient temperature				5 °C to 38 °C			
Relative humidity				5% to 95%			
Atmospheric Pressure				50 to 110kPa			
RFID Reader Specification							
Transmit & Receive on 13.56MHz (nominal). Values indicated below are for maximum allowable power.							
Field Strength @ 30m [uV/m]	30	106	334	15,848	334	106	30
~ dBuV/m (20log(uV))	30	40	50	84	50	40	30
Frequency [MHz]	< 13.110	13.110-13.410	13.410-13.553	13.553-13.567	13.567-13.710	13.710-14.010	> 14.010

FCC Statement



FCC ID: 2BQBY-3337628

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

The FCC ID can also be found in the HyperVue Software in the Settings->About tab.



CAUTION: Changes or modifications not expressly approved by SpectraWAVE could void the user's authority to operate the equipment.

customerservice@spectrawave.com

Telephone SpectraWAVE Customer Service
1-855-DEEPOCT



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