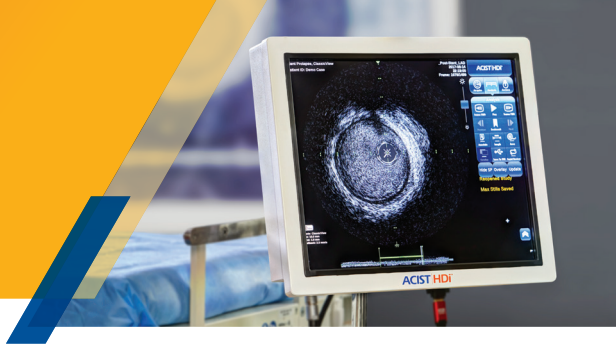
ACIST HDi®
HD IVUS System

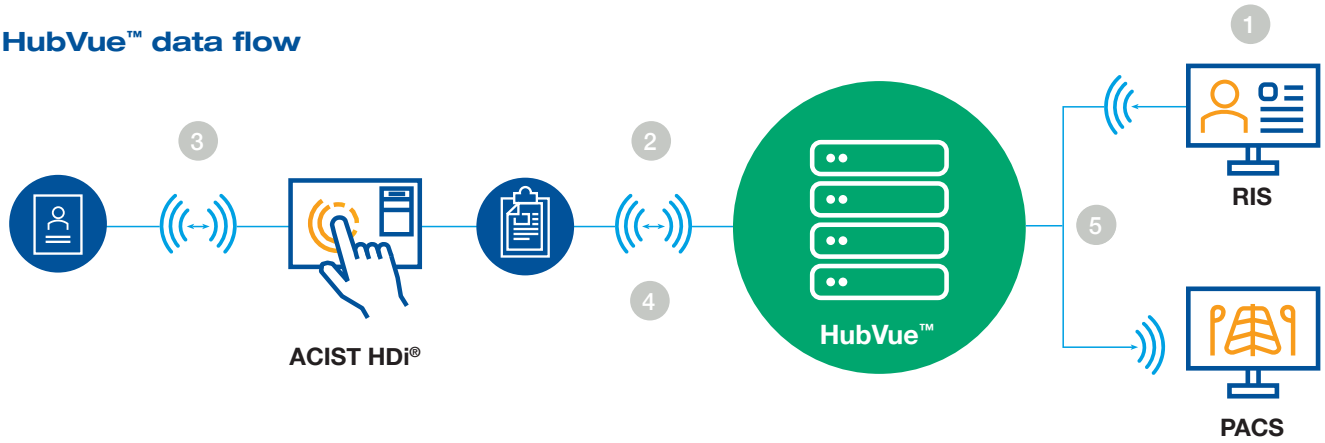
HubVue™
Imaging Workflow System



Streamline Cath Lab Operations

HubVue™ Imaging Workflow System streamlines Cath Lab operations by providing the patient worklist on the ACIST HDi® IVUS System and archiving the acquired images and measurements in your PACS system.

HubVue™ data flow



1. HubVue server queries and receives scheduled procedure from worklist
2. HubVue server sends the relevant procedure list to HDi devices
3. User selects the patient on HDi and performs the procedure
4. HDi sends the acquired images and measurements to HubVue server
5. HubVue sends data to PACS

HubVue™ security features

- Each user is assigned unique login credentials
- User functionality is limited by pre-defined user access levels
- User accounts support LDAP Integration and MS Active Directory accounts
- Secure SSL 128-bit encryption for protecting data in transit
- Data remains secure behind customer's provided on-premise server and firewall
- Anti-virus protection provided by customer based on their security policy

HubVue™ privacy features

- All data is encrypted within the system
- All system activity is recorded in the audit log
- User access is controlled by the site administrator

HubVue™ pre-implementation checklist

Minimum prerequisites

The following section is describing the necessary requirements to ensure the correct operating of the HubVue™ system.

Compatibility

ACIST HDi® version 3.1.3390 and later.

Server environment

HubVue system should be installed onto a **dedicated** Linux® Server, “physical” or “virtual” machine, which shall be compliant to the following minimum “hardware prerequisites”:

	Hardware	Virtual Machine
	vCPU Cores	4 cores minimum (best 8 cores)
	vCPU Frequency	2.4 GHz
	RAM	8 GB, 16 GB or 32 GB
	Ethernet	Full-duplex 1000Mb/s
	Disk Space	200 GB
	Operating System	Ubuntu Server 24.04 LTS x64

Off-the-shelf software environment

HubVue system shall be installed with the following minimum server software requirements:

	Desktop	Linux desktop
	Browser	Google Chrome browser (above v.131)
	Remote Access	RealVNC Server (7 and above)

Ordering information

SKU	Product description
020124	HubVue RIS/PACS Connectivity Server
020125	HubVue per Device Subscription
020126	HubVue Deployment Fee

For more information please visit ACIST.com or scan the QR code

ACIST HDi®
Prior to use, reference Instructions for Use, inside the product carton (when available) or at https://acist.com/library/ for more detailed information on safe use of the device.

Indications for Use: The ACIST HDi. System is intended to be used for the ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. The ACIST Kodama Intravascular Ultrasound Catheter is intended for use with the ACIST HDi System.

Contraindications: Contraindicated for patients with: bacteremia or sepsis; arterial spasm; major coagulation system abnormalities; mechanical heart valves that would be crossed by the catheter; severe hemodynamic instability or shock; total vessel occlusion (prior to initial stages of revascularization). Contraindicated for use in the cerebrovascular arteries. In coronary procedures, the product is also contraindicated for patients who are: disqualified for revascularization surgery; disqualified for balloon angioplasty (PTCA).

Important Safety Info: Intravascular ultrasound procedures using this product should be performed only by physicians and other medical professionals fully trained in the required techniques and procedures. The Kodama catheter contains a short monorail guidewire engagement system. As such, it is susceptible to guidewire entanglement and/or prolapse during catheter deployment and withdrawal. Before use and when possible during use, inspect the Kodama catheter carefully for kinks or any other damage. Do not use a kinked or damaged catheter because vessel damage and/or the inability to advance or withdraw the catheter may occur.

Never advance or withdraw the Kodama catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in elongation or separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.

When advancing the Kodama catheter through a stented vessel, short monorail catheter designs are susceptible to guidewire/ catheter entrapment, catheter tip separation, and/or stent dislocation.

Adverse events that may occur as a consequence of intravascular ultrasound imaging include (but are not limited to): vessel occlusion and/or abrupt closure; air embolism; vessel dissection, injury, or perforation; vessel rupture, injury, or perforation; acute myocardial infarction; cardiac arrhythmias including but not limited to ventricular tachycardia, ventricular fibrillation, and complete heart block; cardiac tamponade; catheter/guidewire entrapment; catheter induced ischemia; death; vessel trauma requiring treatment/surgical intervention, including angioplasty/ stent; infection; stent strut damage; stroke (including cerebral vascular accident and transient ischemic attack); thrombus formation or thromboembolism; vasospasm.

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