

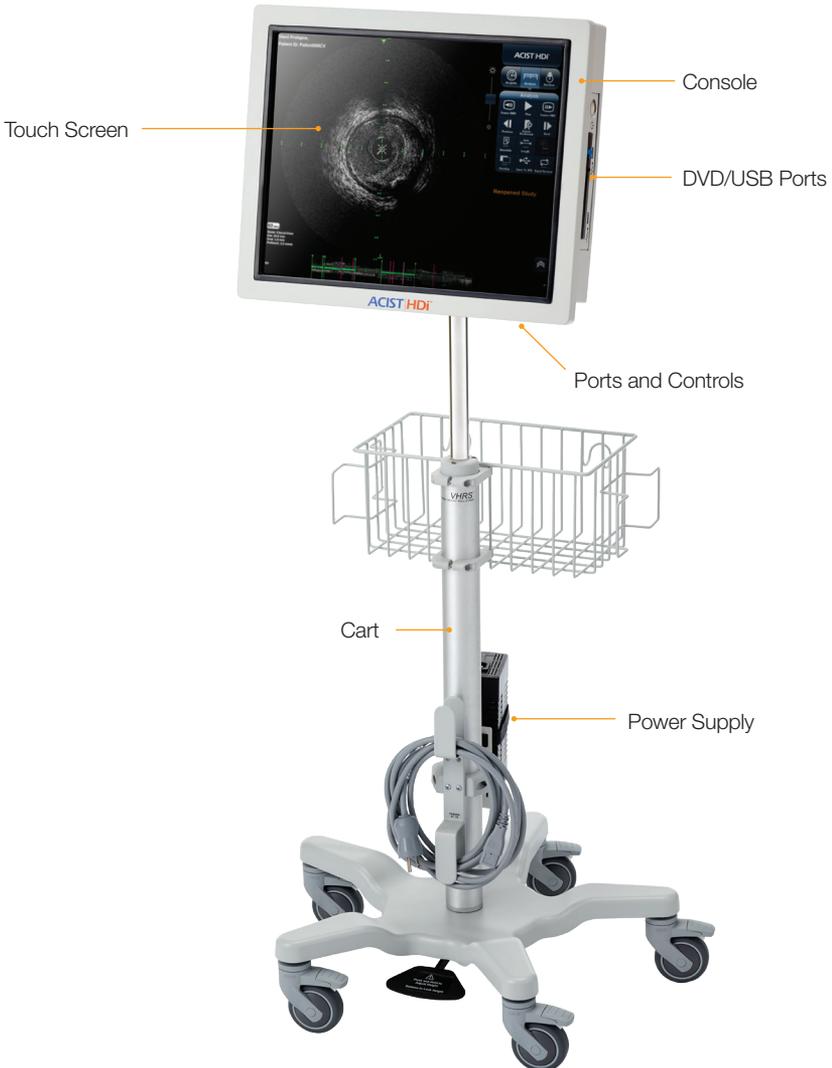
ACIST HDi®
ACIST Kodama®

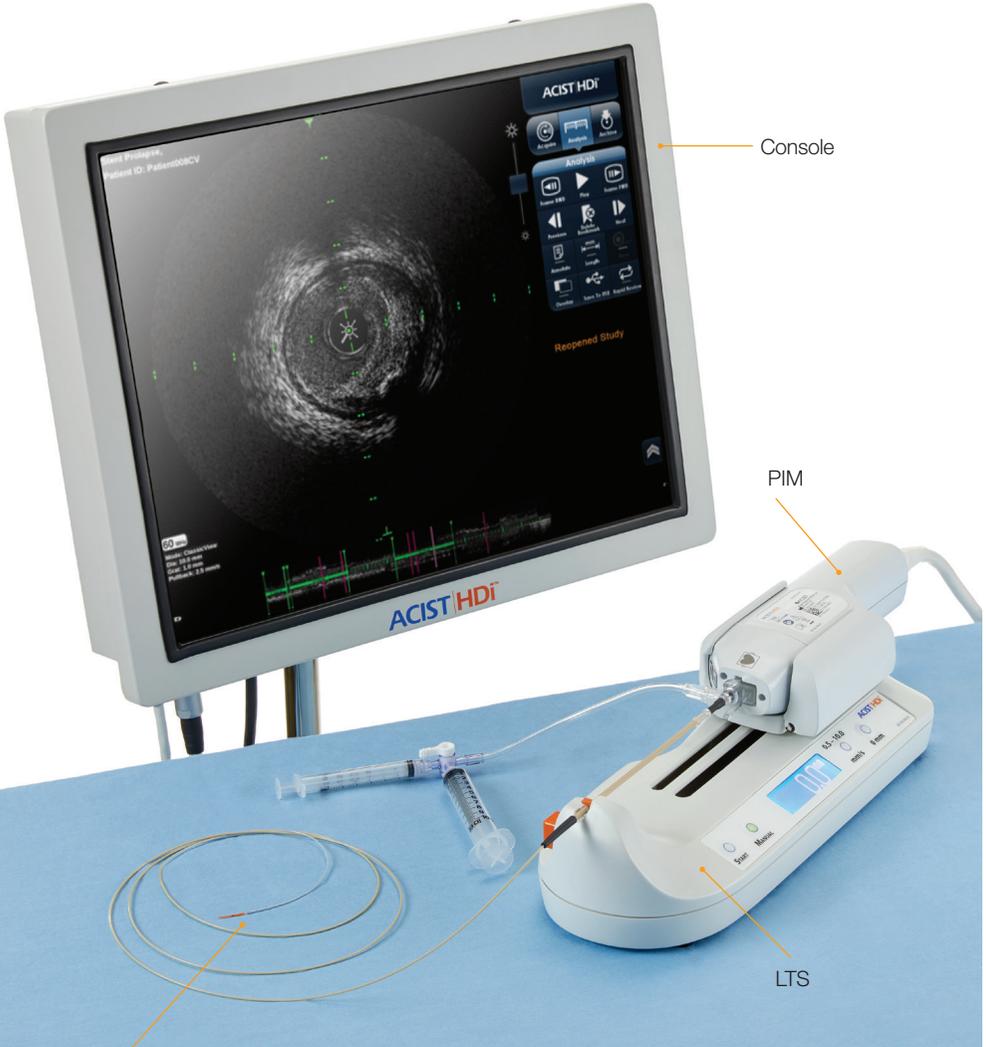


High-definition IVUS System
QUICK GUIDE

Know your ACIST HDi System

HDi IVUS System Components





Console

PIM

LTS

ACIST Kodama[®] Catheter

HDi IVUS System PIM and LTS

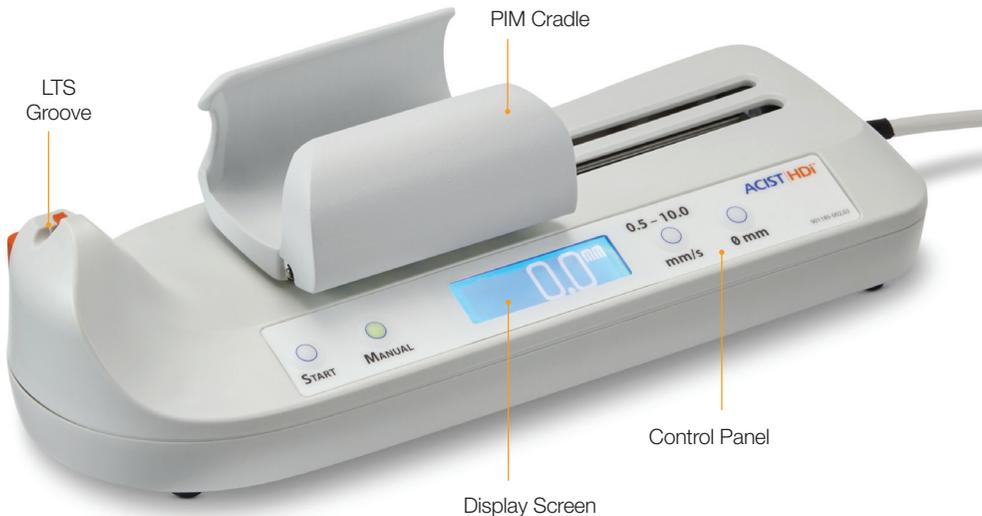
The Patient Interface Module (PIM)

has two buttons, one for turning on and off imaging and the other for recording (orange light when recording).

Record Button
Imaging Button
PIM Nose

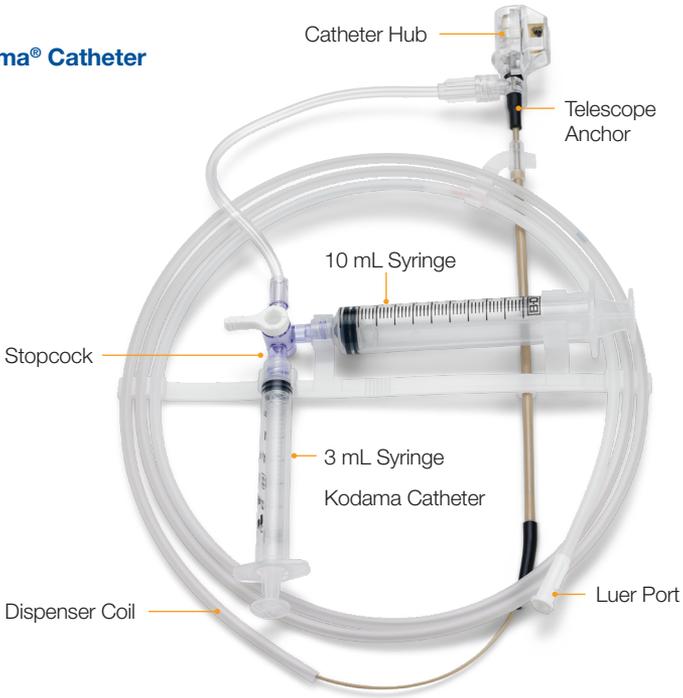


The Linear Translation System (LTS) provides a calibrated pullback (either automatic or manual). Controls include starting and stopping pullback, switching between automatic and manual mode, setting the pullback speed, and zeroing the linear distance traversed.



Hdi IVUS System Consumables

Kodama[®] Catheter



Sterile Bag



Preparing HDi IVUS System for Use



Step 1

Connect PIM to Console PIM Port.

Connect Power Supply to Console Power Supply Port.



Step 2*

Connect optional LTS to Console LTS Port.



Step 3*

Insert PIM into the cradle on the LTS, rotating the PIM until it is securely seated in place.

*LTS is optional during the complete system setup and use



Step 4

Connect the system power cord and press the power button. The system will self-test and start-up sequence will begin.



Step 5

When power up sequence completes, enter the System Login password.



Step 6

Verify the PIM and optional LTS show as white text to ensure the devices are properly connected.

Preparing the Kodama® Catheter



Step 7

Non-sterile operator: Slide PIM/LTS carriage to the fully retracted position.



Step 8

Sterile operator: Unfold the sterile bag, making certain that the bag attachment is on top of the fold-out section.
Insert your hands into the folds of the sterile bag as indicated.



Step 9

Using two-operator sterile technique, insert the PIM/LTS assembly into the open bag and grasp the proximal edge of the sterile bag and pull it over the PIM/LTS cables*.

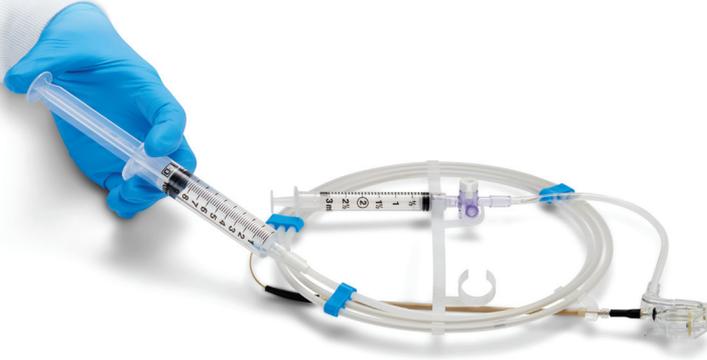
*The non-sterile, exposed cables should not come into contact with the sterile field.



Step 10

Fully seat the three-pin bag attachment into the three receptacles on the PIM nose.

Preparing the Kodama® Catheter



Step 11

Disconnect 10 mL syringe and fill with saline.

Reconnect the syringe to the Luer port on the dispenser coil.
Flush coil with saline to activate hydrophilic coating.

Reconnect the filled 10 mL syringe to the catheter stopcock.



Step 12

Fill 3 mL syringe with saline from the 10 mL syringe.

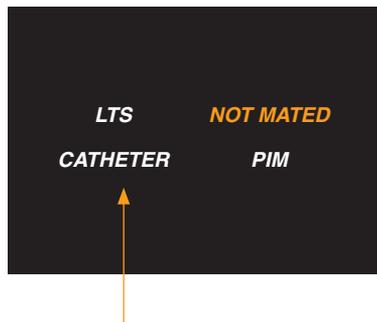
Rotate the stopcock so that the 3 mL syringe is set to introduce saline into the catheter.

The 10 mL syringe is the reservoir for refilling the 3 mL syringe.



Step 13

Connect the catheter hub to PIM nose through the sterile bag until click.



Step 14

Ensure **CATHETER** indicated on touchscreen turns from orange to white.

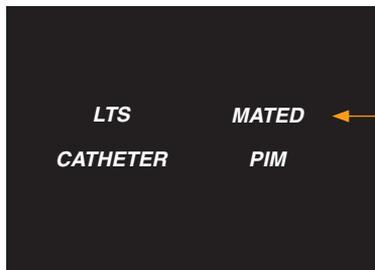
Preparing the Kodama® Catheter



LTS Groove

Step 15

While pressing the orange button on the side of the LTS, slide the telescope open and insert the telescope anchor into the LTS groove. Ensure the orange hook is fully closed and centered on the telescope anchor.



Step 16

Ensure **MATED** indicator on touchscreen turns from orange to white.



Step 17

Flush catheter TWICE using the full 3 mL syringe.
Use stopcock and 10 mL syringe to refill as needed.



Step 18

Slide PIM/LTS carriage all the way forward. Press the **MANUAL** button to lock the PIM in the forward position.

Adjust bag as needed.

Patient Information

Manual Entry



Step 1

Press **ARCHIVE**

ARCHIVE opens the section where you can enter patient information, and open, close, delete and export studies.



Step 2

Enter required patient information or select patient data field you want to modify.



Step 3

Press **ACQUIRE**

The system opens to the **ACQUIRE** interface screen, where imaging and recording occur.

Patient Information

Automatic Entry with ACIST Connect™



Step 1

Press **ARCHIVE**



Step 2

Press **PATIENT LIST**

1977-03-27	Male	2017-06-01	
1933-10-27	Female	2017-06-01	

Select

Step 3

Using the column heading to sort, find the patient's name. Press their name to highlight and press **SELECT**



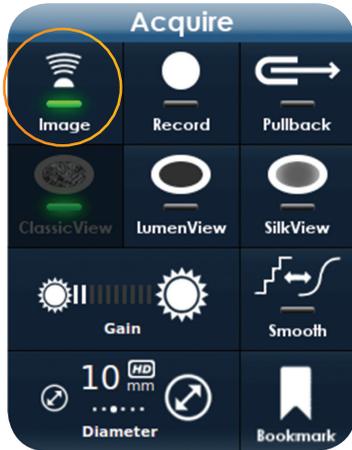
Step 4

Verify all patient information is correct. If necessary, enter or modify information.

Step 5

Press **ACQUIRE**

Start and Stop Live Imaging



Option 1 – Console Touchscreen Control

Press **IMAGE** button on touchscreen, green button will illuminate.

Confirm normal system operation by observing the bright ring pattern on the touchscreen.

Press **IMAGE** button again to stop imaging.



Option 2 – PIM Control

Press the imaging button  on the PIM to start imaging.

Press the imaging button  on the PIM to stop imaging.

Record a Loop PIM only



Step 1

Press **RECORD** on touchscreen or record button  on PIM to start recording.



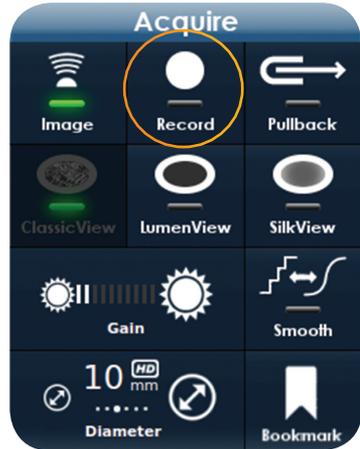
Step 2

Firmly grasp telescope anchor.



Step 3

Without moving anchor, slowly draw back the PIM to pull back the imaging element.



Step 4

Press **RECORD** on touchscreen  on PIM to stop recording.

Record a Loop

Manual pullback with LTS



Step 1

Press **MANUAL** button on LTS.
Confirm green light is illuminated on the button.

Step 2

Press **RECORD** on touchscreen or record button 
on PIM to start recording. (See previous page for visual)



Step 3

Slowly draw back PIM along the tracks of LTS to pull back imaging element.

Step 4

Press **RECORD** on touchscreen or record button 
on PIM to stop recording. (See previous page for visual)

Record a Loop

Motorized LTS Pullback



Step 1 - Start

To start pullback, press **PULLBACK** on touchscreen or press **START** button on the LTS.

When pullback starts, the following events will occur automatically:

- Imaging starts (if it wasn't already started)
- Recording starts (if it wasn't already started)



Step 2 - Stop

To stop pullback, press **PULLBACK** on the touchscreen or press **START** button on the LTS.

Shut Down



Option 1

Press **ACIST | HDI®** to open the information screen.

Press **SHUT DOWN** button located at bottom of the screen.



Option 2

Or Press the physical power/off button on the side of the console.

HDi System Messages

LTS Error Messages

- LTS Communication Error
- LTS Pullback Error
- LTS Command Fail Error
- LTS Download Error

Probable Cause(s)	Corrective Actions
An operational failure occurred.	<p>Note the error number.</p> <p>Try the following actions:</p> <ul style="list-style-type: none"> • Disconnect and reconnect the LTS. • Restart the system. • If the error message reoccurs, connect a different LTS. • Restart the system. <p><i>If the problem persists, contact an ACIST service representative.</i></p>

PIM Error Messages

- PIM Imaging Error
- PIM Communication Error
- PIM Recording Error
- Short Vector Error

Probable Cause(s)	Corrective Actions
An operational failure occurred.	<p>Note the error number.</p> <p>Try the following actions:</p> <ul style="list-style-type: none"> • Disconnect and reconnect the PIM. • Restart the system. • If the error message reoccurs, connect a different PIM. Restart the system. <p><i>If the problem persists, contact an ACIST service representative.</i></p>

HDi System Messages

Internal Error Messages

- Internal System Communication Error
- Internal Systems Initialization Error
- Internal Systems Timeout Error
- Internal Temperature Error

Probable Cause(s)	Corrective Actions
An operational failure occurred.	Note the error number. Restart the system. <i>If the problem persists, contact an ACIST service representative.</i>

DVD Error Messages

- Unable to write the Study to the DVD.

Probable Cause(s)	Corrective Actions
The system was unable to write to the DVD.	<ul style="list-style-type: none"> • Ensure that a blank DVD is inserted. • Try a different DVD. <i>If the problem persists, contact an ACIST service representative.</i>

USB Error Messages

- Export of Logs to USB failed – no writable USB storage partition found.
- Disk space error. Unable to perform archive to USB.
- Screenshot was not saved to USB.

Probable Cause(s)	Corrective Actions
An operational failure occurred.	Insert a USB drive with sufficient free space.

Kodama Catheter Troubleshooting

- Image fades during use.
- Image cannot be recovered.

Corrective Actions

- Flush the Kodama catheter with saline for several seconds.
 - Remove the Kodama catheter from the PIM and reinsert the Kodama catheter into the PIM (refer Step 13 for visual).
 - Confirm the catheter indicator on the touchscreen turns from orange to white.
 - If the condition persists, withdraw the Kodama catheter and use another. Return the malfunctioning Kodama catheter to an ACIST representative for analysis.
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For full operating instructions and troubleshooting, please refer to the HDi System User's Guide and Kodama IFU.



ACIST Medical Systems, Inc.

7905 Fuller Road
Eden Prairie, MN 55344
USA

acist.com

Service

Tel (USA): +1 888 670 7701
Fax: +1 952 253 4524
customer.support@acist.com



ACIST Europe B.V.

Argonstraat 3
6422 PH Heerlen
The Netherlands

Bracco Pty, Ltd.

PO Box 19
Roseville NSW 2069
Australia

Tel: 02 9415 8950

Service

Tel: +31 (0)45 750 7025
acistservice@bracco.com

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P/N: 30-100058_US 2/20 Rev 02

