

AVVIGO™ +

Multi-Modality Guidance System



General Specifications

Indication

The AVVIGO + Multi-Modality System is used to obtain physiologic and/or intravascular pathology information about a patient's coronary arteries. AVVIGO + Multi-Modality System may also be used to obtain intravascular pathology information in the peripheral vasculature and/or intracardiac structure. The IVUS modality is intended for intravascular ultrasound examinations in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. Also, IVUS modality is designed provide the visualization intracardiac anatomy and visualization of devices positioned within the heart with precise details in real time. FFR and DFR modalities are indicated to provide blood pressure gradient across coronary lesions of patient that undergo endovascular diagnostic and treatment procedures.

Weight and Dimension

AVVIGO Mobile System weight (unpacked and configured)	50 ± 1 kg (110.83 lb)
AVVIGO Mobile System dimensions (configured)	174 cm (68.5 in) H x 71.1 cm (28 in) W x 71.1 cm (28 in)
AVVIGO Integrated System weight (unpacked and configured)*	37.2 kg (82.0 lb)
AVVIGO Integrated System dimensions	25.4 cm (10 in) H x 58.4 cm (23 in) W x 50.8 cm (20 in) D
LCD MONITOR DISPLAY (mobile system only)	21" screen with Full HD 1920 x 1080 resolution (full dimension incl. borders) 550mm W x 360 mm H x 63.66 mm D
TABLET	13.3" LED-backlight screen with capacitive touch and easy (un)lock mechanism (full dimension incl. borders) 337 mm x 232mm
Table Side Control (option, integrated system only)	15" Capacitive Touch Screen, 369 mm x 223 mm

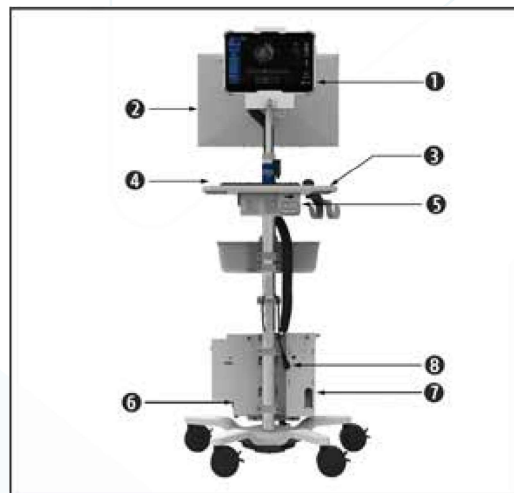
AVVIGO+ Multi-Modality System | Mobile Cart

Mobile Cart Bundle

Description	UPN
AVVIGO + Mobile System Bundle, EU + ROW	BUN30AVPLUSMOB
AVVIGO + Mob System, EU + ROW	H749 2493320C 0
MOTOR DRIVE MDU5 PLUS FPB	H749 MDU5PLUSF 0
Permanent Sled	H749 39316010 0

Mobile System Setup

Make sure that the Mobile System is in the location and position required.



1 Tablet Power Button, 2 Secondary Monitor, 3 Tray with Handles, 4 Keyboard and Mouse, 5 Main System Power Switch, 6 Acquisition Processor Power Button, 7 System Identification Label (not shown, back side), 8 Plug Power Cable to Medical Grade Hospital Mains.

Mobile Cart spare parts and accessories

Description	UPN
Mobile pole with 25in base	H749 00298 0
Isolation Station Transformer	H749 00982 0
AVVIGO Mouse and Keyboard Kit	H749 00983 0
AVVIGO PC Power Cords and Ethernet Kit	H749 00984 0
AVVIGO Mobile Monitor with Power Supply	H749 00986 0
AVVIGO Mobile Platform	H749 00988 0
AVVIGO Cable Clips and Monitor Mount Kit	H749 00989 0
Pole Docking Station	H749 09767 0
15ft Power Cable CEE 7/7 EU	H749 09774 0
Clamp Mobile V4 Acq PC and power supply	H749 2493010 0
Bin Mobile MDU Storage	H749 2493011 0
AVVIGO+ Zipper Cable Sleeve and Straps	H749 2493013 0
AVVIGO + TABLET New, Global	H749 2493022 0
AVVIGO+ Display Adapters	H749 2493043 0
AVVIGO+ Mouse and Keyboard Kit	H749 2493068 0
V4 Acq PC and power supply New Global	H749 24930ACQFRU 0
AVVIGO+ HDMI Splitter Kit	H749 24930TSC15 0

Localized Power Cable *

*Localized Power Cable Options EU

Description	UPN
15ft IsoX Power Cable CEE 7/7 EU	H749 09774 0
15ft IsoX Power Cable UK	H749 09775 0
15ft IsoX Power Cable Italy 3 prong	H749 09776 0
15ft IsoX Power Cable Denmark	H74 909791 0

AVVIGO+ Multi-Modality System | Integrated Configuration

Integrated Configuration

The Integrated System is customized for the clinical environment where it is used. In a typical integrated configuration, the system components, are shown.



1 Tablet in Desktop Docking Station, 2 System Identification Label, 3 Isolation Station power button, 4 Keyboard and Mouse are installed in the control room adjacent to the procedure room.

Integrated System Setup-Procedure Room

In Installed configurations, the Primary Display (tablet) is located in the Control Room. A Secondary Display, compatible resolution of 1920 px X 1080 px, can be directly connected to the HDMI port on the tablet desktop docking station, and is an identical monitor with precisely the same information.

Tableside Control, compatible resolution of 1920 px X 1080 px, is a rail-mounted touchscreen display that allows for interaction with the system at the bedside to improve the overall procedural workflow.



1 Secondary Display, 2 FFR Link, 3 Tableside Control, 4 Acquisition Processor located either behind the monitor or on the floor, 5 Motor drive unit.

Integrated System Bundles

Description	UPN
AVVIGO + Integrated System Bundle, EU + ROW (without Table Side Control)	BUN30AVPLUSINT
AVVIGO + Integrated System Bundle, EU + ROW (with Table Side Control)	BUN30AVPLUSINTTSC
AVVIGO + Int System, EU + ROW	H749 24933201 0
MOTOR DRIVE MDU5 PLUS FPB	H749 MDU5PLUSF 0
Permanent Sled	H749 39316010 0
AVVIGO + Table Side Control Kit	H749 24930TSC01 0

Integrated System spare parts and accessories

Description	UPN
Installed PC to Xformer Power Adapter	H749 00932 0
Isolation Station Transformer	H749 00982 0
AVVIGO Mouse and Keyboard Kit	H749 00983 0
AVVIGO PC Power Cords and Ethernet Kit	H749 00984 0
Desktop Docking Station	H749 09772 0
15ft Power Cable CEE 7/7 EU	H749 09774 0
AVVIGO+ Zipper Cable Sleeve and Straps	H749 2493013 0
AVVIGO + TABLET New, Global	H749 2493022 0
AVVIGO+ Display Adapters	H749 2493043 0
AVVIGO+ Mouse and Keyboard Kit	H749 2493068 0
V4 Acq PC and power supply New Global	H749 24930ACQFRU 0
Localized Power Cable*	



AVVIGO+ Multi-Modality System | Specifications

Type	Parameter	Value
Electrical	Power requirements	100 VAC to 240 VAC, frequency 50 Hz / 60 Hz
	AVVIGO Mobile System power consumption (steady state)	600 VA maximum
	AVVIGO Integrated System power consumption (steady state)	600 VA maximum
	Catheter frequencies supported	9 MHz to 60 MHz
	Safety	Class I per EN 60601-1, UL2601-1, JIS-T-0601-1, ANSI / AAMI ES60601-1 Applied part for IVUS modality: (Motodrive Unit) Defibrillation-proof type CF and any of the IVUS catheters specified in Appendix C. Applied part for Physiology: Comet II Pressure Guidewire
	Ingress Protection Rating	IPX1 **
	LAN In / Out	10 / 100 / 1000 BaseT Ethernet LAN for DICOM
	Video Out	HDMI Compatible Connector 1920 px X 1080 px (Full HD)
	Tablet Bluetooth	The operating frequency of the Bluetooth Communication Module is 2.4 GHz to 2.4835 GHz. The range of the Bluetooth Communication Module is up to 7 meters, line-of-sight. The maximum output power of the Bluetooth Communication Module is 9.5 dBm.
Physical	AVVIGO Mobile System weight (unpacked and configured)	50 ± 1 kg (110.83 lb)
	AVVIGO Integrated System weight (unpacked and configured)	* 37.2 kg (82.0 lb)
	AVVIGO Mobile System dimensions (configured)	174 cm (68.5 in) H x 71.1 cm (28 in) W x 71.1 cm (28 in) D
	AVVIGO Integrated System dimensions	25.4 cm (10 in) H x 58.4 cm (23 in) W x 50.8 cm (20 in) D
Environmental (operating)	Temperature	10 °C to 40 °C (50 °F to 104 °F)
	Relative humidity	30 % RH to 75 % RH
	Atmospheric Pressure	700 hPa to 1060 hPa
Environmental (storage / transit)	Temperature	- 29 °C to 60 °C (- 20.2 °F to 140 °F)
	Relative humidity	30 % RH to 85 % RH
	Atmospheric Pressure	700 hPa to 1060 hPa

Single Use Devices | Information

	Product Name	Recommended Guide Catheter or Sheath Size	UPN
Coronary	COMET II Pressure Guidewire	5F	H749 3935931 0
	OPTICROSS HD Imaging Catheter	5F	H749 3935202 0
	OPTICROSS 6 HD Imaging Catheter	6F	H749 3935406 0
	OPTICROSS Imaging Catheter	5F	H749 51812 0
	OPTICROSS 6 Imaging Catheter	6F	H749 518126 0
Peripheral	OPTICROSS 18	6F	H749393270018 0
	OPTICROSS 35	8F	H7493932 80135 0
Intra-cardiac	ULTRA ICE™ PLUS Catheter	n/a	M004 9910 0
Accessories	Permanent Sled Bag	n/a	H74939315010 0
	MOTOR DRIVE MDU5 PLUS FPB	n/a	H749 MDU5PLUSF 0

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IEU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.