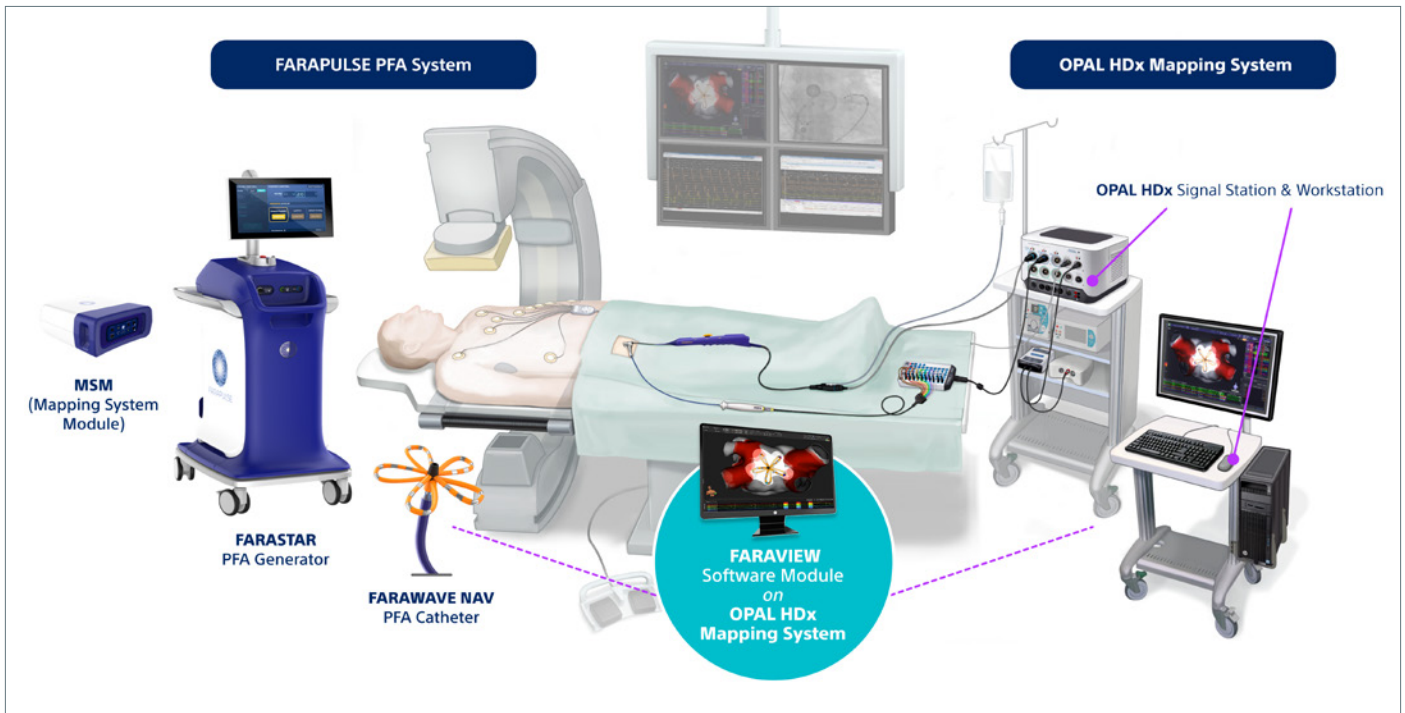


OPAL HDx™ Mapping System

Signal Station, Workstation PC, Localization Generator, FARAWAVE™ NAV Pulsed Field Ablation Catheter, INTELLAMAP ORION™ Mapping Catheter, Carts



The OPAL HDx Mapping System provides integrated mapping for both RF and pulsed field ablation procedures while giving enhanced access to the transformational capabilities of the FARAPULSE™ Pulsed Field Ablation System. Offering a complete range of mapping solutions, OPAL HDx Mapping System provides you visualisation for the therapy modality that best meets your case needs.

System specifications

The OPAL HDx Mapping System includes the following components:

- Workstation (PC, Software, Monitor, and Accessories)
- Signal Station
- Localization Generator
- Breakout Boxes (IC In), IC Out Direct Connect Cables, and IC-72 Out Universal Cable
- ECG In Cables, ECG Out Boxes, and ECG Out Direct Connect Cables
- Ablation Connection Boxes (accessory of Ablation System)
- System and Workstation Carts (available as optional accessories)



OPAL HDx™ Mapping System

A full-spectrum mapping experience

System specifications

SIGNAL STATION

The Signal Station (SiS) accepts signals from the intracardiac catheters and ECG electrodes used during Electrophysiology (EP) procedures. It amplifies and digitizes these signals and transfers them to the Workstation for real-time processing and display. The SiS also supports catheter localisation/tracking and diagnostic stimulation.

- Position:
 - The Signal Station should be placed on a dedicated table or cart that is adjacent to the foot of the patient table
- Dimensions (W x D x H):
 - 41.0 x 38.9 x 26.2 cm; 16.2 x 15.3 x 10.3 in
- Patient Inputs:
 - 12 lead ECG
 - 64 intracardiac channels for the INTELLAMAP ORION™ Mapping Catheter
 - 136 additional intracardiac channels to connect commonly used diagnostic and ablation catheters
- Connectivity with other lab equipment:
 - Stimulator: Up to 2 stimulator channels
 - Recording System: Outputs all signals to a recording system including Direct Connect IC and ECG Out Cables for LABSYSTEM™ PRO and GE CardioLab Recording Systems
 - FARASTAR PFA Generator: Mapping System Module: (19 x 41 x 46 cm; 7.5 x 16.2 x 18.1 in).
 - RF Generators: MAESTRO 4000™ and INTELLAGEN™ cardiac ablation system

- Signals Specifications:
 - Resolution: 24 bits
 - Noise floor: 10 μ V
 - Input Amplitude Accuracy: < 5%



- HDx power supply label:
 - 100-240V, 3.0A, 50Hz
 - 100-220V, 3.0A, 60Hz
- Safety:
 - IEC 60601-1; IEC 60601-1-1; IEC 60601-1-2; IEC 60601-2-27; IEC 60601-1-6
 - CISPR 11/EN 55011:2009+A1:2010, Group 1, Class A
 - Protection against electric shock: Class I, Type CF
 - Protection against fluid ingress: IPX1
 - Isolation: >5000V

System specifications

WORKSTATION PC

The Workstation includes computer hardware (e.g., computer, monitor, keyboard, mouse, and power cords) and system software. It acquires, interprets, and displays the data received from the Signal Station during EP mapping procedures. In addition to operating the system software, the Workstation can also store, retrieve, and export study data.

- Position:
 - The Workstation is typically positioned in the control room
- Operating System: Linux
- Dimensions (W x D x H):
 - EMBEDTEK – 17.3 x 47.5 x 43.2 cm; 6.8 x 18.7 x 17.0 in
- Connection to Signal Station:
 - Fibre optic cable
- CPU Power Inputs:
 - Input Voltage: 100-240 VAC
 - Input Current: 10-5 A
 - Input Frequency: 50-60 Hz
- Accessories: Keyboard and mouse
- Monitor:
 - Display Size: 24"
 - Resolution: 1920 x 1200



- Dimensions (W x D x H):
 - 56.2 x 6.1 x 36.8 cm; 22.1 x 2.4 x 14.5 in
 - Dimensions with stand (W x D x H):
 - 56.2 x 23.5 x 42.9 cm; 22.1 x 9.3 x 16.9 in
- Monitor Power Inputs:
 - Input Voltage: 100-240 VAC
 - Input Current: 1.0A
 - Input Frequency: 50-60 Hz

OPAL HDx™ Mapping System

A full-spectrum mapping experience

System specifications

LOCALIZATION GENERATOR

The Localization Generator generates magnetic fields under the patient table, to support catheter localization.

- Position:
 - The Localization Generator is placed under the patient table
- Dimensions (W x D x H):
 - 45.0 x 55.4 x 7.0 cm; 17.8 x 21.9 x 2.8 in



System specifications

MAPPING SYSTEM MODULE

The FARASTAR™ MSM is intended to filter/protect the inputs of the OPAL HDx Mapping System from their connection to the patients during PFA delivery.

- Dimensions (W x D x H):
 - 19 x 41 x 46 cm; 7.5 x 16.2 x 18.1 in



Mapping for PFA

Specifications

FARAWAVE™ NAV Pulsed Field Ablation Catheter

Reduce catheter exchanges by mapping and ablating with the magnetically tracked FARAWAVE NAV Pulsed Field Ablation Catheter. Part of the FARAPULSE™ Pulsed Ablation System, the FARAWAVE NAV Pulsed Field Ablation Catheter is integrated into the OPAL HDx Mapping System.

- Variable deployment, 31–35 mm distal diameter
- Thumb-activated slider on handle

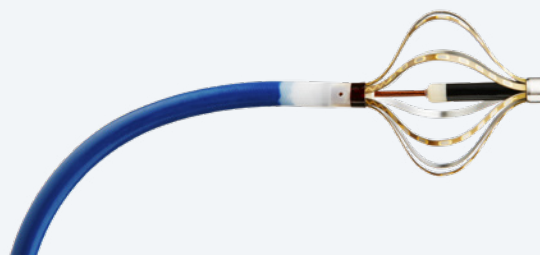


Mapping for thermal ablation

INTELLAMAP ORION™ Mapping Catheter

The INTELLAMAP ORION is a 64-electrode catheter designed to acquire high-resolution signals from all cardiac chambers.

- 8.5F, bi-directional steerability
- 64 0.4 mm² electrodes, 8 splines
- Variable deployment, 3–22 mm diameter
- Connects directly to the Signal Station with a direct connect umbilical cable



OPAL HDx™ Mapping System

A full-spectrum mapping experience

Additional equipment

Optional

Carts may be acquired to enhance system storage and transportation.

- System Cart:
 - Holds the Signal Station, Localization Generator, and accessories
- The System Cart can also hold a monitor:
 - Dimensions (W x D x H) without monitor: 71.2 x 57.2 x 109.3 cm; 28.0 x 22.5 x 43.0 in
 - Dimensions (W x D x H) with monitor: 71.2 x 57.2 x 177.9 cm; 28.0 x 22.5 x 70.0 in
- Workstation PC Cart:
 - Holds the Workstation, monitor, keyboard, and mouse
 - Dimensions (W x D x H) with monitor: 71.2 x 57.2 x 147.4 cm; 28.0 x 22.5 x 58.0 in



RHYTHMIA HDx™ is now OPAL HDx™ Mapping System.

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.IFU-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.

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FARAPULSE Pulsed Field
Ablation System – CE 0459,
OPAL HDx, INTELLAMAP ORION –
CE 2797