

# Medtronic

## Affera™ Mapping and Ablation System with Prism-2 Software

### Experience a new paradigm in electrophysiology.

The integrated design of the Affera mapping and ablation system with Prism-2 software establishes the Affera ecosystem as the hub of the electrophysiology (EP) lab, streamlining the procedural workflow by incorporating the all-in-one, dual-energy, wide-area Sphere-9™ catheter.

With synergy navigation (magnetic and calibrated impedance), Prism-2 also provides visualization of non-sensor-based diagnostic catheters such as a coronary sinus (CS) catheter, further enabling a low-fluoro workflow.

Additionally, the Prism-2 software empowers users with the latest hardware to support upcoming innovations.



### Ordering information

The components below are typically ordered together to create a functioning system.

Order information	Details
AFR-00016 Affera integrated mapping system	Includes Prism-2 mapping software, magnetic field generator, HexaMap CIU, workstation, cables/accessories
AFR-00004 HexaGen™ RF generator	Includes RFG assembly, remote control, foot pedal, cables/accessories
AFR-00005 HexaFlow™ irrigation pump	Includes pump, pole mount, cables/accessories
AFR-00008 HexaPulse™ PF generator	Includes PFG assembly, cables/accessories
AFR-00013 System cart	Customized for Affera system components

⋮ Optional

### Compatible accessories

Order information	Details
AFR-00015 Impedance localization patch kit	Includes 4 kits per order; 6 impedance localization patches per kit
AFR-00002 Tubing kit	Includes 4 tubing kits per order; compatible with HexaFlow irrigation pump
AFR-00001 Sphere-9 catheter	Combined mapping and ablation catheter
AFR-00006 Catheter extension cable	Single-use cable for use with Sphere-9 catheter and Affera system



## HexaFlow Irrigation Pump

Optimized irrigation delivery for compatible Affera catheters

### Specifications

Flow rate	Baseline: 4 mL/min PF delivery: 15 mL/min RF delivery: 30 mL/min
Air bubble detection	$\geq 2 \mu\text{L}$
Power supply	100 V-240 VAC, 50/60 Hz
Weight	11 kg
Dimensions (W x H x D)	28 cm x 28 cm x 27 cm



## HexaGen RF Generator

Temperature-controlled RF energy delivery

### Specifications

RF output voltage	0-240 V (rms)
Impedance operating range	20-120 $\Omega$
RF output current (peak)	0-3.75 A (rms)
Ambient operating range	15-30 °C
Power supply	100 V-240 VAC, 50/60 Hz
Weight	17 kg
Dimensions (W x H x D)	39 cm x 30 cm x 35 cm



## HexaPulse PF Generator

Providing unipolar/biphasic PF energy delivery

### Specifications

PF output voltage (peak)	3333 V
Impedance operating range	20-120 $\Omega$
PF output current (peak)	57 A
Ambient operating range	15-30 °C
Power supply	100 V-240 VAC, 50/60 Hz
Weight	11 kg
Dimensions (W x H x D)	39 cm x 14 cm x 35 cm



## HexaMap™ Catheter Interface Unit (CIU)

Magnetic and impedance navigation and map acquisition with intracardiac electrogram and electrocardiogram display, recording, and pacing

### Specifications

Pacing current	20 mA max
Power supply	100 V-240 VAC, 50/60 Hz
Weight	15 kg
Dimensions (W x H x D)	39 cm x 14 cm x 37 cm

## Full Affera system with cart

### Specifications

Ambient operating range	15-30 °C
Cart dimensions (W x H x D, not including pole)	64 cm x 116 cm x 72 cm
Cart capacity	150 kg

## Affera™ Integrated Mapping and Ablation System Brief Statement Indications

The Sphere-9 catheter is indicated for use in cardiac electrophysiological mapping (stimulation and electrogram recording) and for treatment of drug refractory, recurrent, symptomatic persistent atrial fibrillation (episode duration less than 1 year) and radiofrequency ablation of cavotricuspid isthmus dependent atrial flutter when used with the Affera mapping system.

The Affera Integrated Mapping System is intended to be used for catheter-based cardiac electrophysiological mapping. The mapping system allows pacing and real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The acquired patient signals, including body surface electrocardiograms and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

### Contraindications

Do not use this device under the following circumstances:

- In patients with an active systemic infection.
- In patients who have had cardiac surgery in the preceding eight weeks, as the risk of perforation may increase.
- In patients with intracardiac thrombus or myxoma, as the catheter may precipitate an embolus.
- In coronary vessels with diameter smaller than the expandable ablation electrode, as the catheter may damage the coronary vessels.
- In patients with prosthetic valves, as the catheter may damage the prosthesis.
- Using the transaortic retrograde approach in patients who have had aortic valve replacement.
- Using the transseptal approach in patients with an interatrial baffle or patch, as the opening could persist and result in an iatrogenic atrial shunt.

### Warnings and Precautions

Do not reuse, reprocess, or resterilize devices labeled single-use only. Only use with compatible devices listed in the IFU. The Integrated Affera Mapping System requires use of a set of proprietary localization patches to detect patient displacement and respiratory motion and deliver low energy patient auxiliary signals.

Treatment location should be confirmed using alternative techniques (e.g. fluoroscopy, intracardiac electrograms, intracardiac echocardiography) before treatment.

A connection to a compatible cardiac stimulator is allowed provided the stimulator is electrically isolated or physically disconnected when RF or PF energy is applied to the patient, outputs of the generator and stimulator must be isolated to prevent patient injury or damage to equipment.

The pacing functionality in the Affera Integrated Mapping System is not a life support device and is for diagnostic purposes only. Pacing may induce intentional or unintentional life-threatening cardiac arrhythmias.

Intravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. Patient injury may result from excessive delivery of fluids. Anticoagulation treatment should adhere to consensus guidelines,

Avoid steering the Sphere-9 catheter near other catheters to reduce the possibility of the catheters becoming entangled. Cardiac devices may be damaged by energy delivery. Catheter interactions with implantable leads may result in lead dislodgement or possible thrombus.

Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias.

Care should be taken when ablating near sensitive structures (i.e., conduction system, coronary arteries) as unintended patient harm may occur. Catheter entrapment within the heart is a possible complication of cardiac ablation procedures that could necessitate surgical intervention.

The Affera Integrated Mapping and Ablation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. System operation may be temporarily interrupted if exposed to excessive external electromagnetic disturbance or ESD.

### Potential Adverse Events or Potential Complications

Atrioesophageal fistula, Cardiac perforation / tamponade, Cardiac or respiratory arrest, Stroke

Conduction system injury, Coronary artery spasm / occlusion / stenosis, Damage / dislodgement to ICD or implantable pacemaker, Death, Embolism, Hemoptysis, Infection, Myocardial infarction, Phrenic nerve palsy / paralysis, Pulmonary edema, Pulmonary vein stenosis, Valve damage, Vessel dissection

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at [www.medtronic.com](http://www.medtronic.com).

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

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