

Medtronic

Affera™ Mapping and Ablation System

Experience a new paradigm in electrophysiology.



The compact, sleek Affera mapping and ablation system boasts a truly modern and integrated design unlike any other mapping and ablation systems in the lab today. The thoughtful design supports broad system control from the interactive touchscreens on the HexaGen™ RF generator or remote control (not pictured) while also sharing unique ablation parameters from the ablation generators to the Affera™ Prism-1 mapping software (located on a workstation – not pictured).

Ordering information

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

Order information	Details
AFR-00003 Affera mapping system	Includes Prism-1 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

Full system

Affera system with cart

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



Temperature-controlled RF energy delivery

HexaGen™ RF Generator

Specifications

RF output voltage	0-240 V (rms)
Impedance operating range	20-120 Ω
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

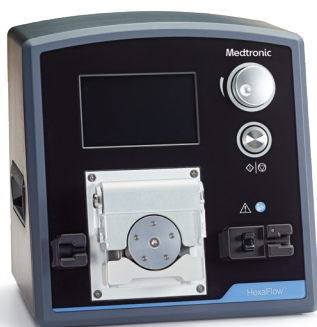


Providing unipolar/biphasic PF energy delivery

HexaPulse™ PF Generator

Specifications

PF output voltage (peak)	3333 V
Impedance operating range	20-120 Ω
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



Optimized irrigation delivery for compatible Affera catheters



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

HexaFlow™ Irrigation Pump

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

HexaMap™ Catheter Interface Unit (CIU)

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 35 cm

Compatibility

Order information	Details
AFR-00007 Location reference patch kit	Includes 4 kits per order; 2 magnetic 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

Brief Statement

Affera™ Mapping System

Indications

The Affera 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 intracardiac electrograms, may also be recorded and displayed on the system's display screen.

Contraindications

Refer to the instructions for use accompanying the compatible catheter for contraindications prior to use with the system.

Warnings and Precautions

General useuse –Treatment location should be confirmed using alternative techniques (e.g. fluoroscopy, intracardiac electrograms, intracardiac echocardiography) before treatment. • Use only compatible accessories. The use of other accessories, or modification of accessories, can alter system performance and lead to damage or patient harm. • The Affera Mapping System requires use of a disposable Location Reference Patch Kit to detect patient displacement and respiratory motion. The Location Reference Patch Kit is intended for use only with the Affera Mapping System. The location reference patch and compatible catheters are intended for single patient use only.

System connections and safetyuse – The Affera mapping system is designed for direct connection to compatible catheters and accessories only. System operation may be temporarily interrupted if exposed to excessive external electromagnetic disturbance or ESD. • 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 injury to the patient or damage to the equipment. • The system has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment, use may result in patient injury.

Pacinguse – The pacing functionality in the Affera mapping system is not a life support device and is for diagnostic purposes only.

• Pacing may induce intentional or unintentional life-threatening cardiac arrhythmias.

Potential Adverse Events or Potential Complications

Refer to the instructions for use accompanying the compatible catheter for potential complications and adverse events associated with cardiac mapping procedures.

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.

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

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