

Affera™ mapping and ablation system with Prism-2 software

Intuitive. Refined. Streamlined.

The Prism-2 software and hardware upgrade for the Affera mapping and ablation system delivers meaningful capabilities today and serves as the foundation for upcoming innovation.

Specifically, Prism-2 introduces Synergy Navigation (magnetic and calibrated impedance tracking) which enables visualization of non-sensor-based catheters to improve support of low- or zero-fluoro workflows.

Additionally, Prism-2 enhances clinical workflows with the addition of features including Beat Matching and Pace Tagging and further streamlines EP lab integration with improved lab setup efficiencies.

Some features are only supported with the Sphere-9 catheter.



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-00012 Sphere-360™ pulsed field ablation catheter	Combined mapping and ablation catheter
AFR-00006 Catheter extension cable	Single-use cable for use with Sphere-9 catheter, Sphere-360 catheter, and Affera system
AFR-00022-C Sphere-360 ablation cable	Single-use cable connecting catheter to the PF generator module of the Affera ablation system for energy delivery



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

† Sphere-360 catheter is nonirrigated and operating the pump is not required during use.



HexaGen RF generator

Temperature-controlled RF energy delivery

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





HexaPulse PF generator

Providing unipolar/biphasic PF energy delivery

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



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

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s).

Please note that the intended use of a product may vary depending on geographical approvals.

See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events.

For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI.

If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com.

Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices.

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