

Medtronic

# Affera™ Mapping System

Automate | Inform | Optimize

## Automate

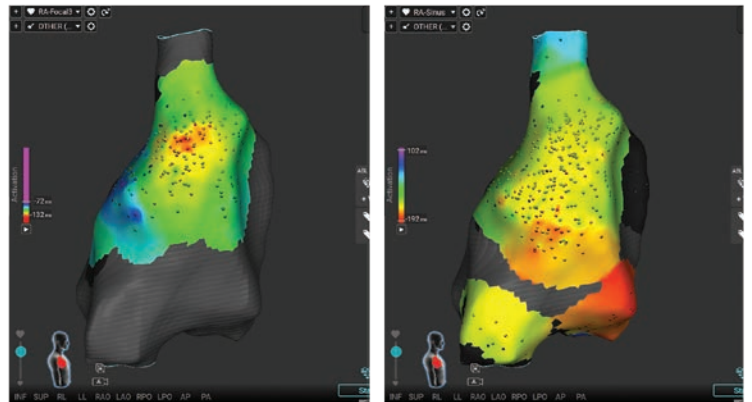
The Affera mapping system is designed to enhance and streamline the mapping workflow with fast processing speeds and low latency.

### Automatic and continuous collection

Collect everything and display the rhythm you want to see.

### Fast remap and cloning

Start a new map quickly and efficiently while maintaining the active map's geometry, chamber, rhythm, window of interest, or even EGM data.

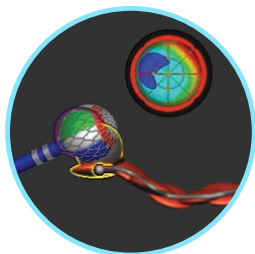


Left: AT at 400 ms

Right: AT at 300 ms

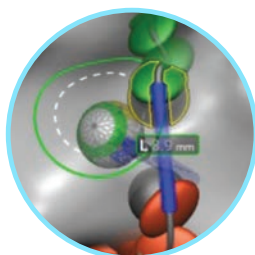
## Inform

The Affera mapping system provides optimized clinical tools to reduce intraprocedural complexity.



### Automatic tags

Tag shape and colors provide instant insights about tip location, orientation, and lesion creation.

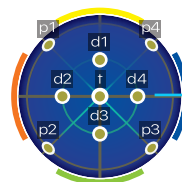


### AfferConnect™ line

Visually confirm ablation groups and lesion set contiguity.

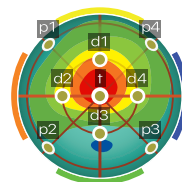
### Sensor globe

Real-time mapping and ablation guide



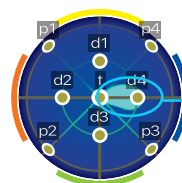
### Real-time local impedance

Providing tissue proximity feedback



### Tissue temperature display

During RF and PF delivery

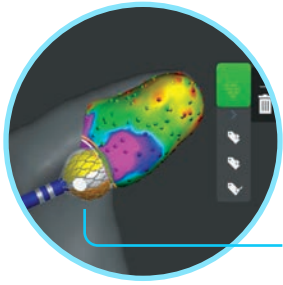


### PF Signature™ software

Exclusive, visual representation of PF energy delivery to the tissue

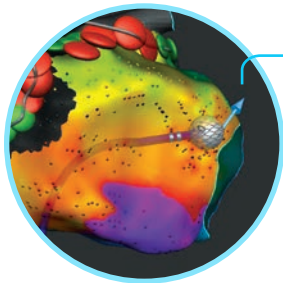
## Optimize

The Affera mapping system reduces additional technologies required during a procedure while advancing clinical workflows



### Vein mode

Designed to delineate complex regions of the heart; which may reduce the use of fluoroscopy.<sup>1,2</sup>

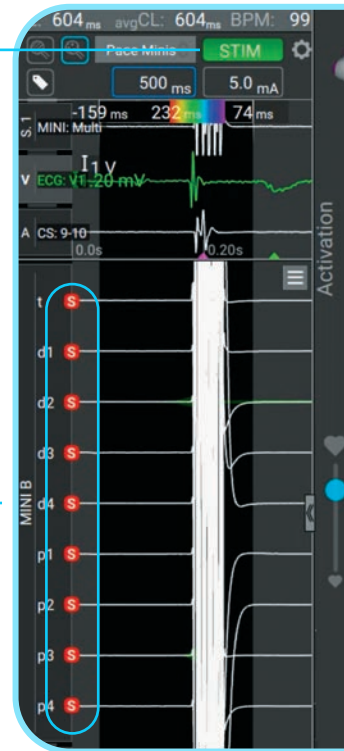


### Propagation arrow

Assess wavefront directionality for every beat before and after ablation to enhance clinical decision making.

### Integrated stimulator

Validate ablation using custom pacing modes and expedite differential pacing workflows.



## Modern and integrated system design

Built from the ground up to optimize the user experience:

- A. Full system control with space-saving remote control
- B. Switch between energy modes (RF and PF) with the tap of a foot
- C. Quick connect cabling with integrated, universal plug for ease of deployment

A



B



HexaFlow™  
irrigation pump

HexaGen™  
RF generator

HexaPulse™  
PF generator

HexaMap™  
catheter interface  
unit (CIU)

C



1. Anter E, Mansour M, Nair DG, et al. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial. *Nat Med*. August 2024;30(8):2302-2310.
2. Affera Mapping System Software Manual – M050220C001 (Agile).

## **Affera™ Mapping System Brief Statement**

### **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 use – 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 safety – 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.

Pacing – 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](http://www.medtronic.com).

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

# **Medtronic**

710 Medtronic Parkway  
Minneapolis, MN 55432-5604  
USA

Toll-free in USA: 800.633.8766  
Worldwide: +1.763.514.4000

**[medtronic.com](http://medtronic.com)**

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