

Advancing science for life[™]

INTELLANAV STABLEPOINT™ Overview

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EP-816102-AA

Advancing the Rhythmia Solution





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Nav-Enabled Catheter Portfolio



RHYTHMIA's Versatile Nav-Enabled Catheter Portfolio

From the Simple to the Complex



Nav-Enabled Ablation Catheters – RHYTHMIA Portfolio



Solid Tip Catheters



INTELLANAV STABLEPOINT Contact Force & Local Impedance







STABLEPOINT Evolves the RHYTHMIA Offering



INTELLANAV STABLEPOINT Design





INTELLANAV STABLEPOINT Anatomy



Open-Irrigated Design Goals



Force Design Goals

FORCE MEASUREMENT



Open-Irrigated Distal Shaft Evolution





STABLEPOINT User Interface: Force Graph & Catheter Tip Visualization





Force Value & Angle Widget



Displays force value Indicates force angle

INTELLANAV STABLEPOINT User Interface





Deeper Insights with DIRECTSENSE





Dynamic information on volumetric heating below the surface to indicate lesion formation

Localized tissue insights to understand:

- Tissue characterisation for potential to deliver energy
- Efficient ablation at the right power for the right duration verified by real-time local impedance drop
- Dynamic lesion formation information with tissue heating below the surface
- Safely monitor RF delivery / lesion feedback by local impedance drop to prevent overheating
- Predictable with controlled RF delivery where neighboring lesions should have a similar local impedance drop for a consistent line

Garrott, K. et al. 2020. "Combined Local Impedance and Contact Force for Radiofrequency Ablation Assessment." Heart Rhythm. Swine model: n=11

Garrott, K. et al. 2020. "Local Impedance on a Force Sensing Catheter Predicts Volumetric Lesion Temperature Changes [abstract]." European Heart Rhythm Association. Ex vivo swine tissue: n=14 (76 total lesions)

DIRECTSENSE without Mini-Electrodes



DIRECTSENSE measures local resistivity (including changes due to temperature during RF delivery). The values measured by DIRECTSENSE are **dependent on the catheter type and electrode vector used to create the field**.

VALUES will differ between STABLEPOINT & INTELLANAV MIFI OI because the starting field is different, and the sensing pair is different. Both methods are sensitive to the same BIOPHYSICAL CHANGES that lead to changes in DIRECTSENSE metric.



Catheter creates an electric field between electrode 1 & 4

When catheter approaches tissue, electric field changes, affecting impedance measurements



INTELLANAV MIFI OI uses 4 electrode method with minis INTELLANAV STABLEPOINT OI uses 3 electrode method without minis

NOTE: See usage guidance deck for more on how to use and the effect of change on DIRECTSENSE values

DIRECTSENSE without Mini-Electrodes



Changes in local resistivity (including changes due to temperature rise) modify the local electric field, which is picked up by the DIRECTSENSE metric



DIRECTSENSE on INTELLANAV MIFI OI uses the **Mini Electrodes** to sense the expansion and compression of the field lines and measure an impedance value



DIRECTSENSE on STABLEPOINT uses the **Tip Electrode** to sense the expansion and compression of the field lines and measure an impedance value.

NOTE: See usage guidance deck for more on how to use and the effect of change on DIRECTSENSE values



Z α L, where L is the length between electrodes

The difference in the electrode configuration changes the value but not its relative relationship to local physiology.

ELN 9237068

Values may be different, but the accuracy is not!

STABLEPOINT + DIRECTSENSE



Contact Force



Local Impedance



Force confirms mechanical contact & tip to tissue stability

Provides information into tissue resistivity, volumetric heating below the surface, & lesion formation

STABLEPOINT & DIRECTSENSE Combined



GUI allows for customization & physician preference to view only selected widgets during case



AutoTag Setup



Tag Drop Parameters are user-defined settings that determine what criteria must be met in order to earn a tag.

Example:

Stability & Force to earn a tag



Tag Coloring Parameters show where in the user-defined color range you are (*denoted by a moving marker on the color bar*) for an AutoTag based on a three-point scale.

Example:

DirectSense Impedance Drop colors the tag

Ablation Workflow: STABLEPOINT, DIRECTSENSE, & AUTOTAG





Guiding Ablation with Conventional Approach



STANDARD ABLATION:

✓ Electrograms

 $\checkmark\,$ Relative Position



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Guiding Ablation with Force



Force provides feedback to confirm effective contact.

FORCE SENSING:

- ✓ Electrograms
- $\checkmark\,$ Relative Position
- ✓ Contact Force & Catheter stability



Guiding Ablation with Force & DIRECTSENSE

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DIRECTSENSE[™] gives information on RF delivery to tissue. Force provides feedback to confirm effective contact.

FORCE + DIRECTSENSE:

- ✓ Electrograms
- $\checkmark\,$ Relative Position
- ✓ Contact Force & Catheter stability
- ✓ Tissue Properties
- \checkmark Heating During RF



STABLEPOINT System Components (Used on Rhythmia Software 4.0)





Model Numbers: Standard Curve: M004 ERFSDS9620 0 Large Curve: M004 ERFSDS9620K2 0

Model Number: M004 RARC03 0 **Model Number:** M004 **RA6301** 0

Only compatible with Maestro 4000 RF Generator & MetriQ Pump

STABLEPOINT Technical Specs





- Tip design (size / length): 7F / 4mm
- Shaft size: 7.5F
- Ring Electrode size: 8F
- Compatible sheath: ≥ 8.5F
- Electrode spacing: 4mm (Tip to Ring 1), 2.5mm (between rings)
- Electrode material: Platinum / Iridium
- Shaft material/construction: Polymer shaft w/ stainless steel metal braid
- Shaft length: 110 cm
- Curves: Standard & Large

- **Sensors:** Force, Navigation, Thermal
- Force design: Spring w/ 3 Inductive Sensors
- Compatible System: Maestro 4000 & MetriQ Pump
- Max power: 50W
- Generator Control Mode: Power
- Connections: Cable M004 RARC03 0

INTELLANAV STABLEPOINT Contact Force & Local Impedance







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