Ablation of Atrial and Dual-loop Ventricular Tachycardia in a Patient with Congenital Heart Defect: Guided by the Rhythmia™ Electroanatomic Mapping Solution

Case and Images provided courtesy of Dr. Tom Wong
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*Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.*
• 54 Year Old Male

• Referred after recurrent palpitations and electrocardiogram (ECG) documentation of both ‘narrow’ and broad complex tachycardias

• Termination of tachycardia required both intravenous amiodarone and DC cardioversion

• Peri-operative myocardial infarction

• Ross Procedure performed by Mr. Donald Ross at the Royal Brompton Hospital.

• Uncorrected right coronary artery fistula to the right atrium
Ventricular Tachycardia (VT)
VT Activation Map, with Voltage Map during atrial pacing 0.2-0.4mV. LV access via retrograde Aortic approach.
VT Activation Map
VT Activation and Voltage Map
VT Propagation with Voltage Map
Ablation of VT Isthmus
AT1 300ms Cycle Length
Concealed Entrainment from CTI with IntellaMap™ Orion

300ms
Atrial Tachycardia Propagation

AT2 – Re-entry around lateral wall

AT1 – Typical CCW RA Flutter
AT1 and AT2 Propogation

AT2 – Re-entry around lateral wall

AT1 – Typical CCW RA Flutter
Post CTI Ablation - AT2 300ms Cycle Length with Different P Wave Morphology from AT1
Long Post Pacing Interval with Entrainment from CS proximal
Concealed entrainment from posterior lateral wall

300ms
AT2
AT2 Propagation
AT2 Ablation
**WARNINGS and PRECAUTIONS**

The use of the Rhythmia Mapping System in conjunction with radio frequency ablation and other medical devices, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose a risk of adverse events, such as cardiac perforation and arrhythmias (new and/or exacerbation of existing arrhythmias) that may require additional intervention. Do not operate the Rhythmia Mapping System near flammable anesthetics. System operation near flammable anesthetics may cause an explosion that could cause injury or death to the patient or user. All devices that are connected to the Rhythmia Mapping System must meet IEC 60601-1 requirements and any other relevant safety standards.

When connected to other devices, the combined systems’ configuration must meet the IEC 60601-1-1 safety standards. The use of the Rhythmia™ Mapping System with accessories and devices that do not comply with relevant standards may reduce the safety of the system, cause equipment damage or system malfunction, or harm to the patient or user. Only stimulators that are certified for IEC 60601 should be used with the Rhythmia Mapping System. Do not connect life-sustaining pacing through the Rhythmia Mapping System. The system is not intended to provide life-sustaining therapy and should not be used as such. In case of need for emergency pacing or defibrillation, devices such as the IBI™ RF Generator and the Rhythmia Mapping System. Do not apply RF energy larger than 50W to ablation catheters that are connected to the IBI RF generator and the Rhythmia Mapping System. To reduce the risk of electric shock or equipment damage, do not clean the Rhythmia Mapping System when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to a power source may cause an electrical shock that could cause injury or death to the patient or user. To reduce the risk of electric shock, ensure that any ECG cables and electrodes are not in contact with any other conductive parts, including ground. To reduce the risk of electric shock during defibrillation, ensure that the exposed connector tips on the ECG output box are covered at all times with the protective, non-conductive material provided with the ECG output boxes. Do not use the ECG output box if the protective cover is damaged (see ECG Output Box). The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system’s normal operation and reduce the quality of catheter localization, and signals. Magentic Localization System

Do not operate the Localization Generator within 200 mm of installed cardiac implantable electronic devices (CIEDs). Do not use RF energy larger than 150W to ablation catheters that are connected to the Stockert™ or the Rhythmia Mapping System. Do not apply RF energy larger than 70W to ablation catheters that are connected to the Stockert RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 50W to ablation catheters that are connected to the IBIRF generator and the Rhythmia Mapping System. To reduce the risk of electric shock or equipment damage, do not clean the Rhythmia Mapping System when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to a power source may cause an electrical shock that could cause injury or death to the patient or user. To reduce the risk of electric shock, ensure that any ECG cables and electrodes are not in contact with any other conductive parts, including ground. To reduce the risk of electric shock during defibrillation, ensure that the exposed connector tips on the ECG output box are covered at all times with the protective, non-conductive material provided with the ECG output boxes. Do not use the ECG output box if the protective cover is damaged (see ECG Output Box). The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system’s normal operation and reduce the quality of catheter localization, and signals.

**Magnetic Localization System**

Do not use the system with other RF ablation generators. Compatibility with other RF ablation generators has not been demonstrated. Do not apply RF energy larger than 150W to ablation catheters that are connected to the Stockert™ or the Rhythmia Mapping System. Do not apply RF energy larger than 70W to ablation catheters that are connected to the Stockert RF generator and the Rhythmia Mapping System. Do not apply RF energy larger than 50W to ablation catheters that are connected to the IBI RF generator and the Rhythmia Mapping System. To reduce the risk of electric shock or equipment damage, do not clean the Rhythmia Mapping System when it is plugged in, turned on, or connected to a patient. Cleaning the system while it is in use and connected to a power source may cause an electrical shock that could cause injury or death to the patient or user. To reduce the risk of electric shock, ensure that any ECG cables and electrodes are not in contact with any other conductive parts, including ground. To reduce the risk of electric shock during defibrillation, ensure that the exposed connector tips on the ECG output box are covered at all times with the protective, non-conductive material provided with the ECG output boxes. Do not use the ECG output box if the protective cover is damaged (see ECG Output Box). The system generates electrical impedance fields as part of its normal operation. Do not use other systems that also generate electrical impedance fields in the same procedure, as this may interfere with the system’s normal operation and reduce the quality of catheter localization, and signals.

**Abbreviated Statement**

**RHYTHMIA™ MAPPING SYSTEM INSTRUCTIONS FOR USE**

The Rhythmia™ Mapping System and accessories are indicated for catheter-based atrial and ventricular mapping. The mapping system allows real-time visualization of intracardiac catheters as well as display of cardiac maps in a number of different formats. The acquired patient signals, including body surface ECG and intracardiac electrograms, may also be recorded and displayed on the system’s display screen. CONTRAINDICATIONS There are no known contraindications. WARNINGs and PRECAUTIONs The use of the Rhythmia Mapping System in conjunction with radio frequency ablation and other medical devices, as a part of the diagnosis and treatment of cardiac arrhythmias, may pose a risk of adverse events, such as cardiac perforation and arrhythmias (new and/or exacerbation of existing arrhythmias) that may require additional intervention. Do not operate the Rhythmia Mapping System near flammable anesthetics. System operation near flammable anesthetics may cause an explosion that could cause injury or death to the patient or user. All devices that are connected to the Rhythmia Mapping System must meet IEC 60601-1 requirements and any other relevant safety standards.
Abbreviated Statement

INTELLAMAP ORION™ High Resolution Mapping Catheter INDICATIONS FOR USE The IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart. CONTRAINDICATIONS The IntellaMap Orion Catheter should not be used in: Patients who are not candidates for transvascular catheter procedures. Patients with a hypercoagulable state or who cannot tolerate heparin anticoagulation therapy. Patients with prosthetic or stenotic valves, in the chamber where the prosthetic or stenotic valve reside. Patients with active systemic infection. Pediatric patients. Pregnant and/or nursing patients. Patients with any other condition where catheter manipulation may not be safe. The IntellaMap Orion Catheter should not be used for radio frequency (RF) ablation. The IntellaMap Orion Catheter should not be used inside an MRI machine. WARNINGS Keep the connector dry; wet connector pins may affect performance. Do not allow the handle or cabling to be immersed in fluid. Do not use the catheter to deliver ablation therapy. Do not expose the catheter to alcohol or other cleaning solvents. Do not operate the catheter against resistance. If resistance is felt during advancement, retraction, articulation, deployment or un-deployment, stop and evaluate device location under fluoroscopy. Do not advance or retract the catheter through a sheath when deployed or articulated. In order to reduce the risk of clot formation: Maintain an activated clotting time (ACT) of greater than 300 sec. at all times during use of the catheter, and continuously flush the electrode array with saline via the irrigation port at the proximal end. Do not use the catheter with equipment (such as stimulators or recording systems) that is not isolated. PRECAUTIONS To avoid cardiac damage, do not use excessive force when manipulating the catheter in vivo. Specifically, use caution when maneuvering while undeployed. Note that mapping and recording data do not require the use of force on the tissue. Always undeploy the catheter prior to removal from the patient. Use visualization (such as fluoroscopy) to verify undeployment. Always move the articulation control lever to its neutral position to straighten the catheter prior to removal from the patient. Only use guiding sheaths with curves that allow passage of the catheter without using excessive force. When used with a steerable guiding introducer sheath: Ensure under fluoroscopy that the guiding introducer sheath distal end is straight or, if necessary, only minimally curved prior to advancing or retracting the catheter through the sheath. Do not articulate the sheath while the catheter array is inside the articulating section. Do not deploy or articulate the catheter while the distal end is inside a sheath. Do not apply RF energy on an ablation catheter that is in direct contact with the electrodes on the IntellaMap Orion Catheter. To prevent entanglement, use care when using the catheter in the proximity of other catheters. When pacing, verify desired waveform is observed. Prior to insertion into vasculature, ensure removal of all air from the catheter lumen; use a pressured saline bag to flush saline through the catheter shaft and electrode array. POTENTIAL ADVERSE EVENTS Serious adverse events have been reported in the literature in relation to cardiac catheterization including: stroke, cardiac tamponade, perforation, myocardial infarction, pulmonary embolism, and death. Complications reported included also (in alphabetical order): air embolism, arrhythmia, AV fistula, hematomas, hemothorax, pneumothorax, pseudoaneurysm, thromboembolism, valvular damage, vascular bleeding, and vasovagal reactions.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Directions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator’s Instructions.