



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria

Auditorium
della Tecnica

9^a Edizione

30 Settembre
1 Ottobre
2022



Aritmologia clinica ed interventistica

SISTEMA DI MAPPAGGIO CARDIACO NON INVASIVO: QUALI APPLICAZIONI IN ARITMOLOGIA



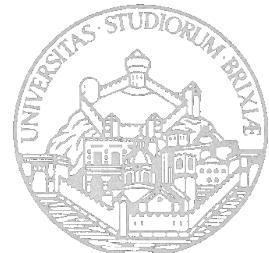
Dott. Gianmarco Arabia

Università degli studi di Brescia

Spedali civili di Brescia

UO di Cardiologia

Laboratorio di elettrofisiologia ed elettrostimolazione

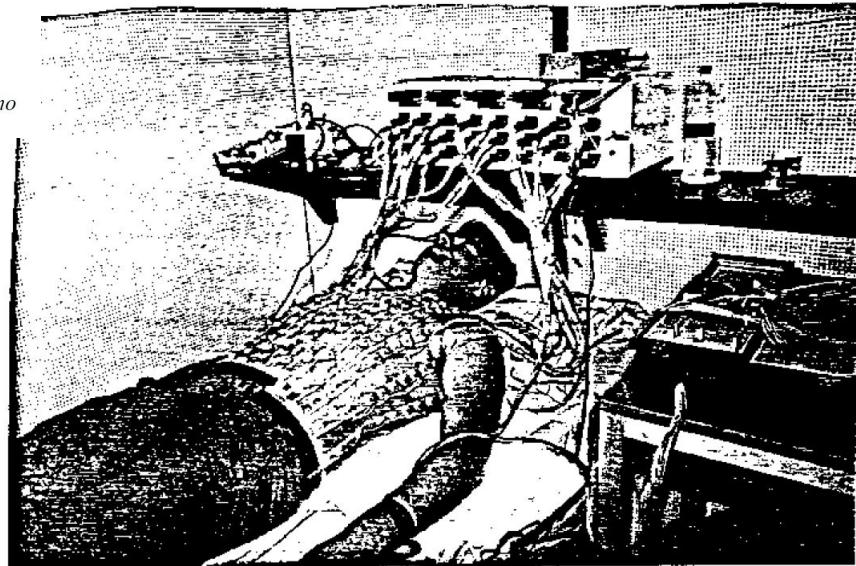
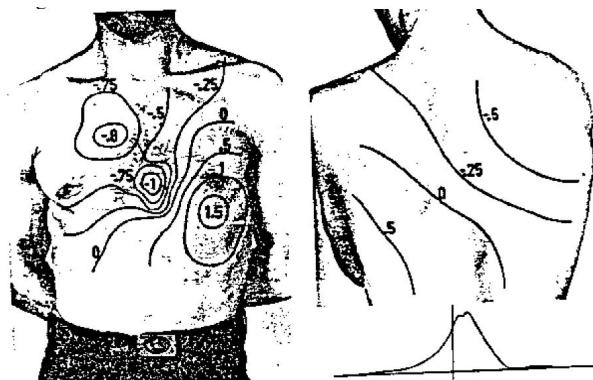




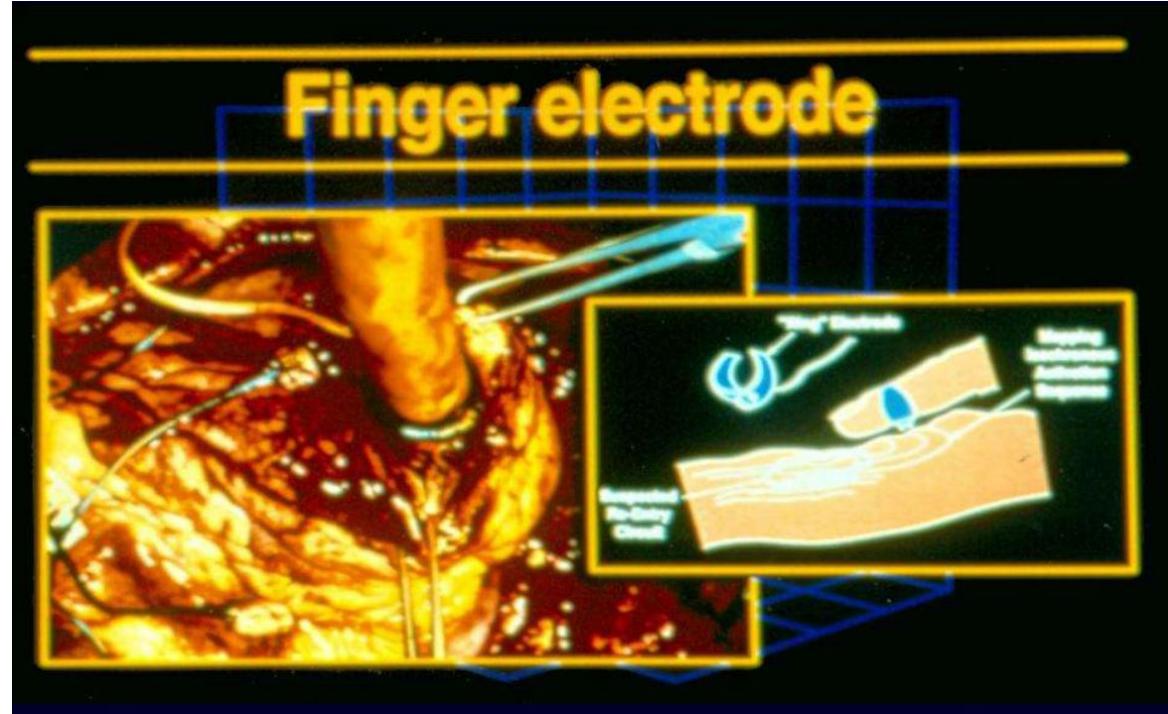
Le Elettromappe Cardiache

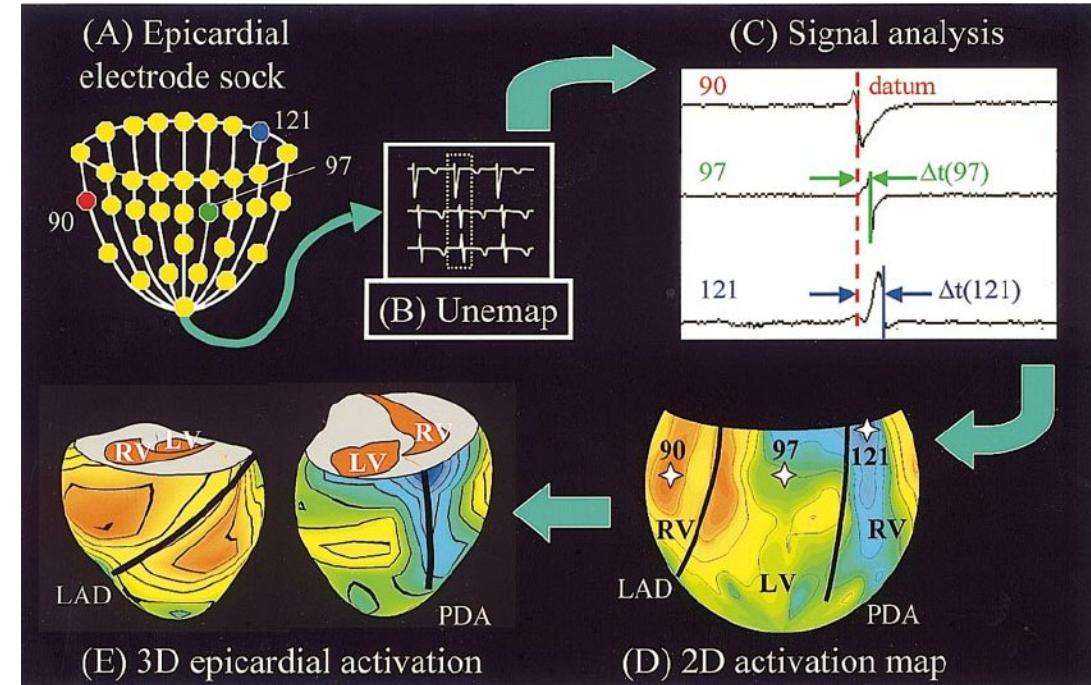
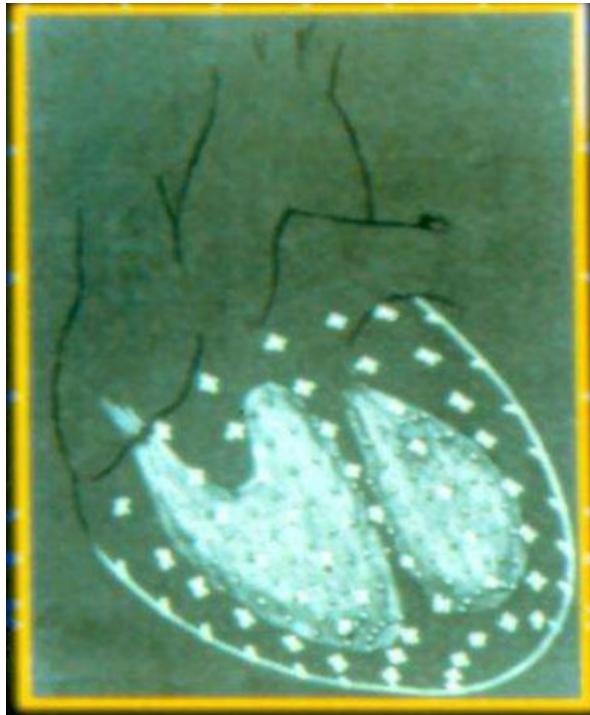
B. TACCARDI - Direttore dell'Istituto di Fisiologia Generale dell'Università di Parma

L. DE AMBROGGI - Assistente ordinario nell'Istituto di Clinica Medica I dell'Università di Milano

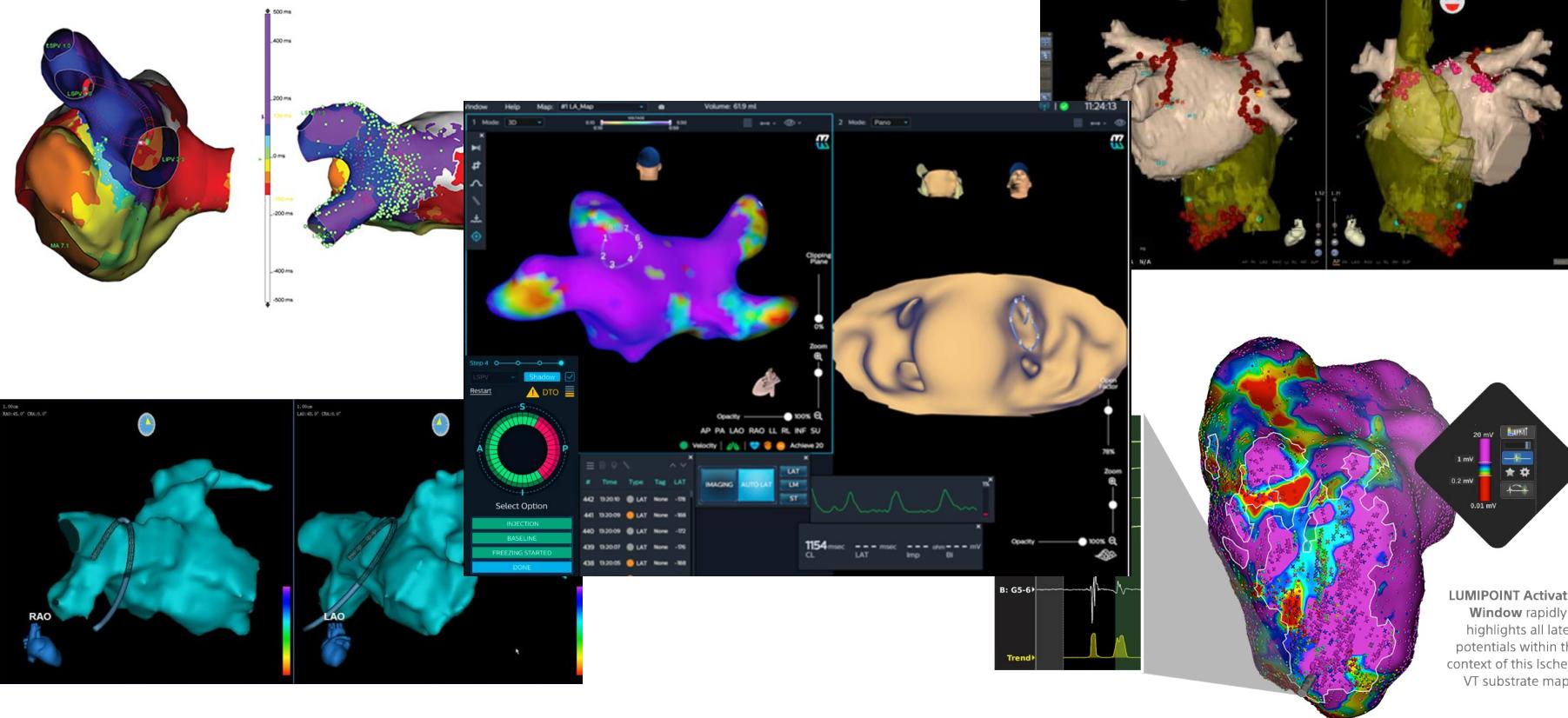
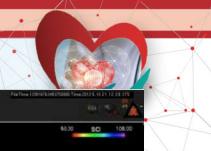


TACCARDI B., DE AMBROGGI L., *Le elettromappe cardiache.* Cardiologia d'oggi (a cura di A. Beretta Arguissola e V. Puddu). Ediz. Medico Scientifiche, Roma (1975).





The sock electrode array: a tool for determining global epicardial activation during unstable arrhythmias
 L Harrison, R E Ideker, W M Smith, G J Klein, J Kasell, A G Wallace, J J Gallagher



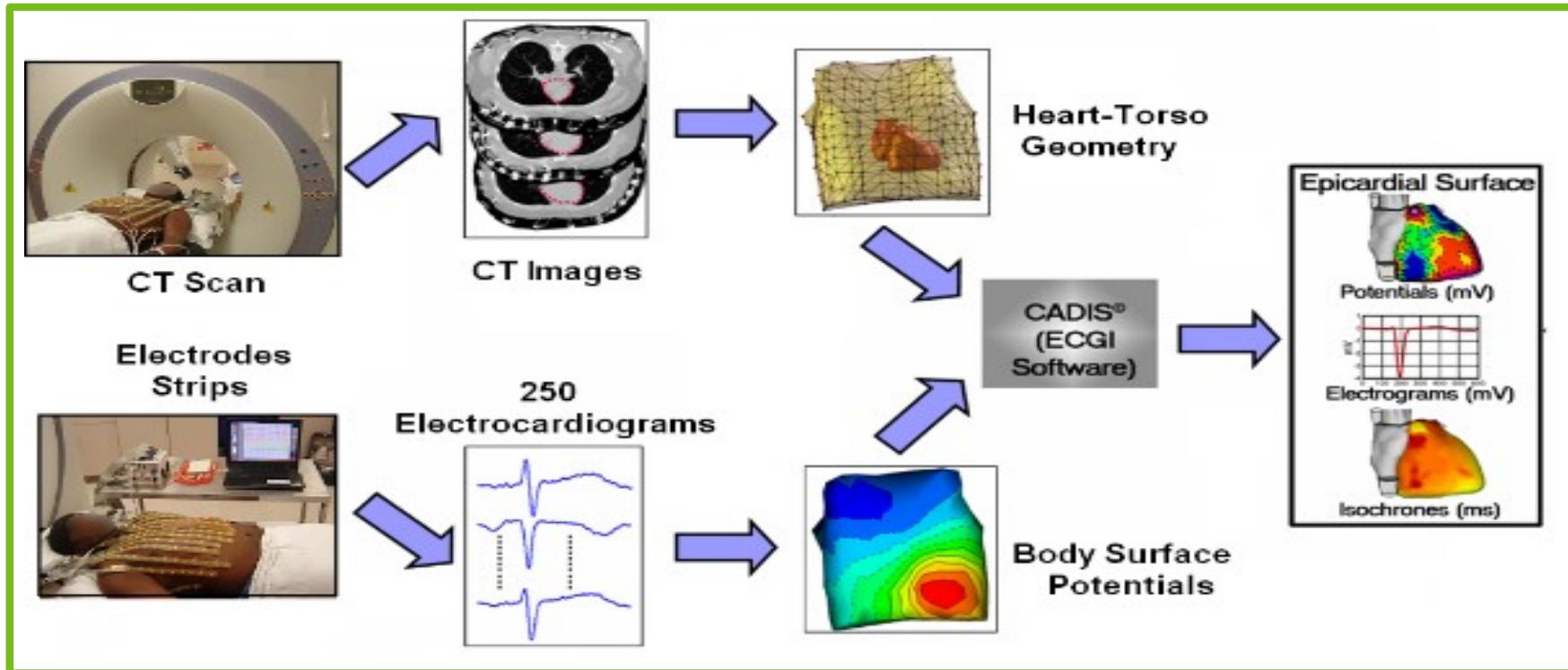
LUMIPOINT Activation
Window rapidly highlights all late potentials within the context of this Ischemic VT substrate map.



What if... we can electrically map the heart
without entering the body?



COMPONENTS FOR ELECTROCARDIOGRAPHIC IMAGING (ECGI) NONINVASIVE, PANORAMIC, SINGLE-BEAT EP IMAGING TECHNOLOGY



Ramanathan, Ghanem, Jia...Rudy. Nat Med, 2004



The Cardioinsight system

CARDIOINSIGHT NONINVASIVE 3D MAPPING SYSTEM

252 Electrodes

Single use ≤8hrs

4 Sizes



CardioInsight™ Mapping Vest

Amplifier

Workstation



CardioInsight™ Workstation

- Noninvasive mapping
- Visualize arrhythmias prior to treatment
- Mobile workstation: Map inside and outside of the EP lab



Noninvasive mapping

THROUGHOUT PATIENT CARE CONTINUUM

1 Prep patient and apply vest



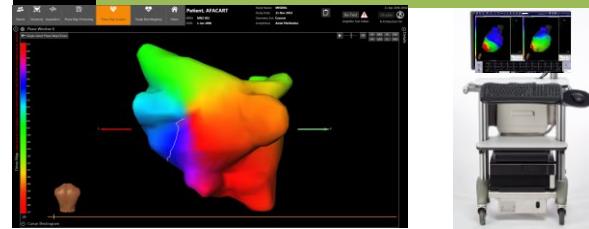
2 Obtain CT scan for heart-torso geometry



3 Record cardiac signals from vest



4 Select beats and create maps



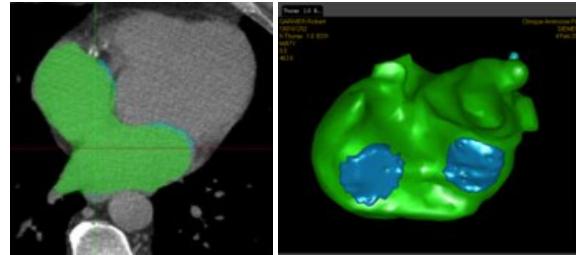


Ct scan

ACQUIRE HEART – ELECTRODE RELATIONSHIP



Patient lies in supine position



CT scan
Segmentation algorithms
Manually edit geometry



Vest included in scan field of view



Electrode labeling algorithms

CT SCAN, ACQUISITION, AND MAP CREATION

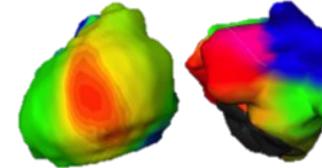


Activities Do Not Require The EP

Apply vest on patient



CT Scan to define heart-torso information



Create and display 3D electro-anatomical maps



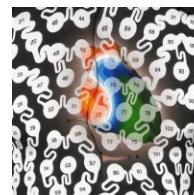
Record signal data in-lab

Fibrillatory Maps

- Phase
- Composite

Non-Fibrillatory Maps

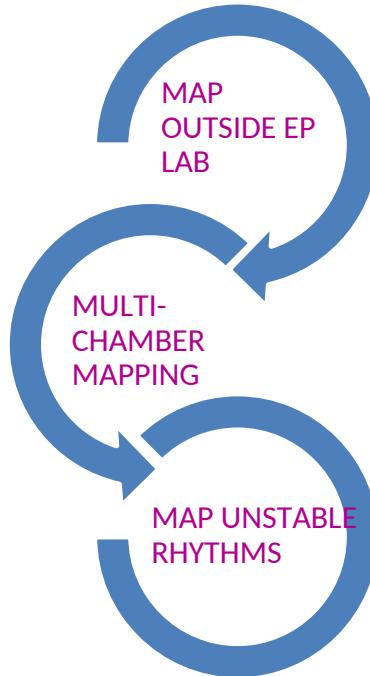
- Potential
- Activation
- Voltage
- Slew Rate
- Propagation



Record cardiac data from patient torso



Mapping capabilities



The CardiolInsight™ Solution.

- 1 Noninvasive**
Map without catheterization. Map anytime outside the EP lab throughout patient care pathway. Supports flexible patient management, pre-procedural planning, and lab use.
- 2 3D Simultaneous Multi-chamber Mapping**
Captures and panoramically displays rhythms that span multiple chambers or vary in cycle length, such as atrial fibrillation (AF).
- 3 Insight with a single beat**
Produce maps with one beat's worth of data for infrequent, unstable rhythms, such as ventricular tachycardia (VT) or some supraventricular tachycardias (SVTs), such as AT.



Indications for use

The Mapping System is intended for acquisition, analysis, display and storage of cardiac electrophysiological data and maps for analysis by a physician.



Cardioinsight Value proposition

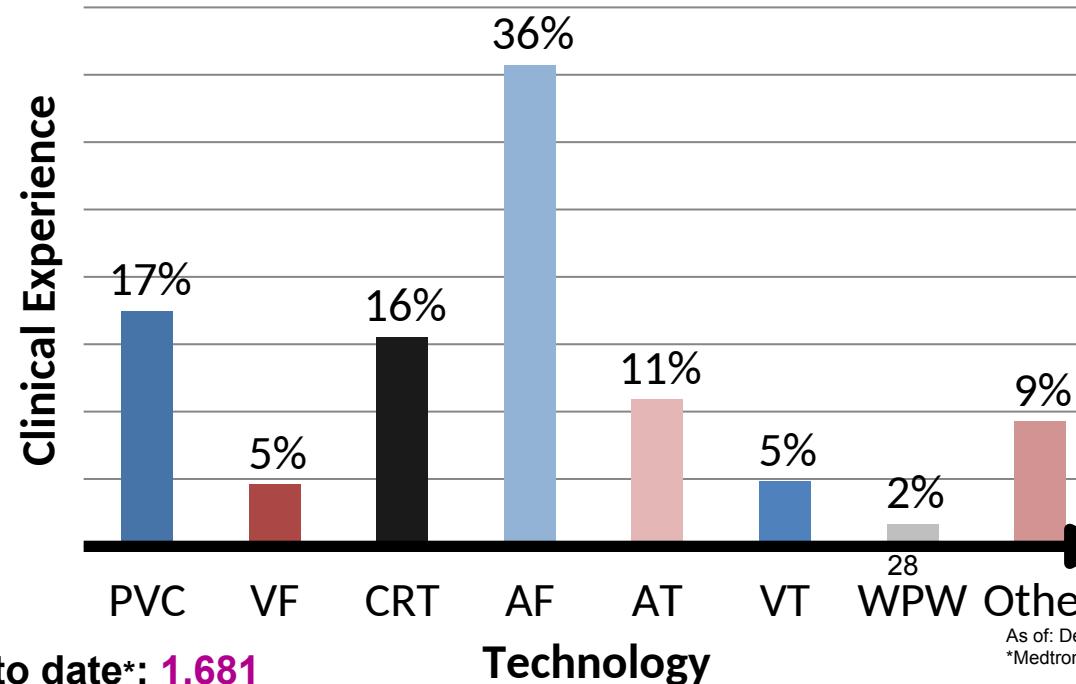
PATIENT SEGMENTATION

Clinical Application	Product Functionality	Patient Cohort	Value Proposition
Idiopathic VT: Localizing onset	Localization of 6.8 +/- 2 mm region of interest and global activation pattern	<ul style="list-style-type: none"> ▪ Index (no previous ablation) ▪ Redo ▪ Congenital 	<ul style="list-style-type: none"> ▪ Plan therapy strategy before entering EP lab ▪ Observed reduction in procedural and/or ablation time for VT ¹⁷ ▪ 92-100% focal localization ^{12,17,20} ▪ Useful in congenital cases with complex anatomy ^{40, 41}
Re-entrant AT Characterization	Localization of global activation pattern, identify possible circuits	<ul style="list-style-type: none"> ▪ P-wave amplitude >0.1mv on 12 lead 	<ul style="list-style-type: none"> ▪ Plan therapy strategy before entering EP lab
AF Activity Detection	Detect & display potential rotation/focal patterns during AF using phase mapping technique Detect & display potential AF ablation targets	<ul style="list-style-type: none"> ▪ P-wave amplitude >0.1mv on 12 lead ▪ Index Persistent ▪ Redo (PVI only) 	<ul style="list-style-type: none"> ▪ Plan therapy strategy before entering EP lab ▪ System may help reduce invasive procedure time by "... performing an important task of identification of AF drivers" ⁴ ▪ Ablation of drivers yielded 64% AF termination ³



experience and technology evolution

VERSATILE, MULTI-RHYTHM





PUBLISHED STUDIES

Clinical evidence

Summary of Literature Reporting the Use of non invasive ECG Cardiac Mapping

System	Total Number Patients, Studies	Accuracy of Diagnosis Weighted Average†	Acute Success Weighted Average††	Chronic Success Weighted Average ††
Persistent Atrial Fibrillation ¹⁻⁴	N=283 Range: 2-118 4 studies	N/A	76% 72%-100% (n=283, 4 studies)	79% 77%-100% (n=223, 3 studies)
Atrial Tachycardia ⁵⁻¹²	N=132 Range: 2-48 8 studies	88.6% 75%-100% (n=132, 8 studies)	85% 93%-100% (n=96, 4 studies)	100% (n=2, 1 study)
Ventricular Arrhythmias ¹³⁻²²	N=135 Range: 1-44 8 studies	95% 82%-100% (n=135, 8 studies)	96% 89%-100% (n=115, 6 studies)	93% 88%-96% (n=69, 3 studies)
Accessory Pathways ²³⁻²⁸	N=21 Range: 1-7 6 studies	95% 86%-100% (n=21, 6 studies)	90% 86%-100% (n=10, 4 studies)	88% 86%-100% (n=8, 2 studies)
Cardiac Resynchronization Therapy (CRT) ²⁹⁻³⁹ †††	N=264 Range: 1-61 11 studies	N/A	N/A	N/A
Total	N=835 Range: 1-118 29 studies	N=288 14 studies	N=504 14 studies	N=302 7 studies

For complete list of references, see final slides.

Single beat mapping



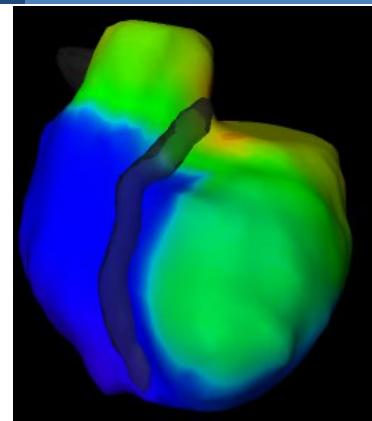
Single beat Map generation

1. Record Vest Signals

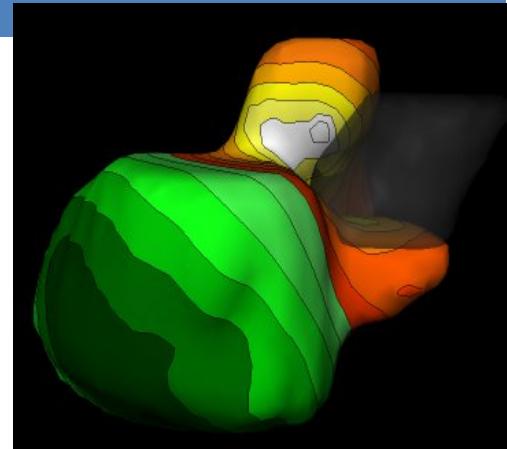
- Define interval
- Capture beat and combine with CT

2. Create and Review Single Beat Maps

- Allows for visualization of global activation pattern
- Identify arrhythmia region of interest
- Ability to 3D pace map to confirm source (comparing visually to clinical PVC)



Activation map displays LV earlier than RV²⁰

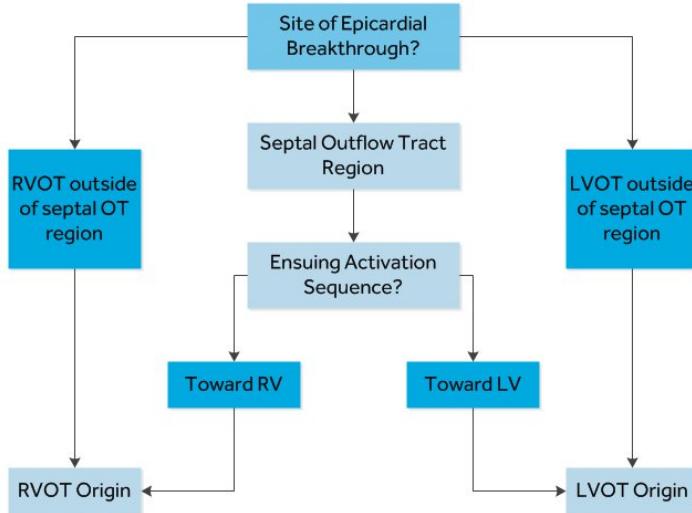


Potential map at electrical onset highlights outflow tract²⁰

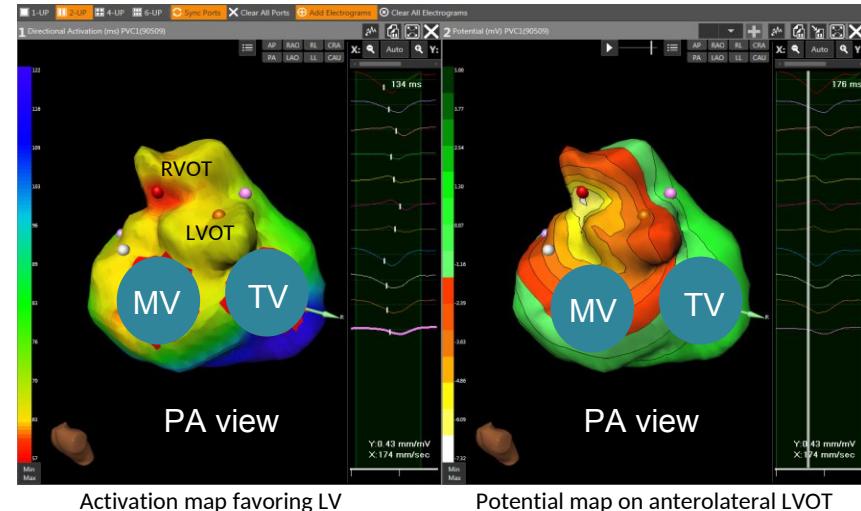


Case Example #1: Bedside recorded PVC

ECM Method of Localisation of Ectopy²⁰



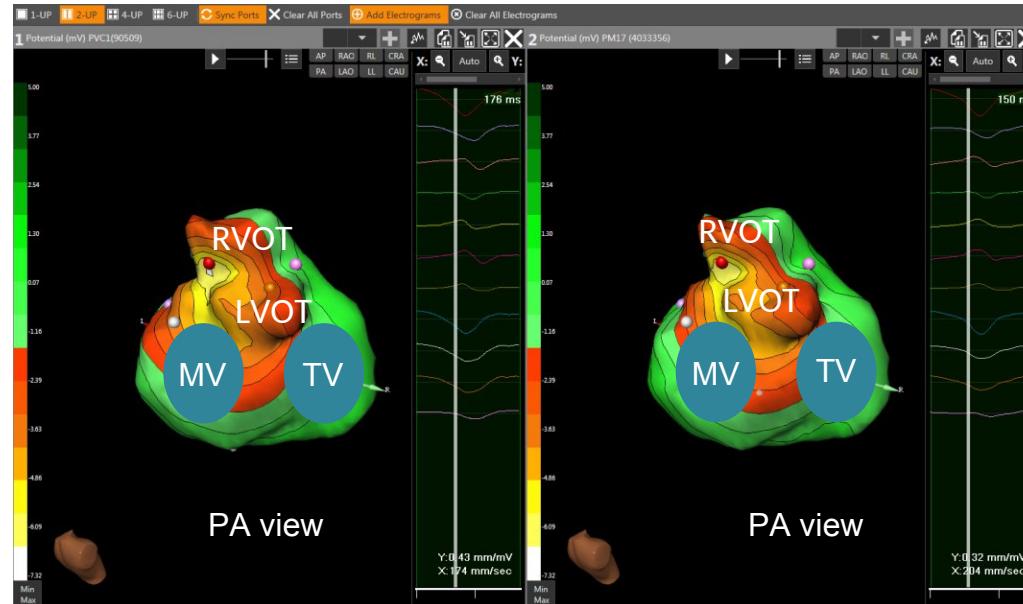
Anterolateral LVOT



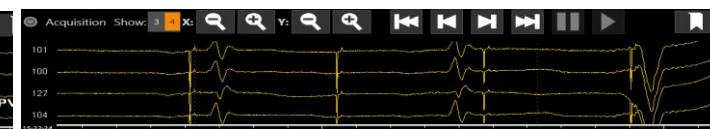


Case Example #1: 3D pace map match

Anterolateral LVOT



Potential map of PVC bedside at A/L LVOT



3D Pace map of catheter at A/L LVOT

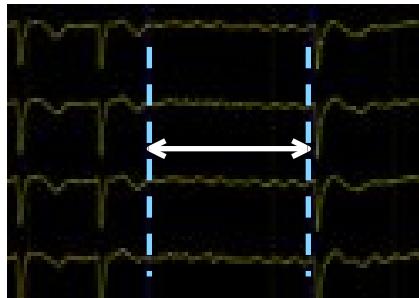
Mapping fibrillation



Fibrillation map generation

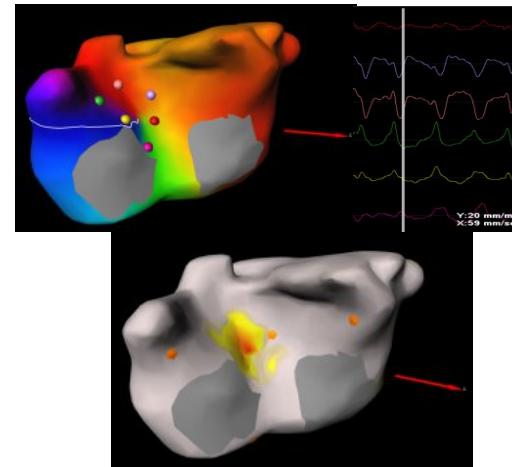
1. Record Vest Signals

- Tag interval of interest
- Capture beat and combined with CT



2. Create and Review Phase and Composite Maps

- Visualize electrical wavefront in phase map*
- Review detections in the Composite Map
- Identify rotation and foci: chamber and region of interest

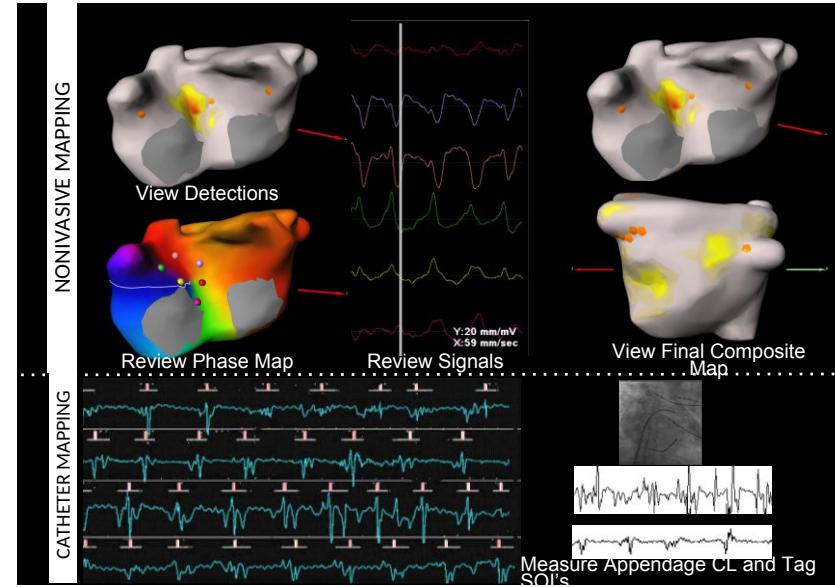


*The clinical significance of solely utilizing phase maps to classify arrhythmia mechanisms has not been validated by clinical investigations.



AF MAPPING Workflow

3. Viewed detections in composite map
 - **Displayed** rotational core and phase divergences on the map
4. Reviewed signals from each detection
 - **Confirmed** signals have clear activation sequences
5. Viewed final composite map to plan ablation
 - **Prioritized** areas of highest to lowest detection density
 - **Tagged** continuously activated bipolar catheter signals(SOI's) at each site – ablation targets.

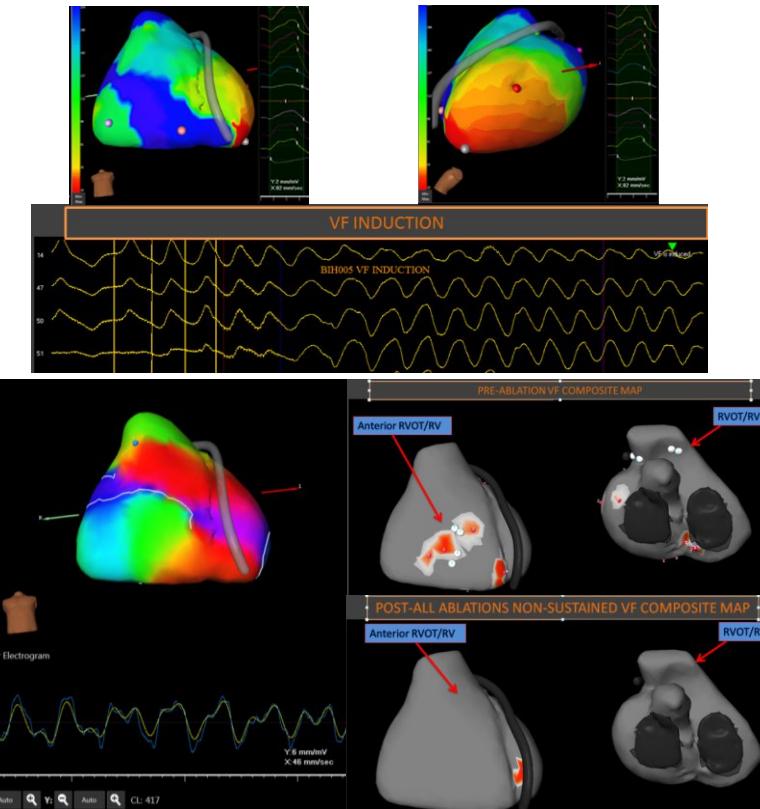




MAPPING Workflow

1. Recorded and Mapped Sinus Rhythm
2. Induced and Acquired VF in-lab
3. Created Maps and Reviewed:
 - Electrogram analysis
 - Phase maps and activation patterns
 - Composite Maps

Mapped both Sustained and Non-Sustained VF (Pre- and Post-Ablation Comparisons)



RESEARCH AREAS OF INTEREST

For EPs who need more information to develop patient specific strategies for complex arrhythmias

RE-DO AF

Mapping Non-PV Detections

- Ability to map non-PV detections
- Two-procedure feasibility:
 - 1st - PVI
 - 2nd - PVI + CIT detections
- Evaluate clinical and economic value in redos

PVC MAPPING

Demonstrate Value

- Value of pre-procedure single beat mapping for routine and intermittent PVCs
- Broaden PVC indication for low burden patients

INDEX

PeAF

Individualized Treatment Strategy

- Pre-ablation Roadmap
- PVI vs. PVI+ stratification
- Cryo + CIT ablation feasibility
- Define AF subgroups
- Customized ablation strategies and outcomes

VT/VF MAPPING

BASIC RESEARCH

Further understand mechanisms and treatment of arrhythmias using CIT as a research tool



- **Non invasive:** Map without catheterization. Map anytime outside the EP lab.
- **3d simultaneous multichamber mapping**
- **Insight with a single beat** Produce maps with one beat's worth of data for infrequent, unstable rhythms, such as VT or some SVTs



What if...

we can electrically map and treat arrhythmias
without entering the body?

- Il nostro gruppo con il gruppo di cotignola ha in atto un protocollo sulla valutazione nella sindrome di brugada.
- Un protocollo sulle aritmie negli atleti agonisti

BIBLIOGRAPHY

Clinical Evidence

Persistent Atrial Fibrillation

1. Haissaguerre M, Hocini M, Shah A, et al. Noninvasive panoramic mapping of human atrial fibrillation mechanisms: a feasibility report. *Journal of Cardiovascular Electrophysiology*. 2013;24(6):711-717.
2. Lim HS, Denis A, Middeldorp ME, et al. Persistent Atrial Fibrillation From the Onset: A Specific Subgroup of Patients With Batrial Substrate Involvement and Poorer Clinical Outcome. *JACC: Clinical Electrophysiology*. 2016;2(2):129-139.
3. Knect SD, Sohal MD, Deisenhofer I, et al. Multicenter evaluation of noninvasive batrial mapping for persistent atrial fibrillation ablation - the AFACART Study. Accepted to *Europace*. not yet published
4. Haissaguerre M, Hocini M, Denis A, et al. Driver Domains in Persistent Atrial Fibrillation. *Circulation*. 2014;130(7):530-538.

Atrial Tachycardia

5. Caulked I, Sahadevan J, Arruda M, et al. Confirmation of Novel Noninvasive High Density Electrocardiographic Mapping with Electrophysiology Study: Implications for Therapy. *Circ Arrhythm Electrophysiol*. 2013;6(1):68-75.
6. Cakulev I, Sahadevan J, Stambler B, et al. Novel noninvasive high density electrocardiographic mapping (ECM) accurately predicts successful site of ablation. *Heart Rhythm*. 2011;8(5):S75.
7. Gomez F, Roy K, Mantzari L, et al. Experience with non-invasive mapping system (ECVUE) to guide ablation. *Europace*. 2015;17(3):474.

BIBLIOGRAPHY

Clinical Evidence

Atrial Tachycardia (cont.)

8. Hocini M, Shah Ashok J, Chaumeil A, et al. Focal Arrhythmia Ablation Determined by High-Resolution Noninvasive Maps: Multicenter Feasibility Study. *Journal of cardiovascular electrophysiology*. Jul 2015;26(7):754-760.
9. Lindsay BDD, Dubois R, Shah A, et al. Novel directional activation map using local propagation between adjacent electrograms. *Heart Rhythm*. 2011;8(5): S312.
10. Lindsay BDD, Ramanathan C, Zuckerman S, et al. Accurate noninvasive 3D electrocardiographic mapping of focal and macroreentrant atrial tachycardia. *Heart Rhythm*. 2011;8(5): S311.
11. Neumann TD, Greiss H, Pajitnev D, et al. Feasibility and accuracy of non-invasive mapping and ablation of different atrial tachycardias. *Heart Rhythm*. 2015;12(5): S74.
12. Shah Ashok J, Hocini M, Xhaet O, et al. Validation of novel 3-dimensional electrocardiographic mapping of atrial tachycardias by invasive mapping and ablation: a multicenter study. *J. Am. Coll. Cardiol.* Sep 3 2013;62(10):889-897.

Ventricular Arrhythmias

13. Cakulev I, Sahadevan J, Arruda M, et al. Confirmation of Novel Noninvasive High Density Electrocardiographic Mapping with Electrophysiology Study: Implications for Therapy. *Circ Arrhythm Electrophysiol*. 2013;6(1):68-75.
14. Cakulev ITD, Sahadevan J, Stambler B, et al. Novel noninvasive high density electrocardiographic mapping (ECM) accurately predicts successful site of ablation. *Heart Rhythm*. 2011;8(5):S75.

BIBLIOGRAPHY

Clinical Evidence

Ventricular Arrhythmias (cont.)

15. Cakulev I, Sahadevan J, Arruda M, et al. Confirmation of Novel Noninvasive High Density Electrocardiographic Mapping with Electrophysiology Study: Implications for Therapy. *Circ Arrhythm Electrophysiol.* 2013;6(1):68-75.
16. Cakulev ITD, Sahadevan J, Stambler B, et al. Novel noninvasive high density electrocardiographic mapping (ECM) accurately predicts successful site of ablation. *Heart Rhythm.* 2011;8(5):S75.
17. Erkapic D, Schmitt J, Hamm Christian W, et al. Clinical impact of a novel three-dimensional electrocardiographic imaging for non-invasive mapping of ventricular arrhythmias-a prospective randomized trial. *Europace.* Apr 2015;17(4):591-597.
18. Gomez F, Roy K, Mantzari L, et al. Experience with non-invasive mapping system (ECVUE) to guide ablation. *Europace.* 2015;17(3):474.
19. Hocini M, Shah Ashok J, Chaumeil A, et al. Focal Arrhythmia Ablation Determined by High-Resolution Noninvasive Maps: Multicenter Feasibility Study. *Journal of cardiovascular electrophysiology.* Jul 2015;26(7):754-760.
20. Jamil-Copley S, Bokan R, Kojodjojo P, et al. Noninvasive electrocardiographic mapping to guide ablation of outflow tract ventricular arrhythmias. *Heart Rhythm.* 4/2014;11(4):587-594.
21. Varma N, Strom M, Chung MK. Noninvasive Voltage and Activation Mapping of ARVD/C Using ECG Imaging. *JACC: Cardiovascular Imaging.* 2013;6(12):1346-1347.
22. Zhang J, Desouza KA, Cuculich PS, Cooper DH, Chen J, & Rudy Y. Continuous ECGI mapping of spontaneous VT initiation, continuation, and termination with antitachycardia pacing. *Heart Rhythm.* 2013;10:1244-1245.

BIBLIOGRAPHY

Clinical Evidence

Accessory Pathways

23. Cakulev I, Sahadevan J, Arruda M, et al. Confirmation of Novel Noninvasive High Density Electrocardiographic Mapping with Electrophysiology Study: Implications for Therapy. *Circ Arrhythm Electrophysiol.* 2013;6(1):68-75.
24. Cakulev ITD, Sahadevan J, Stambler B, et al. Novel noninvasive high density electrocardiographic mapping (ECM) accurately predicts successful site of ablation. *Heart Rhythm.* 2011;8(5):S75.
25. Gomez F, Roy K, Mantzari L, et al. Experience with non-invasive mapping system (ECVUE) to guide ablation. *Europace.* 2015;17(3):474.
26. Hocini M, Shah AJ, Chaumeil A, et al. Focal Arrhythmia Ablation Determined by High-Resolution Noninvasive Maps: Multicenter Feasibility Study. *Journal of cardiovascular electrophysiology.* Jul 2015;26(7):754-760.
27. Hocini M, Shah AJ, Cochet H, Maury P, Denis A, & Haissaguerre M. Noninvasive electrocardiogram mapping facilitates previously failed ablation of right appendage diverticulum associated life-threatening accessory pathway. *J Cardiovasc Electrophysiol.* 2013;24:583-585.
28. Hocini M, Shah AJ, Denis A, Cochet H, Haissaguerre M. Noninvasive 3D mapping system guided ablation of anteroseptal pathway below the aortic cusp. *Heart Rhythm.* 1/2013;10(1):139-141.

BIBLIOGRAPHY

Clinical Evidence

CRT

29. Eschalier R, Ploux S, Lumens J, et al. Detailed analysis of ventricular activation sequences during right ventricular apical pacing and left bundle branch block and the potential implications for cardiac resynchronization therapy. *Heart Rhythm.* 1/2015;12(1):137-143.
30. Eschalier RD, Ploux S, Meillet V, et al. Evaluation of epicardial ventricular repolarization during left bundle branch block, left ventricular pacing and cardiac resynchronization therapy: A pilot study. *Heart Rhythm.* 2015;12(5): S389.
31. Lumens J, Ploux S, Strik M, et al. Comparative Electromechanical and Hemodynamic Effects of Left Ventricular and Biventricular Pacing in Dyssynchronous Heart Failure: Electrical Resynchronization Versus Left–Right Ventricular Interaction. *J. Am. Coll. Cardiol.* 12/24/ 2013;62(25):2395-2403.
32. Ploux S, Barandon L, Ritter P, Bordachar P. Positive hemodynamic and clinical response to tri-left ventricular pacing in a nonresponder to traditional cardiac resynchronization therapy. *Heart Rhythm.* 2/2011;8(2):315-317.
33. Ploux S, Eschalier R, Whinnett ZI, et al. Electrical dyssynchrony induced by biventricular pacing: Implications for patient selection and therapy improvement. *Heart Rhythm.* 4/2015;12(4):782-791.
34. Ploux SD, Eschalier R, Lumens J, et al. Per procedure assessment of electrical dyssynchrony for CRT optimization. *Heart Rhythm.* 2015;12(5):S473-S474.
35. Ploux SD, Eschalier R, Strik M, et al. Comparison between baso and MID-LV pacing sites during CRT in terms of hemodynamics and activation sequence. *Heart Rhythm.* 2015;12(5): S391.

BIBLIOGRAPHY

Clinical Evidence

CRT (cont.)

36. Ploux SD, Lumens J, Montaudon M, et al. Noninvasive electrocardiographic mapping to improve patient selection for cardiac resynchronization therapy: Beyond QRS duration and left bundle branch block morphology. *J. Am. Coll. Cardiol.* 2013;61(24):2435-2443.
37. Ploux SD, Xhaet O, Ramanathan C, et al. Electrocardiographic imaging for electrical asynchrony evaluation: Insight into a new patient selection strategy. *Heart Rhythm.* 2011;8(5): S14.
38. Varma NP. Variegated left ventricular electrical activation in response to a novel quadripolar electrode: Visualization by non-invasive electrocardiographic imaging. *Journal of Electrocardiology.* 2014;47(1):66-74.
39. Xhaet O, Shah A, Linton N, et al. Non-invasive electrocardiographic mapping highlights electrical dyssynchrony in heart failure patients with narrow QRS complexes. *Acta Cardiologica.* 2011;66(1):107-108.

†The ECVUE-based diagnoses were validated against standard methods including ECG and invasive electrophysiological mapping studies. For example three studies referenced were Shah et al.¹², Cakulev et al¹⁵ and Jamil-Copley et al.²⁰

‡Acute and chronic success is defined uniquely in individual studies. For AF, acute success is defined as AF termination.

+++Use of ECVUE in CRT cannot be evaluated for performance in the same way as the other electrical disorders. See “Cardiac Resynchronization (CRT)” section below for more detail.

BIBLIOGRAPHY

Clinical Evidence

Adult Congenital

40. S Ernst et al Utility of Noninvasive Arrhythmia Mapping in Patients with Adult Congenital Heart Disease Card Electrophysiol Clin 7 (2015) 117-123.

Other

41. Medtronic data on file – K140497