St. Jude Medical brings to market an automated, flexible and precise solution for cardiac mapping

The EnSite Precision™ cardiac mapping system from St. Jude Medical is designed to provide automation, flexibility and precision for tailored treatment in patients with cardiac arrhythmias. This is a next-generation version of the current EnSite™ Velocity™ system, which is employed in over 2,000 labs worldwide and is used in cardiac ablation procedures to visualise and navigate catheters in the heart. The system provides highly detailed anatomical models and maps to enable diagnosis of a wide range of arrhythmias, guide therapy and provide expanded procedural options to tailor care for patients. The system received CE mark in January 2016 and is in a limited market release in Europe. The company is currently pursuing US Food and Drug Administration clearance.

Dr. Srijoy Mahapatra (vice president of Clinical, Medical and Scientific Affairs for St. Jude Medical) comments that the launch of the EnSite Precision cardiac mapping system constitutes an “introduction of an entirely new suite of technologies including innovations in hardware, catheters, surface electrodes (patches) and software features designed for improved ease of use.”

“We developed the EnSite Precision system with insight from world-renowned electrophysiologists to encompass leading mapping capabilities,” Dr. Mahapatra comments. “It was designed in part to give the physician a tool to precisely navigate within the heart but also to give them higher density diagnostic data to better inform their diagnosis while allowing them to use the tools that make sense for each individual patient and situation.”

Automation, flexibility and precision: key differentiating features

“The EnSite Precision system allows more diagnostic mapping data to be collected in a shorter amount of time compared to today’s technologies. Unlike other mapping systems available, the EnSite Precision system allows the physician to use any electrophysiology (EP) catheter to automatically collect mapping points based on the patient’s ECG morphology. This provides us the flexibility to use the correct tools for each particular case and allows us to automatically reject erroneous data such as catheter induced ectopy,” Dr. Mahapatra says.

Additionally, he continues, “the TurboMap™ software feature, unique to the EnSite Precision system, allows physicians to build maps of secondary arrhythmias at “Turbo” speed, which can be especially helpful for patients experiencing multiple morphology ventricular rhythms.

The EnSite Precision system, which is built upon a platform that has been used in hundreds of thousands of patient procedures, fully integrates contact force data and also includes the ability for the physician to automatically place lesion markers based on the data collected.”

During the initial launch, the system has been used in a variety of procedures, from simple to complex, including atypical flutter, paroxysmal and persistent atrial fibrillation, and ventricular tachycardia. Cardiac Rhythm News speaks to two of the first adopters of the EnSite Precision cardiac mapping system in Europe: Dr. Philipp Sommer (Leipzig, Germany) and Prof. Dr. Isabel Deisenhofer (Munich, Germany) about their experience using this novel technology.
EnSite Precision™ cardiac mapping system offers a “more reliable and faster mapping experience”

Dr. Philipp Sommer (Department of Electrophysiology, Heart Center, University of Leipzig, Leipzig, Germany) is one of the first European users of the EnSite Precision cardiac mapping system. With over 300 cases performed, he talks about his experience using this novel technology.

What attracted you to start using the EnSite Precision cardiac mapping system?
I worked with the previous platform (EnSite Velocity cardiac mapping system) for many years and I was curious to see how the new magnetic catheter tracking of the EnSite Precision cardiac mapping system was going to change the quality of the maps. Besides that, what really attracted me to using this technology were the new algorithms that have been added such as AutoMap (automated annotation of signals according to predefined criteria) and AutoMark. These two algorithms help to facilitate complex ablation procedures.

How many and what kind of cases have you performed?
After our “first-in-man” procedure at the end of January 2016, in our centre we have performed more than 300 cases using the EnSite Precision cardiac mapping system. Most of these cases were ablations for atrial fibrillation, but they also included supra ventricular tachycardia like ectopic atrial tachycardias, Wolff-Parkinson-White (WPW) syndrome and premature ventricular contractions—mainly from the outflow tract.

What do you consider to be the key features of this technology?
Better quality of the geometries due to magnetic catheters probably is the most striking novelty. The maps now look very real, three dimensional and more realistic. The AutoMark tool makes high-density maps possible within a reasonable time-window. Using the AutoMark feature for annotation of ablation points can provide more detailed information about catheter stability and lesion quality. The system can still be used with literally every available device, which makes it very flexible so operators can still stick to their preferred catheters. Additionally, the system provides greater stability due to redesigned patches which are not only a lot smaller than previously but also provide reliable information in longer procedures and changing conditions, such as changing fluid status, patient sweating or repeated cardioversions. In summary, a change in fundamental technological background and multiple innovations led to a more reliable and faster mapping experience.

Has the system helped you to achieve successful results; could you give an example with a particular case?
I remember a patient with an atypical flutter at a cycle length of 190ms, which makes the patient hardly suitable for entrainment manoeuvres. So we mapped both atria using the AutoMap module in combination with a multipolar circular mapping catheter. Within 10 minutes, we identified a micro-reentry in the superior vena cava to be responsible so a biatrial map with >2,000 points was achieved revealing earliest activation just opposite to the right superior pulmonary vein, which I suspected to be the origin of the clinical tachycardias mostly after only a few minutes of mapping.

How does the EnSite Precision cardiac mapping system differentiate from other mapping systems in the market?
The main difference is that the system still works as an open platform, which means that virtually any catheter can be visualised and that the operator is not restricted to few compatible products. I believe that the new EnSite Precision cardiac mapping system has now closed the gap that existed in the market and provides an attractive offer to electrophysiology centres.

Has the system met or exceeded your expectations?
It has exceeded my expectations since I did not believe that an automatic annotation of signals would be that precise and reliable. The rate of false annotated electrograms is <5%, so the maps reveal the mechanism of the tachycardias after five seconds of energy delivery.

What advice would you have for your peers who are considering using this system?
Even with this new generation system, it is still the operator who needs to lead the system. We still have to understand the underlying mechanism of the tachycardia, set the criteria for the AutoMap module accordingly and map the right regions. If we do so, we should be able to make meaningful maps in a short time, leading to more targeted procedures and more effective treatments.

The importance of automation

One of the key features of the EnSite Precision™ cardiac mapping system is that it uses intelligent automation tools, which are designed to enable faster and more accurate high density maps allowing tailored treatment for a variety of cardiac arrhythmia patients, including complex cases.

At the Asia Pacific Heart Rhythm Society Scientific Sessions (19–22 November 2015, Melbourne, Australia), Boyce Moon et al presented a study that compared manual electro-anatomical mapping with automation of point collection using the EnSite™ AutoMap module software. The authors commented that manual electro-anatomical mapping systems require the operator to directly evaluate each point during map construction, which makes point collection a “slow process.” Automation of point collection, they stated, “has the potential to improve key mapping metrics”.

In their study, the researchers performed manual electro-anatomical mapping and...
Automated mapping of all four heart chambers in five animals in sinus rhythm using three different catheters (4-pole ablation, 20-pole circular and 64-pole basket) for a total of 160 maps. They found that automated point collection resulted in "a statistically significant reduction in map completion time, increase in valid map points and point collection rate for all catheters in all chambers mapped." Additionally, automated point collection resulted in "faster mapping, greater point density, and superior map precision with comparable accuracy and equivalent editing times with respect to manual mapping," they highlighted. The system also effectively excluded ectopic beats during mapping.

Prof. Dr. Isabel Deisenhofer (Department of Electrophysiology, German Heart Center Munich, Technical University of Munich, Munich, Germany), also one of the first European adopters of the EnSite Precision cardiac mapping system (since January 2016) with over 200 cases performed, considers that automation is one of the key features of the system. She says: “With automation, we now have the possibility to move our catheter through a heart chamber and the system will automatically decide which electrograms will be taken into consideration. For local activation timing mappings or for voltage mappings, this is something that used to be done by a second operator sitting in the control room. Now, the system is picking automatically the points that are truly correct and omitting what is not needed. This is tremendously helpful, especially if you are the only operator available.”

Prof. Dr. Deisenhofer, who has mostly performed atrial fibrillation and atypical left atrial flutter procedures with the EnSite Precision system, notes that automation is very useful in the diagnosis of arrhythmias. She says, “You could do most of these cases by hand but it is cumbersome and it will take more time. Automation allows you to spare time and maybe manpower. It is definitely a nice tool to simplify your work." The system allows you to map secondary arrhythmias up to 10 times faster with the TurboMap feature. She continues, “It is also very important that the ablation points are taken automatically. That is a major step forward because it avoids tricking yourself about how long you have been in a certain location helping you to be more honest about your true ablation location.”

Apart from decreasing mapping time, Prof. Dr. Deisenhofer highlights that automation has helped her also to get more reliable, precise and accurate mapping results. “For voltage maps, you see bridges of high or low voltage in between two other locations. You can see the conductive channels. This is something that is sometimes lost when you do it manually. With automation you get these images very clearly,” she comments.

**Automation for complex mapping**

Prof. Dr. Deisenhofer notes that automation has also helped her to enhance complex mapping of persistent atrial fibrillation or ventricular tachycardia mapping of conductive channels. She comments: “I think that automation can help in this kind of procedures, maybe most in the ventricles, where you have a lot of mechanical ventricular premature complexes. When you take these points by hand, then you will have a lot of ventricular premature complexes in between that you will have to delete manually afterward. This is time consuming and cumbersome and not very precise. Or sometimes there is one sinus beat in between seven ventricular premature complexes and you miss that one sinus beat. The system will not miss it, but will additionally delete automatically the seven ‘wrong’ beats. So this is more precise in the end." So far, Prof. Dr. Deisenhofer has performed some ablations in ventricular extra systolic and in ischaemic ventricular tachycardia.

An additional feature which is helping in the mapping of complex arrhythmias, according to Prof. Dr. Deisenhofer, is the fractionation index feature. She explains that it is a new addition to the EnSite Precision system, which she has found “extremely helpful” at least for the ablation of persistent atrial fibrillation. With this feature, she comments “you have simultaneous detailed 3D imaging of the voltage of the left atrium and at the same time you have highlighted certain locations where the local electrograms are extremely fractionated. This provides you with an interesting combination of ECG morphology, mapping and voltage mapping.”

Overall, Prof. Dr. Deisenhofer comments that the EnSite Precision cardiac mapping system has met and exceeded her expectations: “It has met my expectations regarding the quality of the 3D anatomic rendering of complete cardiac structures. It has exceeded my expectations regarding the mapping possibilities with the EnSite™ AutoMap and AutoMark module’s accuracy and usefulness.”

**Advertorial June 2016**

**Cardiac Rhythm News**

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