



EP lab robotic support

Philips and Hansen team to enhance complex EP procedures

Who/where

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Challenge

Improve an electrophysiologist's ability to maneuver and map with a catheter during complex EP procedures

Solution

Install Hansen Medical's Sensei™ Robotic Catheter Control System for use with the Philips Allura Xper FD10 fluoroscopic imaging system

At the University of Virginia's Atrial Fibrillation Center, physicians are experiencing a renewed sense of confidence, control and accuracy of catheter movement by employing a unique robotic guidance system.

Fine catheter control is central to any successful electrophysiology procedure. Yet, difficult anatomy, operator fatigue, and detailed mapping requirements can combine to challenge even the most experienced electrophysiologist. Manual catheter manipulation is only as precise as the operator who is maneuvering it.

So why not use a robot? Dr. J. Michael Mangrum, Associate Professor of Medicine and Director of the Atrial Fibrillation Center at the University of Virginia (UVA), and his team have done just that for the past several months.

A quality of excellence

“Our center draws patients from all over the country,” states Mangrum. “Over the last three years, we’ve had patients come from 20 different states and three foreign countries. Key to that great draw is our advanced flexible robotics technology and clinical expertise.”

Searching for a technology that would increase precision and improve outcomes, management at UVA selected the Sensei™ Robotic Catheter System by Hansen Medical



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to use with the Philips Allura Xper FD10 imaging system to assist Dr. Mangrum's team. The Sensei system is designed to aid electrophysiologists in the treatment of complex cardiac arrhythmias by giving the operator remote catheter control with superb precision and stability.

Integrating a new tool

The Atrial Fibrillation Center at UVA boasts three full-time EP labs with a cath lab borrowed as a fourth when case volume

PHILIPS

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requires. Over 700 ablations and 400 implantations are performed every year. At the center of each lab is a Philips interventional X-ray system, supported by the full range of related mapping, recording, intracardiac echocardiography (ICE) and hemodynamic equipment.

But in one lab, you’ll see something quite different. The patient support table of the Allura Xper FD10 X-ray system is outfitted with Hansen Medical’s Robotic Catheter Manipulator, one of the central components of the Sensei Robotic Catheter System.

This advanced, yet ergonomically simple, system is comprised of three basic elements:

1. Artisan™ Control Catheter
2. Robotic Catheter Manipulator
3. Sensei workstation

Together, they provide Dr. Mangrum with an alternative to difficult manual catheter manipulation.

How does it work?

Using a technology called ‘instinctive motion’, EP doctors are able to navigate and direct catheter movement remotely, from a workstation, using a joystick control.

“Many times,” says Mangrum “you have to struggle to get a catheter into a challenging position such as the right inferior pulmonary vein, or the left atrial appendage ridge. Then later, if you have to go back, you must repeat that same difficult maneuver. The Sensei system gives you very precise catheter movements and exceptional stability. And with the Sensei system, you can reproducibly get back to sites with greater ease.”

The precision of the Sensei system is accomplished through a carefully orchestrated set of controls and commands:

- A working catheter of the physician’s choice is guided by the Artisan Control Catheter, (ostensibly a steerable sheath)

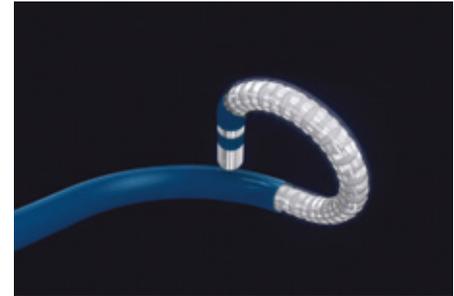
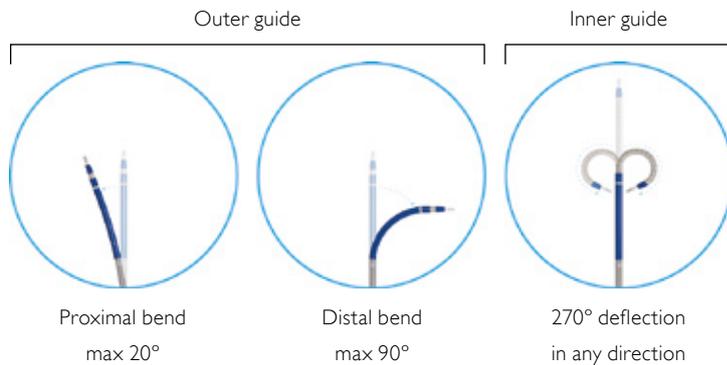
- The progress of the Artisan Control Catheter is managed by the Robotic Catheter Manipulator (set tableside) which is designed to facilitate manipulation, positioning and control of mapping
- The Robotic Catheter Manipulator is in turn controlled by a physician seated at the Sensei workstation

Catheter manipulation

In complex procedures, Dr. Mangrum finds this new system gives him improved localization and mapping capabilities. He explains, “A flutter ablation, for instance, requires very precise point-by-point mapping of complex flutter circuits. It requires me to maintain very steady catheter movements, while at the same time do advanced mapping of the circuits. When I’m standing up and moving the catheter manually, I’m not able to control the mapping system. I must rely on someone else to do that mapping for me.”

“Using the Sensei workstation, I’m able to concentrate on both the mapping and moving of the catheter simultaneously.”





Seated at the Sensei workstation, Dr. Mangrum can manipulate the Artisan Control Catheter by engaging the outer and inner guide sheaths. The outer guide, controlled by a pendent with the left hand, allows for a proximal bend of 20° and a distal bend of 90°. The inner guide (controlled by a three-dimensional joystick in the right hand) offers up to 270° deflection in any direction. The physician's hand movements at the workstation are replicated inside the patient's heart.

After completing a transeptal puncture, Dr. Mangrum suggests the process is rather simple, "First, I put the Artisan catheter into the right atrium. Then, I set the Artisan catheter onto the robotic arm. Now I step back into the control room, and from the workstation, I drive the sheath across into the left atrium."

He continues, "I use both of my hands to move the Artisan catheter to a precise location, but I can let go of the joystick, and the catheter stays exactly in its last position. You can't do that manually. I can easily switch to focus on mapping, with the knowledge that the catheter is in the very spot I left it."

Complex mapping

With his hands free, Dr. Mangrum can concentrate on his mapping efforts. The Sensei workstation provides visual information that clearly depicts the location and movement of the catheter.

After introducing the Artisan catheter, the next critical step is to assure the Sensei 'virtual' catheter image, displayed on the center screen, is aligned with the real catheter in the body. To do this, Dr. Mangrum turns to the Philips Allura Xper FD10 system to acquire an image. "I align the Sensei system with Allura fluoroscopy in two views, 50° apart," he says. "Then, once I align it, I generally never have to realign it. It integrates very nicely with the Sensei system, and allows us to use fairly low-intensity fluoro with good visualization, so that helps with the overall fluoro exposure that the patient experiences." Since Dr. Mangrum performs the procedure while seated at the Sensei console, he experiences none of the radiation exposure that he would experience in a manual case.





The final component at Dr. Mangrum's disposal is Hansen Medical's optional CoHesion™ 3D Visualization Module. This module offers a software interface between the Sensei Robotic Catheter system, and EnSite™ System advanced mapping software from St. Jude Medical, Inc. The CoHesion module imports the EnSite System's 3D cardiac chamber model with anatomic labeling into the Sensei system's main navigation window, allowing Dr. Mangrum to see the location of the Artisan Control Catheter within the heart in 3D. The CoHesion software also allows Dr. Mangrum to drive the Artisan catheter instinctively within his chosen view in EnSite, eliminating the need for him to perform the three-dimensional, spatial transformations that he must do in his head during a manual case.

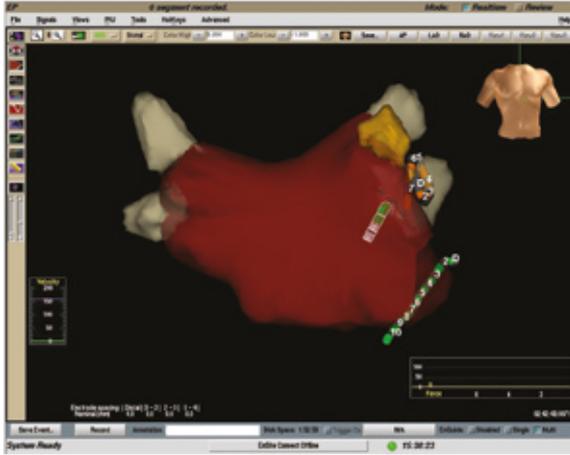
"The CoHesion software allows me to construct a three-dimensional map on the right screen that I match to the fluoro image, which is subsequently calibrated and aligned with the Sensei system." CoHesion permits Dr. Mangrum to drive instinctively inside a 3D model, and

to localize the tip of the catheter within that 3D space. Once a spot is marked in this navigational schema, the operator can maneuver away and still be able to return with relative ease.

Real world application

Dr. Mangrum recounts a case where the Sensei system made a real impact, "A 65 year old man, who had an A-fib ablation three years ago, developed a left-sided flutter. This can be quite challenging to map—to identify the problem circuit. In this instance, not only did we use the Sensei system, but we used the CoHesion software and its full integration with EnSite mapping."

"We manipulated the Artisan catheter into all the areas that had been ablated before, and created a very precise map. Then we did an activation map, to see where the circuit was going, and found it to be right next to an area that had been ablated before. The Sensei system allowed us such precise movements that we found this complex circuit quickly, and ablated it with just one lesion."



Clinical and economic advantages

“You can only focus for so long on a complex ablation,” says Mangrum. “When you stand wearing ten pounds of lead for four hours or more, it’s tiring. The Sensei system takes the fatigue factor out of the process.” So Dr. Mangrum describes one of the many tangible benefits of the Sensei Robotic Catheter Control System. By removing the tedium and strain of manual catheter manipulation during lengthy procedures, the Sensei system frees the physician to concentrate.

Other clinical benefits include the ability to:

- Use any physician preferred catheter 8F or smaller
- Achieve easy, reproducible catheter maneuverability
- Maintain catheter stability, hands free
- Create very precise mapping with 3D anatomical guidance
- Lessen X-ray dose for the physician (workstation can be in control room)
- Integrate with any mapping system
- Increase physician confidence

Additionally, through close partnership with Philips Healthcare, users of the Sensei Robotic Catheter Control System will benefit from greater integration with the Philips Allura Xper family of interventional X-ray systems.

Economic benefits are substantial too:

- Small footprint
- Small tableside robotic arm that fits seamlessly into any EP lab
- No special room construction or shielding requirements
- Fits any existing EP lab and integrates with standard imaging equipment
- Moveable among multiple EP labs

Removing limitations

When technology does not hinder, but instead supports physicians, they can deliver the best possible treatment—without constraint. Hansen Medical and Philips Healthcare are committed to developing solutions that sustain this strategy. The University of Virginia has found the Sensei Robotic Catheter Control System to be an exceptional example of functional, supportive design.

“My patients are also very aware of this technology,” concludes Mangrum. “I tell them what I’m using, and how I use it. Once I tell them I’m using a robot, they’re very impressed. They like the thought of having high-end technology help with their procedure. I do too.”

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