

Navigating the Heart



Global Positioning System (GPS) technology provides the position of an object or a person on a map; the MediGuide Technology from St. Jude Medical is analogous to GPS but it determines the location of a device inside the body. This technology could change the way in which physi-

cians track and navigate a catheter through the heart. Professor Gerhard Hindricks, M.D. at the Heart Center of Leipzig University in Germany and his senior physician, Associate Professor Christopher Piorkowski, M.D., have explored this potential in interventional electrophysiology. Because in the

treatment of arrhythmias, catheter ablation is often more effective than a drug treatment, this form of therapy has progressed rapidly in recent years. Crucial impetus has also come from the Department for Rhythmology under the direction of Hindricks. At approximately 100 centers in Germany, some 12,000



Siemens Healthcare has combined the MediGuide Technology from St. Jude Medical in its Artis zee angiography systems. It is already being used at the Heart Center at the University of Leipzig in Germany. The MediGuide Technology determines the precise position of a catheter using magnetic localization techniques and projects it in real time onto a previously acquired fluoroscopy image. Hence catheters equipped with a sensor can be quickly and safely navigated through the heart without the necessity of constantly subjecting the patient to X-rays.

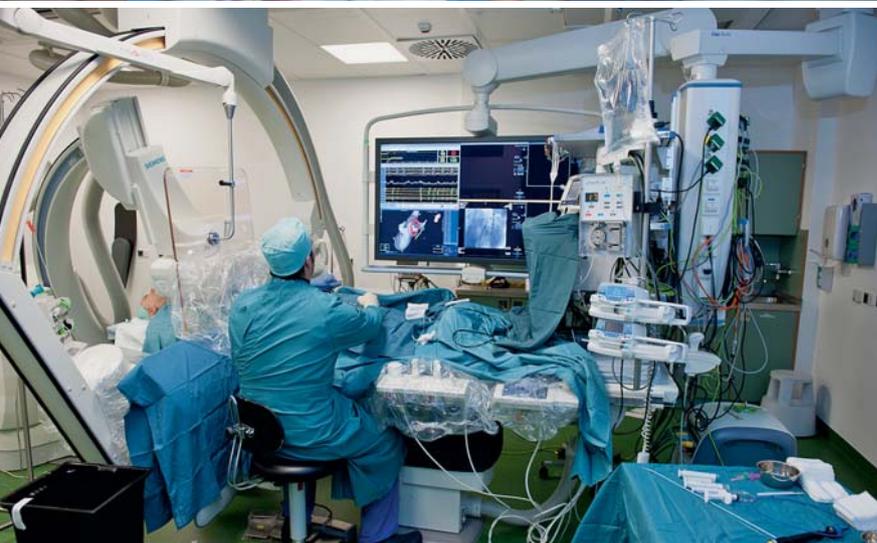
By Hildegard Kaulen, PhD

The combination of MediGuide™ Technology and Artis zee system leverages the precise navigation within the beating heart.

catheter ablations were carried out for the treatment of atrial fibrillation in 2011, of these some 10 percent alone in Leipzig. Together with the Cleveland Clinic in Ohio and the Mayo Clinic in Rochester, Minnesota, Hindricks' department is among the leading rhythmology centers worldwide. The cardiologist is

one of the pioneers of catheter ablation and has been using this therapy since 1985. Hindricks and Piorkowski have been using the MediGuide Technology integrated in their Artis zee system for the last eighteen months. Until just a few weeks ago, their department was the first and only center that had

such an installation at its disposal. "We've always put our trust in high-end tools to help with our interventions, because the problems we treat can be very challenging," says Hindricks. The MediGuide Technology is a 3D electrophysiology (EP) catheter tracking system that is fully integrated in



conventional fluoroscopy and which is registered with the mapping system. The fluoroscopy space and the three dimensional electromagnetic sensor field used are carefully aligned. The systems no longer work independently, but rather together. "We're dealing with a new tool," stresses the cardiologist. Another special feature, according to Piorkowski, is the fact that the technology compensates for cardiac and respiratory motions. "Until now we were working on a moving organ using static images. Now we can even exploit the fourth dimension, since the movements of the patient are counterbalanced," says Piorkowski.

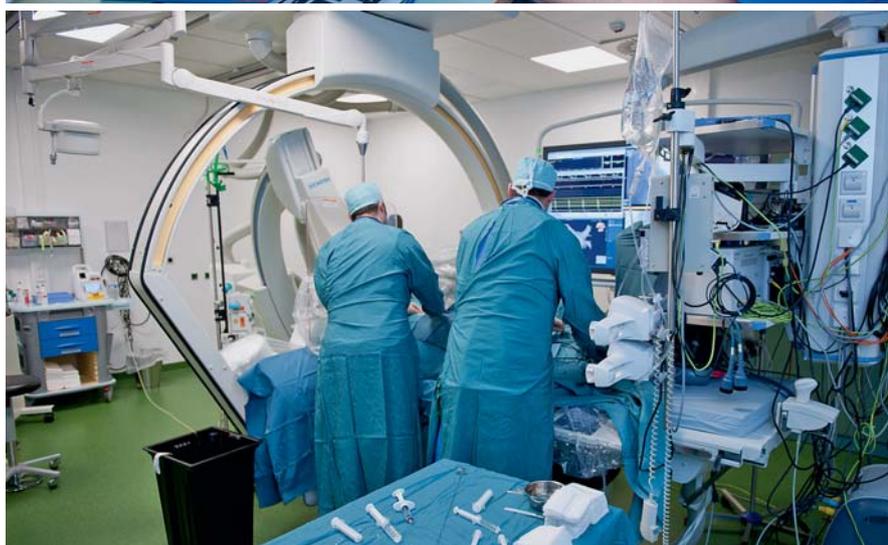
Catheter Tracking Technology

In order to be able to integrate the MediGuide Technology, three components are required. The first are transmitters that generate a low-intensity ($< 200 \mu\text{T}$) alternating electromagnetic field and are integrated in the Artis zee fluoroscopy detector. The second component involved is a miniaturized passive single-coil sensor in the tip of the EP catheter, and the third is an electromagnetic field reference sensor attached to the patient's sternum. The movements of the catheter are detected based on the voltage changes generated in the magnetic field. The exact position and orientation of the catheter is a function of its position in relation to the reference sensor that remains attached to the sternum throughout the whole of the intervention. In order to determine the compensation for the cardiac and respiratory motions, in addition to the reference sensor the real-time ECG derived from the heart is used. The fluoroscopy images, upon which the position of the catheter can be tracked in real time, are generated prior to the introduction of the catheter. It is based on two cine loops with a length of three heart cycles. They are prerecorded in the standard projections, e.g. right anterior oblique 30° and left

anterior oblique 60°, but more projections can be taken if preferred by the physician.

Atrial Fibrillation, a Widespread Disease

Under what indications have Hindricks and Piorkowski used catheter tracking without continuous fluoroscopy up until the present time? "The prime indications are atrial fibrillation and ventricular tachycardia," says Hindricks. "To date we have carried out around 150 procedures with the aid of the MediGuide Technology; 120 catheter ablations with a focus on atrial fibrillation, 20 interventions with ventricular tachycardia, and ten cardiac resynchronization operations." Atrial fibrillation is an illness with increasing incidence. The cardiologist expands on this by saying that this is partially due to improved methods of detection but also to the fact that older people suffer from atrial fibrillation more frequently than younger people. Hence the incidence increases in relation to the increased age of the population. Piorkowski adds: "But we are also increasingly treating younger, lone atrial fibrillation patients. For example, the patient we treated this morning with a catheter ablation was born in 1961. He had tried out several antiarrhythmic drug therapies, all of which brought him no relief at all. Eight months ago we carried out an initial ablation and have now treated him for gaps in the electrical isolation. For him the catheter ablation is a potential curative therapy, since following the ablation of the remaining focal trigger he in all probability again will have a stable sinus rhythm, and this without medication." According to Hindricks, this shows that innovations in medicine are not inevitably cost drivers. After all, through the potential cure of atrial fibrillation considerable costs for drugs and other treatments can be saved. Hindricks therefore also welcomes the fact that the new guidelines for atrial fibrillation



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Heart Center of Leipzig University, Leipzig, Germany



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recommend that the primary catheter ablation of paroxysmal or persistent atrial fibrillation be used after only a few unsuccessful attempts at using drug therapy. He expects that after their revision, the German guidelines will also contain such a Class 1 recommendation for this indication.

Personalized Ablation

What are the benefits of the integration of the navigation technology in Artis zee? "Fluoroscopy has clear limits," says Hindricks, "because it only provides a two-dimensional image of the beating heart and because it involves exposure to radiation. With the sensor-guided navigation of an intracardiac EP catheter, we reduce the radiation exposure and have a motion-corrected tracking system. This can also help us to personalize the ablation. After all, in the long term we want to move away from the 'one approach fits all' strategy. At present we are primarily carrying out circumferential pulmonary vein isolation in order to isolate this electrically since we know that for the majority of patients with atrial fibrillation this is where the focus of the irregular sinus rhythm lies. However, our objective is to achieve an electro-anatomically guided, personalized ablation strategy." Cardiologists also see a great advantage in the reduction of the exposure to radiation. In the ideal case, only two fluoroscopy scenes would be required: at the beginning of the intervention and at the end to check on the success.

Piorkowski says: "With the ablations carried out so far using the MediGuide Technology, we were able to reduce the exposure to radiation by half. The reason why we haven't achieved even better results is related to the fact that we still don't have an ablation catheter equipped with a sensor available to us because the CE Certification is still outstanding. At present we still need fluoroscopy in order to display the position of the conventional ablation catheter during the procedure."

Also, tools with MediGuide sensors embedded in them to facilitate the delivery of cardiac resynchronization therapy (CRT) are under development. "In the case of interventions for CRT, it has already been possible to reduce the radiation exposure to ten percent of the previous value," adds Hindricks. "This reduction not only benefits the patients but also his colleagues," he says, since during these interventions the radiation exposure for doctors and support staff is normally very high.

A Treatment Platform

For what other types of interventions is the Artis zee system with integrated MediGuide Technology also suited? "We see the system as a treatment platform for cardiovascular illnesses, with electrophysiology being the first application," says Hindricks. "The system could be considered for all situations where devices have to be tracked in the body under X-ray guidance," adds the cardiologist. "I can well imagine that this sys-

tem could also be used to implant heart valves, to deposit stem cells in the heart or to place special drugs in specific spots, such as in oncology. Ultimately the applications will depend upon what instruments are equipped with a sensor for navigation," explains Hindricks. Will catheter ablation be safer with the use of navigation? "At present it is not possible to say exactly since the number of cases treated is too small – but we expect this to be the case," says Hindricks. However, a catheter ablation is no longer new territory today. It is a routine procedure with a measurable complication rate of three percent. The three key complications are thromboembolisms, a pericardial tamponade, which leads to a rapid fall in blood pressure, and the esophageal-atrial fistula following injury to the esophagus, that lies on the rear wall of the left atrium. Hindricks and Piorkowski advocate that catheter ablations should only be carried out in centers that possess the necessary experience and equipment and that have documented this through a certification process.

Dr. Hildegard Kaulen is a molecular biologist. Following further studies at the Rockefeller University in New York and the Harvard Medical School in Boston, she has been working for prestigious daily newspapers and scientific magazines as a freelance journalist since the mid-nineties.

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