Guide for Localizing Medical Instruments With 3D Magnetic Tracking

3D Guidance

medSAFE™

Ascension Technology Corporation

Making Minimally Invasive Possible

About 3D Guidance medSAFE

medSAFE is our pulsed-DC magnetic tracker for surgical navigation. It tracks the instant position and orientation of micro-miniaturized sensors for intrabody navigation, measurement, and localization. Unique in the world, it features a transmitter design that overcomes the distorting effects of ferrous metals found in OR and procedural tables. Measurements are also immune to distortion from common hospital metals, such as 300- series stainless steel, titanium and aluminum. Sensors are priced for low cost disposability for high volume applications. medSAFE is customizable to meet myriad procedural requirements.

Key Benefits

- Low cost sensors for localizing disposable catheters and devices in three dimensions.
- Sensors ranging from 8 mm to 0.9 mm diameter for unobtrusive instrument guidance.
- 3rd generation magnetic technology to overcome environmental limits of earlier AC and DC trackers.
- Precise tracking without line-of-sight restrictions or radiation.
- Freedom to track sensors without distortion of measurements from ferrous metals beneath our flat transmitter.
- Simultaneous tracking of multiple sensors for gating, referencing and navigating devices.
- Compliant with medical safety standards.

Quick Facts: 3D Guidance is…

- Designed for high volume procedures.
- Backed by a design team with 100+ years experience making trackers work in all kinds of environments
- Fully integrated with medical visualization and rendering software.
- Winner of an R&D 100 new product of the year and Frost & Sullivan innovation awards.

Key Features

Parameters	Feature
Technology	Pulsed DC Magnetic Fields with Advanced Signal Processing and New Optimization Tools
Multiple Sensor Options *	8, 2, 1.5, 0.9 mm (outer diameter)
Update Rate	➢ Short & Mid Range Transmitters: Up to 375 Times/Sec ➢ Flat Transmitter: Up to 160 Times/Sec.
Multiple Transmitter Options *	➢ Mid range (9.5 cm cube) ➢ Short range (5.6 cm cube) ➢ Flat (58.4 cm x 58.4 cm x 2.54 cm)
Interfaces to Your Host Computer	RS-232, USB, Ethernet (factory option)
Metal Immunities	➢ 5X less distortion to non-magnetic conductive metals than AC magnetic trackers ➢ Outputs unaffected by composite materials ➢ Capable of driving errors induced by highly conductive metals (such as aluminum) to zero using "Optimizations Tools"
Full Windows API	➢ Easy access to tracker functions & settings ➢ Programmable default settings for customized power-up

* NOTE: Not all sensor options support all transmitter options. Contact Ascension for the current status of available configurations.

Comparisons with microBIRD

3D Guidance medSAFE succeeds microBIRD -- a PCI-card based tracker -- released in 2005 for beta testing of small sensors by medical researchers.

See below comparative chart:

Parameter	medSAFE	microBIRD
Interface	USB, Ethernet	pci Bus Only
Number of Sensors Supported	8 – 6DOF	2 – 6DOF
Transmitters Supported	Flat, Mid & Short Range	Mid & Short Range
Update Rate	Up to 375 Times/Sec.	Up to 90 Times/Sec.
Signal Processing	Advanced with Filtering DSP	Limited
Dynamic Performance: Movements <200 mm / second	< 1 mm RMS	4 – 6 mm RMS
Hot Swapping	Yes	No
Customizable Settings	Yes	No
Digital Processing	Yes	No
Biocompatible Sensors	Yes	No
Time Stamping Data Records	Yes	Yes
Patient Isolation	Yes	No
Medical Certifications	IEC 60601-1-1: Class 1, Type CF, Defib Proof	Laboratory/Evaluation Use Only – General Safety

Applications

Over 50 medical procedures have been identified as candidates for image-guided procedures.

Specialty	Prominent Uses	Benefits
Cardiology	➢ Navigation of catheter & map heart chambers. ➢ Guidance of catheters for AFIB therapy ➢ Localization of stents for deployment. ➢ Functional heart measurements	Real-time 3D guidance and feedback without radiation using low cost, disposable sensors.
Obstetrics	➢ Measurement of fetal and maternal anatomy. ➢ Continuous digital record of the progress of maternal labor	Real-time visualization and quantification of birthing stages. Reduction in C–section rate, now over 30% of all births in USA.
Oncology	➢ Targeted delivery of chemo and	Reduction in trauma to patient

Specialty	Prominent Uses	Benefits
	therapeutic agents. ➢ Volumetric measurements, fusion of ultrasound and CT/MRI image planes. ➢ Percutaneous guidance of biopsy needles. ➢ 3D localization of ablation catheters.	through use of minimally invasive procedures. Faster and more accurate diagnosis and therapy.
Pulmonary	➢ Navigation of next-generation broncho-scopes to deep-seated lesions.	Diagnosis and treatment of early stage lung lesions before they become symptomatic.
Gastro-enterology	➢ Quantifiable measurement of size and location of polyps. ➢ Guidance of flexible scopes in GI tract.	Reduction cost, procedural time, and complication rate of minimally invasive GI tract procedures.
Orthopaedics	➢ Interactive guidance for implanting surgical screws and other devices.	Accurate location of implants in human anatomy without ionizing radiation.

Frequently Asked Questions

What factors are driving the growth of minimally invasive procedures?

1. Fewer traumas to patients due to smaller incisions with less pain and faster recoveries.
2. Reduced procedure time, hospital stays/cost.
3. More precise and optimized delivery of treatment supporting improved outcomes.
4. Lower benefit payouts by private and government insurers.
5. Competition among hospitals to provide newest and less costly procedures.

What is the advantage of magnetic tracking over current methods of localization?

Despite the phenomenal growth potential of minimally invasive procedures, one critical restraint has always been limited 3D visualization within the patient. X-ray/fluoroscopy permits 2D vision, but must be used discriminately to minimize health risks to both patient and clinician.

A real-time, miniaturized magnetic sensor, on the other hand, solves key issues of real-time imaging, reduction in ionizing radiation, and procedural vision.

Magnetic tracking lets a physician view 3D imagery that corresponds precisely to patient 3D anatomy. This in turn enhances the physician's view by providing depth perception and overcoming foreshortening effects. Since, the human body does not attenuate magnetic tracker signals, a clear "line of sight" need not be maintained for continuous tracking. Once inserted in a catheter, hollow needle or scope, the sensor's outputs function as a 3D reference point that can be superimposed on pre-acquired or real-time images (CT, MRI, US) of anatomical features. This co-registration of instrument tip location with internal anatomy, allows clinicians to precisely map and locate features, to navigate to pre-identified locations, and to deliver therapies to targets. Of growing importance is the fact that magnetic localization reduces reliance on ionizing radiation and contrasting agents.

How does magnetic tracking work?

Both AC and DC magnetic tracking technologies use a small transmitter to create magnetic fields that induce instant measurable changes in one or more sensors. These changes are processed by an electronics unit to compute and output spatial measurements of position and orientation.

How does DC magnetic tracking differ from AC tracking technology?

AC trackers work accurately when there are no electrically conductive metals, such as stainless steel, copper, aluminum etc, or ferrous metals are located near the transmitter or sensor. In the presence of these metals, the transmitted AC signal induces *eddy currents* in the metals. It, in turn, generates a secondary magnetic field that distorts the transmitter's signal and sensor measurements.

Ascension's proprietary DC approach significantly reduces the conductive metal distortion problem by taking advantage of the steady state of pulsed DC magnetic fields. The system reduces field distortions by waiting long enough, i.e. about 2.5 mS, for eddy currents to decay substantially before measuring the steady state component of the transmitted field. As a result, eddy currents are, for the most part, mitigated as a source of measurement error.

What are some of the key advantages of DC technology over earlier AC magnetic tracking technologies?

1. Avoidance of numerous errors, difficult or impossible to fully correct with AC systems. These errors are related to sensor cross coupling, cable impedance, component matching, and conductive metals in the environment.
2. Inherently insensitive to medical type metals such as 300-series stainless steel and titanium, even when operating at a high measurement rate. AC trackers exhibit large position errors when near these metals.
3. Capability to drive other conductive metal errors to zero by measurement rate reduction. In an AC based system, the eddy current error is reduced slightly with decreased operating frequency.
4. Insensitivity to cable and signal conditioner bandwidth issues, critical factors in designing small sensors and cable geometries.
5. Freedom from distortion in the presence of composite materials.
6. Immunity to ferromagnetic distortion from metal in an OR table that is beneath our flat transmitter.

How does the flat transmitter negate steel and iron alloy distortion from OR beds and procedural tables?

Accurate tracking of sensors above a metal OR table has always been the *Holy Grail* of magnetic tracking.

Conventional AC trackers require that the area immediately around its transmitter be free from distorting objects. Because it is often impossible to identify underlying metal structures, tracker performance is often unknowingly compromised. This is especially true of OR tables and beds with structural supports made from ferrous metals, such as carbon steel and iron alloys. To overcome this problem, some AC trackers now specify use of a special, non-magnetic table for their procedures.

medSAFE's flat transmitter with a metal-isolating barrier negates the effects of metal **below** its planar surface. It fully shields the transmitted magnetic field from metallic components (distorters) below while "reflecting" clean fields into the hemisphere above. Its unobtrusive, low profile design makes it an ideal choice in a wide variety of procedures even as it overcomes the requirement to modifying existing equipment.

Can sensors be used to track ultra-thin guide wires?

Yes, medSAFE can be configured to track sensors as small as 0.3 mm in diameter.

Does the use of Ascension's DC magnetic tracker pose a health risk?

The strength of medSAFE's magnetic fields is extremely small - about the size of the earth's magnetic field. As such, it is not harmful to patients or clinicians. In the 35 years that magnetic tracking devices have been in use, there have been no reports of adverse effects.