Instrument Tracking and Navigation in OEM Image-Guided Surgery Systems





What is 3D Tracking Technology?

You encounter the applications of optical measurement and electromagnetic tracking technologies almost every day. From closing your car door; to using an ergonomic mouse; to virtual reality game play, tracking technology can be used in research labs or in the real world, directly or as an integrated component, to track the position of a part, handheld-object, or person in 3D space.

Both tracking technologies provide X-Y-Z coordinate data for real-time tracking purposes. Much like GPS navigation for your car, coordinate data are used to show where an object is in 3D space, and where it needs to go next. As with GPS navigation, accuracy matters; it's the difference between arriving exactly at your destination or being off by miles – or microns, as the case is here.

Why Partner with NDI?

NDI is proud to be the industry pioneer and world's leading manufacturer of optical measurement and electromagnetic tracking technology solutions. We've been a longstanding partner of the industry's top medical device OEMs, in some cases, for more than 20 straight years. In fact, nearly 90% of all surgical navigation systems on the market incorporate our technologies.

That trust in our solutions is something we work tirelessly to uphold. Our solutions are designed with ease and speed of integration in mind, boasting flexible customization options to meet your most challenging tracking requirements. Decades of technical expertise, dedicated account management, scalable manufacturing, and continuous product innovation make NDI the partner of choice to help bring your tracking applications—and industry breakthroughs—to life.

Electromagnetic Tracking

Our Aurora® electromagnetic (EM) tracking solutions use micro-sensors in conjunction with an EM field generator to provide reliable positional data and tracking of OEM medical instruments within confined, difficult to view/access areas. Even if the sensor is not visible, continuous tracking is maintained. No line-ofsight is needed. Sensors can be embedded into rigid or flexible devices such as ultrasound probes, endoscopes, guidewires and catheters, even at the tip of a needle.

The sensor serves as a localization point with the EM tracking volume. When integrated as a component into the workflow of image-guided surgery or interventional systems, the Aurora acts as the link between patient image sets and 3D space, enabling the instrument's position and orientation to be instantly visualized within the operative field. It does so with the exceptional speed, accuracy, and precision required by today's most demanding interventional approaches.

(The above is an example of an original equipment manufacturer's use of electromagnetic tracking technology in its medical device system.)



How Electromagnetic Tracking Works^{*}

- 1. Sensors are embedded into an OEM surgical device, where they act as localization points.
- **2.** The Field Generator emits a low-intensity, varying EM field that establishes the tracking volume.
- **3.** Small currents are induced inside the sensors when they enter the EM field.
- **4.** These currents are relayed to the Sensor Interface Unit, where they're amplified and digitized as signals.
- **5.** The signals are transmitted to the System Control Unit, which calculates each sensor's position and orientation as transformations.
- **6.** Tracking data are communicated to the host application for real-time navigation of instruments relative to patient image sets.

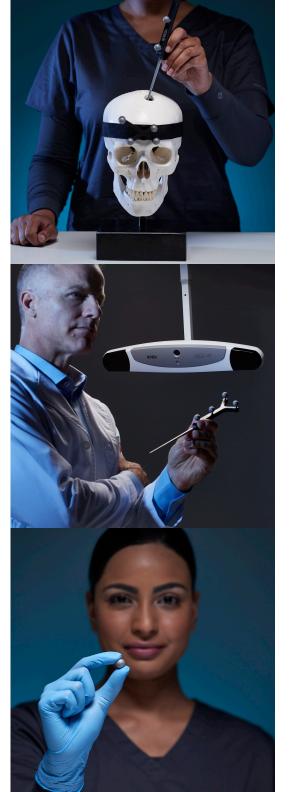
*Example of an original equipment manufacturer's use of Aurora in its medical device system

Optical Measurement

Optical measurement (tracking) has long been a mainstay of surgical navigation systems, using near-infrared light to detect and track reflective markers attached to OEM surgical instruments. Using triangulation, the position of each marker is calculated and translated into 3D coordinates. When incorporated as a component into the workflow of surgical navigation systems, the reflective markers provide a visual reference for pinpointing the surgical instrument in 3D space, and for guiding the instrument in relation to patient image sets.

Our Polaris® suite of optical measurement solutions provides real-time instrument tracking with sub-millimetre accuracy over a large measurement volume – without the use of wires. Optical tracking is also known for its reliable performance in almost any clinical environment. Since its first use in computer-assisted neurosurgery in 1994, our OEM customers continue to trust our Polaris optical measurement solutions to bring real-time tool tracking to ever-more complex surgical system workflows.

(The above is an example of an original equipment manufacturer's use of optical measurement technology in its medical device system.)



How Optical Measurement Works^{*}

- 1. Retro-reflective markers are attached to OEM surgical instruments.
- **2.** The Polaris Vega unit floods the measurement volume with infrared (IR) light.
- **3.** This light is reflected from the markers back to IR sensors on the Polaris Vega.
- **4.** The points where the light intersects are used to triangulate the markers' 3D (X-Y-Z) coordinates within the measurement volume.
- Coordinate data are mapped to the associated instrument and used to calculate the transformations (poses) of the instruments.
- **6.** Tracking data are communicated to the host application for real-time navigation of instruments relative to patient image sets.

*Example of an original equipment manufacturer's use of the Polaris Vega in its medical device system

Technology Comparison

No one tracking technology can fulfill all tracking requirements. The environment in which tracking occurs, the tool type, volume size, desired application outcomes, accuracy thresholds, and other factors will dictate what is the optimal technology for the application at hand. Fortunately, our Polaris and Aurora solutions provide distinct advantages to cover almost any tracking application.

	Technology Advantages	Technology Limitations
Optical Measurement	 Exceptional sub-millimetre accuracy Large measurement volume Wireless tracking Reliable measurement data quality Stable performance in most clinical environments Easy-to-design tools 	 Line-of-sight required Best suited to use with larger tools, which can impede clinical workflow Reflectivity of contaminated markers can reduce accuracy Tools must be rigid, with the tool tip fixed relative to markers
Electromagnetic Tracking	 No line-of-sight required; allows for in-vivo tool tracking Sensors can be embedded into flexible or rigid tools Sensors can be placed at the tip of flexible tools or needles Small sensor sizes allow for integration into tools with minimal change to tool form factor Most components integrate directly inside OEM system or cart 	 Can be less accurate than optical measurement Smaller tracking volume than optical measurement Sensors must be wired Susceptible to environmental interference Measurement data quality can be distorted in the presence of conductive and/or ferromagnetic metals

Medical OEM Customer Applications

The remarkable accuracy and versatility of the Polaris[®] and Aurora[®] solutions enable 3D measurement and tracking technology to be integrated into increasingly sophisticated applications across increasingly diverse markets, including automotive, AR/VR, academic research, and medical device manufacturers. Here are examples of how the latter have incorporated tracking technology as a component of their system workflow:

Optical Measurement Applications



Neurosurgery

Establish the patient coordinate system using rigid bodies, which act as fiducial markers during patient-to-image registration. Point-based mapping enables tool planning through cranial anatomy.



Orthopaedic & Spinal Surgery

Fuse tracking data with preoperative images, which helps enable instrument visualization and navigation during planning and placement of pedicle screws or joint implants.



Radiation Therapy

Maintain accurate positioning and delivery of radiation to the target site by monitoring movement of the patient couch, and movement of the marker block used for respiratory gating.

Eectromagnetic Tracking Applications



Interventional Radiology & Imaging

Localize and visualize an ultrasound transducer and needle relative to each other with the same measurement volume, and tag and re-navigate both against anatomical landmarks.



Guidewire & Catheter Tracking

Track guidewires and catheters through difficult-to-access arteries during endovascular procedures such as stent and shunt placement, and abdominal aortic aneurysm repair.



Cardiology & Electrophysiology

Embed a sensor into the tip of the ablation catheter to navigate the catheter through blood vessels to map the heart, and when targeting the treatment area.

Aurora Electromagnetic Tracking System Components

Field Generators (FGs)

Emits a low-intensity, varying electromagnetic field and establishes the position of the tracking volume. NDI offers multiple FG types that feature plug-and-play functionality with the System Control Unit:



Planar 20-20 Field Generator: Mounts to a positioning arm for unobtrusive placement within the physical workflow.



Tabletop Field Generator:Placed between the patient and the table;includes a thin barrier to minimize distortions.



Window Field Generator:

Features an open center that enables fluoroscopy imaging through the FG.



Planar 10-11 & 10-11H Field Generators: Supports localized handheld tracking applications with its small size.



System Control Unit (SCU)

Controls the FG, collects information from the SIUs, calculates the position and orientation of each sensor, and interfaces with the host computer.



Sensor Interface Unit (SIU)

Amplifies and digitizes the signals from the sensors Up to 2 SIUs can be connected to a single SCU. Available in both enclosed and PCB formats.

Sensors and Tools

NDI offers a wide selection of both individual sensors and ready-to-use tools for use with the Aurora System. The sensors' cost-effective designs enable use in disposable applications. One of our sensors measures just 0.3 mm in diameter—the smallest on the market—for OEM integration into smalldiameter tools such as catheters and guidewires. Our ready-to-use tools come wired to a connector and programmed for immediate use. Select tools are able to withstand multiple autoclave cycles.

The Polaris Optical Measurement Product Suite

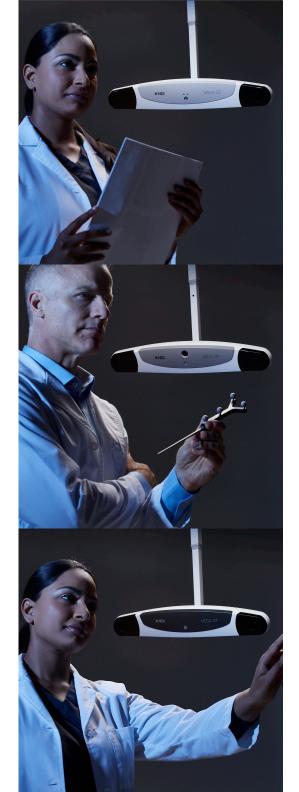
Polaris Vicra

This compact optical tracker provides a smaller measurement volume for targeted tracking of smaller tools within a confined area. Weighing less than a kilogram, the lightweight and portable design of the Polaris Vicra allows it to be mounted almost anywhere. A volumetric accuracy of 0.25 mm RMS and 95% confidence interval of 0.5 mm ensure the most subtle tool movements are precisely tracked and localized.





This sterile, single-use reflective sphere is used to calibrate the image-guided surgery system and provide pinpoint accuracy for localizing surgical tools within the 3D space. The NDI Passive Sphere is the industry's original—and world's leading—marker sphere, with a consistent sphere shape, surface, and placement for optimal tracking performance. (The NDI Passive Sphere is an FDA-regulated medical device.)



Polaris Vega ST

Our standard optical tracker delivers exceptional measurement accuracy and reliability – hallmarks of our entire Polaris line. Volumetric accuracy to 0.12 mm RMS is achieved over a large measurement volume, with tracking data streamed via Ethernet. An optional Extended Pyramid Volume and Positioning Laser augment flexibility and control.

Polaris Vega VT

This industry-first optical tracker combines HD video and IR tracking to capture a live or recorded view of tracked tools within the measurement volume. Video data and IR tracking data are aligned in real time to a common frame of reference. Different camera resolutions and settings maximize the capture of high-contrast images.

Polaris Vega XT

Our most advanced optical tracker delivers volumetric accuracy to 0.12 mm RMS with minimal noise, latency of just 6 milliseconds, and a frame rate as high as 250 Hz, for measurement data that is capable of real-time integration into robot-assisted surgery systems. Tight data synchronization and Ethernet connectivity add to best-in-class measurement performance.

About NDI

When the world's top OEMs and academic institutes need to track something, they call NDI. Why? Because no one can beat the accuracy and reliability of our 3D measurement and motion tracking solutions. Since 1981 we've helped our OEM and direct customers in medicine, manufacturing, and life sciences bring optical and electromagnetic tracking technologies to image-guided surgery, automotive assembly and testing, neuroscience research, speech studies, surgical simulators, AR/VR, and so much more. @NDI

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Almost 40 years later, we're still as passionate as ever to break new ground in 3D/6D tracking. We thrive on finding inventive ways to solve our customers' most complex tracking challenges – it's why nearly 50% of our team is dedicated to research and development. NDI is headquartered in Waterloo, Canada, with offices in the U.S., Germany, and Hong Kong.

Disclaimer

The Polaris Vega, Polaris Vicra, Aurora, and Aurora sensors and tools are general metrology products, and are not approved, cleared or developed for medical use. Suitability of these products in a particular application must be determined by the OEM customer or the end user. NDI has not validated or otherwise tested these general metrology products for any medical purpose. Testing, certification, and validation are the responsibility of the original equipment manufacturer or the end user and should be completed prior to use in any application, or any other application involving living humans.





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