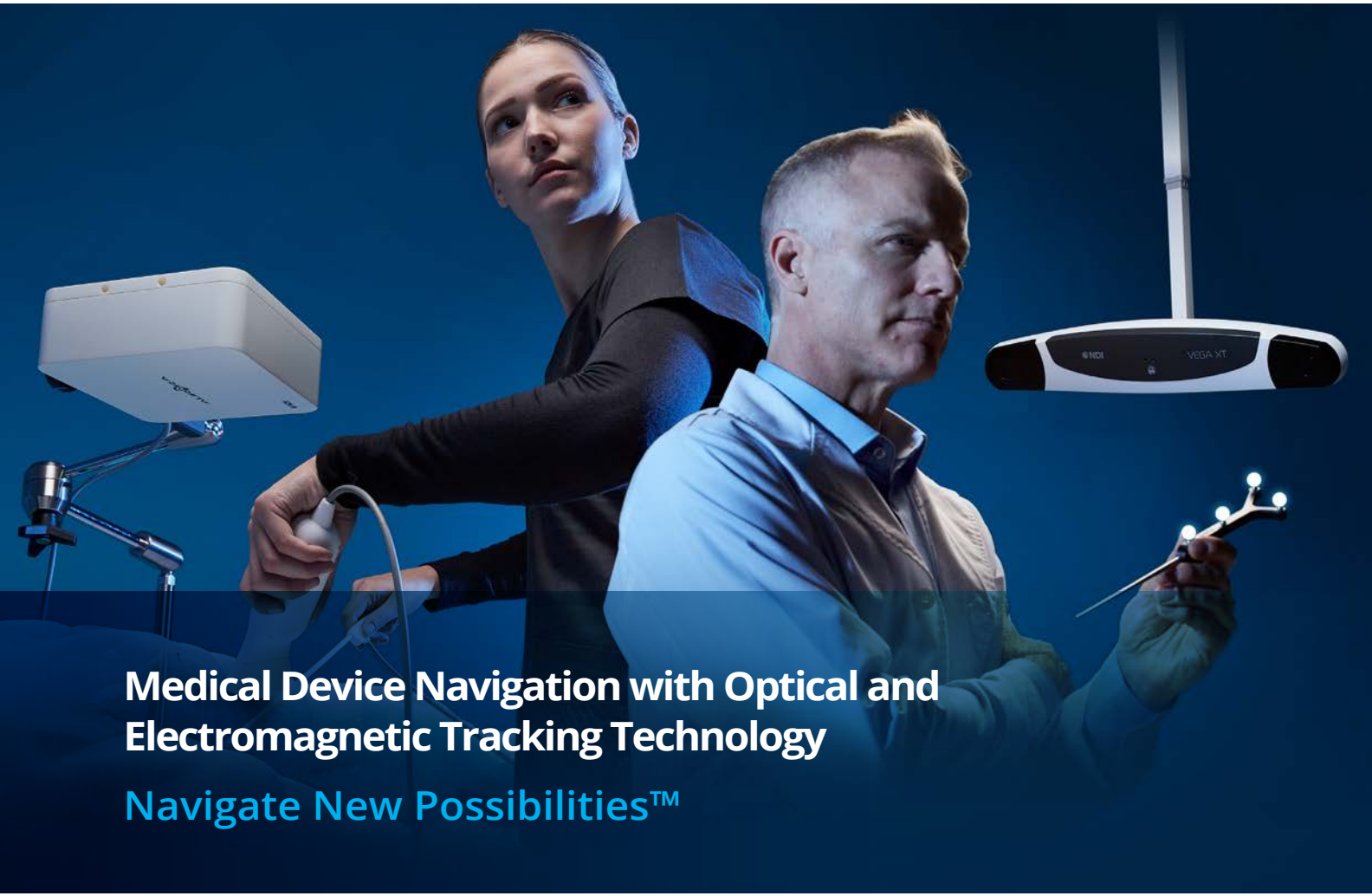


Medical Device Navigation with Optical and Electromagnetic Tracking Technology

Navigate New Possibilities™

NDI

Navigate New Possibilities with NDI

NDI is the global authority and industry pioneer of optical measurement and electromagnetic (EM) tracking technology solutions. Backed by over 40 years of innovation and expertise, we're the partner of choice for world's top medical device OEMs, in some cases, for more than 25 straight years. In fact, nearly 90% of all surgical navigation systems on the market incorporate our technologies.

Our optical and EM tracking technologies are trusted for their accuracy and reliability. They act like GPS navigation for OEM medical instruments, showing where an instrument is located relative to patient imaging, so that the clinician can plan where it needs to go next. As with GPS navigation for your car, accuracy matters; it means reaching your destination (target treatment area) exactly as expected, or being off by kilometres – or millimetres in clinical procedures.

Our OEM customers have integrated our optical and EM tracking technologies into a broad range of medical devices and clinical workflows, with new applications being explored every day:

Optical Measurement

- Neurosurgery
- Orthopaedic & Spinal Surgery
- Robotic-Surgery Guidance
- Transcranial Magnetic Stimulation (TMS)

Electromagnetic Tracking

- Interventional Cardiology
- Endoscopy
- Diagnostic & Therapeutic Ultrasound
- Vascular & Neurovascular

Electromagnetic Tracking

Our Aurora® electromagnetic (EM) tracking solution uses 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-of-sight 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

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:

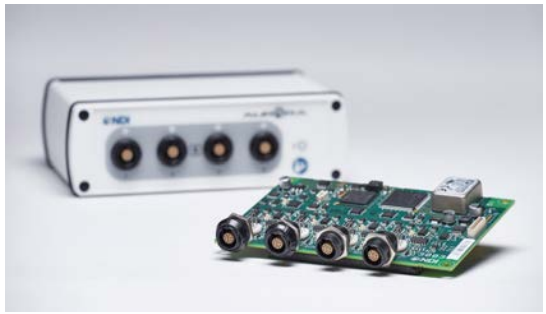
Planar 20-20 Field Generator:
Mounts to a positioning arm for unobtrusive placement within the physical workflow.

Window Field Generator:
Features an open center that enables fluoroscopy imaging through the FG.

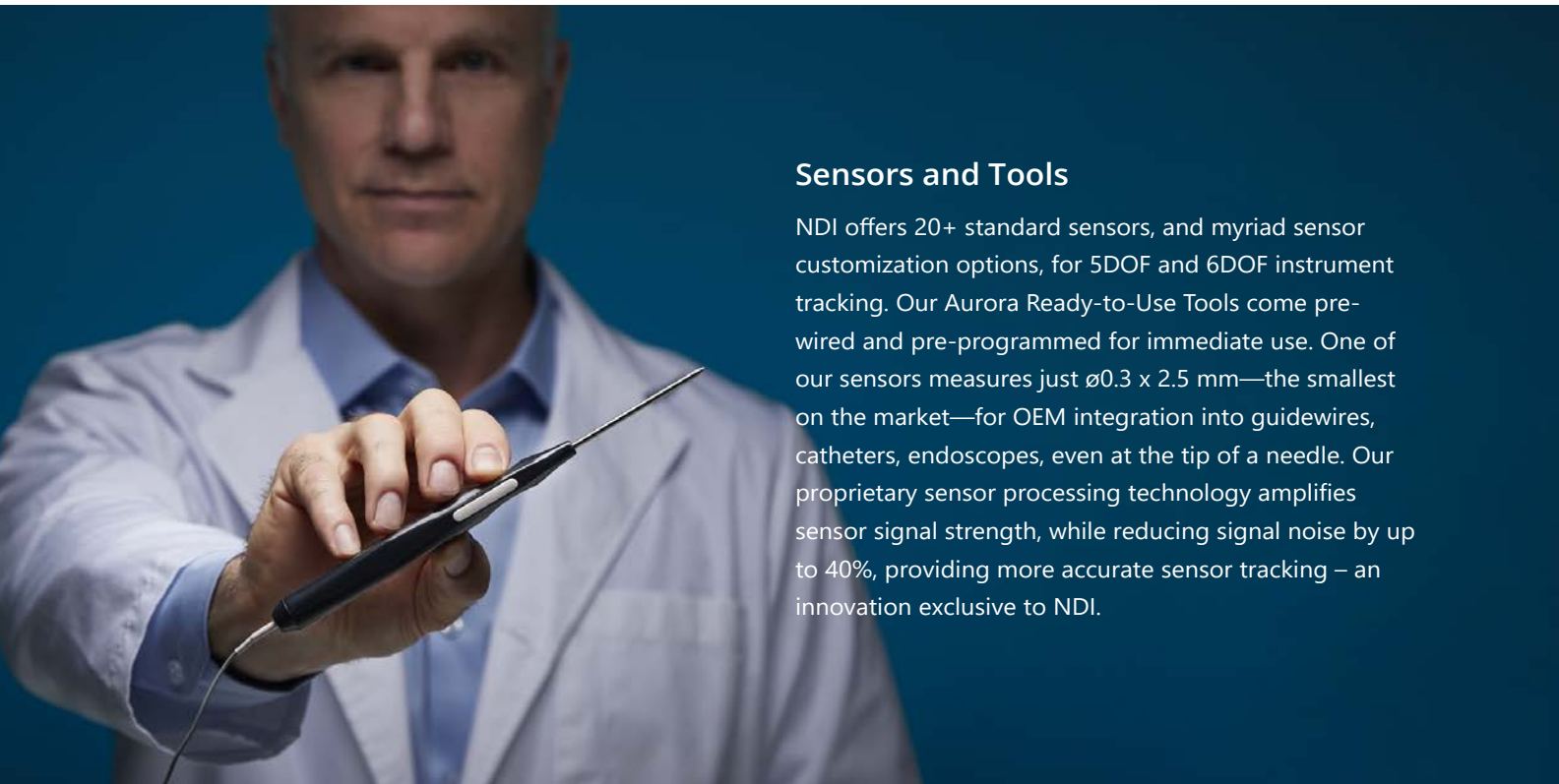
Tabletop Field Generator:
Placed between the patient and the table; includes a thin barrier to minimize distortions.

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

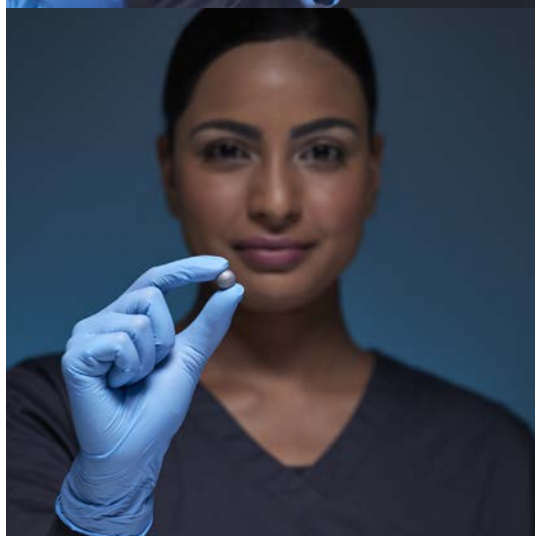
NDI offers 20+ standard sensors, and myriad sensor customization options, for 5DOF and 6DOF instrument tracking. Our Aurora Ready-to-Use Tools come pre-wired and pre-programmed for immediate use. One of our sensors measures just ø0.3 x 2.5 mm—the smallest on the market—for OEM integration into guidewires, catheters, endoscopes, even at the tip of a needle. Our proprietary sensor processing technology amplifies sensor signal strength, while reducing signal noise by up to 40%, providing more accurate sensor tracking – an innovation exclusive to NDI.

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.
5. 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

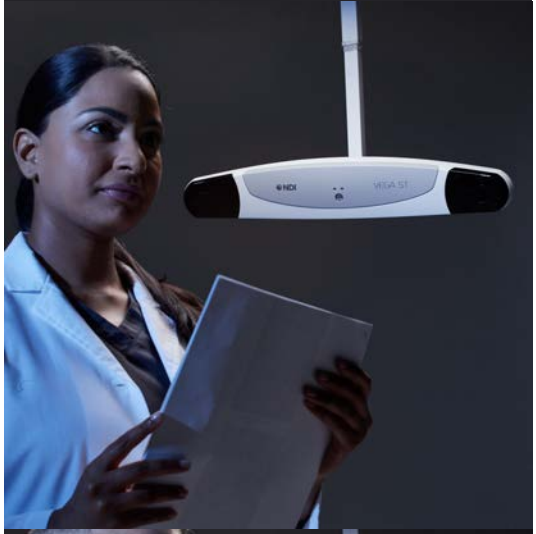
The Polaris® Optical Measurement Product Suite

Polaris Lyra® (coming soon)

NDI's compact optical tracker has a wide measurement volume and short stand-off, for targeted tracking of individual body segments via smaller tools. Weighing less than a kilogram, and with a small footprint, the Polaris Lyra can be mounted almost anywhere, benefiting use in confined clinical suites. A volumetric accuracy to 0.20 mm RMS, frame rate of 60 Hz (standard), and low data latency, provide accurate and reliable OEM tool tracking and navigation. Ethernet connectivity (PoE+) and third-party equipment synchronization via GPIO port (General Purpose Input/Output) simplify integration.

NDI Passive Sphere™

This sterile, single-use reflective sphere is used to calibrate the Image-Guided Surgery System (IGS) 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. Spheres are packaged in procedure trays that provide the exact quantity needed for common IGS procedures, simplifying procedure use, purchasing, and inventory management. (The NDI Passive Sphere is an FDA-regulated medical device.)

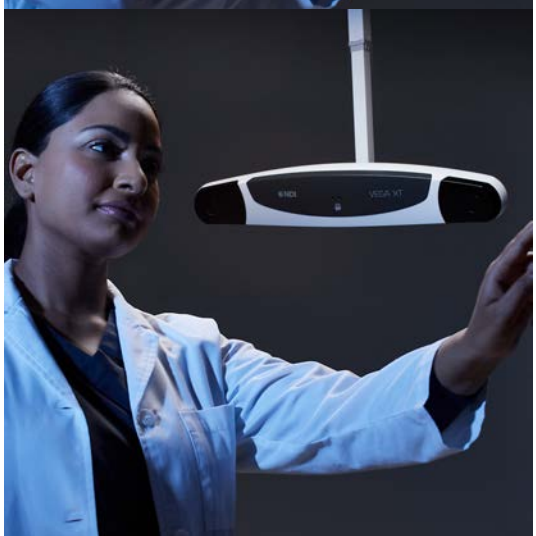


Polaris Vega® ST

Our standard optical tracker delivers exceptional measurement accuracy and reliability. Volumetric accuracy to 0.12 mm RMS is achieved over a large measurement volume, with tracking data streamed via Ethernet. The Radiation Hardening option provides extra protection from radiation via a shielded processor and modified memory management.

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, latency below three milliseconds, and industry-leading frame rate up to 400 Hz that remains constant when tracking multiple tools. Support for TCP and UDP network protocols allows for wireless host communication during time-sensitive applications, while tight data synchronization and Ethernet (PoE+) connectivity add to best-in-class measurement performance.

Integrations that Drive **Innovation**

Robotic Navigation Development Kit

NDI's optical tracking technology has robust integration options, which are used to maximum effect in this joint development kit with KUKA and MPE. The development kit bundles together the Polaris Vega XT and KUKA LBR Med 14 R820 collaborative robot with sample code, packaged in a medical cart from MPE.

The development kit provides medical device start-ups and scale-ups with a low-risk solution for fast-tracking the design, prototyping, and bench-testing of a market-ready product for integration into robotic-assisted surgical applications. It offers a streamlined development path for executing the following technical tasks, so that the OEM can focus on clinical workflow integration:

- Synchronizing two separate coordinate systems and conventions.
- Tracking the robot using a multi-faced end effector with attached markers.
- Creating custom tools that are optimized to specific application workflows.
- Adjusting the robot's path in real time based on tracked tool positions.
- Merging disparate data streams and communication protocols into one interface.

Dual-Modality Hybrid Tracking Solution

NDI's optical and EM tracking technologies share the same foundation of 3D tracking excellence; unrivalled measurement accuracy and reliability; groundbreaking engineering and design. But no one tracking technology can fulfill all tracking requirements.

In this industry-first, dual-modality tracking solution, NDI combines our optical and EM navigation technologies to provide synchronous hybrid tool navigation within a common coordinate system. Both tracking data streams are reconciled and displayed within a dynamic, visually-rich interface. The overlapping measurement volumes of each technology are shown for enhanced tool tracking visualization.

Working seamlessly in tandem, the Polaris Vega and Aurora can provide continuous, accurate OEM medical device navigation in almost any environment, where each tracking technology plays to its unique strengths, and offsets the limitations of the other.

This solution also showcases the deep technical expertise of the NDI Integration Team, who work alongside our customers to find answers to their toughest tracking integration questions.

Why Partner with NDI

NDI's optical and EM tracking solutions are built on a commitment to quality, performance, and continuous innovation, which is evident throughout their design, manufacture, and integration. Our products adhere to numerous ISO, IEC, UL, CSA, EC, and other regulatory and quality standards. Proprietary characterization algorithms, a focus on systemic noise reduction, and factory calibration emphasize tracking performance.

Near-countless customization options allow the Polaris and Aurora solutions to be tailored to your medical device and workflow requirements, for an OEM image-guided surgical/interventional system that is uniquely your own. With almost 50% of our staff dedicated to R&D, we thrive on finding inventive solutions to the industry's most challenging—and evolving—navigation applications. This is especially true of our integration team, who work directly with your team to navigate the intricacies of optical and EM tracking technology integration at the system, tool, and application levels.

Dedicated account management, lifetime product support, and scalable manufacturing further make NDI the partner of choice to help you bring your medical device navigation—and clinical breakthroughs—to market.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