Optical Measurement Technology
in Medical Device OEM Systems

The Polaris® Product Suite

NDI

Navigate New Possibilities™

From the time it was first integrated by a medical device OEM into a computer-assisted neurosurgery system in 1996, the Polaris® optical measurement solutions have helped our OEM customers achieve ever-more complex surgical navigation systems and procedural breakthroughs. Much like GPS navigation for your car, the Polaris solutions capture 3D measurements (coordinates) that can be used to calculate the positions and orientations of a surgical instrument in 3D space and show where it needs to go next.

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Why Choose Optical Measurement?

Optical measurement (optical tracking) has long been an important component of OEM surgical navigation systems, where it can provide measurement data for real-time surgical tool tracking. The Polaris optical trackers deliver measurement data with sub-millimetre accuracy and precision, over a large measurement volume, without wires. Optical measurement is also known for its robust and reliable tracking performance in almost any environment.

When integrated into the workflow of surgical navigation systems, the Polaris optical tracker acts as the link between patient image sets and the physical 3D space. It enables the positions and orientations of surgical tools to be instantly localized and visualized within the operative field. Multiple tools can be tracked at once without interrupting the surgical workflow.

For more than 20 years the Polaris name has been synonymous with the capabilities—and breakthroughs—achieved in OEM surgical navigation through optical measurement technology. Every advancement of the Polaris product suite makes ever-more complex surgical navigation approaches and systems possible, where today's technology innovations become tomorrow's standard of care.

(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*

The Polaris Vega and Polaris Vicra are based on passive optical measurement technology, using near-infrared (IR) light to detect and track the 3D positions of navigation markers (for example, passive marker spheres, Radix™ Lenses) attached to tools. Each tool has a unique array of attached markers; this allows for differentiation among tools. The coordinate data for each marker are mapped to a specific tool and used to calculate the tool transformation; i.e. determine the tool's position and orientation.

Much like GPS navigation, coordinate data pinpoint in real time where the markers—and the tools to which they're attached—are in 3D space. When these tracking data are integrated into the OEM's host application, surgical tools can be navigated against patient image sets. Tracking occurs within a pre-calibrated Pyramid or Extended Pyramid measurement volume, with all tool transformations reported in the Polaris optical tracker's global coordinate system.

1. Markers can be attached to OEM surgical instruments.
2. The Polaris optical tracker floods the measurement volume with infrared (IR) light.
3. This light is reflected from the markers back to IR sensors on the Polaris optical tracker.
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 instrument.
6. Tracking data are communicated to the host application for real-time visualization and navigation of instruments relative to patient image sets.

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

Measurement You Can Trust

Accuracy and reliability are the foundation of the Polaris optical measurement solution. However, accuracy represents more than measurement values hitting a theoretical 'bullseye' (although that's important, too). It symbolizes the confidence users feel when they navigate surgical tools to a physical target (treatment area) and reach it exactly as expected, every time. This focus on trusted measurement performance is evident throughout the design, manufacture, and integration of the entire Polaris solution:

Characterization

The Polaris' characterization models are based on proprietary algorithms that leverage decades of progressive applied physics and mathematics research. These models encompass every conceivable aspect of 3D tracking to maximize spatial measurement accuracy.

Manufacturing Process

The design and manufacture of Polaris system components and passive spheres adhere to numerous ISO, IEC, UL, CSA, EC and other regulatory and quality standards, providing a reliable tracking system that operates exactly to stated accuracy specifications.

Factory Calibration

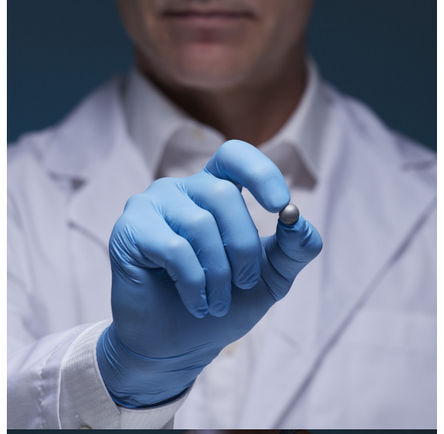
The accuracy and repeatability of 3D positions are verified using a coordinate measurement machine (CMM) within our manufacturing facility for validated measurement performance that is free of scale errors or variabilities

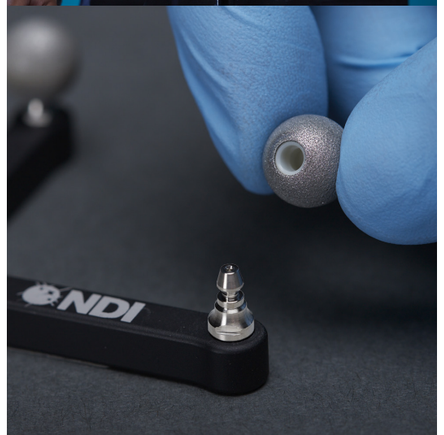
End-to-End Tracking

The Polaris optical tracker and NDI Passive Sphere™ are designed to work together to achieve optimal measurement performance. The unique properties of one product accentuate the benefits of the other, as evidenced during characterization, calibration, and tracking.

OEM Industry Partnerships

Our partners are at the forefront of medical discovery, pushing the boundaries of what surgical navigation systems are capable. Our partners' unique insights have helped NDI to innovate increasingly more versatile optical measurement solutions.





Polaris Customization Options

The Polaris solution offers four different optical tracker models, each with distinct options and specifications relating to hardware size, measurement rate, latency, accuracy, data connectivity and mounting. Available options such as Positioning Laser, Extended Pyramid Volume, and Radiation Hardening further expand system functionality.

Although the form factor of the optical tracker is fixed, the parameters of how it tracks, and the design of OEM rigid bodies and tools, are highly configurable. With so many options that enhance versatility and utility, no two Polaris solutions are exactly alike – each is unique to its specific medical device OEM customer.

- Four different models of optical trackers
- Four types of navigation markers
- Custom OEM Bezel (to match OEM branding)
- Myriad options for creating custom OEM tools

Medical OEM Customer Applications

The remarkable accuracy and reliability of the Polaris solution enables real-time optical measurement technology to be integrated into increasingly sophisticated applications across increasingly diverse markets, including academic research, surgical trainers, and medical device manufacturers. Here are examples of how the latter have incorporated tracking technology as a component of their system workflow:

Neurosurgery

Use rigid bodies and probes to register patient anatomy to preoperatively acquired patient images. This supports real-time instrument navigation and accurate execution of the surgical plan.

Robotic Surgery

Track the positions of surgical tools attached to the robot end-effector, at update rates required for closed-loop, robotic-guided orthopaedic procedures such as spinal fusion and joint replacements.

Radiation Therapy

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

Orthopaedics - Arthroplasty

Register and track bony anatomy for positioning and alignment of implant fit, measurement of joint rotations and offsets, and to visualize and guide the angle and depth of tool cuts.

Spinal Surgery

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

ENT or FES Surgery

Track the positions of endoscopes, shavers, and suction devices in real time to avoid contacting the optic nerve as well as other critical cranial anatomy near the sinuses.

Dental Surgery

Maintain correct drilling angle and depth (and avoid the mandibular nerve) by tracking the jaw's position relative to preoperative CT scans. Visualize and position the placement of dental implants.

Augmented Reality (AR)

Augment the tracking of surgical tracking tools within existing procedures by adding an AR visualization (overlay) of internal structures via image fusion.

The Polaris Optical Measurement Product Suite

The strength of the Polaris product suite lies in the commonalities and differences of its optical trackers. All are based on passive optical measurement technology. All share the same foundation of sub-millimetre measurement accuracy and reliability. All are engineered and manufactured to deliver superior tracking performance. But it's their differences that provide boundless opportunities for customizing and integrating the Polaris Vega or Polaris Vicra into OEM system workflows.

There are four Polaris optical tracker models, each with distinct options and specifications relating to hardware size, measurement rate, latency, noise, accuracy, data connectivity, and mounting. There are four marker types. Three different-sized measurement volumes. Three different software packages. A full library of API commands. And near-countless options for designing custom OEM rigid bodies and tools.

Just as no two tracking applications are exactly alike, each solution within the Polaris product suite is unique to its OEM customer. They just happen to have the same technical excellence and expert product execution in common.

Polaris Vega® XT

Break new ground in OEM surgical navigation and robotic-assisted surgical systems with our premier optical measurement solution. Upgraded from its predecessor, the Polaris Vega XT combines unrivalled measurement accuracy, higher-speed tracking, and lower latency. These enhanced features, alongside the new UDP communication protocol and data averaging, support workflow integration within emerging surgeon-controlled and autonomous OEM robotic systems.

As a component of an OEM robotic-assisted surgical system, the Polaris Vega XT can be used to track the positions of the robot base and end-effector in 3D space via attached markers. Markers can also be attached to handheld tools. This enables the robot, tools, and patient to be tracked in real-time relative to each other within the same coordinate system, and visualized instantly within the OEM host application.

Polaris Vega® XT

Exceptional Measurement Accuracy

The Polaris Vega XT delivers volumetric accuracy to 0.12 mm RMS with minimal noise. Track tools with total confidence; hardware characterization, and factory calibration optimizes accuracy for measurements that are highly repeatable and reliable.

Enhanced Communication Protocol

The Polaris Vega XT optical tracker now supports both TCP and UDP network communication methods. Selectable through the API, the addition of UDP provides users with a better option for wireless host communications in time-sensitive applications.

Unrivaled Measurement Rate

The Polaris Vega XT has an improved maximum frame rate of 400 Hz and reduced typical latency below three milliseconds, which allows for fast and efficient transfer of tracking data within robot-control systems. The frame rate remains constant even when multiple tracked tools are in view.

Ease and Speed of Integration

The Polaris Vega XT includes software, source code, and API tools to streamline the design and development of tools, and to speed integration with OEM software applications. The software suite also includes utilities to support ongoing system diagnostics and maintenance.

Polaris Vega XT: Technical Specifications

PERFORMANCE	
Volumetric Accuracy[1,2] RMS	Pyramid Volume: 0.12 mm Extended Pyramid: 0.15 mm
95% Confidence Interval[1,2]	Pyramid Volume: 0.20 mm Extended Pyramid: 0.30 mm
Maximum Frame Rate	400 Hz
Average Latency	< 3 ms (typical)
Measurement Volume	Pyramid / Extended Pyramid (optional)
TOOL TRACKING	
Tool Types	Passive, Active Wireless
Maximum Number of Tools	Load up to 25 tools (maximum of 6 active wireless)
Maximum Number of Markers per Tool	6 single-face/20 multi-face for passive or active wireless tools
DATA COMMUNICATION & CONNECTIVITY	
Data Communication	Gigabit Ethernet
Communication Protocol Options	TCP (Transmission Control Protocol) UDP (User Datagram Protocol)
Network Synchronization	Precision Time Protocol (PTP)
Data/Power Interface	Ethernet, RJ45
HARDWARE	
Dimensions (LxWxH)	591 x 103 x 106 mm
Weight	1.7 kg
Mounting	Four M4 x 0.7 mm pitch x 10 mm deep threaded holes, rear mount

1 Based on a single marker stepped through more than 900 positions throughout the measurement volume using the mean of 30 samples at each position at 20°C.
2 Accuracy stated based on overall volume.

Polaris Vega® VT

Envision new possibilities in OEM surgical tool tracking and navigation with the industry's first optical tracker to combine HD video and infrared tracking. As our specialized optical tracker, the Polaris Vega VT delivers best-in-class optical measurement and live video streaming to help medical device OEMs bring augmented reality (AR) and machine vision to surgical navigation.

Video data is aligned with IR tracking data to a common coordinate system; the video camera and IR sensors 'see' the same thing at the same time. This pre-calibrated transformation eliminates the need to determine the offset between the video and IR tracking data streams. These capabilities can open the way to new tracking applications; for example:

- Add AR visualization of internal structures via image fusion
- Study joint range of motion before/after implant surgery
- Register tools automatically by scanning barcodes
- Augment patient case files with procedural recordings
- Consult with remote staff via streamed video feed
- Record pre-op rehearsals to enhance surgical planning

Polaris Vega® VT

Exceptional Measurement Accuracy

The Polaris Vega VT delivers volumetric accuracy to 0.12 mm RMS at 60 Hz, with minimal noise while streaming video. Track with confidence; hardware characterization and factory calibration optimize accuracy for measurements that are highly repeatable and reliable.

Augmented Reality Overlay

The Polaris Vega VT software enables a live augmented reality overview of tools within the video stream, which is aligned to the IR data coordinate system. Create virtual tools and new video-enhanced applications using the built-in API and available software and source code.

Integrated HD Video Camera

The Polaris Vega VT video camera provides a live view of the measurement volume via third-party streaming clients. Camera resolution, frame rate, and other features can be quickly configured in-field to capture sharp, high-contrast images in most operative environments.

Seamless Data Synchronization

The Polaris Vega VT uses the Precision Time Protocol (PTP) for network synchronization, and the Real-Time Streaming Protocol (RTSP) for streaming video. Tight data communication and synchronization are achieved by Gigabit Ethernet, and system power via POE (Power over Ethernet).

Polaris Vega VT: Technical Specifications

PERFORMANCE	
Volumetric Accuracy[1,2] RMS	Pyramid Volume: 0.12 mm Extended Pyramid: 0.15 mm
95% Confidence Interval[1,2]	Pyramid Volume: 0.20 mm Extended Pyramid: 0.30 mm
Maximum Frame Rate	60 Hz
Average Latency	< 16 ms (typical)
Measurement Volume	Pyramid / Extended Pyramid (optional)
TOOL TRACKING	
Tool Types	Passive, Active Wireless
Maximum Number of Tools	Load up to 25 tools (maximum of 6 active wireless)
Maximum Number of Markers per Tool	6 single-face/20 multi-face
DATA COMMUNICATION & CONNECTIVITY	
Data Communication	Gigabit Ethernet
Network Synchronization	Precision Time Protocol (PTP)
Data/Power Interface	Ethernet, RJ45
Video Streaming Protocol	Real-Time Streaming Protocol (RTSP)
HARDWARE	
Dimensions (LxWxH)	591 x 103 x 106 mm
Weight	1.7 kg
Mounting	Four M4 x 0.7 mm pitch x 10 mm deep threaded holes, rear mount
Video Camera Lens	Fixed focus; point of focus 2.5 m from centre of Position Sensor
Video Camera Focal Length	4.35 mm

1 Based on a single marker stepped through more than 900 positions throughout the measurement volume using the mean of 30 samples at each position at 20°C.
2 Accuracy stated based on overall volume.

Polaris Vega® ST

Enable new OEM surgical tool tracking and navigation applications with our versatile optical tracker. The Polaris Vega ST provides a trusted technical foundation that supports accurate and reliable tracking in a diverse range of applications, across most clinical environments.

Unique to the Polaris Vega ST is its Radiation Hardening option, in which the optical tracker is protected against gamma and neutron radiation via a shielded processor and modified memory management. This enables the Polaris Vega ST to be safely integrated into radiation therapy workflows and environments.

Additional options further enhance system utility. The Positioning Laser aids with positioning the optical tracker and/or surgical equipment within the measurement volume. The Extended Pyramid Volume roughly doubles the measurement volume for applications that require a clear view of multiple tools at once.

Polaris Vega® ST

Exceptional Measurement Accuracy

The Polaris Vega ST delivers high volumetric accuracy to 0.12 mm RMS with low noise. Track passive spheres attached to tools with confidence; hardware characterization and factory calibration optimize accuracy for measurements that are highly repeatable and reliable.

Streamlined Tool Design

The Polaris Vega ST has a built-in API and available software to facilitate tool development and accelerate integration into OEM and end-user software applications. The NDI ToolBox software includes utilities to support ongoing system diagnostics and maintenance.

Robust Hardware Design

The Polaris Vega ST can include optional radiation hardening to maintain accurate and reliable performance in harsh environments, such as those found in radiation therapy suites. Consistent operation in variable room conditions add to product robustness.

Ethernet Connectivity

The Polaris Vega ST streams tracking data to the OEM host application via Gigabit Ethernet, as powered by POE (Power over Ethernet). Ethernet connectivity allows for greater flexibility, interoperability, and scalability of equipment setup and use within the operative space.

Polaris Vega ST: Technical Specifications

PERFORMANCE	
Volumetric Accuracy[1,2] RMS	Pyramid Volume: 0.12 mm Extended Pyramid: 0.15 mm
95% Confidence Interval[1,2]	Pyramid Volume: 0.20 mm Extended Pyramid: 0.30 mm
Maximum Frame Rate	60 Hz
Average Latency	< 16 ms (typical)
Measurement Volume	Pyramid / Extended Pyramid (optional)
TOOL TRACKING	
Tool Types	Passive
Maximum Number of Tools	Load up to 25 tools (maximum of 6 active wireless)
Maximum Number of Markers per Tool	6 single-face/20 multi-face
DATA COMMUNICATION & CONNECTIVITY	
Data Communication	Gigabit Ethernet
Network Synchronization	Precision Time Protocol (PTP)
Data/Power Interface	Ethernet, RJ45
HARDWARE	
Dimensions (LxWxH)	591 x 103 x 106 mm
Weight	1.7 kg 2.15 kg (Radiation Hardening option)
Mounting	Four M4 x 0.7 mm pitch x 10 mm deep threaded holes, rear mount

1 Based on a single marker stepped through more than 900 positions throughout the measurement volume using the mean of 30 samples at each position at 20°C.
2 Accuracy stated based on overall volume.

Polaris Vicra®

Bring the power of optical measurement to confined tracking areas. The Polaris Vicra shares the same trusted measurement performance as all Polaris optical trackers, but in a smaller form factor. Its compact size can allow medical device OEMs to integrate the Polaris Vicra into surgical workflows where equipment space is limited.

Polaris Vicra®

Exceptional Measurement Accuracy

The Polaris Vicra tracks 3D tool positions with sub-millimetre accuracy and repeatability. Volumetric accuracy to 0.25 mm and 95% confidence interval of 0.5 mm ensure the most subtle OEM surgical tool movements are precisely tracked and localized in real time.

Compact Hardware Design

The Polaris Vicra features a compact form factor and weighs just 0.8 kg, which allows it to be mounted or transported almost anywhere – even in areas where equipment space is limited. A pre-calibrated measurement volume and quick system start-up add to its portability.

Optimized Tracking Volume

The Polaris Vicra has a measurement volume that is optimized for targeted tool tracking within localized areas. To complement this smaller measurement volume, the Polaris Vicra tool geometries are reduced, resulting in more ergonomic, lightweight tools that allow for finely controlled movements.

Customizable System Implementation

The Polaris Vicra comes with different software utilities to customize how the optical tracker and tools interface with the OEM host application. A built-in API speeds application development and integration, while tool geometries and other tracking parameters are set via a tool definition file.

Polaris Vicra: Technical Specifications

PERFORMANCE	
Volumetric Accuracy[1,2] RMS	0.25 mm
95% Confidence Interval[1,2]	0.50 mm
Maximum Frame Rate	20 Hz
Measurement Volume	Vicra Volume
TOOL TRACKING	
Tool Types	Passive, Active Wireless
Maximum Number of Tools	Load up to 15 tools; simultaneously track up to 6 passive and 1 active wireless
Maximum Number of Markers per Tool	6 single-face/20 multi-face
DATA COMMUNICATION	
Interface	USB
HARDWARE	
Dimensions (LxWxH)	273 x 69 x 69 mm
Weight	0.8 kg
Mounting	¼” thread tripod mount or secured via three M3 x 0.5 mm pitch x 9.0 mm deep threaded holes, rear mount

1 Based on a single marker stepped through more than 900 positions throughout the measurement volume using the mean of 30 samples at each position at 20°C.
2 Accuracy stated based on overall volume.

Polaris Vega® Family Model Comparison

	Polaris Vega® ST	Polaris Vega® VT	Polaris Vega® XT
ACCURACY			
Volumetric Accuracy RMS (Pyramid): 0.12 mm	x	x	x
Volumetric Accuracy RMS (Extended Pyramid): 0.15 mm	x	x	x
95% Confidence Interval (Pyramid): 0.20 mm	x	x	x
95% Confidence Interval (Extended Pyramid): 0.30 mm	x	x	x
PERFORMANCE			
Maximum Frame Rate: 400 Hz			x
Maximum Frame Rate: 60 Hz	x	x	
Average Latency: < 3 ms (typical)			x
Average Latency: < 16 ms (typical)	x	x	
DATA COMMUNICATION			
Ethernet Connectivity	x	x	x
MECHANICAL			
Dimensions: 591 mm x 103 mm x 106 mm	x	x	x
Weight: 1.7 kg	x	x	x
Weight with Radiation Hardening: 2.15 kg	x		
OEM CUSTOM BRANDING			
Custom Bezel Available	x	x	x
ENHANCED FUNCTIONALITY			
HD Video Camera		x	
Optional Radiation Hardening	x		
Optional Extended Pyramid	x	x	x
Optional Positioning Laser	x	x	x

Polaris Vega® and Polaris Vicra® Comparison

	Polaris Vega® XT	Polaris Vicra®
PERFORMANCE		
Volumetric Accuracy[1,2]	0.12 mm	0.25 mm
95% Confidence Interval[1,2]	0.20 mm	0.50 mm
Maximum Frame Rate	400 Hz	20 Hz
Measurement Volume	Pyramid Extended Pyramid (optional)	Vicra
HARDWARE		
Dimensions (LxWxH)	591 x 103 x 106 mm	273 x 69 x 69 mm
Weight	1.7 kg	0.8 kg
Mounting	Four M4 x 0.7 mm pitch x 10 mm deep threaded holes, rear mount	¼" thread tripod mount or secured via three M3 x 0.5 mm pitch x 9.0 mm deep threaded holes, rear mount
TOOL TRACKING		
Tool Types	Passive, Active Wireless	Passive, Active Wireless
Maximum Number of Tools	Load up to 25 tools (maximum of 6 active wireless)	Load up to 15 tools; simultaneously track up to 6 passive and 1 active wireless
Maximum Number of Markers per Tool	6 single-face/20 multi-face	6 single-face/20 multi-face
DATA COMMUNICATION		
Data Communication	Gigabit Ethernet	USB
Network Synchronization	Precision Time Protocol (PTP)	Precision Time Protocol (PTP)
Data/Power Interface	Ethernet, RJ45	Host USB Convertor
Communications Protocol	TCP, UDP	RS-232

NDI Passive Sphere

The industry's original—and world's leading—passive marker sphere, the NDI Passive Sphere™ is a sterile, single-use reflective sphere. As a key component of the Polaris solution, NDI Passive Spheres* are attached to OEM surgical instruments, where they act as triangulation points for the instrument within the 3D operative space. The NDI Passive Sphere and the Polaris optical tracker are used together as an end-to-end solution to localize, detect, and track surgical instruments with pinpoint accuracy.

High Visibility and Detection

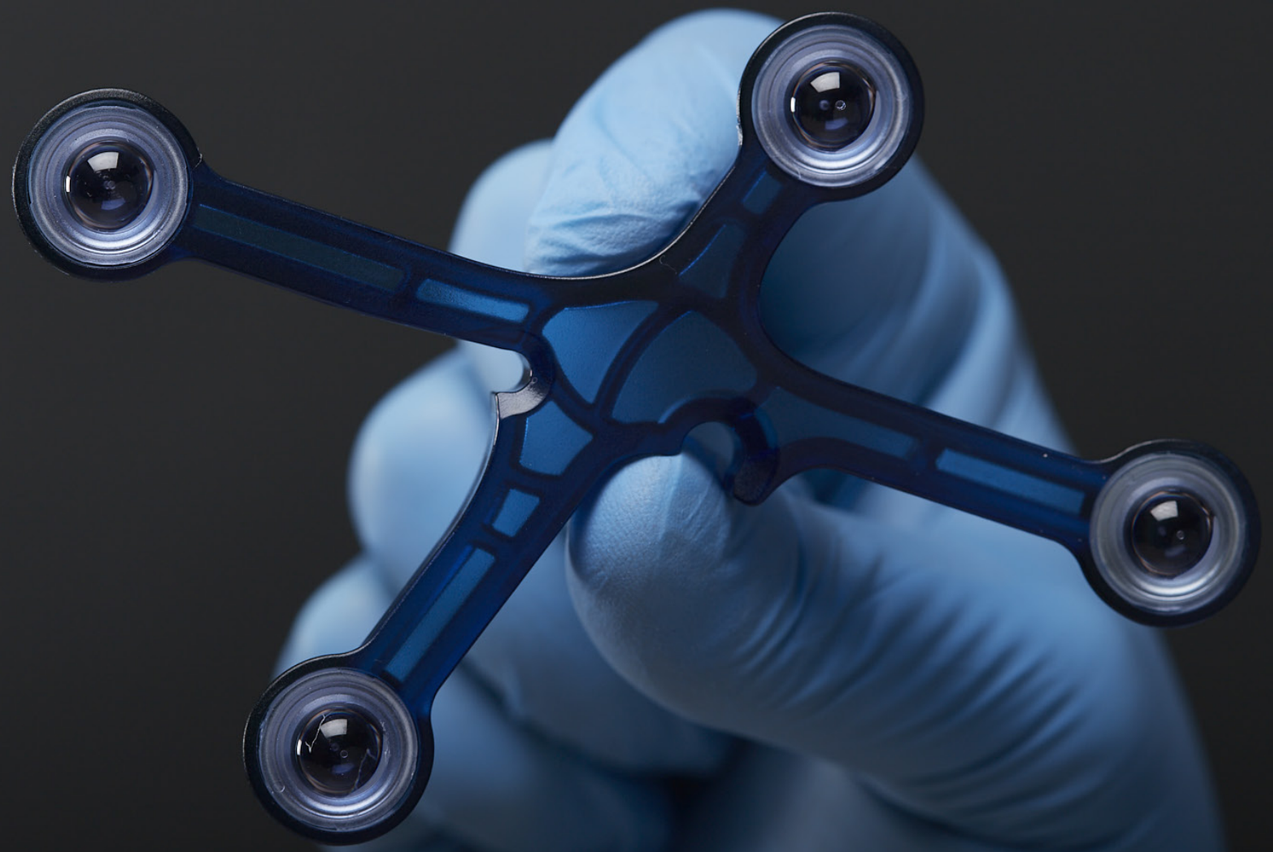
The tracking range of the passive marker sphere depends on its location within the characterized measurement volume, and the defined viewing angle from the Polaris optical tracker. For example, using the default maximum viewing angle of ±90° and distance of 2.4 m out from the Polaris optical tracker, the sphere has an actual range of use of 168.1°. This means the NDI Passive Sphere, which measures just 11.5 mm in diameter, is highly visible (and trackable) throughout the entire measurement volume.

Optimal Measurement Performance

The NDI Passive Sphere is also used to calibrate the Polaris optical tracker during factory calibration, and during patient registration of the OEM surgical navigation system. It is engineered to maximize optical measurement performance and provide ease of use within the OR.

- Coated in a special retro-reflective surface that consists of tens of thousands of microbeads that act like precision lenses to reflect IR light.
- Delivers reliable tracking across different procedures thanks to consistent sphere shape, surface, and placement.
- Mounts on standard snap-on sphere posts, with an audible click that ensures secure attachment. For threaded sphere posts, the Disposable Reflective Marker Sphere is also available.
- Packaged in procedural trays that contain the exact number of spheres required by the surgical navigation procedure.
- Situated in deep-seated tray pockets that make it easy to remove spheres without dropping or dumping.

*The NDI Passive Sphere is an FDA-regulated medical device.



Radix Lens

For tracking procedures that require a retro-reflective marker that is more impervious to liquid and particulate contamination, the Radix™ Lens (a retro-reflective lens) is an excellent substitute to the passive marker spheres. The Radix Lens features a smooth plastic surface that naturally sheds liquid and is easily cleaned. The lens does not need to be replaced if contaminated. Just wipe the lens clean to resume tracking.

Resistant to Partial Occlusions

Another benefit of the Radix Lens is its form factor, which is inherently resistant to partial occlusions. An occlusion that partially covers one side of the lens will be reflected on the opposite side. Due to the resulting symmetrical occlusion, the marker centroid is still visible and accurate. Its viewing angle of ±60° ensures the Radix Lens is readily detected by the Polaris optical tracker.

Reduced Marker Interference

The low marker profile of the Radix Lens also alleviates possible marker-to-marker interference on tools. Radix Lenses and NDI Passive Spheres can be used on two separate tools within the same measurement volume, during the same procedure. However, due to their different reflective intensities, they can't be mixed-and-matched on a single tool. For example, Radix Lenses could be attached to the base of an OEM surgical robot to track its relative position, while NDI Passive Spheres are affixed to the surgical instruments.* The Radix Lens requires custom tool integration; it must be incorporated into a mounting base before it can be attached to the instrument/tool.

*The Radix Lens is not a medical device; its suitability, testing, certification, and validation in a particular application must be determined and completed by the OEM medical device customer or end user prior to use.

Rigid Bodies and Tools

Optical measurement is achieved using rigid bodies; i.e. tools that are rigid in nature. With the Polaris solution, three or more markers (passive marker sphere, Radix Lens) must be mounted to the rigid body tool. The distance between markers is fixed so that there is no relative movement between them during tracking. The geometry, or array, of these markers is unique to each tool, which allows the Polaris optical tracker to identify each tool separately.

Diverse Tool Tracking Parameters

Tools can be defined as single-face or multi-face, depending on the expected rotation of the tool and/or its shape. Tool tracking parameters such as acceptable marker angles, minimum number of markers, and error thresholds further inform the Polaris system which markers to use to calculate a tool transformation, and when to report tool transformations. This information is stored in the tool definition file and set during tool characterization.

Flexible Tool Design and Customization

Polaris tool design, marker geometries, and tool tracking parameters are decided entirely by the medical device OEM. This level of flexibility lets OEM customers create the exact tools needed for the procedure, and control exactly how those tools are tracked by the Polaris optical tracker within the specified surgical workflow. A near-countless combination of tool customization options means the OEM's rigid body tools are as unique as their surgical navigation systems; no two are exactly alike.

For research applications and the exploratory phase of OEM research and development, NDI offers four ready-to-use (non-medical) rigid body tools:

Passive 4-Marker Probe

Single-faced probe tool designed for image registration and to investigate cavities and narrow passages.

Passive 4-Marker Rigid Bodies

Single-faced rigid bodies available with minimum marker spacing of 30 mm* or 50 mm.
*For use with the Polaris Vicra only.

Tool Kit

NDI offers a Tool Kit that contains core components needed to get started with the Polaris Vega or Polaris Vicra: 2 Rigid Bodies, 1 Probe, 2 Clamps, and a package of NDI Passive Spheres. Polaris optical tracker must be purchased separately.

Tool Developer Kit

NDI offers a Tool Developer Kit that contains tool mounting posts and a package of NDI Passive Spheres for cost-effective and flexible development of custom rigid bodies.

Accuracy Assessment Kit

Measurement accuracy isn't just essential to the performance of the Polaris solution; it's what provides end-users with confidence when navigating OEM surgical tools. Accuracy is the difference between arriving at the *exact* treatment site or being completely off target - and where the difference of just one millimetre matters.

The Polaris Vega and Polaris Vicra have features to maintain factory-calibration and measurement accuracy. Their robust hardware is designed to withstand a high degree of physical shock, as well as a wide range of environmental temperatures. If a physical shock is strong enough to compromise accuracy, the bump sensor is triggered, and the user is alerted. Additional user confidence is provided by the (optional) Accuracy Assessment Kit (AAK).

The AAK consists of an accuracy assessment tool and software to assess the in-field accuracy of the Polaris optical tracker within the application environment. The combined hardware and software solution guides the user through predefined positions in the measurement volume. Upon calculation of measurement results, the AAK software will generate an accuracy pass/fail report. The entire accuracy assessment procedure can be completed in less than 15 minutes. Although not a substitute for factory-calibration, the AAK can complement OEM navigation system calibration and startup protocols.

Software Packages

NDI ToolBox

This collection of utilities allows OEM developers to configure, upgrade, troubleshoot and test the Polaris solution. It also supports tool tracking, and the collection and saving of tool tracking data. For the Polaris Vega VT, the NDI ToolBox software also provides a video client application for easily streaming video.

NDI 6D Architect

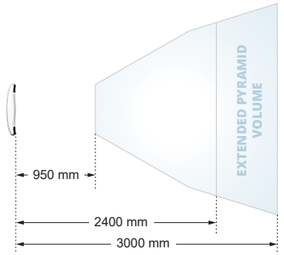
This software program is an essential component of the tool characterization process and is necessary for the creation of tool definition files. The program makes it easy to measure relative marker positions, set important parameters, assign markers to faces, define the local coordinate system, and test marker geometries.

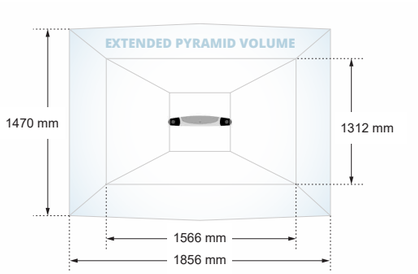
Application Program Interface (API)

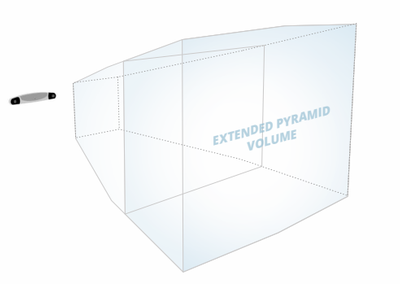
The Polaris API makes it easy for OEM developers to integrate different Polaris Vega operating commands and parameters into their host application software. The API encompasses a wide range of functions, from data streaming and measurement rates, to tool transformations and user alerts. The Polaris Vega contains over 49 standard commands—and over 100 user parameters—for configuring and controlling the Polaris Vega from the host application software. Specific commands for the Polaris Vega VT video camera are also included.

Measurement Volumes

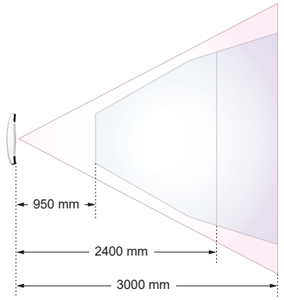
Polaris Vega® ST, XT

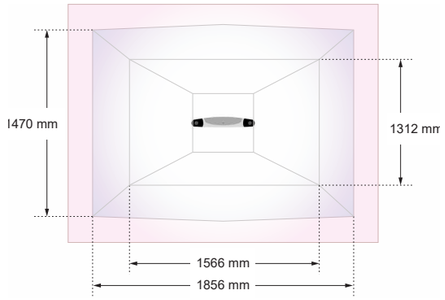


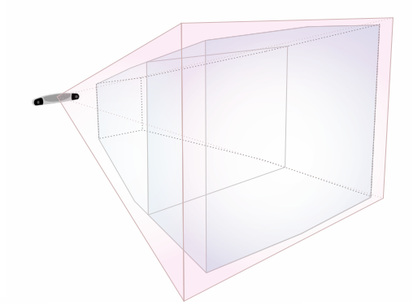




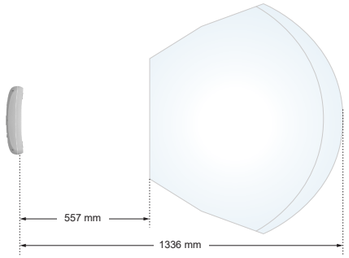
Polaris Vega® VT

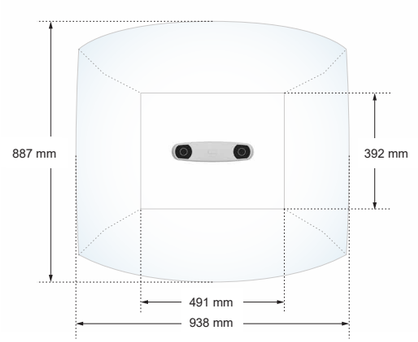


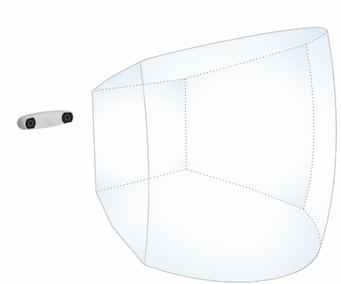




Polaris Vicra®







Measurement Volume

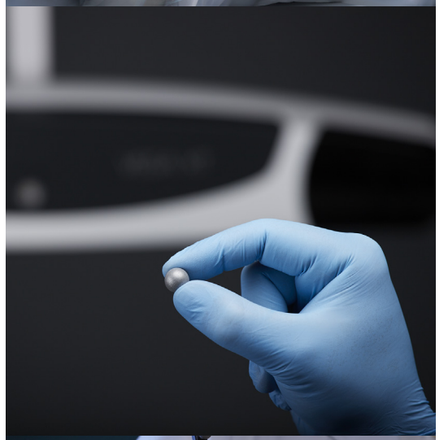
Video Camera Field of View

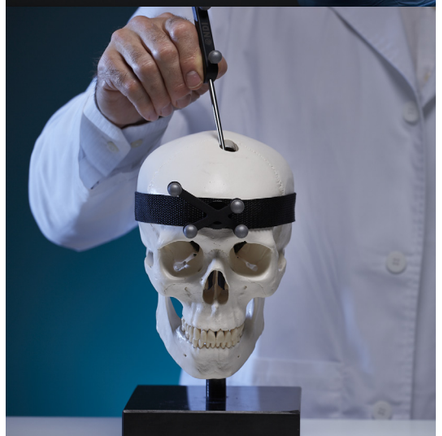
Why Partner with NDI?

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 long-standing 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, lifetime technical support, 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 market.

Commitment to Quality

NDI is committed to monitoring customer feedback and meeting customer requirements, maintaining customer satisfaction and regulatory compliance in the markets we serve. Our Quality Management System processes are intended to support our goal of demonstrating excellence in the design, development, manufacture, distribution, and servicing of safe and effective innovative measurement solutions. Our solutions comply with a number of global regulatory and quality standards: ISO 9001, ISO 13485, UL, CSA, EC; adhere to REACH and RoHS directives; and are capable of being compliant with IEC 60601-1 (3rd Edition).





Disclaimer

The Polaris Vega, Polaris Vicra, and Radix Lenses 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. The NDI Passive Sphere is an FDA-regulated medical device.

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 research customers bring optical and electromagnetic tracking technologies to image-guided surgery, robotic-assisted surgery, interventional medical systems, surgical trainers, advanced medical research, and so much more.

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.

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