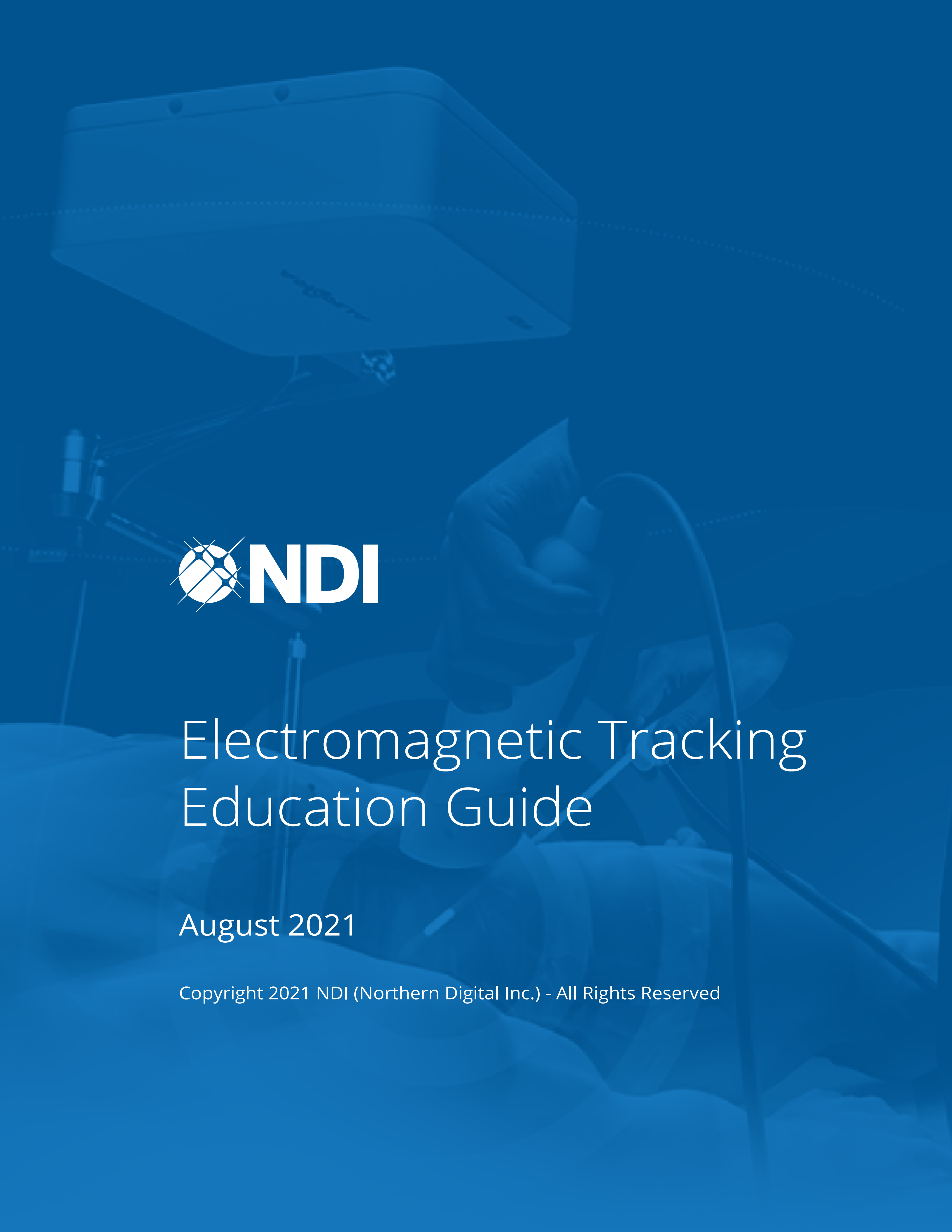

Electromagnetic Tracking Education Guide

August 2021

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Contents

What is Electromagnetic Tracking?

Electromagnetic (EM) tracking systems work by generating a defined EM field in which EM sensors are tracked. All EM trackers (or magnetic trackers, as they're also known) consist of similar components that follow the same principles of operation, with an emitting coil (field generator) that produces a magnetic field, and receiving coil (sensor) that produces an electrical current when inside that magnetic field.

This electrical current can be translated into position and orientation data that correlates the sensor's location relative to the field generator (and other assigned reference landmarks). When attached to moving objects (such as medical instruments), the sensors measure the poses (positions and orientations) of these objects within the measurement volume created by the field generator.

EM tracking technology was first popularized in military simulation applications, where the sensors were mounted to the HUD (heads-up display) helmet to track pilot head movements. However, it wasn't until sensors shrank drastically in size that EM tracking technology became a viable navigation method for image-guided surgical systems and procedures. In that capacity, EM tracking technology has transformed minimally invasive interventions, introducing a gold standard for medical instrument tracking without line-of-sight obstructions.

GPS Navigation for Image-Guided Surgery Systems

In image-guided surgical procedures, EM tracking technology is like GPS navigation for the host OEM image-guided surgery system, bridging the gap between static patient image sets and dynamic 3D instrument movements. It shows where an object is in 3D space in real time.

The sensor acts as a localization point for the instrument inside the body, as visualized against preoperative image sets. To apply the GPS analogy, patient imaging sets represent the map; the treatment site is the destination; and the EM sensor—and the instrument in which it's embedded—acts as the vehicle.

Unlike other tracking technologies, a clear line of sight between the EM tracking system and sensors is not required for tracking to occur. As such, EM tracking technology occurs without the risk of occlusions for uninterrupted tracking of sensors, making it an effective solution for surgical procedures where instruments are obscured from view.

EM sensors can be integrated into rigid or flexible OEM medical instruments such as catheters, endoscopes, guidewires, and needle tip. Sensors today are so small (less than one millimetre in diameter) that they can be embedded directly inside the majority of these instruments, becoming an invisible part of the instrument.

Benefits of EM Tracking in Surgical Procedures

To align preoperative and live patient sets a separate reference sensor is placed on the patient. This process allows the instrument (via the embedded sensor) to be tracked in relation to patient anatomy when targeting the treatment site. All instruments are tracked relative to the reference sensor's fixed location. As the instrument is navigated through anatomy, the sensor enables a 'live view' of the instrument's path to be visualized, planned, and displayed to the clinician in the host OEM software interface. This instrument visualization occurs without the need for intraoperative fluoroscopy, which can help reduce clinician exposure and overall procedure times.

As sensors become smaller, they can be embedded into progressively smaller instruments (e.g. guidewires and microcatheters). Multiple sensors, and thus multiple instruments, can be tracked at once without disrupting the procedure workflow. The clinician can safely and confidently navigate these instruments deep inside the body through tortuous and/or delicate anatomy to target treatment areas that were previously inaccessible.

However, EM tracking technology does have some limitations. EM tracking systems have wired sensors, and the overall measurement volume (and thus procedure area) is smaller than that provided by other tracking technologies. The tracking environment must also be free of conductive or ferromagnetic metals that cause distortions in the EM field – distortions will degrade tracking performance.

That said, the benefits of EM tracking technology outweigh its limitations. Accordingly, EM tracking technology supports the growing trend of open surgeries moving towards minimally invasive approaches, which carry inherent benefits of smaller incisions, fewer surgical complications, and shorter recovery times.

From Electrical Currents to Tracking Data

To generate and convert the electrical currents into tracking data that can be used by the OEM image-guided surgery system, EM tracking systems typically consist of the following interconnected components (see Figure 1: How EM Tracking Works):

1. **Field Generator (FG):** contains sets of emitting coils that are arranged in a specific configuration. A low-intensity, varying EM field is generated when an electrical current is run sequentially through these coils. The EM field establishes the measurement volume, the size and shape of which are unique to the FG. Also known as a transmitter.

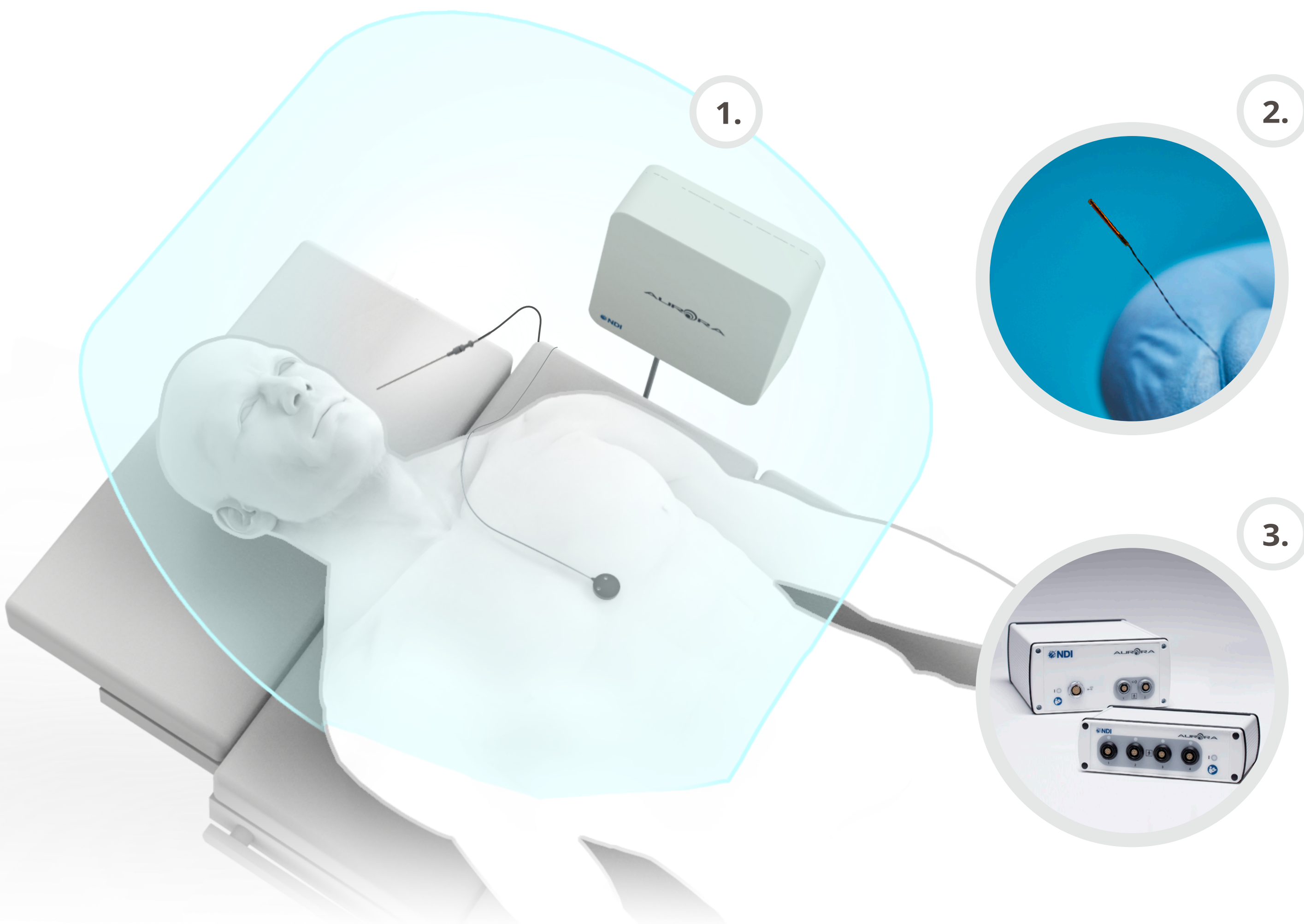
2. **Sensors:** the sensor (receiving coil) consists of very fine insulated wire wound around a microscopic metal core. A small current (voltage) is induced inside the coil when the sensor

enters the EM field. Sensors can be embedded into an OEM medical instrument, where they serve as localization points for the instrument in 3D space. The FG's sets of emitting coils induce currents inside the sensor; the combination of these induced currents allow the sensor's position and orientation to be calculated.

3. **Processing Unit:** the current is relayed via lead wires to a processing or computing unit(s) where the current is A) amplified and digitized as signals, and B) the signals are used to calculate the sensor's position and orientation as a transformation (pose). With the Aurora® solution from NDI, these processes are split across two interrelated units: current amplification and digitization are managed by a Sensor Interface Unit (SIU), with signal calculations and transformations handled by a System Control Unit (SCU). The 3D Guidance® solution from NDI combines these processes into one unit, known as an Electronics Unit.

In the case of image-guided surgical procedures, tracking data (as transformations) are communicated to the OEM host software interface, where they are overlayed onto patient image sets for real-time instrument visualization and navigation.

Figure 1: How EM Tracking Works



Field Generator and Measurement Volume

Most EM tracking systems offer FGs in different sizes to support various surgical procedures. FGs that contain more and/or larger coils with more loops per coil can generate a stronger and larger EM field, especially if a higher voltage is run through the coils. The result is a larger measurement volume.

A larger measurement volume will encompass a larger anatomical region, ensuring multiple medical instruments (via sensors) can be simultaneously tracked within the same coordinate system (explained below). Larger FGs are typically used for procedures in Interventional Cardiology, where the FG is mounted directly to the patient table. The FG design can also allow for intraoperative fluoroscopy imaging through the FG or shielding to minimize tracking distortions caused by conductive or ferromagnetic materials below it.

However, the hardware size of the FG doesn't always correlate with the size of the resultant measurement volume. That is, a large FG doesn't necessarily produce the largest measurement volume. A physically smaller FG can still generate a large measurement volume. Additionally, the condensed size and lightweight design of a smaller FG allows it to be positioned nearer the treatment area for localized instrument navigation. In these cases, such as during ENT procedures, a large measurement volume wouldn't be necessary.

The volume type and corresponding proportions are other factors to consider when selecting an FG. The volume type describes the overall shape (geometry) of the measurement volume; for example, a cube or cylinder. The proportions describe whether that shape is symmetrical or asymmetrical, and the respective lengths of its axes. The size and shape of the measurement volume are set during manufacture; they cannot be changed.

The strength of the EM field is highest near the FG and falls off with the inverse cube of distance from the FG. In terms of tracking sensors within the measurement volume, this means the sensor's positional accuracy tends to be highest when closer to the FG, where the induced current will be stronger.

Global Coordinate System

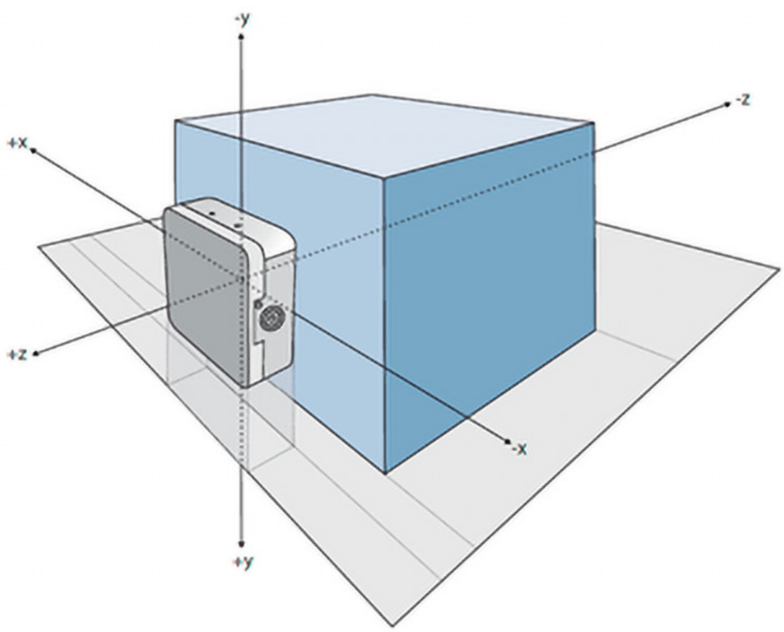
A global (or absolute) coordinate system is a frame of reference in which the coordinates of defined points are reported in 3D space. Where the EM field generates the physical space in which tracking occurs, and the measurement volume defines the 3D space in which tracking occurs, the coordinate system describes where in the defined 3D space tracking occurs. The coordinate system is a subset of the measurement volume, which is a subset of the EM field.

More specifically, EM tracking systems report these coordinates in a Cartesian coordinate system, which is composed of three invisible axes (lines) that intersect through a common point – an origin. A coordinate is stated as a triplet of numbers that specify the distance from the origin along the X, Y and Z axes; for example, (-3,2,2).

The origin of the measurement volume (and coordinate system) is usually located on the surface of the FG, with the axes aligned relative to the FG. See Figure 2: Global Cartesian Coordinate System for an example. The positions and orientations of sensors will be referenced and reported in millimetres against this origin within the global coordinate system.

Additionally, each sensor has its own local coordinate system, whereby the sensor's origin and three axes are defined. This information is required to calculate the sensor's position and orientation within the global coordinate system. Think of the global coordinate system as being like a street (or boundary) consisting of numerous houses; the local coordinate system represents the individual house number.

Figure 2: Global Cartesian Coordinate System



Tracking Sensor Position and Orientation

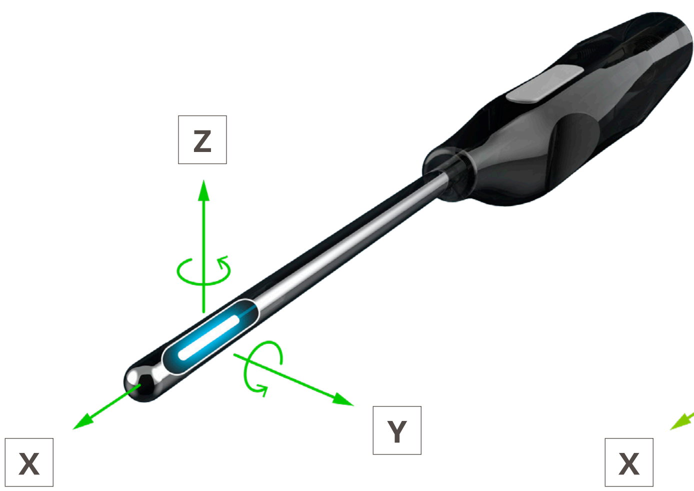
Sensors are defined as either 5DOF or 6DOF, where degrees of freedom (DOF) describes the number of axes in which a rigid body moves in 3D space. Tracking movement along each of these axes corresponds directly with calculating the sensor's position (translations) and orientation (rotation) as transformations (poses).

6DOF: the initial three DOF relates to the translation of the sensor on the X-axis (forward/back), Y-axis (left/right), and Z-axis (up/down). Note, the associated axes and direction (for example, X = forward/back) may differ by EM tracking system. The additional three DOF refers to rotation on these axes, which provide orientation data of roll (tilting side to side along the longitudinal/X-axis), pitch (tilting side to aside along the Y axis), and yaw (tilting side to side along the Z axis).

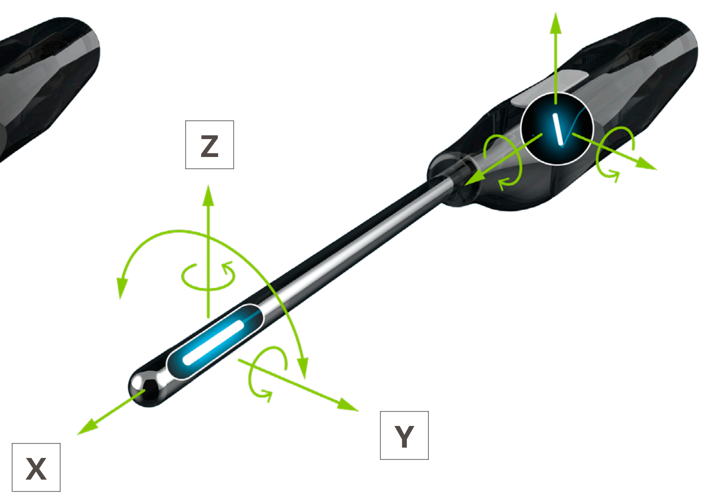
5DOF: similar to 6DOF, all three translations on the X, Y and Z axes are reported, as well as two of the three rotation values of roll, pitch, and yaw.

Sensor manufacturers have different means for how they obtain 6DOF measurements. Aurora sensors (by NDI) use two 5DOF coils that are fixed relative to each other inside one sensor. The combined values of both 5DOF coils are compared to calculate all six degrees of freedom. Because only one coil is used, Aurora 5DOF sensors are smaller (in diameter and length) than their 6DOF counterparts. For 3D Guidance sensors (also by NDI), each sensor is comprised of multiple sensor coils that are fixed relative to each other to achieve 6DOF tracking. See Figure 3: The Difference Between 5DOF and 6DOF (Aurora), for an example of instrument translations and rotations.

Figure 3: The Difference Between 5DOF and 6DOF (Aurora)



5DOF
Positional data on the X, Y and Z-axis. Rotational data on the Y-axis (pitch), and Z-axis (yaw).



6DOF
Positional data on the X, Y, and Z-axis. Rotational data on the X-axis (roll), Y-axis (pitch), and Z-axis (yaw).

Integrating Sensors into OEM Medical Instruments

When integrating sensors into an OEM medical instrument, the number and placement of the sensors will determine whether 5DOF or 6DOF measurements are reported, and thus dictate the overall tracking application of the instrument.

An instrument can contain A) one 5DOF sensor; B) two 5DOF sensors; or C) one 6DOF sensor (consisting of two 5DOF coils fixed relative to each other). If only one 5DOF sensor is integrated, the instrument would be considered a ‘single sensor coil tool’; rotation around the sensor’s Z-axis (roll) cannot be determined.

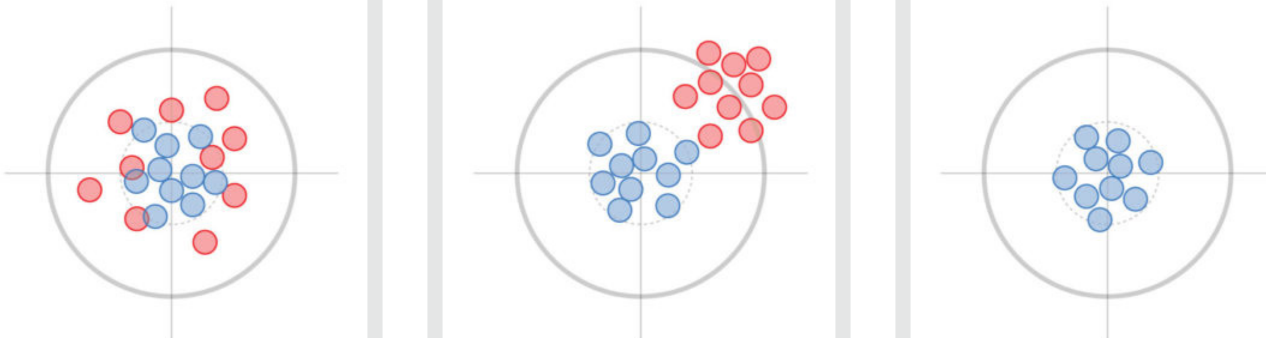
An example of a single-sensor tool could be an ablation needle, in which the single 5DOF sensor is embedded at the needle’s tip. (Note, ablation needles can also be tracked in 6DOF.) Depending on the procedure, 5DOF tracking may be sufficient, as tracking needle roll is less important than knowing the position of the needle’s tip, and where the tip is pointing. The 5DOF sensor would be placed at a point of interest (the needle’s tip) where accuracy is most important. In this example, the unreported rotation does not negatively affect the tracking application. And having only one 5DOF coil reduces the space requirements at the instrument tip, and procedure cost.

For applications that require 6DOF tracking, a single 6DOF sensor can be embedded into the instrument. For example, in Interventional Radiology procedures where ultrasound is used, the clinician needs to know the location of the transducer as it moves over the patient. An ultrasound transducer employs a full range of movements (sliding, tilting, rocking, rotating), therefore all six translation and rotation values must be captured to match the tracking data to a physical location on the patient. 6DOF sensors require more space within an instrument, as based on the increased number of sensor coils, and required connectors and wires.

How is Accuracy Determined?

Although often used interchangeably, the terms ‘accuracy’ and ‘precision’ have separate scientific meanings. The term accuracy encompasses the concepts of trueness and precision. Trueness refers to the closeness of agreement between the mean of test results and the true (accepted) reference value. It denotes systematic errors. Precision refers to the closeness of agreement between test results. It denotes noise and random errors. The concepts of trueness and precision can be visually depicted as a target; see Figure 4: Trueness and Precision.

Figure 4: Trueness and Precision



Trueness represents how close measurements are to the bullseye (the true reference value). In this example, the red and blue targets are both true, but the red measurements are less precise because they are far apart.

Precision represents how close repeated measurements are to each other (test results). In this example, the red and blue measurements are both precise, but the red measurements are less true because they are off target.

Accuracy represents measurements that are close to the bullseye and close to each other. In this example, the measurements are both true and precise.

Accuracy is decreased by random and systematic errors; the former affects measurement precision, while the latter affects trueness. Excluding errors caused by users, random errors are the result of electronic noise or precision limitations of the EM tracking system, as well as inconsistent measurements by the system. Systematic errors are due to imperfect characterization of the EM tracking system and distortion caused by the setup environment (i.e., system and application errors). All measurement systems (including EM tracking systems) have some degree of error in their measurements.

Manufacturers will characterize the sensor within a known EM field size, stating the sensor's positional accuracy in millimetres RMS (Root Mean Square) with a Confidence Interval (CI) level (usually 95%) in a defined measurement volume (e.g. 500 mm x 500 mm x 500 mm).

In the context of EM tracking systems, RMS is a statistical method for reporting the amount of error compared to the true reference value; i.e. how far off the coordinates are from the bullseye as a distance in millimetres. For example, 0.40 mm RMS. For Confidence Interval, if the accuracy is stated as 0.80 mm CI 95%, this means that 95% of the sampled coordinate values in the dataset will have an error interval that equal to or below 0.80 mm as compared to the true reference value.

To calculate these numbers, the coordinate values of the EM tracking system are compared against identical coordinate values of a measurement system of higher accuracy, with the more accurate measurement system providing the true reference value (the 'ground truth').

The Important of Accuracy in Surgical Procedures

In the case of surgical procedures, the bullseye could be a tumor. A highly accurate image-guided surgery system (with integrated EM tracking technology) will be able to track and report the position of the instrument (via the sensor) in relation to that tumor as close as 0.40 mm.

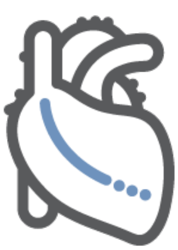
For procedures that require navigation and targeting of the instrument through critical anatomy or twisting vasculature—where there is no room for error—an accurate image-guided surgery system provides assurance that the instrument will be shown at its exact position, without deviation or error. After all, when it comes to avoiding delicate anatomy or preserving healthy tissue, there is a big difference between 1.00 mm and 1.00 cm.

For clinicians, high tracking accuracy provides confidence that when they navigate the instrument's path to the treatment site (the target), they will reach it exactly as expected every time. As it relates to future surgical procedures, high tracking accuracy can allow for increasingly minute (and safer) instrument targeting of very small lesions in areas of the body that would have once been inoperable. As a result, using an accurate image-guided surgery system can help shorten procedure times and minimize surgical invasiveness, which supports improved patient outcomes.

Common Applications of EM Tracking Technology

Due to its ability to track without line-of-sight constraints, EM tracking technology is commonly integrated into OEM medical devices that need to traverse deep inside the body via minimally invasive approaches. Here are some examples of where EM tracking technology has been used by medical device OEMs:

Interventional Radiology
Fusing live ultrasound images with preoperative CT or MRI image sets to localize an ultrasound transducer and needle relative to each other in multiple modalities, within the same measurement volume.



Interventional Cardiology and Electrophysiology
Embedding sensors into the tips of diagnostic and ablation catheters to create electro-anatomical maps, which can be used to navigate and target areas of the heart to be treated.

Guidewire and Catheter Tracking

Tracking guidewires and catheters through difficult-to-access and/or tortuous anatomies for a wide variety of vascular, abdominal, and minimally invasive procedures.

Endoscopy

Embedding a sensor into a scope to map and navigate complex anatomical tracts during colonoscopies and bronchoscopies, and to monitor the real-time position of the patient during the procedure.

Conclusion

EM tracking technology imparts several benefits on OEM image-guided surgery systems: occlusion-free tracking, small sensor sizes, 6DOF instrument tracking, and high measurement accuracy. However, no one tracking technology can address all tracking applications; EM tracking technology—like all tracking technologies—does have some limitations. However, these limitations are not insurmountable, which is why there is a growing trend towards EM tracking technology being adapted to, and in some cases introducing new, minimally invasive approaches.

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Printed in Canada, August 2021. P/N DOC-10007017 Rev001