ELECTROMAGNETIC SURGICAL NAVIGATION

Technology and Applications

Electromagnetic Surgical Navigation Overview

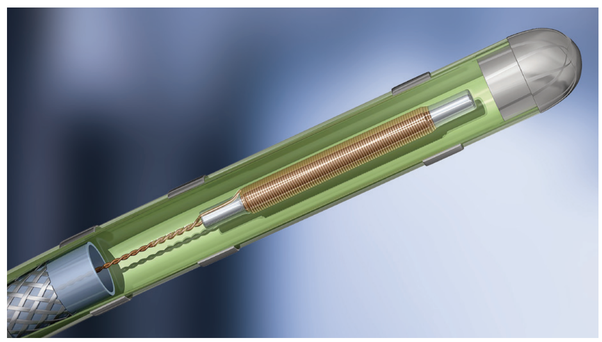
Since its inception in the 1990's to widespread adoption by the late 2000's, electromagnetic navigation (EMN) has emerged as the clear choice for surgical navigation and has been widely adopted in the fields of interventional bronchoscopy, urology, neurosurgery and cardiology. A properly designed EMN system has several advantages:

- It can localize with the precision of optical tracking without the need for a line-of sight;
- Offers the convenience of fluoroscopy for intra-patient visualization without the application of ionizing radiation;
- Exposes the patient to energy fields that are no more harmful than ultrasound.

Unlike alternative navigation technologies which rely upon backscattered radiation, EMN utilizes a passive measurement scheme. The surgically relevant region is saturated in a spatially inhomogeneous magnetic field which effectively serves as an invisible and biosafe x-y-z coordinate grid. Miniature sensors within this effective grid detect and transmit information regarding their precise location, which is then processed by an external computer system. Since EMN only records the point locations of electromagnetic (EM) sensors, it is often used in conjunction with other visualization systems; within clinical applications, the location of the sensor (generally placed within an interventional device) is often graphically superimposed upon 3D pre-operational scans of the patient. In this way, real-time visualization of the interventional device within the anatomy of a patient can be realized.

While there are numerous advantages of EMN components in interventional devices, it takes careful optimization of EM sensors within a device to achieve the maximal performance. One-size-fits-all solutions rarely reflect the complexities of a particular clinical application, nor do they automatically provide optimal performance within modern interventional devices.

This overview begins with a look at principles of EMN device operation and then takes a closer look at sensor optimization and key aspects of the design process related to permeability, magnetic saturation and Johnson-Nyquist noise. The advantages of full-length device design for electromagnetic compatibility will also be considered.



By utilizing Intricon's proprietary hybrid theoretical/experimental modeling to guide the design as well as leveraging extensive capabilities in full device assembly, we can apply our knowledge of EMN sensor technologies as a Joint Development Manufacturer to offer customized solutions tailored to device requirements and clinical applications.

Principles of Operation

EMN relies upon localizing a sensor with respect to a reference magnetic field. The magnetic field is provided by a calibrated field generator, which projects a field which is inhomogeneous in space and of known geometry. The EMN sensor must (indirectly) record the field at the location in which it is placed, which in turn can be translated into positional information. Several kinds of EMN sensors exist—for example fluxgate[1] and wireless[2]—but the focus of this document will be on the wired induction sensors, which have received the most widespread adoption in interventional clinical applications.

Wired induction sensors consist of one or more windings wound around a solid or hollow core and leaded out to a twisted wire pair for signal transmission. An electrical signal can be induced by virtue of Faraday's law, which implies that an electromotive force (or voltage) will be generated in any closed path that is subjected to a varying magnetic field. In this case, the closed path is contributed by the wire wrappings of the induction sensor, which also

1 This type of sensor has not been widely adopted into clinical applications due to the size and relative complexity of the device.

2 Wireless sensors utilize sensors that must function simultaneously as receivers and emitters. The bulky size of these sensors coupled with the size and complexity of the external drive system limits surgical applications.

serves as a conduit for current flow. For the sake of logical continuity and mathematical aesthetics, the full form of Faraday's law is described as follows:

$$\vec{\nabla} \times \vec{E} = -\frac{\partial \vec{B}}{\partial t}$$

which can be reduced to the following form by Stokes theorem:

$$EMF = V = -\frac{d\emptyset_{\perp}}{dt}$$

where Ø is the magnetic flux component that is perpendicular to windings of the induction sensor and flux is loosely defined as the product of magnetic field and cross-sectional area.

Intricon sensors are compatible with commercial AC magnetic field generator systems such as those from Northern Digital, Inc. (NDI), Quadrant Scientific, Radwave Technologies and Polyhemus as well as custom systems developed by various clients. These systems provide an AC magnetic field map in space via arranged field coils. Whereas the specific field coil arrangements and localization methods are proprietary, some general principles of operation are shared between all systems. Because magnetic field magnitude decays by the cube of the distance from the any field coil, the intensity of the magnetic field (and induced voltage) within a sensor can be used as proxy for the distance between the sensor and the field coil arrangement. Different methods exist for full 3D localization, some of which include pulsing spatially distant coils to achieve triangulation or by excitation along the various coordinates. Intricon coils are compatible with either localization scheme and can be customized to perform within custom localization volumes.

Sensor Design and Optimization

Fundamentals

The goal of any custom EMN sensor is to provide the ultimate signal integrity within the smallest possible envelope size. For practical EM sensor applications, it is beneficial to maximize the voltage induced in the coil to maximize signal-to-noise ratio and increase localization precision. The pertinent term is sensitivity, which is defined as the voltage amplitude generated by a coil when subjected to a unit AC magnetic field of standard frequency. Analysis of equation [1] reveals that sensitivity increase can be most easily achieved by either increasing the number of winds—which effectively increases the effective cross-sectional area through which the magnetic field traverses—or by directly increasing the diameter of the sensor core. However, there are limitations to these methods. Unrestricted increase of physical sensor dimensions is rarely compatible with the tight working channel of most interventional devices, so alternative methods of boosting coil sensitivity are necessary.

Permeability

The optimal core material balances trade-offs between permeability, saturation and material strength. Intricon continuously improves our understanding of these properties in order to provide the best product to our clients.

Permeability is a physical property which characterizes the induced magnetic field within a material when exposed to an external magnetic field. Highly permeably materials will effectively trap or contain magnetic fields in their vicinity, effectively amplifying[3] fields by a factor that scales with permeability.

The field amplification effect arises from a fundamental property of electrons; every electron exhibits an intrinsic magnetic dipole moment. Accordingly, each electron can be modeled as a miniature bar magnet with a distinct north and south pole. In most materials, these electron magnetic moments are oppositely aligned and cancel due to quantum mechanical interactions known as Hund's rules. However, some materials such as iron contain an abundance of unpaired electrons which are free to align when exposed to an external magnetic field. When electron-electron interactions facilitate parallel ordering, the combined magnetic fields of individual electrons lead to high permeabilities.

In the absence of boundary conditions, this amplification leads to increases in magnetic field by factors up to 1,000,000[4]. However, this ideal amplification factor is not achieved in realistic applications due to finite size effects. Different core shapes and aspect ratios will modify the field amplification factor in accordance with Maxwell's equations.

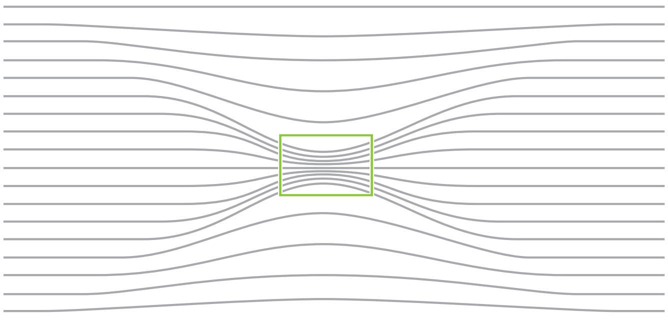


Figure 1
Magnetic Core in Field. Figure depicts effect of magnetic core (outlined in red) absorbing magnetic field lines in its vicinity. The lines represent the magnetic field directed from left to right, and the density of lines represents the magnetic field intensity.

In general, cores with a greater length will have a greater average field amplification than shorter cores, at least for axial fields. Aspect ratio plays a critical role in coil design; for the case of cylindrical cores, the length-to-diameter ratio is crucial. Below is a plot of the effective volume-averaged field amplification factor (or Shape Permeability) as a function of initial permeability for a range of cylindrical core length-to-diameter ratios. Volume-averaged permeability for several length-to-diameter ratios (or aspect ratios) are shown for varying intrinsic material permeability. It is apparent that the core aspect ratio sets a limit for field amplification which is significantly less than intrinisic permeability.

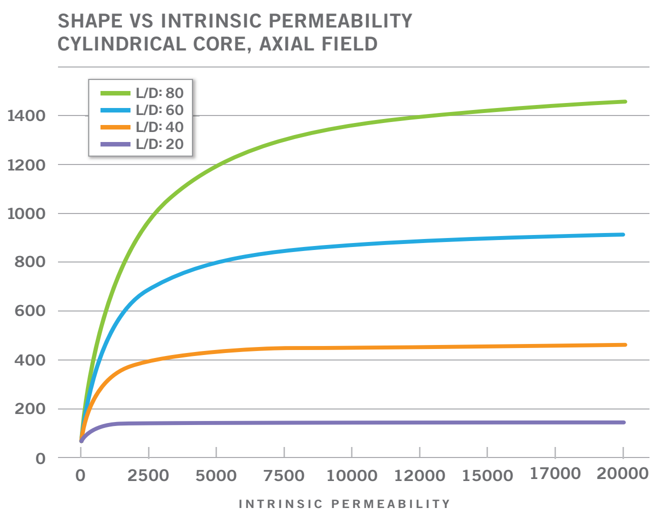


Figure 3
Visual Representation of relative intrinsic permeability vs relative shape permeability for cylindrical cores. Length-to-diameter ratio (L/D) or aspect ratio strongly impacts the shape permeability of the core.

The surprisingly rich electromagnetic behavior necessitates a careful consideration for the ideal core material and geometry. Due to the flattening of the curve at high intrinsic permeabilities, the limited returns of increased intrinsic permeability become apparent. Therefore, the intrinsic permeability of a potential core material cannot be used to fully capture the capabilities of a core within an assembly.

Magnetic Saturation

The previous section has conveyed that magnetic field is a function of core geometry. It is crucial to Intricon's coil designs to consider the impact that field intensity might have on the effective core permeability. Most

3 This amplification does not occur in the engineering sense of the term, as the interaction of the permeable material with the field is entirely passive. Visually, the total number of field lines is not changed when a permeable material is introduced into the field.

4 Typical maximum permeability for high-permeability nickel-iron alloys known as permalloy. These factors are compared to permeability in air or other nonpermeable core material.

commercial field generators produce magnetic fields[5] which have field magnitudes up to several hundred amps per meter[6]. Therefore, induction sensors must be designed with the ability to perform well within the wide range of field amplitudes that occur closest to the field generator.

In general, permeability is a function of field magnitude. The salient properties of this relation are depicted below.

The permeability curve has three main features: the initial permeability, which dictates the low-field response of the sensor; the maximum permeability, which determines the peak sensitivity of the induction sensor; and the saturation region, which is the region where the intrinsic permeability curve begins to flatten at high field intensities.

INTRINSIC PERMEABILITY VS FIELD STRENGTH

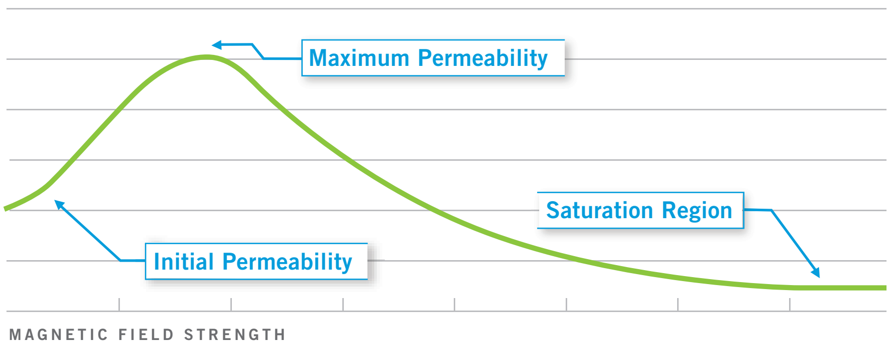


Figure 4
Permeability as a function of field intensity. Note the presence of a low initial permeability and a saturation region.

The general shape of this curve can be understood qualitatively in many cases. The low initial permeability response can sometimes be correlated to crystal grain size; local forces imposed by physical grain boundaries or crystallographic defects can reduce the ability of magnetic domains to freely align in response to an external magnetic field. The domains can become "pinned". This energy cost is overcome at stronger applied fields, cumulating in rising permeability with magnetic field strength. The magnetic response peaks when saturation begins to occur. At saturation, electron spins rapidly approach uniform parallel alignment with the external field and the benefits from increased magnetic field become progressively slighter.

The initial permeability and the maximum permeability are important: a sensor with insufficient initial permeability cannot effectively function in low-field regions which are experienced as the sensor is moved further away from the field generator. The importance of maximum permeability as it relates to sensitivity is straightforward. However, the saturation region nuances the analysis. The saturation region marks the region at which the core no longer reacts effectively to an external field. Of course, this would not seem to be a serious issue, as high-amplitude AC magnetic fields – such as those experienced near the field generator – must necessarily pass through low-field regions as the field cycles. However, the nonlinearity of the permeability curve presents serious complications to signal integrity; induced voltages become distorted by nonlinearity and strain the capabilities of signal analysis software. This effect can cause a tracking failure or "drop-out" near the field generator. Other application-specific circumstances may precipitate saturation, for example, the magnetic fields required for magnetically actuating surgical mechanisms.

Circumventing dropout requires the flattening of the permeability curve. To achieve this, Intricon has devised several proprietary techniques, both through material choice and by geometric considerations. These methods are adaptable to induction sensor design for any commercial or custom EM generator system.

Johnson-Nyquist Noise

Johnson-Nyquist noise is another design consideration for induction coil sensors. Proprietary methods of understanding this source of noise have allowed Intricon to achieve excellent localization precision in custom low-volume

5 NDI, Polyhemus, Quadrant Scientific, and Radwave Technologies use AC magnetic fields.

6 This value is approximately an order of magnitude greater than the earth's magnetic field for several commercial field generators. Custom EMN systems or those designed for specific applications may have differing maximum field intensities. The overall intensity is considered weak and widely biocompatible.

sensor applications. A properly designed coil will have localization precision from 0.3 – 0.7 mm, depending on the requirements of the application and physical constraints. An improperly designed coil might exhibit supra-millimetric precision at unfavorable orientations within the reference, resulting in the tracked location of an induction sensor appearing to jitter randomly about a central location.

The most obvious cause for jitter is a poor signal-to-noise ratio and the most obvious solution is the application of more winds to the sensor to increase sensitivity. However, as is often the case with electromagnetic sensor design, the solution may exacerbate the problem if not carefully prescribed. Johnson-Nyquist noise arises from thermal agitations instigated by insufficient heat dissipation. Because increasing the number of winds increases thermal insulation, a complicated nonlinear relation develops between the number of winds and localization precision. Experience with this and other nonintuitive aspects of sensor design allows Intricon to efficiently optimize EM sensor performance.

Full-Length Device Design for Electromagnetic Compatibility.

The seamless integration of EM sensors within interventional devices is a specialty of Intricon and our expertise with electromagnetic and physical design allows for optimal performance to be achieved. While Intricon is happy to supply customized, stand-alone EM coils, with our comprehensive catheter and assembly capabilities, our expertise in fine-wire connectivity and our ability to perform final packaging, Intricon is able to work with our business partners as a full-fledged a joint development manufacturer to deliver full-length devices (complete “tip-to-handle” solutions) for optimal electromagnetic and clinical performance. Intricon’s design process incorporates a keen awareness of magnetic components within the finished device.

The design acumen of Intricon is critically important to device performance because magnetic components distort the reference field provided by field generators, thus reducing localization precision. The mitigation of magnetic interference is nontrivial, given the number of metallic components that exist in modern interventional devices.

For example, a typical device will contain multiple metallic components which may include braids, compression coils, pull wires and biopsy mechanisms. These components are typically made from SS304 or SS316 stainless steel, materials which are favored for their low cost, bio- and cryogenic compatibility, and – most importantly for electromagnetic navigation—weak magnetic properties. Even though these steels are often promoted as nonmagnetic, it is necessary to carefully consider electromagnetic properties before integrating them into an interventional device. SS304 and SS316 are usually described as austenitic, which is a crystal phase which is not conducive to magnetic ordering, unlike the ferritic, martensitic and duplex phases seen in magnetic steels.

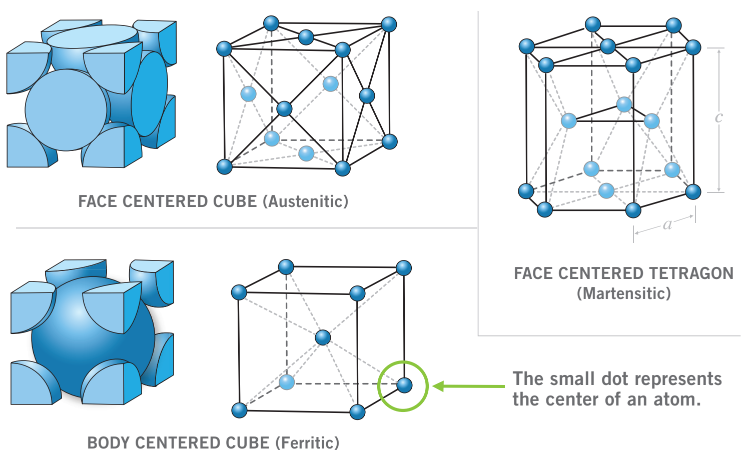


Figure 5
Different crystal phases of steel. The nonmagnetic Austenitic phase is easily converted into the magnetic Martensitic and Ferritic phases by cold working.

However, any process which changes the crystal structure (such as cold-working, welding, machining or drawing) introduces magnetic crystalline patterns into otherwise austenitic steels and the possibility of magnetic interference. It is often not feasible to replace these stainless-steel components with fully nonmagnetic materials such as titanium or

Nitinol. Intricon understands these complexities and strives to provide conscientious material sourcing, nonmagnetic alternatives, and informed “tip-to-handle” integration for our customers.

Afterword

Intricon understands the uniqueness of each customer and every EMN application. As a Joint Development Manufacture with experience in both sensor and full-device design, Intricon is uniquely positioned to provide expert advice and support at each stage of product’s life cycle from development to high-volume manufacture.

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