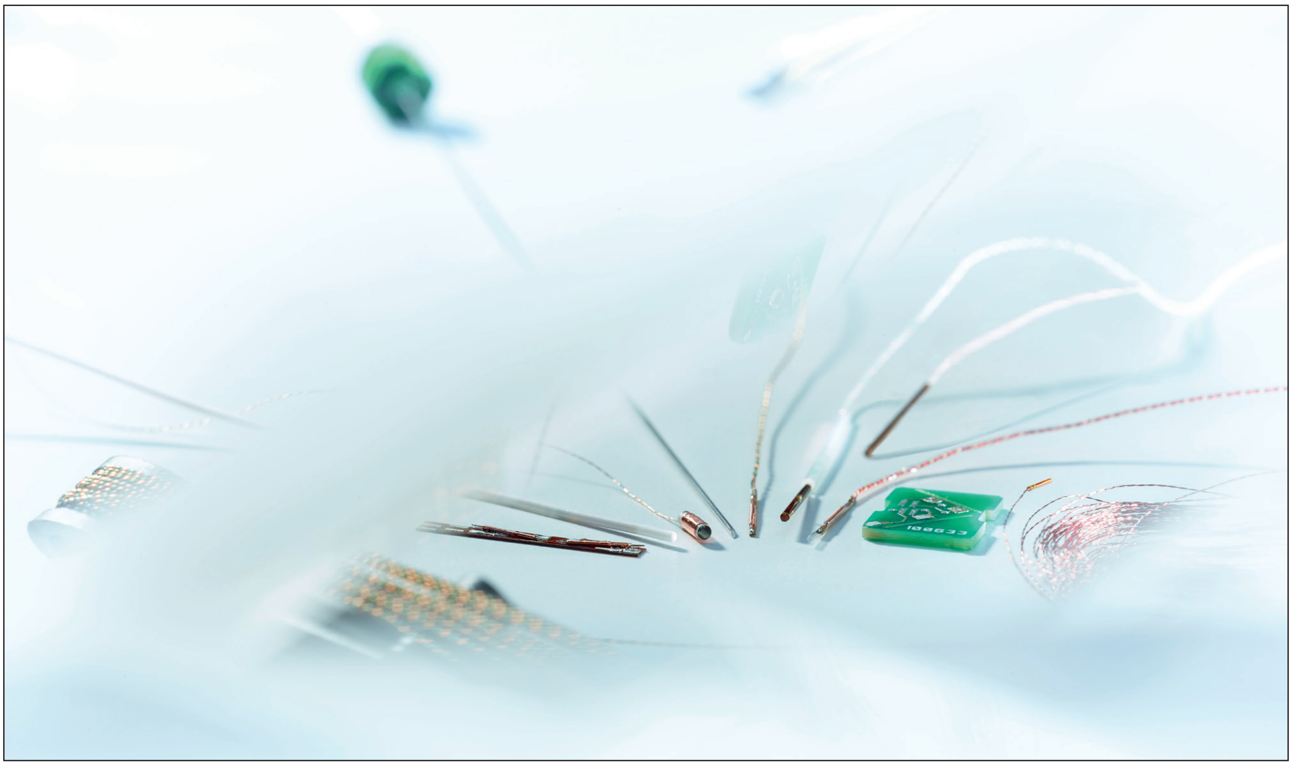
Aurora®

TOOL DESIGN GUIDE

This guide details information concerning all aspects of the design, construction, and characterization of tools for use with the NDI Aurora® System.



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Tool Design Guide

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Important: Please read this entire document before attempting to design tools to use with an Aurora® System

1 Read Me First!

Read this section before continuing with the rest of the guide.

1. Single sensor coil and dual 5DOF tools are not capable of detecting magnetic field disturbances. The tool designer should be aware of the single sensor coil and dual 5DOF tool limitations in combination with the application, and advise the customer and/or user accordingly. Applying transformations from a system using single sensor coil and dual 5DOF tools in a disturbed magnetic field may result in injury when the application involves personal safety.
2. Do not bend or kink tool cables, or use tools with damaged tool cables. Inspect tool cables regularly for damage. Applying transformations from a system with damaged tool cables may result in injury when the application involves personal safety.
3. Do not wrap the tool cable around the Field Generator, as incorrect transformations may result. Applying transformations from a system with the tool cable wrapped around the Field Generator may result in injury when the application involves personal safety.
4. Do not place the tool cable parallel to or in close proximity to the Field Generator cable as incorrect transformations may result. Applying transformations from a system with the tool cable in such a position relative to the Field Generator cable may result in injury when the application involves personal safety.
5. Do not track a tool unless you are sure that its SROM device is programmed correctly, and with the correct settings. For example, avoid using similar tools programmed with the same SROM information if they have different tool-tip offsets. Using a poorly programmed tool may produce inaccurate transformations and possible personal injury.
6. Do not use cables, transducers, or accessories other than those recommended by NDI. To do so may result in increased emissions and/or decreased immunity of the Aurora® System. This may increase the possibility of personal injury.
7. Make sure that patient auxiliary leakage currents do not exceed allowable limits. Give special consideration to insulation materials and thicknesses to ensure the galvanic isolation of multiple tools connected to the Aurora® System. Failure to do so may lead to personal injury. Consult IEC60601 and applicable national differences and amendments for guidance.
8. NDI is not responsible for the programming of the SROM device. Incorrect tool SROM device programming may result in incorrect transformations. Applying transformations from a system with incorrect tool SROM device programming may result in injury when the application involves personal safety.

2 About This Guide

This guide details information concerning all aspects of the design, construction, and characterization of tools for use with the NDI Aurora® System. Before attempting to design a tool, you should have a thorough understanding of:

- the subject matter detailed in this guide, including basic wiring concepts and techniques for electronic components, and
- the NDI Aurora® System, including electrical safety considerations and the basic concepts of tool types and tool tracking as detailed in the documentation that accompanied the system.

NDI is not responsible for the design of tools. NDI provides the “Aurora® Tool Design Guide” only as reference to assist you in the design of tools. Decisions about materials, ergonomics, design, application, tool functionality, and tool material biocompatibility are your responsibility.
There are many aspects of tool design and development that are beyond the scope of this guide and NDI's areas of expertise. Further, this document cannot anticipate all of the relevant concerns across the broad range of tools that may be developed. For help in understanding the concepts explained in this guide, or to discuss specific design implementation, contact NDI technical support. „Contact Details“ on page 31.

Warnings, Classifications and Approvals

A complete list of the warnings, classifications, and approvals that apply to the NDI Aurora® System is included in the “Aurora User Guide,” which can be downloaded from NDI Support Site at https://support.ndigital.com.

3 Basic Concepts: Tool Types

3.1 Introduction

This guide provides information on how to design tools for use with the Aurora® System. To ensure that the tools operate correctly and safely it is necessary that you read and understand all the information in this guide before you begin to design any tool.

You will also require a technical understanding of the Aurora® System. Refer to the documentation delivered with the system. For further information contact the NDI office nearest your location. „Contact Details“ on page 31.

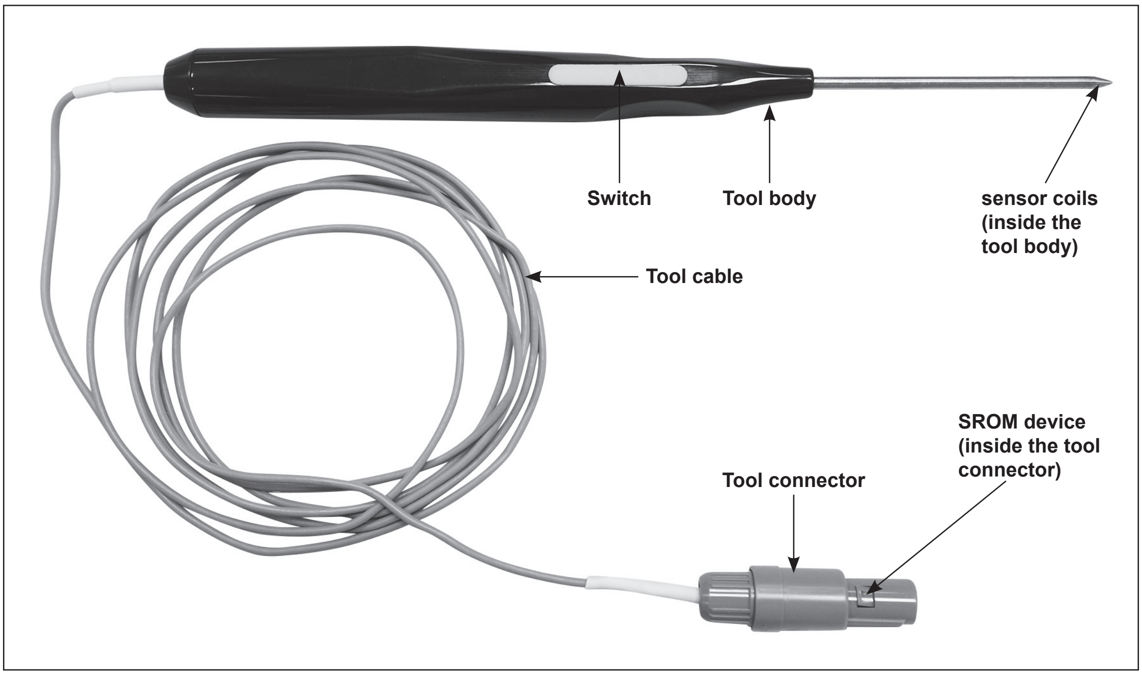
3.2 Tool Components

Aurora® System tools consist of a combination of six basic components (some of which are optional):

Component	Description
Sensor	The sensor coil comprises a very fine insulated wire wound around a small metal core. The sensor may be mounted on a PCB and/or connected to a pair of lead wires. A tool can contain up to two (0, 1, or 2) sensor coils.
Serial Read Only Memory (SROM) device	The SROM device stores an individual tool's specific information and (if necessary) characterization data. An SROM device is hardware that can be programmed only once. It is normally located inside the tool connector.
Tool connector	The keyed connector normally encloses the SROM device and is where all tool component wiring is terminated.
Tool cable	A shielded cable connects the sensors, switches, LEDs and other input/output devices to the tool connector.
LEDs and switches (optional)	Input/output devices indicate or initiate a tool function. Each tool can support up to three input/output devices.
Tool body	The tool body incorporates the tool's sensor coils, LEDs, switches and other input/output devices into a tool.

Note:
NDI supplies sensor coils specifically designed and tested for use with the Aurora® System. If you use sensor coils from any other source, be aware that NDI does not guarantee the accuracy of measurements made with those sensor coils.

The following diagram shows an example tool incorporating each basic tool component:



3.3 Degrees of Freedom

Aurora® tools are defined as either 5DOF or 6DOF, where DOF means degrees of freedom. 5DOF and 6DOF are defined as follows:

- 5DOF: Five of the six degrees of freedom. Three translation values on the x, y and z-axes and any two of the three rotation values roll, pitch and yaw.
- 6DOF: Six degrees of freedom. The three translation values on the x, y and z-axes; and the three rotation values roll, pitch and yaw.

The number and placement of sensors incorporated in a tool determines whether the tool is 5DOF or 6DOF and consequently the kind of measurements the Aurora® System can perform.

5DOF

If a tool incorporates only one sensor, the rotation around the sensor's z-axis (Rz) (refer to „Tool Types“ on page 10) cannot be determined. As such, only five degrees of freedom (5DOF) can be determined for single sensor tools.

For example, how much a needle physically rolls is not as important as where it is pointing and where the tip is located; as such, a needle can be a 5DOF tool, with only one sensor incorporated into its design.

6DOF

If a tool incorporates two sensors fixed relative to each other and ideally orthogonal, the system can determine six degrees of freedom (6DOF) for the tool. First, the system determines 5DOF information for each sensor. Next, the system combines and compares this information, applies the tool description data, and determines six degrees of freedom (6DOF) for the entire tool.

For example, an ultrasound technician needs to know the location of the ultrasound probe as it moves over a subject, in order to match its findings to actual physical locations on that subject. Incorporating two sensors into the ultrasound probe produces 6DOF measurements and ensures that all translation and rotation values of the probe are captured.

3.4 Aurora® Tool Types

A tool can be categorized as one of several basic types, depending on the number of sensor coils embedded in it:

Sensor coils	Tool type	Sensor coil placement	5DOF / 6DOF
0	sensorless tool	not applicable	not applicable
1	single sensor coil tool	anywhere	5DOF
2	dual 5DOF tool	not fixed relative to each other	dual 5DOF
	6DOF tool	fixed relative to each other	6DOF
	co-linear sensor coil tool	fixed relative to each other in a co-linear fashion	5DOF
	parallel sensor coil tool	fixed relative to each other in a parallel fashion	5DOF

The different arrangements of two sensor coils in one tool are further explained in section „Tool Types“ on page 10.

3.5 Tool Definition File

A tool definition file (.rom file) describes the sensor or tool to the Aurora® system. This file is necessary for the Aurora® system to be able to track the tool. The tool definition file contains the following information:

- Definition of the tool's local coordinate system
(see section 4. „Global and Tool (Local) Coordinate Systems“ on page 9).
- Placement of the sensors relative to one another, if the tool incorporates multiple sensors.
- Whether the tool is 5DOF, dual 5DOF, or 6DOF (see section 3.3 „Degrees of Freedom“ on page 7).
- Manufacturer information about the tool (manufacturer name, tool part number, etc.).
- Definition of GPIO lines to power LEDs or switches (see section 9. „Constructing a Tool“ on page 19 for more information on GPIO lines).
- Proprietary tracking information which is specific to the type of sensor. This information is cannot be viewed or changed.
- User-defined data. A small section of the tool definition file is reserved for the tool manufacturer or system integrator to use for any purpose.

The tool definition file can be programmed into the tool's SROM device. When the tool is connected to the Aurora® system, the tool definition file is automatically read from the SROM device as soon as the tool is initialized. It is possible to track a tool that has an unprogrammed SROM, or no SROM device connected, by manually uploading a tool definition file to the software.

Note:
The proprietary tracking information is pre-programmed into the generic and template files for each type of sensor. When creating a tool definition file from scratch, always begin by using the correct generic or template file for the sensor type, then modify it to define the local coordinate system or any of the other settings listed above. The correct tool definition file for each sensor is listed on the sensor's datasheet. Tool definition files and datasheets can be downloaded from NDI Support Site at https://support.ndigital.com.

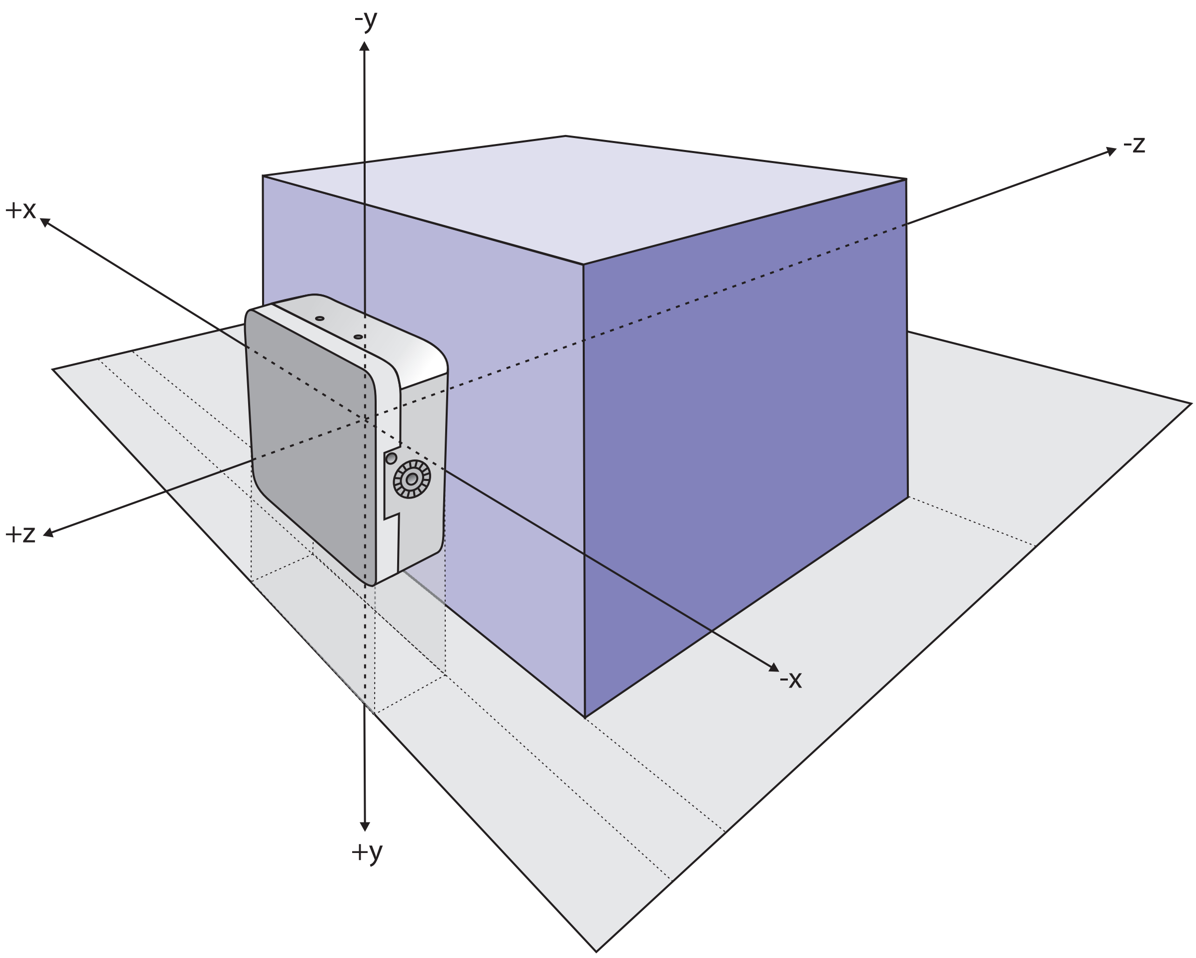
4 Global and Tool (Local) Coordinate Systems

This section explains the different coordinate systems that are used by the Aurora® System to calculate the positions and orientations of tools. It is important to understand the nature of both the global and the tool coordinate systems.

4.1 Global Coordinate System

Each Field Generator type uses a coordinate system with the origin located approximately on the surface of the Field Generator and the axes aligned relative to the Field Generator. This global coordinate system is defined during manufacture and cannot be changed.

The Aurora® System will report the transformations of tools in the global coordinate system. However, if you are using a reference tool, software can calculate and report transformations in the local coordinate system of the reference tool. See section 7.2 „Constructing a Tool“ on page 19.



4.2 Tool Coordinate System

Each tool has its own local coordinate system that is defined by an origin and three axes. Tool coordinate systems are an integral part of the measurement process, and the Aurora® System cannot calculate a tool's position or orientation without them.

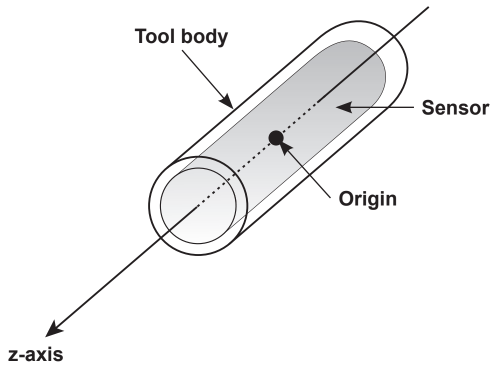
The following section 5 describes typical arrangements of local coordinate systems.

For information on how to change or define the tool coordinate system, including setting the location of the origin, the orientation of the axes, and offset vectors, see section 6. „Points and Axes of Interest, Offset Vectors“ on page 13.

5 Tool Types

5.1 Points Single Sensor Tools

The single sensor tool's local coordinate system is based directly on that of its sensor. By default, the system assigns the z-axis along the sensor's length, with an origin at the sensor's magnetic centre. The origin can be defined anywhere on the z-axis. The x- and y-axes are not fixed due to the inability to determine rotation about the z-axis.

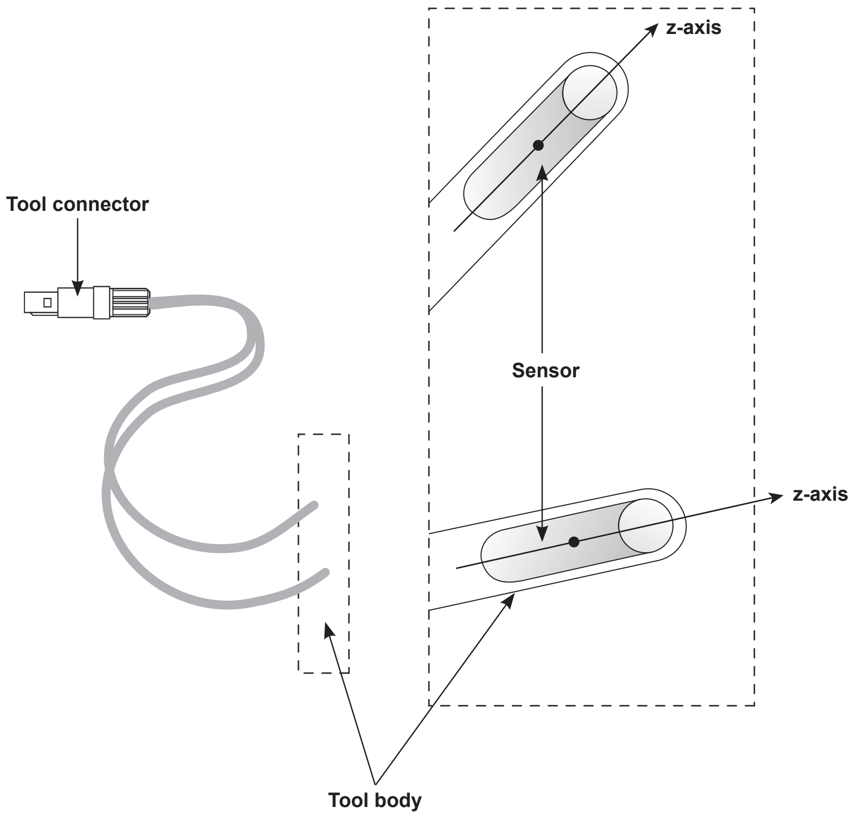


Note:
Single sensor tools do not return an indicator value.
For more information about indicator values, see section 7.1.1 „Indicator Value“ on page 14.

5.2 Dual Sensor Tools

Dual 5DOF Tools

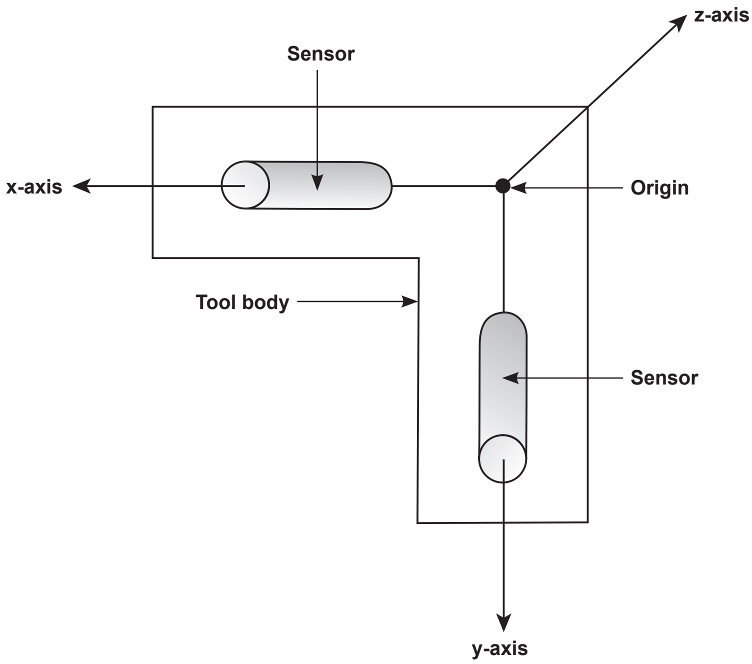
A dual 5DOF tool is essentially two single sensor tools joined to the same tool connector. As such, the tool actually has two local coordinate systems, each based on one of the sensors incorporated into its design. These local coordinate systems are determined in the same way as that of a single sensor tool.



Dual 6DOF Tools

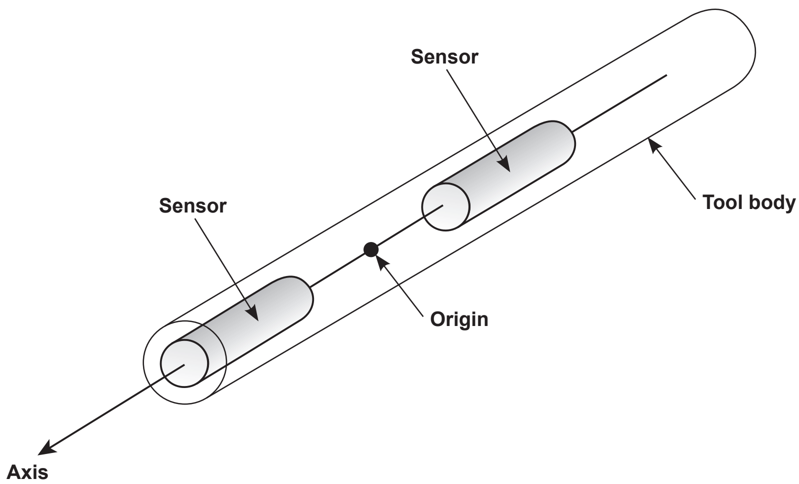
A 6DOF tool incorporates two sensors fixed relative to each other. A 6DOF tool has one local coordinate system for the tool as a whole (not one for each sensor). Each tool includes a tool definition file programmed, onto the tool's SROM device. The tool definition file contains information about the tool and its sensors, including the definition of the tool's local coordinate system.

The following figure shows a sample 6DOF tool with a coordinate system independent of its sensors. When the Aurora® system calculates this tool's position and orientation, it will return only one transformation as well as an indicator value.



Co-linear Sensor Tools

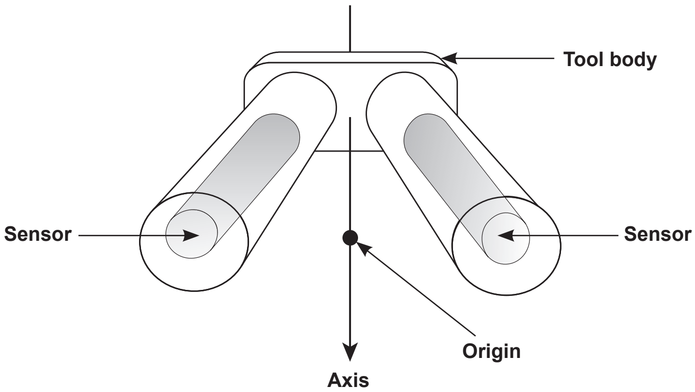
When two sensors are fixed in a co-linear fashion, the system will calculate 6DOF, but the rotation about the common axis will not be accurate. This is because the two sensors are co-linear rather than orthogonal. As such, this tool is considered a 5DOF tool.



One advantage of a co-linear sensor tool is that, unlike single sensor tools, you can define the axis running the length of the two sensors as something other than the z-axis. You can also assign the tool's point of origin, as long as it falls upon this axis. Another advantage is that it provides an indicator value. For further information on indicator values see section 7.1.1 „Indicator Value“ on page 14.

Parallel Sensor Tools

When two sensors are fixed parallel to each other, the system will calculate 6DOF, but the rotation about the common axis will not be accurate. This is because the two sensors are parallel rather than orthogonal. As such, this tool is considered a 5DOF tool.



As shown in the figure above, you can assign the axis running lengthwise between the two sensors. You can also assign the tool's origin, as long as it falls upon this axis. The axis must be parallel to the two sensors and exactly half way between them.

Note:
If the tool's two sensors are fixed relative to each other in a co-linear or parallel fashion, the system will provide 6DOF information for the tool, but it will not be as accurate. This is because the two sensors have a very small angle between them. As such, this tool should be considered a 5DOF tool that returns an indicator value.

6 Points and Axes of Interest, Offset Vectors

6.1 Points of Interest

Points of interest may be defined as points on or near a tool where accuracy is most important and is determined by the tool's intended use.

When designing a tool, it is important to understand and consider the relationship between points of interest, the origin of the tool's local coordinate system, and the resulting transformations that will be returned by the system. The aim is to design a tool that produces the greatest accuracy at the point(s) of interest.

Points of interest are an important consideration when placing sensors in the tool. The closer the sensors are placed to the point(s) of interest, the greater the accuracy at the point(s) of interest.

Ideally the origin of the local coordinate system, sensors and point(s) of interest would all be the same. In practice this is not always possible, and in some cases not even advisable.

Consider a simple probe. It is not possible to place the sensors at the probe's tip because of physical restrictions. However, placing the sensors as close to the tip as possible will minimize the offset vector required and improve accuracy. Offset vectors are discussed below in section 6.3.

The point of interest must be rigidly fixed relative to the sensors.

6.2 Axes of Interest

Similar to a point of interest, an axis of interest represents an imaginary vector in (or projected from) a tool where measurement accuracy is most important. For example, if the tool is a probe that needs its trajectory to be in a particular direction before being used, the axis of interest is an imaginary line travelling along that trajectory.

The same criteria discussed for points of interest also apply to axes of interest.

Axes of interest need to be considered when placing sensors and defining the tool's local coordinate system. The closer one of the sensors is aligned with an axis of interest, the greater the accuracy of that axis of interest.

6.3 Offset Vectors

Although you may be able to place sensors such that their origins fall on either the point of interest or axis of interest, there are situations in which this may be physically impossible. For example, you may not be able to embed a sensor inside a probe's tip because the tip is too small, or because it is likely to bend or break.

In such situations, you will need to apply an offset vector to describe the location of the point of interest with respect to the tool's origin. This value can be written into a tool definition file (see section 3.5 „Tool Definition File“ on page 8), permanently stored in the user portion of the SROM device and applied using your application software. It can also be calculated as part of the tool's application, producing an independent and constant value that is applied to collected data in real-time.

Note:
To determine an offset vector for a tool with a tip (otherwise known as the tip offset), you can perform a pivot.
For more information, see section 13. „Pivoting“ on page 28 for more information.

7 Tool Measurement

It is important when designing tools to have a general understanding of the Aurora® System and the concepts that drive its measurement functionality. This chapter explains the most important concepts in greater detail.

7.1 Transformations

Once the Aurora® System has calculated the position and orientation of a tool, it returns a transformation representing the results. A transformation is combination of translation and rotation values that describe a tool's position and orientation. For more information on the format of the transformation, see the "Aurora User Guide."

7.1.1 Indicator Value

With each transformation calculated, the Aurora® System returns an indicator value. The indicator value is an estimate of how well the system calculated that particular transformation. The indicator value is formatted as a number (without unit) between 0 and 9.9 (where 0 is the absence of error and 9.9 is the highest indication of error).

For 6DOF tools, the indicator value compares sensor measurements to the tool's design (as described by the information in the tool definition file (see section 3.5 „Tool Definition File“ on page 8) stored in the SROM device). The greater the difference between the measured sensor positions and orientations and the known positions and orientations of the sensor within the tool, the higher the indicator value. Such discrepancies are often an indication that magnetic field disturbances are affecting the collected data.

For 5DOF transformations, the indicator value is always zero. This does not indicate an absence of error, but the inability to determine the error.

Indicator values less than 1.0 are typically considered acceptable. You should set your own indicator value thresholds, depending on the nature of your application needs.

Note:
The indicator value is not an absolute indication of overall error, but simply an indication that the measurement may be compromised, or that there may be a mismatched tool definition file.

For more information about the indicator value and how to use it with applications, see the "Aurora Application Programm Interface Guide".

7.1.2 Producing Transformations

The following procedure describes how the Aurora® System produces transformations:

1. When a tool is placed in the measurement volume, magnetic fields, produced by the Field Generator, cause the sensors in the tool to produce signals.
2. The system receives the sensor signals via the Sensor Interface Unit (SIU).
3. The system processes the signals using a specific mathematical model. The end result is a 5DOF transformation for each sensor (that is producing signals).
4. The next step the system performs depends on the type of tool, as follows:

Single Sensor Tool:

The system takes the two 5DOF transformations produced in step 3 and processes them using a mathematical model and the information in the tool definition file (see section 3.5 „Tool Definition File“ on page 8), stored in the SROM device. The result is a single 6DOF transformation that reflects the position and orientation of the entire tool. Part of this 6DOF transformation is an indicator value.

Co-linear Sensor Tool/Parallel Sensor Tool:

The system takes the two 5DOF transformations produced in step 3 and processes them using a mathematical model and the information in the tool definition file (see section 3.5 „Tool Definition File“ on page 8), stored in the SROM device. The result is a single 6DOF transformation that reflects the position and orientation of the entire tool. However, the roll component of the transformation cannot be considered accurate because the sensors are not orthogonal in these tool types. Therefore, these tools must be considered 5DOF tools. In addition, the indicator value produced is not as representative as those produced with 6DOF tools, and may not be useful for application's purposes.

7.2 Reference Tools

Issue

Measuring a tool's position and orientation throughout the measurement volume is a simple procedure as long as the following are true:

- The Field Generator does not accidentally and unknowingly shift. If it does shift, the global coordinate system also shifts. This change affects the perceived location of a tool within the global coordinate system, producing misleading measurement data.
- The object of interest does not accidentally shift. If you are using the Aurora® System to place a tool at a specific point on the object of interest, it is very important that the object does not move with respect to the Field Generator while you are trying to place the tool. There is no way for the system to perceive such movement, and you may end up placing the tool in the wrong location.

In many application environments, shifting objects and bumped Field Generators are not uncommon occurrences. As such, the two above requirements are often difficult to meet.

Solution

A reference tool is designed to be affixed to an object of interest. Once affixed, when the object shifts, the reference tool will shift as well. Other tools can be measured relative to the reference tool, that is in the reference tool's local coordinate system.

The Aurora® System measures the reference tool's movement as well as the tracking tool's movement, producing two sets of measurements. You can design your application to interpret these measurements in the following way:

1. Calculate the reference tool's movements to capture any shifting.
2. Calculate the transformation from the tracking tool's local coordinate system to the reference tool's local coordinate system. This reports the tracking tool in the frame of reference of the reference tool (as opposed to the global coordinate system).

8 Designing a Tool

This chapter describes the design considerations required to construct Aurora System tools. It is the responsibility of the tool designer to ensure that each tool complies with the appropriate standards specific to its intended application.

For assistance in the creation of a tool design, please contact NDI.

8.1 Recommended Considerations for Tool Design

The following list explains the considerations you will need to make as you create a tool design:

Degrees of freedom required: If the application requires the tool's full orientation (roll, pitch and yaw) as well as its position, design a 6DOF tool. If the application does not require the roll orientation, a 5DOF tool will work.

Number of sensors required: The number of sensors required depends on the number of degrees of freedom required, and the coordinate system requirements:

- A 6DOF tool requires two sensors that are placed at an angle to each other.
- A 5DOF tool may contain one or, in the case of co-linear or parallel sensor tools, two sensors.
- A tool that simply acts as an input/output device without being tracked does not require any sensors.

Accuracy required: The accuracy required will directly influence the number of sensors and the placement of the sensors:

- 6DOF measurements are more accurate than 5DOF measurements.

The closer a sensor is to the point of interest, the better the accuracy. See section 6. „Points and Axes of Interest, Offset Vectors“ on page 13.

- For 6DOF tools, The larger the angle between the two sensors (up to 90°), the more accurately the Aurora® System can measure the position and orientation of the tool.

Indictor value requirement: If the tool must produce an indictor value, it must be a 6DOF tool.
See section 7.1.1 „Indicator Value“ on page 14.

Tool shape and points/axes of interest: Taking into account the number of sensors that need to be incorporated into the tool's body, consider a shape that best suits the application needs. Then determine if it has any points or axes of interest. This will be useful in deciding where to best place the sensors. See section 6. „Points and Axes of Interest, Offset Vectors“ on page 13 for more information on points and axes of interest.

Sensor placement: Taking into account the locations of the tool's points of interest and/or axes of interest, begin to plan the placement of the sensors. For more information about this very important step, see section 8.2.

Tool coordinate system: Determine how the tool's local coordinate system will be defined, based on the points and axes of interest. This local coordinate system will be assigned to the tool during the characterization process. See section 4. „Global and Tool (Local) Coordinate Systems“ on page 9 for more details on the local coordinate system.

8.2 Sensor Placement

Planning sensor placement is one of the most important tool design tasks. This section describes the different options available, so that you can plan the best possible placement in a particular tool.

Tools without Sensors

A sensorless tool is a tool which does not need to be tracked, but is still connected to the Aurora® system in order to make use of the GPIO lines. Such a tool might incorporate, for example, a switch or LED that will be controlled via the Aurora® API.

Single Sensor (5DOF) Tools and Dual 5DOF Tools

For a description of what single sensor 5DOF tools and dual 5DOF tools are, see section 5. „Tool Types“ on page 10.

The local coordinate system for a single sensor tool is automatically defined based on the sensor; it cannot be changed by characterization. As such, the sensor placement in the tool directly affects the tool's local coordinate system.

Guidelines for sensor placement:

- The ideal location for the sensor's origin is at the tool's point of interest.
- The sensor should be placed on the tool's axis of interest, with the sensor's z-axis aligned to the tool's axis of interest.

The tool will require an offset vector if you cannot place the sensor so that its origin is on the tool's point of interest. This offset vector must align along the sensor's long axis (z-axis). See section 6.3. „Offset Vectors“ on page 13 for more information about offset vectors.

Note:
Performing a pivot is one method of determining an tool's offset value. See section 13. „Pivoting“ on page 28 for more information.

6DOF Tools

For a description of what 6DOF tools are, see section 5. „Tool Types“ on page 10.

A 6DOF tool has one local coordinate system for the tool as a whole (not one for each sensor). This local coordinate system does not depend on the sensor placement.

Guidelines for sensor placement:

- The sensors should be placed as close to each other as is practical within the design constraints, but no closer than 2 mm. If two sensors are placed closer than 2 mm, they may interfere with each other.
- The sensors must be firmly affixed inside the tool body, so that they cannot move from their assigned position.
- The larger the angle between the two sensors, the more accurately the Aurora® System can measure the position and orientation of the tool. An angle larger than 60° (up to maximum 90°) does not significantly increase the accuracy.
- At least one of the sensors should be placed as close as physically possible to the point of interest.
- The sensors should be placed symmetrically about and as close as physically possible to the axis of interest.
- To optimize the measurement repeatability, locate the tool's origin at the translational average of the tool's two sensors.

Co-linear Sensor Tools

For a description of what single sensor co-linear tools are, see section 5. „Tool Types“ on page 10.

A co-linear sensor tool can only return 5DOF data, but differs from the single sensor tool in the following ways:

- On average the co-linear sensor tool is more accurate than a single sensor tool, and will provide an indicator value.
- You can define the axis running the length of both sensors as something other than the z-axis. See section 5. „Tool Types“ on page 10 for details.
- You can assign the tool's origin anywhere along the axis running the length of both sensors.

Guidelines for sensor placement:

- The sensors should be placed as close to each other as is practical within the design constraints, but no closer than 2 mm. If two sensors are placed closer than 2 mm, they may interfere with each other.
- At least one of the sensors should be placed as close as physically possible to the point of interest.
- If possible, the sensors should be placed so that the axis running the length of both sensors aligns with the tool's axis of interest.

Parallel Sensor Tools

For a description of what parallel sensor collinear tools are, see section 5. „Tool Types“ on page 10.

The parallel sensor tool can only return 5DOF data, but differs from the single sensor tool in the following ways:

- On average the parallel sensor tool is more accurate than a single sensor tool, and will provide an indicator value.
- You can define the axis running parallel to and between both sensors as something other than the z-axis. See section 5. „Tool Types“ on page 10 for details.
- You can assign the tool’s origin anywhere along the axis running parallel to and between both sensors.

Guidelines for sensor placement:

- The sensors should be placed as close to each other as is practical within the design constraints, but no closer than 2 mm. If two sensors are placed closer than 2 mm, they may interfere with each other.
- The sensors should be placed so that the axis running parallel to and between both sensors aligns with the tool’s axis of interest.
- The sensors should be placed so that the tool’s origin will fall along the axis running parallel to and between both sensors.

9 Constructing a Tool

This chapter provides the following information on how to assemble an Aurora® System tool correctly.

Included at the end of this chapter is a sample tool wiring schematic diagram, for reference.

See “Aurora User Guide” for electrical safety considerations and tool port information.

Note:
You should consider the tool’s verification process when designing the tool. This is to ensure that the tool will meet the requirements of its intended application.

9.1 Sensor Handling

Aurora sensors are rather small electrical devices and therefore must to be handled with care.

The following chapter provides “Dos and Don’ts” on how to reduce the risk of sensor damage when you are working with Aurora® sensor.

Do:

- Use only mechanical or electrical conditions that are suitable for the sensor. Parameters such as maximum temperature or tensile force are given in the sensor data sheet.
- Use tweezers with plastic tips, if possible. Metal tweezers can easily harm the insulation of the sensor wires.
- Maintain the twisting of the sensor wires as close as possible to the connection. Untwisting can lead to a higher susceptibility for electromagnetic interference.
- Remove the sensor very carefully from its packaging. Some sensor types are very fragile and can be easily damaged.

Don’t:

- Touch the portion of the sensor where the sensor coil is located, if possible.
- Bend the sensor, the sensor coil, or the soldering connection between sensor and its wiring. Bending can affect the tracking accuracy of the sensor.
- Use excessive sensor wire lengths (longer than 4m). Long sensor wires lead to increased noise on the sensor signal.
- Bring sensors and/or metal components of the tool close to permanent magnets.
- Use temperatures higher than 150°C during your integration process. Higher temperatures may have an effect on the tracking performance of the sensor.

9.2 Constructing the Tool Body

Consider the following guidelines when designing the tool and selecting tool body materials:

Material: The tool body should be constructed of low conductivity materials (such as plastics), rather than high conductivity materials (such as metals and carbon). When metal is used, it should be non-ferromagnetic and low conductive. This practice will reduce the distortion of the electromagnetic field produced by the Field Generator.

Note:
Metal tube configurations, such as needles, may work well. Test any tool configuration that incorporates metal.

Moisture protection: The tool body should be sealed to reduce the possibility of moisture coming into contact with the internal components of the tool. Moisture coming into contact with the internal components of the tool, such as the sensors, may result in tool damage.

Isolation: Electrical isolation should be considered for all internal tool components as well as other objects with which the tool may come into contact (depending on the required application). Sensors should be electrically isolated from all metallic or conductive materials.

Rigidity: The tool body material strength should be considered when designing a rigid type tool. Using a rigid type tool that has been bent may result in inaccurate measurements.

Curing and shrinking: Take care when selecting adhesives, shrink tubing, etc. because:

- Some materials require higher temperature to cure/shrink than the sensors can tolerate.
- Some materials have high shrink rates when curing/shrinking; this can cause mechanical stress to the sensors, which can affect tracking performance.

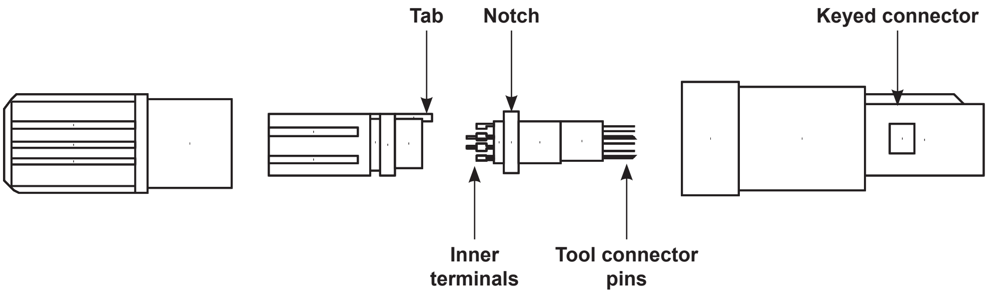
Moisture protection: The tool body should be sealed to reduce the possibility of moisture coming into contact with the internal components of the tool. Moisture coming into contact with the internal components of the tool, such as the sensors, may result in tool damage.

Biocompatibility: For tools that may come into contact with a patient, it is the responsibility of the tool designer to analyze tool body materials to ensure only biocompatible materials are used.

Warning:
The interaction of non-biocompatible materials between the tool and the patient may result in injury. It is the responsibility of the tool designer to determine the biocompatibility of tool body materials.

9.3 Tool Connectors

The following section provides information on how to connect the sensor to the Sensor Interface Unit (SIU). The pinout described below is valid for all connector types. Disassemble the tool connector by unscrewing the two halves of the outer tool connector body. This will expose the inner terminals that connect to the SROM device and the cable wiring:

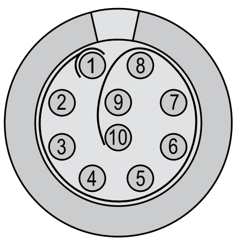


All tool components (apart from the body) connect to the tool connector. Refer to the following table and diagram when determining these wiring connections:

Pin	Pin function	Pin	Pin function
1	#1 Sensor +	6	Jumpered to pin 8 (to provide tool-in-port signal) SROM device interface (see section „9.6“)
2	#1 Sensor -	7	GPIO 1 (typically switch or LED) max. 10 mA
3	#2 Sensor +	8	SIU circuit ground Connect to cable shield if required Jumpered to pin 6 (to provide tool-in-port signal)
4	#2 Sensor -	9	GPIO 2 (typically switch or LED) max. 10 mA
5	SROM device interface (see section „9.6“)	10	GPIO 3 (typically switch or LED) max. 10 mA

Note:
The wiring construction for each individual sensor (pin connections 1-4) are included on the datasheet for the sensor, which can be downloaded from NDI Support Site at https://support.ndigital.com.

Tool connector pin orientation - Viewed from rear



Note:
If pin 6 is not jumpered to pin 8, the Aurora® System will not detect when the tool is connected to the system, making it unusable.

9.4 Tool Cables

Consider the following guidelines if you plan to use a tool cable to connect the tool to the tool connector.

Twisted pairs: Each sensor must be connected to a dedicated twisted pairs.

Grounding: The shield of the cable should be connected to the SIU circuit ground (pin 8). All unused wires within the tool cable may also be connected to pin 8. Not grounding unused wires may result in increased sensor measurement noise.

Length: Cable length should be kept as short as possible to reduce noise on the sensor signal. The recommended overall length of the tool cable (from the sensors to the tool connector) is 2.5 m. Longer cables may have an effect on tracking performance, resulting in an increase of repeatability error due to higher noise, so please verify the system performance together with the tool when using longer cables.

Interconnections: Avoid using additional interconnections between the sensor and the SIU, if possible. If interconnections are necessary, maintain the twisting of the sensor wires as close as possible to the connection. Untwisting can lead to a higher susceptibility for electromagnetic interferences.

Warning:
Do not kink tool cables or use tools with damaged tool cables. Inspect tool cables regularly for damage. Applying transformations from a system with damaged tool cables may result in injury when the application involves personal safety.

9.5 Wiring Sensors

This section will help you to correctly wire the sensors to the tool connector or tool cable. For detailed wiring instructions, see the datasheet for the sensor, which can be downloaded from NDI Support Site at https://support.ndigital.com.

Wiring recommendations:

- Most of the sensor lead wires can be stripped using a soldering iron at approx. 300°C.
- Care should be taken to avoid damage to the sensor lead wires during handling and mounting of the sensors (in particular, the wires close to the sensor). The soldering point on the sensor (where the lead wires attach) is extremely delicate.

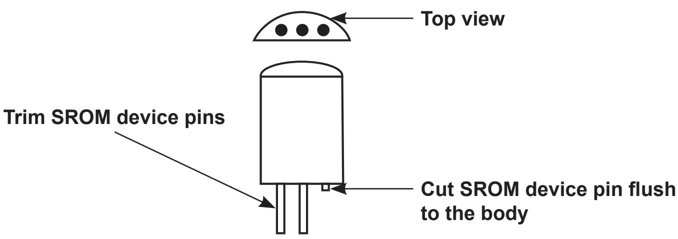
Warning:
Sensors should be mounted securely within the tool body. Should a sensor move out of position, this will affect the accuracy of the tool.

9.6 Installing SROM Devices

The following instructions will help you install the NDI standard SROM device in the tool connector:

Caution:
When working with SROM devices, the system integrator must handle the components in an ESD-safe manner. Failure to do so can damage the components.

1. Before wiring the SROM device to the tool connector, trim all SROM pins to approximately 5 mm in length. This will allow the SROM device to fit inside the standard 10-pin circular plastic connector.
2. Refer to figure and cut the pin identified in the figure flush to the body of the SROM device. This is to avoid accidental short-circuiting with the connector pins.
3. Connect the SROM device centre pin to the tool connector pin 5 (SROM device wire interface).
4. Connect the SROM device remaining pin to the tool connector pin 6 (tool-in-port present).
5. Jumper the tool connector pin 6 to pin 8 (SIU circuit ground).



Note:
If pin 6 is not jumpered to pin 8, the Aurora® System will not detect when the tool is connected to the system, making it unusable.

9.7 LEDs and Switches

Although other devices can interface with the Aurora® System (through the tool connector), LEDs and switches are the ones most commonly used. Consider the following guidelines when adding LEDs, switches or other inputs/outputs to the tool:

- The Aurora® System can support a combination of up to three LEDs or switches per tool port. The maximum current draw for each of these devices is 10 mA.
- LED and switch wiring should be accessible for connection to the tool cable wiring (inside the tool body).

Tracking LED

A tracking LED is a special type of LED functionality. It is not user-controlled; the LED is on solid whenever the Aurora® System can calculate a valid transformation for the tool, and flashes when the Aurora® System cannot calculate a valid transformation. A tracking LED can be implemented as follows:

- The tracking LED must be connected to pin 7 (GPIO 1). The tracking LED functionality is not supported on any of the other GPIO lines.
- The tracking LED must be defined as a tracking LED in the tool definition file.

Wiring Instructions

1. Connect one side of each switch, or the anode side of each LED, to tool connector pin 7, 9 or 10.
2. Connect the other side of each switch (or the cathode side of each LED) to tool connector pin 8 (SIU circuit ground). Use an appropriately sized series resistor to limit the current through the LED.

9.8 Managing Metallic Components

The possibility of distortion to the electromagnetic field should be considered when the tool's design includes the use of metallic components.

Metallic component considerations include:

- the type of metal (e.g. ferromagnetic and conducting characteristics)
- the concentration of metal
- isolation from other components
- the proximity of metal relative to the sensors and/or the system's electromagnetic field

When metallic components must be incorporated into the tool design, stainless steel and titanium may offer better results. For more information on metals compatible with Aurora® System, see the "Aurora User Guide".

Some tools may include sensors that are enclosed within a metallic tool component (e.g. needle, endoscope, etc.). For additional information regarding sensors enclosed within a metallic tool component, contact NDI.

9.9 Tool Characterization

Characterization is the process of creating an individual tool definition file that describes a specific tool. NDI provides the software program 6D Architect to help you characterize tools, create tool definition files and program SROM devices. 6D Architect can be downloaded from the NDI Support Site at https://support.ndigital.com.

When creating a tool definition file from scratch, always begin by using the correct generic or template file for the sensor type, then modify it to define the local coordinate system or any of the other settings listed above. This file contains proprietary tracking information that is specific to each type of sensors, so it is important to use the correct file. The correct tool definition file for each sensor is listed on the sensor's datasheet. Tool definition files and datasheets can be downloaded from NDI Support Site at https://support.ndigital.com.

Note:
After characterization, be sure to validate the tool to confirm it is operating as expected and that it is returning correct transformations.

Warning:
For tools not supplied by NDI, the system integrator is responsible for the correctness of the SROM devices. Incorrect tool SROM device programming may result in incorrect transformations. Applying transformations from a system with incorrect tool SROM device programming may result in injury when the application involves personal safety.

9.10 Verifying Tools

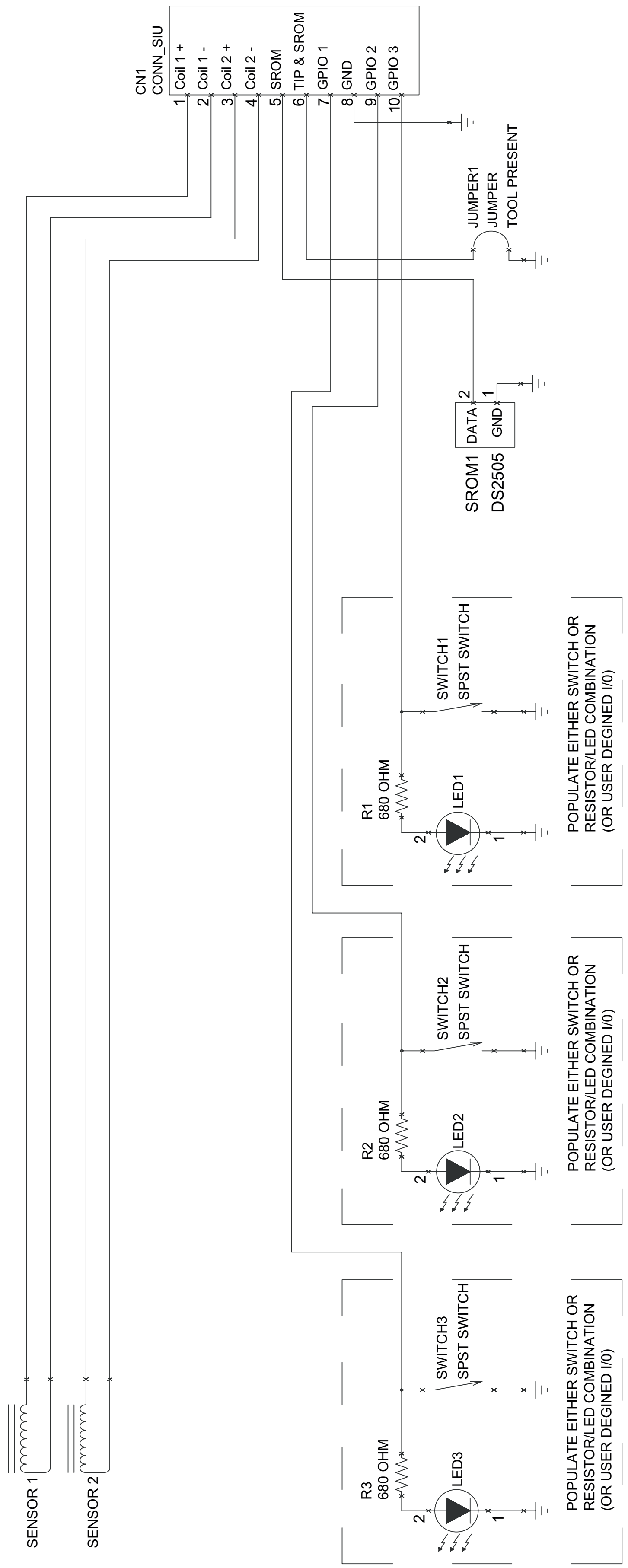
You must perform testing to ensure that the tool will meet the performance requirements in an environment typical of the tool's application.

Integrating a sensor into a tool can affect the sensor's proprietary tracking characteristics. The proprietary sensor parameters are not visible in the NDI tool characterization software. NDI can test the completed tool, to ensure that the tracking parameters in the tool definition file are still appropriate for the tool and provide new ones if necessary. Please contact NDI for more information.

Tool verification guidelines:

- Establish a baseline for the tool's performance. This may include testing in an environment with minimal magnetic field disturbances.
- Introduce each object (that might disturb the magnetic field) and objects that would be typical of the environment used in the required application.
- Establish an indicator value threshold reflective of the required application. (Applicable only if the tool produces an indicator value.)
- Placement of the Field Generator may affect the tool's performance. Change the placement of the Field Generator within the environment in order to simulate the required application.
- Ensure that the tool cable is not wrapped around the Field Generator or is in close proximity to the Field Generator cable.
- Verify the tool in an environment that will simulate the required application environment.
- Refer to the section 1. „Read Me First!“ on page 4 at the beginning of this guide to ensure that all possible hazards have been taken into account during the design and construction of the tool.

9.11 Sample Tool Wiring Schematic Diagram



10. Electrical Safety Considerations

It is beyond the scope of this guide to describe all electrical safety issues associated with tool design. Furthermore, the Aurora® System is only one component in the overall system - safety considerations must also be applied to the work-station, computer peripherals, isolation transformer, the suite of tools, and all other components of the application. It is the responsibility of the OEM manufacturer to test and certify that the entire system complies with the necessary safety standards.

To ensure that the tool design complies with all relevant electrical safety standards, remember the following:

1. Work with an approval agency qualified in testing medical standards. You must consult with the necessary safety approval agencies to obtain advice specific to a particular design.
2. Consult and comply with the following standards:
   - **IEC60601-1** Medical electrical equipment - Part 1:
     General requirements for basic safety and essential performance
   - **IEC 60601-1-2: 2014 / EN 60601-1-2: 2015** Medical electrical equipment - Part 1-2:
     General requirements for basic safety and essential performance - Collateral standard:
     Electromagnetic disturbances - Requirements and tests
3. Consult and comply with additional applicable national standards and amendments.
4. The SIU parts of the Aurora® System are designed for Type BF. System integrator must take into consideration the total isolation concept. See below for more information.

Note:
It is not straightforward to interpret the IEC60601 standard as it applies to tools incorporating sensors, especially when these tools are, in turn, connected to other electro-medical devices such as a surgical microscope or bipolar coagulating forceps. NDI recommends that the OEM manufacturer involve experts from the necessary safety approval agencies at the onset of the development project. This early involvement will potentially avoid an expensive re-design of the tool in order to comply with requirements of the medical standards.

10.1 Tool Port Isolation

The System Control Unit (SCU) has Sensor Interface Unit (SIU) ports suitable for connection to Type BF (body floating) tools. These ports are not, however, isolated from one another. You must take into account this lack of inter-port isolation when considering limits on patient auxiliary- or leakage currents (i.e. leakage current between tools in contact with a patient).

Warning:
Make sure that patient auxiliary- or leakage currents do not exceed allowable limits. Give special consideration to insulation materials and thicknesses to ensure the galvanic isolation of multiple tools connected to the Aurora® System. Failure to do so may lead to personal injury. Consult IEC60601 and applicable national differences and amendments for guidance.

The lack of isolation between SIU ports also requires that when you are designing a tool intended to be attached to other pieces of equipment (e.g. surgical microscope), you must consider isolation of the tool from that equipment. For example, that the isolation between a patient (connected to another tool port via a Type BF tool) and earth-ground and/or mains is preserved. If one tool port‘s isolation is violated, then the isolation of all tool ports on the SIU is violated as well.

11. Troubleshooting

When I plug the tool in and attempt to track it, one or both sensors are not being tracked.

There are several possibilities for the tool not tracking properly:

- Even if a tool has been perfectly designed and constructed, the Aurora® System still will not be able to understand its tracked data without an accompanying file that describes the tool's features and sensor locations. You must either create a tool definition file and program it to the tool's SROM device, or load a tool definition file in the software, before you can actually track the tool. See section 3.5 „Tool Definition File“ on page 8 for information on tool definition files.
- The sensors may not be wired correctly, or their leads may have been accidentally damaged during construction.

When I plug the tool in and attempt to track it, the tracking LEDs and switches do not work properly.

- Check the tool's GPIO wiring to make sure they are soldered correctly and to the right connections.
- Make sure that the tool definition file includes GPIO information so that the Aurora® System knows the LEDs and switches actually exist.

Although the tool is stationary, the Aurora® System returns wavering transformations, implying that the tool is moving.

There are several possibilities for the stationary tool to be returning "moving" data. There may be noise on the signal caused by one of the following:

- There may be another EM field nearby, e.g. caused by a motor.
- You may have accidentally damaged a sensor lead wire when installing it in the tool.
- You may have not soldered the sensor lead wires correctly and to the right connections.
- You may have accidentally soldered the sensor lead wires together during construction.

I use the same tool definition file for several identical sensors, but it works for some sensors and not others.

or

My tool tracks with some Aurora® systems and not with others.

or

My tool shows a high amount of "Bad Fit" values, even though it is in the measurement volume.

The tool definition file may be defined incorrectly. Tool definition files contain proprietary sensor parameters, which are specific to each sensor type. Using an incorrect tool definition file or tool definition template file can result in the creation of a file with incorrect parameters. The proprietary sensor parameters are not visible in the NDI tool characterization software, so please contact NDI technical support for help diagnosing this problem.

12. Abbreviations and Acronyms

Abbreviation or Acronym	Meaning
5DOF	Five Degrees of Freedom
6DOF	Six Degrees of Freedom
GPIO	General Purpose Input/Output
LED	Light Emitting Diode
SCU	System Control Unit
SIU	Sensor Interface Unit
SROM	Serial Read Only Memory

13. Pivoting

Pivoting is the procedure used for tools with tips, to determine the location of the tool tip relative to the position of the sensor(s). There are many applications in which the position of the tool tip needs to be reported. For example, a needle where the sensors cannot physically be located at the tip.

Pivot Block Design

A pivot block should be used to ensure that the pivoting procedure is accurate and repeatable. The following points should be considered when you design a pivot block:

1. It should be designed to have a substantial mass, to reduce the possibility of movement during use.
2. It should be manufactured in a material that is not conductive and has no ferromagnetic properties (e.g. plastic like POM or PEEK).
3. It should be possible to securely fix the pivot block relative to the Field Generator.
4. The divot should match the tip:
   - The tool tip should fit the divot such that the tip does not move during pivoting. For example, the divot should not be so wide that the tool tip moves within the divot, nor should it be so small that the tool tip tends to leave the divot.
   - Shallow divots (dents) work well for pivoting tools with sharp points.
5. An appropriately-sized convex arrangement (ball) should be provided to accommodate tools with concave tips.

Note:
A description in detail on how to perfom a pivot is given in the “Aurora User Guide”.

How to perform a pivoting procedure

A pivot wizard is provided with both the NDI 6D Architect and the NDI ToolBox software tools.
Application specific instructions are detailed in the appropriate documentation.

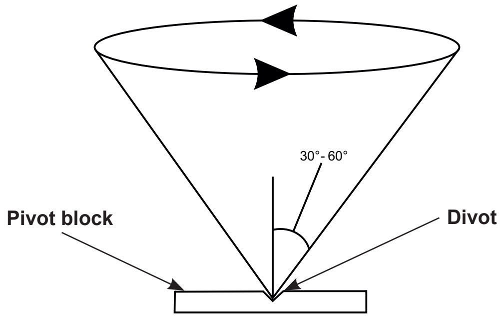
You can use the pivot wizard to calculate the location of a tool’s end-tip. You can use this information to do the following:

- For 6DOF tool, use the vector to transform a local coordinate system so that its origin is located at the end-tip.
- Permanently program the vector as a user-specified tag in a tool’s SROM device.
- Use the vector to test a tool definition file.

Note:
NDI does not recommend permanently transforming a tool’s local coordinate system to its end-tip if the tool design is such that the location of the end-tip can be altered as a result of damage (such as a probe bending as a result of being dropped). It is better to perform a pivot procedure and re-align a local coordinate system as a part of your application procedure, every time you are about to track the tool. Contact NDI for more information about incorporating a pivot procedure into your application.

The physical pivoting procedure is the same in both applications and is as follows:

1. Make sure that the tool and pivot block are within the characterized measurement volume.
2. Position the tool tip in the appropriately sized divot. (The size and shape of the divot must match the tool tip to ensure that the tip does not move.)
3. As the measurement system collects the data, continuously pivot the tool back and forth and side to side, with its tool-tip remaining stationary at the fixed point. Ideally, the angles of your pivot movements should fall between 30 and 60 degrees:



Note:
It is very important that the tool-tip remains stationary while the tool is being pivoted. The design of the pivot block should take into account the shape of the tool’s end-tip.

14. Glossary

5DOF

Five of the six degrees of freedom. Three translation values on the x, y and z axes and any two of the three rotation values roll, pitch and yaw.

6DOF

Six degrees of freedom. The three translation values on the x, y, and z-axes; and the three rotation values roll, pitch and yaw.

Axis of interest

An axis of interest represents an imaginary vector that is projected through a tool and represents an area where measurement values are required. For example, if the tool is a probe, an axis of interest might be an imaginary line travelling along the body of the probe and out its tip.

Characterization (tool)

Characterizing a tool is the process of creating its tool definition file (.rom) which determines the actual positions of its sensors.

Characterized measurement volume

The characterized measurement volume is the volume within the detection region where accuracy is within specified limits. NDI cannot guarantee measurement accuracy outside this region.

Dual sensor tool

A dual sensor tool contains two sensors. If the sensors are affixed relative to each other inside this tool, the system is able to measure the transformations of the tool in 6DOF.

Field Generator

The Field Generator is the component of the Aurora® System that generates the electromagnetic field.

Global coordinate system

The global coordinate system is an NDI measurement system‘s coordinate system. The global coordinate system is used by the measurement system as a frame of reference against which tool transformations are reported. By default, the global coordinate system’s origin is set at the Field Generator.

Indicator value

The indicator value is a unitless estimate of how well the system calculated a particular transformation.

Local coordinate system

A local coordinate system is a coordinate system assigned to a specific tool.

Measurement volume

See characterized measurement volume.

Offset vectors

An offset vector describes the location of the point of interest with respect to the tool origin.

Pivoting

Pivoting is a procedure (of rotating a tool about its tip) used to determine the tool tip offset.

Point of interest

The point of interest is a point on or near the tool that represents a specific point where measurement values are required. For example, if the tool is a probe, the tip of the probe is most likely its point of interest.

Reference tool

A reference tool is a tool whose local coordinate system is used as a frame of reference in which other tools are reported/measured.

Sensor coil

A sensor coil is a coil of wire with a pair of twisted lead wires whose position can be determined in 5DOF by the Aurora® System. A 5DOF sensor contains one sensor coil. A 6DOF sensor contains two sensor coils.

Sensor Interface Unit (SIU)

The SIU is the component of the Aurora® System that connects tools to the System Control Unit (SCU).

Sensorless tools

Tools that have no sensors, and cannot have their position determined. For example, a foot switch.

Single sensor tool

A single sensor tool contains one sensor. This tool provides 5DOF position and orientation information.

SROM device

An SROM device is a memory device located inside a wired tool. A tool definition file can be programmed into the SROM device so that the tool can carry its own information for automatic retrieval by an NDI measurement system.

System Control Unit (SCU)

The System Control Unit (SCU) controls the Aurora® System. The SCU powers and directs the Field Generator's output, collects measurement data from tools, and calculates transformations.

Tool definition file

A tool definition file stores information about a tool. This includes information such as the placement of the tool's sensors, the location of its origin, and its manufacturing data. The tool definition file is formatted as .rom.

Tool origin

The tool origin is the origin of the tool's local coordinate system.

Tool tip offset

The tool tip offset is the distance between the tip of the tool and the tool origin.

Transformation

A transformation is a combination of translation and rotation values that describe the location of the tool in position and orientation.

14. Disclaimers

1. NDI shall make no expressed or implied warranty of any kind with regards to the information contained in the Aurora® Tool Design Guide.
2. NDI is not responsible for the design of tools, and only provides the Aurora® Tool Design Guide as information to assist the tool designer in the design of tools. Usage of the Aurora® Tool Design Guide and the choice of materials, ergonomics, design and/or application, tool functionality and tool material biocompatibility is the sole responsibility of the tool designer.
3. NDI shall not be liable for incidental or consequential damages in connection with or arising out of the furnishing, performance or use of any information contained in the Aurora® Tool Design Guide.
4. NDI supplies sensor coils specifically designed and tested for use with the Aurora® System. If you use sensor coils from any other source, be aware that NDI does not guarantee the accuracy of measurements made with those sensor coils.

Contact Details

If you have any questions regarding the content of this guide or the operation of this product, please contact us:

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Updates

NDI is committed to continuous improvements in the quality and versatility of its software and hardware. To obtain the best results with your NDI system, check the NDI Support Site regularly for update information:
https://support.ndigital.com