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(54) **Title:** CURVE-TRACKED WORKING CHANNEL TOOL

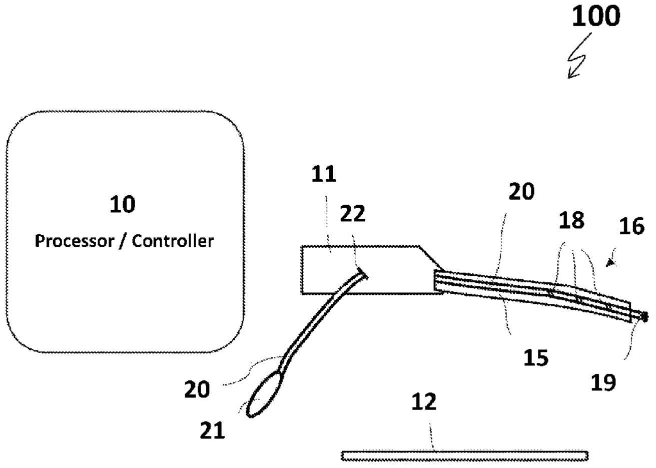

Figure 1

(57) **Abstract:** A curve-tracked working channel tool comprising: a processor/controller; an elongated body comprising at least one flexible printed circuit (FPC); and a curve sensor installed on the FPC, the curve sensor is configured to sense positions and orientations along the tool, in a determined frame of reference, wherein the curve sensor is configured to communicate with the processor/controller via the FPC while inserted into a body lumen, to calculate a curve of the tool, localized in the determined frame of reference, and wherein the processor/controller is configured to curve-track the elongated working channel tool, by receiving multiple magnetic field readings from a plurality of locations along the curve sensor.

[Continued on next page]

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CURVE-TRACKED WORKING CHANNEL TOOL

RELATED APPLICATION/S

This application claims the benefit of priority of U.S. Provisional Patent Application No. 63/537,847 filed on September 12, 2023, the contents of which are incorporated herein by reference in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to fully shape/curve-tracked elongated probe tool and methods for manufacturing thereof, for example a working-channel tool, for example, for catheter and/or endoscopic interventional procedures.

Electromagnetic tracking systems are widely used in clinical applications to track certain instruments inside the patient's body in three dimensions. A common electromagnetic tracking system usually consists of an electromagnetic transmitter, which generates a number of different alternating electromagnetic fields, commonly at different frequencies (for example, 3 different fields at frequencies 1Khz, 2Khz, 3Khz) and an electromagnetic sensor which usually consists of one or more electromagnetic coils (for example, 3 concentric small electromagnetic coils). The alternating fields generate Electromotive Force (EMF) in the sensor's coils which are sensed on the receiving end. The measured fields are then used to compute the position and orientation of the electromagnetic sensor. The solution of a position and/or orientation of the sensor relative to the transmitter relies on the knowledge of the generated EM field values at each point in space relative to the transmitter. By knowing the generated fields, the receiver is able to determine the position and/or orientation of the sensor in space relative to the transmitter such that the measured fields correspond to its solved position and/or orientation.

Certain medical devices exist which combine electronics inside the devices. For example, many endoscopes exist which contain an electrical image sensor (for example, a CMOS sensor) at the endoscope's tip, which is usually accompanied by one or more Light Emitting Diodes (LED). In this case, the image sensor and LEDs are usually powered by a power source which is external to the endoscope, for example, resides in a host station and connected to the endoscope using electrical conductors such as isolated electrical wires inside an electrical cable, and the sensor images are streamed to a host station using one or more electrical conductors, such as isolated shielded electrical wires.

Other types of devices exist which make use of passive electronics. For example, in a traditional EM based tracking system, an EM coil-based sensor may comprise an ultra-thin enameled copper wire wrapped around a small magnetic core (for example, ferrite) and which is placed at the tip of a tracked EM catheter. The wire at its two ends may then be extended in a twisted-pair fashion back to a connected host system, as a differential signal. Usually, each EM coil requires two differential wires. A standard 3D EM coil-based sensor consists for example of three perpendicular coils, which amounts to six wires. For a standard multi-sensor EM application, the number of wires grows linearly with the number of EM sensors in the device.

There exist other types of devices and tools which combine electronic components and sensors, such as, but not limited to: pressure sensor, strain sensor, force sensor, imaging sensor, temperature sensor, etc. Such devices and tools, for example in the medical field, may be: endoluminal ultrasound devices (such as REBUS, IVUS); other endoluminal imaging (such as OCT and spectroscopy devices); ablation devices (such as RF probes, Microwave probes, cryoablation devices); electrical clot and foreign-object retrieval; flexible endoluminal surgical tools; histotripsy and other types of therapeutic ultrasound devices, electrical cauterization. Most electrical devices and tools require electrical powering, connectivity, and hosting of electrical components inside the devices.

Additional background art includes U.S. Patent No. 11,712,309 disclosing an EM curve sensor which consists of a sensor-array made of multiple discrete digital 3D magnetometers assembled on a Flexible Printed Circuit (FPC). The sensor-array may be embedded in an endoscope (or other tubular device) to enable EM curve tracking of that endoscope.

For electromagnetic-based localization, objects in the device environment may create an electromagnetic distortion in space and impact the accuracy of the solved position and orientation relative to the transmitter. For example, certain ferromagnetic, paramagnetic, and/or diamagnetic materials (collectively, magnetic) may be magnetized due to the electromagnetic fields generated by the transmitter and become sources for electromagnetic fields (of similar frequencies). Conductive materials may serve as receivers in the sense that they experience electromotive forces due to the generated electromagnetic fields. These electromotive forces create electrical currents (eddy currents) inside the conductive metals which generate secondary fields, such that the conductive metals may also become sources for electromagnetic fields (of similar frequencies) on their own.

In some clinical applications, for example endoscopic or endovascular (collectively, endoluminal) procedures, a long thin tubular device, for example catheter or endoscope, is inserted into a lumen in the patient’s body, for example gastrointestinal system, lung, or endo-vascular lumen. Such a device can be thin in order to pass through the narrow lumens, and flexible in order to pass through tight curves without damaging the tissue in the lumen wall. The device is preferably durable to withstand the mechanical forces applied during its use by the physician and the patient's tissue.

In some cases, once the device is navigated to the desired target, an interaction is required, for example a biopsy or ablation, therefore some endoluminal devices include an inner lumen or working channel to allow insertion of biopsy or ablation tool. This inner lumen or working channel is required to have as large diameter as possible to allow insertion of large tools.

To achieve minimal outer diameter and maximal inner diameter, endoluminal devices are designed with minimal wall thickness. Incorporating electrical components or wires in the wall of such device, may require an increase in wall thickness or negatively affect the device's mechanical properties, for example flexibility and durability. For this reason, many devices do not include such components and instead have electrical components only at the tip.

Navigation systems exist which provide navigational instructions to guide a device to a specific point inside a patient's organ. For example, in electromagnetic navigational bronchoscopy procedure, an EM position sensor is located inside an endoscope's tip and is used by the navigation system to provide instructions for a physician to reach a certain target inside the patient's lung. In those systems, a device may be tracked using electromagnetic (EM) position sensor or EM shape and/or position sensor or fiber-optic shape sensor. Tracking a device during an endoluminal procedure allows for providing navigational guidance instructions for that device, to navigate the device to a specific, potentially peripheral target, inside a potentially complex lumen structure, based on the shape and/or position sensor. In addition, tracking the shape and/or position of a device during endoluminal procedure can support the steering of that device, for example in a robotic endoscopic procedure, by tracking the shape and/or position of the distal bending section of the device, such that the device is deflected in controlled manner, based on feedback from the shape and/or position sensor.

SUMMARY OF THE INVENTION

Following is a non-exclusive list including some examples of embodiments of the invention. The invention also includes embodiments which include fewer than all the features in an example and embodiments using features from multiple examples, also if not expressly listed below.

Example 1. An endoscopic system, comprising:

a. an endoscopic device comprising a working channel;

b. a working channel tool configured to be inserted within said working channel of said endoscopic device, said working channel tool comprising:

i. an elongated body comprising a proximal end and a distal end;

ii. one or more Flexible Printed Circuits (FPCs) extending along said elongated body; and

iii. a curve/shape sensor comprising a plurality of sensor elements positioned on said one or more FPCs;

c. one or more transmitters;

d. a controller comprising a processor; said processor comprising instructions for calculating a full localized curve along a tracked portion of said working channel tool, relative to the one or more transmitters.

Example 2. The endoscopic system according to example 1, wherein said processor comprises further instructions for allocating energy functions dependent on sensed values by the sensor elements at respective points along said working channel tool, the sensed values incorporate relevant constraints.

Example 3. The endoscopic system according to example 1, wherein said processor comprises further instructions for:

a. obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working channel tool;

b. allocating energy functions dependent on the position and orientation of points along said working channel tool, that incorporate relevant constraints;

c. generating a resultant united energy function for the full shape and/or position of the entire tracked portion of said working channel tool.

Example 4. The endoscopic system according to example 1, wherein said one or more FPCs are twisted about a longitudinal axis of said elongated body.

Example 5. The endoscopic system according to example 1, wherein said plurality of sensor elements are positioned at known intervals on said one or more FPCs.

Example 6. The endoscopic system according to example 1, wherein at least one sensor element from said plurality of sensor elements is positioned at said distal end of said elongated body.

Example 7. The endoscopic system according to example 1, wherein said working channel tool further comprises at least one LED positioned at said distal end of said elongated body.

Example 8. The endoscopic system according to example 1, wherein said working channel tool further comprises at least one camera positioned at said distal end of said elongated body.

Example 9. The endoscopic system according to example 1, wherein said working channel tool further comprises at least one camera support for said at least one camera.

Example 10. The endoscopic system according to example 9, wherein said at least one camera support is configured to be manipulated during a manufacturing process of said working channel tool.

Example 11. The endoscopic system according to example 10, wherein said manipulation is folding.

Example 12. The endoscopic system according to example 11, wherein said folding positions said at least one camera facing distally from said distal end of said elongated body.

Example 13. The endoscopic system according to example 1, wherein said working channel tool further comprises a second working channel extending within said elongated body.

Example 14. The endoscopic system according to example 1, wherein said working channel tool further comprises a mount configured to house at least one camera and at least one LED.

Example 15. The endoscopic system according to example 14, wherein said mount is configured to allow directional positioning of said at least one camera and said at least one LED.

Example 16. The endoscopic system according to example 1, wherein said one or more FPCs further comprise at least one reinforcement material.

Example 17. The endoscopic system according to example 1, wherein said one or more FPCs are wrapped around a core, a mandrel or a fiber.

Example 18. The endoscopic system according to example 17, wherein said core is either hollow or full.

Example 19. The endoscopic system according to example 1, wherein said working channel tool comprises at least two FPCs, and wherein a first FPC is configured to house said plurality of sensor elements and a second FPC is configured to house at least one camera and at least one LED.

Example 20. The endoscopic system according to example 19, wherein said at least two FPCs are assembled one on top of another.

Example 21. The endoscopic system according to example 1, wherein said one or more FPCs are covered with a protective jacket.

Example 22. The endoscopic system according to example 21, wherein said protective jacket is configured for one or more of:

a. providing biocompatibility to said working tool channel;
b. providing protection to electronic component within said working tool channel;
c. enhancing mechanical properties of said working tool channel; and
d. providing protection to tissues and/or said endoscopic device working channel.

Example 23. The endoscopic system according to example 21, wherein said protective jacket provides a round shape to said distal end of said elongated body.

Example 24. A working channel tool configured to be inserted within a working channel of an endoscopic device, said working channel tool comprising:

a. an elongated body comprising a proximal end and a distal end;

b. one or more Flexible Printed Circuits (FPCs) extending along said elongated body;

c. a curve/shape sensor comprising a plurality of sensor elements positioned on said one or more FPCs; and

d. a controller comprising a processor; said processor comprising instructions for allocating energy functions dependent on sensed values by the sensor elements at respective points along said working channel tool, the sensed values incorporate relevant constraints, and calculating a full localized curve along a tracked portion of said working channel tool, relative to one or more transmitters.

Example 25. The working channel tool according to example 24, wherein said processor comprises further instructions for:

a. obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working channel tool;

b. allocating energy functions dependent on the position and orientation of points along said working channel tool, that incorporate relevant constraints;

c. generating a resultant united energy function for the full shape and/or position of the entire tracked portion of said working channel tool.

Example 26. The working channel tool according to example 24, wherein said one or more FPCs are twisted about a longitudinal axis of said elongated body.

Example 27. The working channel tool according to example 24, wherein said plurality of sensor elements are positioned at known intervals on said one or more FPCs.

Example 28. The working channel tool according to example 24, wherein at least one sensor element from said plurality of sensor elements is positioned at said distal end of said elongated body.

Example 29. The working channel tool according to example 24, wherein said working channel tool further comprises at least one LED positioned at said distal end of said elongated body.

Example 30. The working channel tool according to example 24, wherein said working channel tool further comprises at least one camera positioned at said distal end of said elongated body.

Example 31. The working channel tool according to example 24, wherein said working channel tool further comprises at least one camera support for said at least one camera.

Example 32. The working channel tool according to example 31, wherein said at least one camera support is configured to be manipulated during a manufacturing process of said working channel tool.

Example 33. The working channel tool according to example 32, wherein said manipulation is folding.

Example 34. The working channel tool according to example 33, wherein said folding positions said at least one camera facing distally from said distal end of said elongated body.

Example 35. The working channel tool according to example 24, wherein said working channel tool further comprises a second working channel extending within said elongated body.

Example 36. The working channel tool according to example 24, wherein said working channel tool further comprises a mount configured to house at least one camera and at least one LED.

Example 37. The working channel tool according to example 36, wherein said mount is configured to allow directional positioning of said at least one camera and said at least one LED.

Example 38. The working channel tool according to example 24, wherein said one or more FPCs further comprise at least one reinforcement material.

Example 39. The working channel tool according to example 24, wherein said one or more FPCs are wrapped around a core, a mandrel or a fiber.

Example 40. The working channel tool according to example 39, wherein said core is either hollow or full.

Example 41. The working channel tool according to example 24, wherein said working channel tool comprises at least two FPCs, and wherein a first FPC is configured to house said plurality of sensor elements and a second FPC is configured to house at least one camera and at least one LED.

Example 42. The working channel tool according to example 41, wherein said at least two FPCs are assembled one on top of another.

Example 43. The working channel tool according to example 24, wherein said one or more FPCs are covered with a protective jacket.

Example 44. The working channel tool according to example 43, wherein said protective jacket is configured for one or more of:

a. providing biocompatibility to said working tool channel;
b. providing protection to electronic component within said working tool channel;
c. enhancing mechanical properties of said working tool channel; and
d. providing protection to tissues and/or said endoscopic device working channel.

Example 45. The working channel tool according to example 43, wherein said protective jacket provides a round shape to said distal end of said elongated body.

Example 46. A method of manufacturing a working channel tool comprising one or more sensor arrays; said one or more sensor arrays comprising one or more Flexible Printed Circuits (FPCs) and a plurality of electronic components positioned on said one or more FPCs; the method comprising helically winding one or more sensor arrays around said working channel tool; wherein said method comprises positioning said plurality of electronic components along said one or more FPCs so when said one or more sensor arrays are wound around said working channel tool, said plurality of electronic components are aligned in relation to a longitudinal axis of said working channel tool.

Example 47. The method according to example 46, wherein at least one of the FPCs has a spiral shaped FPC design, and is windable as a helix onto a working channel tool.

Example 48. A method for curve/shape-tracking of a working-channel tool, comprising:

a. obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working-channel tool;

b. allocating energy functions dependent on a position and orientation of points along said working channel tool that incorporate relevant constraints;

c. generating a resultant united energy function for a full shape and/or position of said tracked portion of said working channel tool; and

d. calculating a full localized curve along said tracked portion of said working channel tool, relative to a transmitter.

According to an aspect of some embodiments of the present invention there is provided a curve-tracked working channel tool comprising: a processor/controller; an elongated body comprising at least one flexible printed circuit (FPC); and a curve sensor installed on the FPC, the curve sensor is configured to sense positions and orientations along the tool, in a determined frame of reference, wherein the curve sensor is configured to communicate with the processor/controller via the FPC while inserted into a body lumen, to calculate a curve of the tool, localized in the determined frame of reference, and wherein the processor/controller is configured to curve-track the elongated working channel tool, by receiving multiple magnetic field readings from a plurality of locations along the curve sensor.

According to some embodiments of the invention, the tool comprises a tip portion to hold an operational unit, optionally comprising one or more sensors and/or cameras and/or LEDs.

According to some embodiments of the invention, the actionable/operational unit comprises a camera and an illumination source.

According to some embodiments of the invention, the tool is configured to be inserted into a catheter.

According to some embodiments of the invention, the curve sensor is configured to detect and or sense local magnetic fields along the device.

According to some embodiments of the invention, the determined frame of reference is of an external transmitter of magnetic fields.

According to some embodiments of the invention, the curve sensor includes a plurality of magnetic field sensing elements, assembled on the FPC at known locations along the tool.

According to some embodiments of the invention, the at least one of the sensing elements is installed at a tip portion of the tool.

According to some embodiments of the invention, the tip portion includes a camera support spatially manipulated to position the camera to face a progress direction of the tool.

According to some embodiments of the invention, the tool comprises a fold before the camera support, to position the camera to face a progress direction of the tool.

According to some embodiments of the invention, the tool comprises a mount to hold a tip portion of the FPC in a stable and correctly positioned manner, for an intended operation.

According to some embodiments of the invention, the mount is configured to position the camera to face a progress direction of the tool.

According to some embodiments of the invention, the mount comprises: a platform, wherein a side of the platform is configured to support a camera support portion of the FPC; a wall; and a slot between the platform and the wall, in which the tip portion may be inserted, and wherein the platform and the wall define a niche, in which a magnetic field sensor element is installed.

According to some embodiments of the invention, the FPC is twisted about its longitudinal axis.

According to some embodiments of the invention, the FPC is reinforced under sensor elements of the curve sensor to protect the attachment of these components to the FPC.

According to some embodiments of the invention, the tool comprises two FPCs at least partially overlaying one on top of the other.

According to some embodiments of the invention, the curve sensor, the camera and the illumination source (LED) are assembled on one side of the FPC and then the FPC is twisted and/or bent as required.

According to some embodiments of the invention, the FPC is covered with a protective jacket and/or a dome.

According to some embodiments of the invention, the processor controller is configured to: obtain a plurality of predetermined points along a tracked portion of the tool; allocate, for a plurality of the predetermined points, a local energy function dependent on estimated position and orientation of the tool at this point, that incorporates relevant mechanical and sensor measurement constraints for the point; generate a resultant unified energy function for the full shape and position of the entire tracked portion of the tool, the unified energy function is constructed based on the allocated local energy functions, and regional energy functions that relate to constraints of mechanical properties of the tool, with respect to relative locations and orientation of adjacent plurality of the predetermined points; and calculate a full localized curve along the tracked portion of the tool by minimizing the energy function.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

As will be appreciated by one skilled in the art, some embodiments of the present invention may be embodied as a system, method or computer program product. Accordingly, some embodiments of the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment (including firmware, resident software, micro-code, etc.) or an embodiment combining software and hardware aspects that may all generally be referred to herein as a “circuit,” “module” or “system.” Furthermore, some embodiments of the present invention may take the form of a computer program product embodied in one or more computer readable medium(s) having computer readable program code embodied thereon. Implementation of the method and/or system of some embodiments of the invention can involve performing and/or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware and/or by a combination thereof, e.g., using an operating system.

For example, hardware for performing selected tasks according to some embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to some embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to some exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

Any combination of one or more computer readable medium(s) may be utilized for some embodiments of the invention. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electro-magnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

Program code embodied on a computer readable medium and/or data used thereby may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical fiber cable, RF, etc., or any suitable combination of the foregoing.

Computer program code for carrying out operations for some embodiments of the present invention may be written in any combination of one or more programming languages, including an object-oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the "C" programming language or similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

Some embodiments of the present invention may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a computer implemented process such that the instructions which execute on the computer or other programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

Some of the methods described herein are generally designed only for use by a computer, and may not be feasible or practical for performing purely manually, by a human expert. A human expert who wanted to manually perform similar tasks might be expected to use completely different methods, e.g., making use of expert knowledge and/or the pattern recognition capabilities of the human brain, which would be vastly more efficient than manually going through the steps of the methods described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

Figure 1 is a schematic representation of a system for full curve-tracking of a working-channel tool, according to some embodiments of the invention;

Figures 2A-2H are schematic illustrations of a tool assembly, included in a working-channel tool and configured for enabling full curve/shape tracking thereof, according to some embodiments of the invention;

Figure 3 is a schematic representation of a tracked portion of the working-channel tool, according to some embodiments of the invention;

Figure 4 is a flowchart illustrating an exemplary method for curve/shape-tracking of the working-channel tool **20**, according to some embodiments of the invention.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to fully shape/curve-tracked elongated probe tool and methods for manufacturing thereof, for example a working-channel tool, for example, for catheter and/or endoscopic interventional procedures.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Overview and Exemplary principle of the invention

Following the background disclosed above, there is therefore a desire for a shape-sensing/curve tracking device which can be inserted into the working channel of an existing device, for example an endoscope which does not necessarily possess shape-sensing or curve-tracking capabilities, thus enhancing its capabilities, such as navigational and/or steering capabilities, while maintaining dimensional and mechanical properties.

In other applications, an endoluminal device may possess shape-sensing or curve-tracking or tip-tracking capabilities, but a working channel tool (such as a biopsy needle, forceps, brush or other types of instruments) may not contain sensors and may thus not be tracked. Adding tracking capabilities to working channel tools, specifically shape-tracking and/or curve-tracking capabilities, enables tracking of the working channel tool separately from the endoluminal device, for example, such that working channel tools are being tracked while being extended outside of the working channel of the endoluminal device and towards a target (such as a lesion). By curve-tracking a working channel tool as it extends out of the working channel, the instrument can then be guided and navigated away from the endoluminal device's tip and towards a target, and during its interaction with the target. This enables guided target interaction, while potentially using the instrument's tracked shape and/or position to compensate for organ's movement, for example, by applying deformation tracking algorithms based on the instrument's tracked shape. Additionally, by tracking the instrument's shape and/or position while being extended outside of an endoluminal device's working channel, the instrument can be driven robotically based on its tracked shape and towards a potentially moving (deforming/breathing) target, such as a lesion.

An aspect of some embodiments of the invention relate to a working-channel curve-tracked probe tool (referred hereinafter just as working-channel tool) that can be used either for adding shape and/or position tracking capabilities to a non-tracked endoluminal device, as well as for providing tracking and guidance (navigation capabilities) all the way to the target and during the interaction with the target (even in the case of a tracked endoluminal device).

In some embodiments, some curve sensing methods use multiple magnetic sensors along an elongated flexible device and the determined position and orientation or local magnetic field measurements or other local measurements of each sensor to determine an estimated curve of the elongated device. These methods are susceptible to include errors in the estimation, caused by, for example, inaccuracies in the sensors and the need to somehow estimate the shape of the device between the sensors.

In a static environment, where all magnetic and conductive materials are positioned and oriented statically relative to the transmitter and/or the receiver, the distortion fields which are created by nearby metals can be modeled and learned in a mapping and/or calibration process prior to operating the tracking system. For example, in a clinical environment, if a transmitter is fixed to a patient's bed, conductive metals on the bed are located in a static position relative to the transmitter. In this case, the distortion fields caused by eddy currents flowing through the conductive metals or by magnetization of ferromagnetic metals are static in the sense that they do not change during operation of the tracking system.

In some embodiments, by mapping the total field generated in the sensing volume surrounding the transmitter, the system is configured to use the mapped fields (rather than the "neutral" or theoretically expected fields) to perform the tracking. In another example, when an electromagnetic sensing coil is wrapped inside an endoscope around a magnetic stainless-steel metal, the magnetic metal creates a distortion field as described above. Since the sensing coil is fixed to the distorter, the distortion field "moves" together with the sensing coil and its effect is static relative to the receiver and can be modeled in a calibration process. For example, its effect may be modeled as increased sensing gain of the EM sensing coil, or more generally, as a gain matrix applied to measurements of the sensing coils, regardless of the sensor's position and orientation in space.

As described above, static electromagnetic distortion effects can be modeled in a mapping or calibration process. However, dynamic electromagnetic distortion which accounts for distortion fields created by dynamically moving distorting objects (relative to the transmitter and/or the receiver) requires a different solution and cannot be addressed in a pre-calibration or mapping process. In a clinical environment, dynamic electromagnetic distortion can be caused for example by a C-arm which may be centered around the patient and may be rotated and/or moved during procedure. Inside a tracked endoscope (or other tubular device), tools made of magnetic metals may be introduced into the endoscope's working channel and may create dynamic electromagnetic distortion while they are moved and manipulated inside the endoscope's working channel. Such tools may be for example: biopsy tools (such as forceps, needles, cytology brushes); endoluminal ultrasound devices (such as REBUS, IVUS); other endoluminal imaging (such as OCT and spectroscopy devices); ablation devices (such as RF probes, Microwave probes, cryoablation devices, drug delivery needles and probes, brachytherapy devices and seeds, laser and light fiber optics); stents and stent placement tools; clot and foreign-object retrieval tools (such as mechanical baskets, electronic devices, suction microcatheters); embolization devices (such as coils, catheters, and aneurism management devices); fiducials and their placement mechanisms; flexible endoluminal surgical tools; lithotripsy and other types of therapeutic ultrasound devices.

Other forms of dynamic distortion may be caused by electric cauterization. Yet other forms of dynamic electromagnetic distortion may be caused by positioning an EM sensor array in close proximity to metallic or electronic implanted devices, such as pacemakers or electrostimulation devices, orthopedic implants, stents and prosthetics, or dental implants. This dynamic distortion might impact the accuracy of the solved position and orientation of an electromagnetic sensor inside the endoscope. In an endoscopic procedure, this may impact the tracking accuracy of the endoscope during a biopsy or therapeutic process which may impact the yield. It is therefore desired for an electromagnetic tracking system to be highly immune to electromagnetic distortion, especially in a clinical use-case.

As described above, using a standard EM coil-based sensor, the number of wires in the EM tracked device grows linearly with the number of used sensors. For that reason, in most EM tracked devices, a single EM position and orientation sensor is used (usually made of 3 perpendicular EM coils). Using multiple coil-based EM sensors in a single device requires the handling of many wires (for example, 3 twisted-pairs per EM sensor), which can be cumbersome or impractical under certain footprint constraints.

To solve this, and for other reasons, in U.S. Patent No. 11,712,309 an EM curve sensor is disclosed comprising a sensor array, made of a plurality of discrete sensor elements. Each sensor element may be an SMT 3D digital magnetometer, assembled on a Flexible Printed Circuit (FPC). While resolving the problem of finite capacity to thread a growing number of wires through limited space, it may nonetheless pose a potential problem of maintaining the mechanical flexibility and desired footprint of a device. To embed the FPC inside an endoscope, or in a working channel tool, special care needs to be considered for electrical and mechanical constraints. For example, if the FPC were to be embedded inside an endoscope’s wall as an elongated straight FPC, the resulting device’s mechanical flexibility and steerability may be impaired due to the FPC’s inability to stretch axially, and even more so – laterally, to allow endoscope bending.

To overcome this, some embodiments of the present disclosure, and more particularly embodiments disclosed in US Provisional Applications No. 63/415,696 and 63/438,583, include a helix winding of the FPC in a catheter, e.g., wrapping of the FPC helically inside an endoscopic catheter or an endoscope’s shaft, around the endoscope’s working channel. The helical FPC is then able to bend in all directions, surmounting the FPC’s inability to stretch. In other embodiments, as described herein, an FPC containing EM sensor array may be twisted about its own axis to create flexibility of the twisted FPC in all axes.

It will be appreciated, that throughout the present description, the term “curve” means a shape along with a position in space, i.e., a shape that is localized in space in a known frame of reference, for example a shape that is localized in space in a known stationary frame of reference, for example in a frame of reference of a stationary magnetic field transmitter. However, the term “curve” may also mean a shape without position information in space, such as a shape which is being sensed by a fiber-optics shape sensor. In this case position information may be optionally added by using a single EM sensor at the device’s tip, or by proximally anchoring the shape sensor to a mechanical reference of known coordinates in space.

The invention relates to a working-channel tool and methods for manufacturing thereof, for example a working-channel tool for catheter and/or endoscopic interventional procedures.

In some embodiments, the working-channel tool is used to enable curve tracking of existing endoscope devices, for example, endoscope devices which do not have shape tracking or only have partial tracking (such as single-point EM tracking), or do not have shape and/or position tracking at all. These endoscope devices can be for example, manual bronchoscopes used in lung procedures, guided/non-guided robotic endoscopic systems, which may only have single-point EM tracking at their distal end, or which may have fiber-optic relative shape sensing, without information about the accurate position of the tracked relative shape, or which may not be tracked at all (such as standard image-only manual or robotic endoscopes).

In some embodiments, by introducing a working-channel tool, as disclosed herein, into the working channel of existing devices, these devices are enhanced by the added curve tracking capabilities of the introduced working-channel tool and navigated using curve tracking based navigational software and algorithms to specific locations inside organs. In some embodiments, by combining deformation-based navigational software and algorithms, the working-channel tool is then able to transform any existing endoscopic device into a navigable device with superior accuracy inside the anatomy. For example, one possible application may be the guidance of a thin bronchoscope to a peripheral lung lesion, for biopsy and/or localized treatment. In some embodiments, for example, deformation-based navigational software and algorithms use the tracked shape and/or position of the working-channel tool to model the deformation and/or breathing of an organ and tracking it in real-time during procedure. In some embodiments, by tracking the deformation of the organ, real-time deformable and/or breathing registration of the organ is achieved and used during procedure, such that the endoscope device (the working channel tool and/or the endoluminal device into which the working-channel tool is inserted) is accurately localized and navigated inside the luminal structure, which is enabled by the working-channel tool.

In some embodiments, the working-channel tool also serves as a working-channel biopsy and/or therapeutic instrument, such as a forceps, needle, brush, REBUS, ablation or other suitable device. For example, the working-channel tool may be a curve-tracked forceps device (either a custom-built device or an existing off-the-shelf forceps device with wrapped EM shape sensors) which has both shape and/or position sensors as well as biopsy forceps mechanism, and which is curve-tracked during manipulation. In other embodiments, the working-channel tool is a curve-tracked needle, brush or other type of biopsy and/or therapeutic curve-tracked instrument.

In some embodiments, the working-channel tool also has steering capabilities, for example, a steerable curve-tracked needle, forceps or brush instrument. In some embodiments, a steerable working-channel tool (biopsy and/or therapeutic instrument) is used to both provide navigation capabilities to the carrier endoluminal device (into working channel of which it is inserted) as well as being navigated during its interaction with a target (such as a needle). In some embodiments, the steerable working-channel tool is inserted into the working channel of a non-tracked endoscopic device. In some embodiments, the shape and/or position of the endoscope is tracked by the inserted working-channel tool and the endoscopic device is navigated to a lesion using deformable and/or breathing registration algorithms based on the tracked curve of the working-channel tool and a preoperative CT scan of the patient. When reaching a lumen which is close to the target (for example, an airway which is 3mm or 1cm or 2cm close to a target lesion in the lung), the working-channel tool is then pushed further outside of the working channel of the endoscopic device and towards the target lesion, potentially penetrating the tissue, while still being curve-tracked. In some embodiments, using the tool's tracked curve, the deformation of the organ is tracked in real-time to provide real-time deformable and/or breathing registration of the organ and the working-channel tool is steered and guided by the system towards the target lesion and during the interaction with the lesion. In some embodiments, this provides real-time tracking and guidance of the working-channel tool during its interaction with the target. Without real-time tracking of the working-channel tool the working-channel tool is usually manipulated for example under fluoroscopy, which may be inaccurate since it only provides a 2D projection, and also since the target (such as a lesion) is usually invisible under standard fluoroscopy, and exposes both the patient and the physician to potentially harmful X-ray doses. Additionally, with a steerable working-channel tool, the working-channel tool can be manipulated robotically and drive accurately to a target lesion by closing the loop between the tracked curve of the working-channel tool and the robotic drive mechanism. In some embodiments, the working-channel tool contains pull-wires which enable steering of the tip of the working-channel tool, to make the working-channel tool steerable. In some embodiments, the pull-wires may be manipulated by a manual lever which exists in a proximal handle which is attached to the working-channel tool, or can be robotically manipulated through a proximal interface which is attached to the working-channel tool. In some embodiments, the working-channel tool may not be steerable, and the working-channel tool may be guided to a target by steering the endoscopic device during the insertion of the working-channel tool based on the working-channel tool's tracked curve, thus affecting the working-channel tool's insertion direction such that the working-channel tool will eventually reach the target. In some embodiments, this is done robotically by closing the loop between the working-channel tool's tracked curve and the endoscope's steering. In other embodiments, this is done manually where the physician steers the endoscopic device (for example, using a lever) based on the working-channel tool's tracked curve relative to a target, as being displayed on a system display.

In some embodiments, the working-channel tool includes embedded electrical components, as well as a Flexible Printed Circuit (FPC). In some embodiments, the working-channel tool includes a sensor array which comprises discrete sensing elements assembled on an FPC. In some embodiments, the FPC may be manufactured in many configurations, such as a straight elongated FPC, or as a spiral FPC which is unpacked and opened in an assembly process. In some embodiments, the plurality of electromagnetic sensing elements are optionally assembled in known intervals along the FPC. Preferably, at least one of the electromagnetic elements is positioned in proximity to the distal end of the working-channel tool, to enable tracking of the working-channel tool's tip. In some embodiments, the FPC further contains shielded conductors, for example for the electromagnetic sensing elements and/or for a digital or analog endoscopic camera. In some embodiments, signals from the plurality of sensing elements, and optionally from a camera, co-exist on the same FPC, for example in multiple different layers, or in two separate FPCs which may be glued or positioned together. In some embodiments, the FPC is covered with a protective jacket, for example a polymer protective jacket. In some embodiments, the jacket provides biocompatibility, which can potentially reduce the risk of damage to patient tissue and potentially enhances mechanical properties, such as pushability, and/or may protect the tool from moisture or fluids. In some embodiments, in cases where the working-channel tool does not comprise a biopsy and/or therapeutic instrument (such as forceps, brush or needle, or an ablation mechanism), the tip of the working-channel tool is rounded and/or covered with a dome. In some embodiments, a potential advantage of this rounding is that it may potentially reduce the risk of damaging patient tissue or the inner wall of the working channel as the working-channel tool is inserted through, as well as facilitate easier passage over obstacles, steps or other changes in the inner diameter of the working channel. In some embodiments, the polymer jacket is further reinforced, for example using metallic coil or braid embedded in the polymer jacket, to improve mechanical properties such as durability and pushability.

In some embodiments, additionally, the jacket and/or dome may provide a thin and/or unified cross-section, for example suitable for insertion through a working channel of a catheter and/or an endoscopic device.

In some embodiments, the working-channel tool includes a handle for ergonomic grip. In some embodiments, this handle includes mechanisms for fixing the handle to the endoscopic device it is inserted into. In some embodiments, such fixings are configured for preventing axial, rotational, or axial and rotational motion of the working-channel tool relative to the endoscopic device into which it is inserted. In some embodiments, such axial fixings generate positional alignment between the working-channel tool and the endoscopic device therefore the curve measured by the working-channel tool directly corresponds to the curve of the endoscopic device it is inserted into, while rotational fixing maintains alignment of the camera roll between the camera of the working-channel tool and the endoscopic device into which it is inserted, in case both include camera sensors. In some embodiments, such fixing mechanisms are adjustable to allow for fixing in different positions as desired by the user, or to different tools, for example to different endoscopic device models. In some embodiments, the handle of the working-channel tool contains one or more levers to manipulate pull-wires inside the working-channel tool to allow steering of the tip of the working-channel tool or distal bending section. In some embodiments, a potential advantage of this is that it may be useful in the case of a steerable working-channel tool, for example, to navigate the working-channel tool to a target lesion. In some embodiments, the handle of the working-channel tool is an interface which mounts onto a robotic drive mechanism. In this case, the working-channel tool can be manipulated robotically and may also be steered robotically, for example, using robotic motors mechanism which may manipulate pull-wires of the working-channel tool. In some embodiments, the working-channel tool is pushed or pull manually or robotically into the working channel of the endoscopic device.

In some embodiments, the working-channel tool is fixed relative to the endoscopic device’s tip, such that there is a known transformation (e.g., roll) between the working-channel tool’s tracked tip and the endoscopic device’s tip. For example, there is a known roll angle between the working-channel tool’s camera and the endoscopic device’s camera, or between the working-channel tool’s tip and the endoscopic device’s steering wires. In some embodiments, by knowing the transformation between the working-channel tool’s tip and the endoscopic device’s steering wires, the endoscopic device can then be robotically steered based on the working-channel tool’s tracked shape and/or position. In some embodiments, the working-channel tool’s tracked shape and/or position are used to determine the necessary steering actions to apply to the endoscopic device, based on a known transformation between the working-channel tool’s tip coordinate system and the endoscopic device’s steering wires coordinate system. This is made possible, according to some embodiments, by fixing the working-channel tool’s tip relative to the endoscopic device’s tip using a mechanical fixture, to ensure that the transformation between the working-channel tool’s tip and the endoscopic device’s tip (or steering wires, or camera) does not change during the procedure.

In some embodiments, the working-channel tool includes features that keep it centered inside the working channel of the endoscopic device it is inserted into, for example a set of rings or sleeve(s) that are assembled over the polymer jacket to fill the gap between the jacket and the inner diameter of the working channel of the endoscopic device. In some embodiments, these rings or sleeves are applied locally, for example specifically over the electromagnetic sensors, over a long portion of the working-channel tool, for example over the entire curve-sensing section, or over the entire length of the working-channel tool. In some embodiments, these centering features are required to match different working channel diameters, therefore they are flexible, or rigid and provided in different shapes and sizes. In some embodiments, these centering features are removable or incorporated in the polymer casing of the working-channel tool. In some embodiments, keeping the working-channel tool centered relative to the working channel of the endoscopic device is potentially beneficial in order to track the center of the working channel of the endoscopic device and/or in order to avoid dynamic movement of the working-channel tool relative to metals in the endoscopic device, for increased EM accuracy as described herein.

In some embodiments, the working-channel tool includes additional sensing elements other than electromagnetic, for example inertial gyroscopes and/or accelerometers. In some embodiments, readings from such sensing elements are used to further reduce the noise and improve the accuracy of the curve sensing. In some embodiments, such sensors are used to track the rotation of the working-channel tool relative to earth’s gravity and help align the camera sensor’s image with real world frame of reference. In some embodiments, the FPC’s distal end further contains a camera. In some embodiments, the camera is spatiality manipulated, such as through folding, and positioned at the working-channel tool’s tip as part of the assembly process. In some embodiments other sensing elements may be added to the working-channel tool, for example temperature sensing elements. In some embodiments, the working-channel tool contains combined sensing elements, such as magnetic and temperature sensors in a single IC chip. In some embodiments, the magnetic and temperature sensor is a digital IC chip. In some embodiments, the sensor is a DC magnetometer with optional combined temperature sensing capabilities.

In some embodiments, the provided working-channel tool includes a fiber-optics shape sensor to track the relative shape of the working-channel tool. In some embodiments, position information is obtained by adding one or more EM sensors along the working-channel tool, for example, a single EM sensor at the working-channel tool’s tip, or by proximally anchoring the working-channel tool or the entire endoscopic device to a mechanical anchor reference point.

In some embodiments, the working-channel tool includes a plurality of electromagnetic sensor elements along its length and may be inserted into a camera-equipped endoscopic device, thus, for example, adding curve-tracking to the endoscopic device.

In some embodiments, the working-channel tool includes a plurality of electromagnetic sensor elements along its length, and optionally with a camera at the working-channel tool's distal end, and, for example, the working-channel tool is configured be inserted independently, without an endoscopic device or another catheter into a body lumen, for example, for an examination of the body lumen with full-curve tracking and localization, and optionally with visual information. In some embodiments, for example, one or more working-channel tools are inserted using one or more sheaths. In some embodiments, multiple working-channel tools are inserted to multiple body lumens, for example, to track the organ's deformation in real-time, for example, for surgical procedures, such as laparoscopic procedures.

In some embodiments, the working-channel tool is configured to be guided in a lumen, for example a lumen that has multiple bifurcations, and/or may be configured for enabling selection between possible branches of the lumen, into which the working-channel tool should proceed.

In some embodiments, the working-channel tool includes a reinforcing layer and/or coating, for example to improve torqueability of the working-channel tool.

In some embodiments, a certain section at the tip of the working-channel tool may have a certain shape, for example, a curve, to facilitate directing and/or guiding of the tool.

In some embodiments, the working-channel tool is shaped as a J-catheter.

In some embodiments, the working-channel tool comprises pull-wires to provide steerability capability, and the probe can then be steered and navigated inside a lumen structure (with or without a carrier endoluminal device) by manipulating the working-channel tool's pull-wires, either manually (for example, using levers in the device's handle) or robotically (for example, through a robotic mount interface).

In some embodiments, multiple working-channel tools are inserted into an organ, for example, to different airways and lobes inside a patient's lung. In some embodiments, the lung's deformation and/or breathing can then be tracked in real-time based on the tracked curves of the multiple working-channel tools. In some embodiments, the lung's tracked deformation and/or breathing can be used during a laparoscopic procedure, to track the lung as it is being manipulated during a laparoscopic procedure. In some embodiments, features such as blood vessels, airways or lesions of the organ can be displayed (for example, overlayed) on a laparoscopic camera during a laparoscopic procedure based on the deformation tracked organ, based on the curve-tracked working-channel tools inside that organ. In some embodiments, one or more inserted working-channel tools can then serve as a real-time tracked structured skeleton of an organ. In some embodiments, one or more working-channel tools are inserted into an organ in an endoscopic or endovascular procedure. For example, one or more working-channel tools are inserted into a patient’s lung to provide real-time deformable and/or breathing registration of that lung. Additionally, an endoscopic device can then navigate in that lung based on the real-time deformable and/or breathing registration of the lung, with improved accuracy inside the deforming and/or breathing anatomy, based on the data received from the inserted working-channel tools.

In some embodiments, a camera is installed at the tip of the working-channel tool, aligned with the direction of the longitudinal axis and/or the progress axis of the working-channel tool. For example, the FPC is bent at the distal end of the working-channel tool, orthogonally to the longitudinal axis of the working-channel tool, and the camera is then installed on the bent portion, so as to face towards the progress direction of the working-channel tool. In some embodiments, the camera circuit is manufactured separately and then attached to the distal end of the FPC and/or connected electrically to the FPC, for example by soldering of electrical wires.

In some embodiments, the FPC is manufactured in a flat spiral form and then opened and straightened for assembling of the working-channel tool. In some embodiments, the FPC is twisted about its longitudinal axis, for example in order to enable bending of the working-channel tool in all directions. In some embodiments, the working-channel tool may be reinforced, for example, by additional material layers under components of the tool such as, for example, magnetic sensors, a camera, and/or LEDs, for example in order to protect the assembly/soldering of these components to the PCB, especially in case of twisting of the working-channel tool.

In some embodiments, the FPC is wrapped around a tube, to provide bending flexibility in all directions. In some embodiments, the tube may be open to allow further insertion of smaller working channel tools through the working-channel tool. In some embodiments, the tube is braided. In some embodiments, the tube is inserted into a larger outer-diameter endoscope (endoscopic device) and serve as the endoscopic device’s working channel. In this case, the inserted working-channel tool then serves as the endoscopic device’s working channel, while adding shape and/or position tracking capabilities to the endoscopic device. In some embodiments, the working-channel tool is manufactured as a subassembly of the endoscopic device, and the endoscopic device and the embedded working-channel tool serve as a single device/system, where the working-channel tool is fixed inside the endoscopic device. In some embodiments, the working-channel tool is fixed at the endoscopic device’s distal tip and/or at the proximal end of the endoscopic device. In some embodiments, manufacturing of the working-channel tool as a subassembly simplifies the construction of a shape and/or position tracked endoscopic device, by building the shape and/or position of the tracked working-channel tool independently of the endoscopic device. In this case, the working-channel tool no longer serves as an insertable tool into a larger outer-diameter endoscopic device, but rather as a static subassembly of an endoscopic device, which provides both the working channel for that endoscopic device as well as adding shape and/or position tracking capabilities for that endoscopic device.

In some embodiments, the working-channel tool is assembled by using at least two FPCs, one holding electromagnetic sensor elements and carrying their signals back to a processor/controller, and the other carrying a camera and a LED, carrying the camera signals back to the processor/controller. In some embodiments, the two FPCs are assembled (for example, glued) one on top of the other. In some embodiments, the electromagnetic sensor elements, the camera and the LED are assembled on a single FPC, for example on different layers, which carry their signals to the processor/controller. In some embodiments, the working-channel tool's components are assembled on one side of a FPC, and then the FPC is twisted and/or bent as required. In some embodiments, the working-channel tool includes a mount or fixture, made from rigid material such as polymer or metal, upon which the FPC is bent in an accurate manner, and, for example, the camera is then accurately positioned.

In some embodiments, the distal end of the working-channel tool is rounded to minimize tissue and working channel damage. In some embodiments, tip rounding is implemented by adhesive, molded polymers or metallic material. In some embodiments, the rounding at the distal end forms a dome. In some embodiments, tip rounding is also configured for protecting the working-channel tool's components. In some embodiments, tip rounding is also configured to serve as camera fouling protection mechanism.

Additionally, the invention relates to methods for full curve-tracking of a working-channel tool for catheter and/or endoscopic interventional procedures. In some embodiments, some methods use virtual auxiliary curve points between sensor elements of the working-channel tool, and/or include solving of the partial or entire curve of the working-channel tool with a unified energy function, based on mechanical constraints. In some embodiments, such methods constitute a solution to insufficiently accurate curve estimations. As mentioned above, inaccurate curve estimations may be resulted from noisy or faulty measurements by the sensors, from magnetic field distortions and/or from large distances between the sensors on the working-channel tool, that prevent sufficient curve interpolations. In some embodiments, by solving the partial or entire curve of the working-channel tool using mechanical constraints, the noise levels of the tracked curve solution are decreased, which allow reducing the strength of the generated EM fields, as explained in more detail herein. In some embodiments, by solving the partial or entire curve of the working-channel tool using mechanical constraints, the accuracy of the tracked curve solution is increased, even in cases where significant EM distortion is present.

In some embodiments, where the curve estimation is based on individual calculations of location and orientation for each sensor element, it is difficult for the previous methods to incorporate constraints that relate to the entire curve of the working-channel tool. In some embodiments, methods provided herein solve such issues, by solving the partial or entire curve and/or location of the working-channel tool based on measurements from multiple sensors, while taking into account various constraints that reduce the resulting curve inaccuracies, as explained in more detail herein.

Referring now to Figure 1, showing a schematic representation of a system **100** for full curve-tracking of a working-channel tool **20**, according to some embodiments of the invention.

In some embodiments, a working-channel tool **20** is configured to be used within a working-channel of a catheter and/or an endoscopic device in endoscopic interventional procedures. In some embodiments, an exemplary system **100** comprises one or more of: a processor/controller **10**, a transmitter **12** of electromagnetic fields and a curve sensor **16**, which is installed on or inside the working-channel tool **20**. In some embodiments, the working-channel tool **20** is configured to be bent to various positions and shapes, which are sensed by the curve sensor **16**. In some embodiments, the curve sensor **16** is configured to detect and/or sense magnetic fields in multiple locations along the tool **20**, for example magnetic fields produced by transmitter **12**. In some embodiments, the system **100** includes an endoscopic interventional device **11** (referred hereinafter just as endoscopic device **11**) having a flexible shaft **15** (or elongated body), in which the working-channel tool **20** is inserted, for example via an opening **22**. In some embodiments, the curve sensor **16** includes an array of sensor elements **18**, which sense electromagnetic field values, based on which a curve, i.e., a shape and/or a position of the working-channel tool **20** is algorithmically fitted by the processor/controller **10**, relative to the transmitter **12**. In some embodiments, the curve sensor **16** includes a camera **19**, positioned for example at a distal end of the curve sensor **16** and the working-channel tool **20**.

In some embodiments, the processor/controller **10** includes a FPGA/ASIC chip, which samples the curve sensor **16** and/or the sensor elements **18** and/or the camera **19**. Then, the processor/controller **10** is configured to transmit the sensor(s) and/or camera data digitally to a host computer (not shown), for example by Universal Serial Bus (USB). In some embodiments, processor/controller **10** is located inside a handle (or robotic mount interface) **21** of the working-channel tool **20**. In some embodiments, the processor/controller **10** is configured to calculate the curve/shape of the working-channel tool **20** and transmit it to a host computer (not shown).

In some embodiments, during operation, the working-channel tool **20** is configured to be inserted into a body lumen while the transmitter **12** generates magnetic fields. In some embodiments, the flexible shaft **15** is positioned inside the body lumen, and the working-channel tool **20** is inserted into the flexible shaft **15**. In some embodiments, the curve sensor **16** is configured to detect and/or sense local magnetic fields along the working-channel tool **20**. In some embodiments, the processor/controller **10** is configured to calculate a curve/shape of the tool **20**, and in some embodiments, a position of the tool **20** relative to the transmitter **12**. In some embodiments, the transmitter **12** is a flat transmitter which resides under the patient's mattress or bed, or a standalone box which is located for example sideways to the patient.

Reference is now made to Figs. 2A-2H, which are schematic illustrations of a tool assembly **200**, included in a working-channel tool **20** (shown, for example, in Fig. 1), and configured for enabling full curve/shape tracking thereof, according to some embodiments of the invention.

In some embodiments, the tool assembly **200** comprises one or more of a Flexible Printed Circuit (FPC) **30**, a plurality of discrete sensing elements **38** (**18** in Figure 1), for example magnetic field sensing elements, which together define a sensor array, which is assembled on the FPC **30**. In some embodiments, the FPC **30** can be manufactured in many configurations, such as a straight elongated FPC or as a spiral FPC, which is unpacked and opened in an assembly process (as shown in US Provisional Application No. 63/415,696).

In some embodiments, the sensing elements **38/18** are installed on the FPC **30**, for example in known intervals along the FPC **30**. Preferably, at least one sensing element from the plurality of sensing elements **38/18** is positioned in proximity to or upon a distal end **31** of the FPC **30**. In some embodiments, a camera **40** and a LED **41** are installed at the distal end **31**, for example on a camera support **34** in the FPC **30**. In some embodiments, the camera support **34** is configured to be spatiality manipulated, as part of the assembly process, through folding in a fold **32**, to position the camera **40** at the tip of the tool assembly **200** facing the progress direction of the working-channel tool **20**. It will be appreciated that other forms of folds are possible under various embodiments of the present disclosure, for example so as to position the camera **40** at the tip of tool assembly **200** facing the progress direction **"A"** of the working-channel tool **20**.

In some embodiments, more than one camera is installed. For example, two cameras can be assembled on the FPC and wired through the FPC to a controller. In some embodiments, a potential advantage of using two cameras is that it allows the generation of a stereoscopic image and/or wide-angle image, which may be beneficial in endoscopic procedures. In some embodiments, multiple cameras can share a same clock signal. In some embodiments, the working-channel tool **20** does not comprise a camera at all, and is only curve/shape tracked. A potential advantage of not installing a camera is that it potentially reduces the manufacturing price and complexity of the manufacturing process.

In some embodiments, the working-channel tool **20** comprises an inner working channel (not shown). In some embodiments, the working-channel tool **20** with the inner working channel is inserted into a larger working channel of an endoscopic device in order to enhance the endoscopic device with shape sensing/curve tracking capabilities, while still providing an inner working channel allowing for example flushing, suction and insertion of small-diameter tools, such as smaller biopsy and/or therapeutic instruments.

In some embodiments, the working-channel tool **20** with an inner working channel serves as a subassembly and is inserted into a larger outer-diameter endoscope (endoscopic device) in an assembly process. In some embodiments, the working-channel tool can be fixed to the larger outer-diameter endoscopic device on its proximal and/or distal end. In some embodiments, the working-channel tool adds shape and/or position tracking of the larger outer-diameter endoscopic device and potentially simplifies the manufacturing and assembly process of the integrated shape and/or position tracking endoscopic device.

In some embodiments, the working-channel tool **20** comprises a mount **50**, as shown for example in Figure 2D, onto which a distal portion of the FPC **30**, optionally comprising the camera **40** and/or the LED **41** are positioned in a stable and desired manner. In some embodiments, the mount **50** is designed and/or comprises a geometry that facilitates the bending of the FPC **30** in an accurate/desired manner, and, for example, allowing the accurate and stable positioning of the camera **40**. In some embodiments, the mount **50** comprises a platform **52**, a wall **53**, and a slot **51**. In some embodiments, the slot **51** is positioned between the platform **52** and the wall **53**. In some embodiments, the distal end **31** of the FPC **30** is inserted in the slot **51**. In some embodiments, the platform **52** and a side of the wall **53** define a niche at which a sensor element **38/18** is optionally installed, optionally without extending vertically past the wall **53**. In some embodiments, a side of the platform **52** is optionally configured to support the camera **40** and, for example, position the camera **40** perpendicularly to the progress direction **“A”** of the tool **20**, i.e., so as to face the progress direction **“A”** of the working-channel tool **20**. In some embodiments, the FPC **30** is bent over a side of the platform **52** at the distal end of the working-channel tool **20**, orthogonally to the longitudinal axis of the working-channel tool **20**, and the camera **40** is installed on the bent portion, i.e., the camera support **34**, so as to face towards the progress direction **“A”** of the working-channel tool **20**. In some embodiments, the camera support **34** is manufactured separately and is attached to the distal end **31** of the FPC **30** and/or connected electrically to the FPC **30**, for example by soldering of electrical wires.

In some embodiments, as shown for example in Figs. 2D-2H, the FPC **30** is twisted about its longitudinal axis. In some embodiments, a potential advantage of twisting the FPC **30** is that it allows bending of the working-channel tool **20** in all directions, optionally without damaging the FPC **30**. In some embodiments, the FPC **30** is optionally reinforced, for example, by adhering additional material layers **33** under components such as, for example, the sensing elements **38/18**, the camera **40**, and/or the LED **41**, for example in order to protect the attachment of these components to the FPC **30**, especially in case of twisting of the working-channel tool **20**. In some embodiments, the reinforcing materials may include polymer, for example polyimide, which is commonly used in FPC manufacturing, or metallic, for example aluminum.

In some embodiments, the FPC **30** is wrapped around a core, mandrel, fiber, or other substrate. In some embodiments, such core is either hollow or full. In some embodiments, one potential advantage of using a core is to potentially simplify the assembly process and/or increase the bending radius of the FPC compared to twisting the FPC along its axis.

In some embodiments, the working-channel tool **20** is assembled by using at least two FPCs **30**, one holding the sensing elements **38/18** and carrying their signals back to the processor/controller **10**, and the other holding the camera **40** and the LED **41**, carrying the camera signals back to the processor/controller **10**, shown for example in Figure 1. In some embodiments, the two FPCs are assembled one on top of the other. In some embodiments, the sensing elements **38/18**, the camera **40** and the LED **41** are assembled on a single multi-layer FPC (for example, 2-layer FPC, 4-layer FPC), which carry their signals to the processor/controller **10**. In some embodiments, the components of the working-channel tool **20** are assembled on one side of the FPC **30**, and then the FPC **30** is twisted and/or bent as required.

In some embodiments, the FPC **30** is covered with a protective jacket **60**, for example a polymer protective jacket and/or a dome. In some embodiments, the jacket and/or dome provides biocompatibility, reduces risk of tissue damage, enhances mechanical properties, such as pushability, and/or protects the tool and its electric components from moisture or fluids. In some embodiments, the jacket and/or dome provides a thin and/or unified cross-section, for example suitable for insertion through a working a channel of a catheter and/or an endoscope. In some embodiments, the distal end of the working-channel tool **20** is covered by a dome or another rounded shape cover **61**. In some embodiments, the dome or another rounded shape cover **61** is configured to protect the working-channel tool's components and/or to protect the body lumen and/or the working channel in which the working-channel tool **20** is inserted.

Exemplary methods

In some embodiments, the invention relates also to methods for full curve/shape-tracking of a working-channel tool for catheter and/or endoscopic interventional procedures.

In some embodiments, as mentioned before, the sensing elements **38/18** are each configured to sense transmitted magnetic fields. For example, the transmitter **12** (shown in Fig. 1) may transmit multiple magnetic fields with known frequencies and intensities. In some embodiments, a shape/position of a working-channel tool **20** may be estimated by finding the position and/or orientation of each sensing element **38/18** individually, according to the sensed magnetic fields, and fitting a curve through all locations of the sensing elements **38/18** along the working-channel tool **20**, for example, such as spline interpolation and/or extrapolation methods. As described herein, such methods may incorporate errors and may have low accuracy and/or increased jitter due to distorted EM fields, interference and sensor noise.

For example, the transmitter **12** may include N_c coils to generate corresponding N_c different magnetic fields with different frequencies, and the working-channel tool **20** may include N_x sensing elements **38/18**. In various embodiments, the transmitter **12** may include other means to generate different magnetic fields, such as, for example, various formations of rotating magnets. The theoretical resulting magnetic field X_i which is expected to be sensed at the location and orientation of the sensor i is

$$X_i = R_i^T B(\vec{r}_i)$$

Wherein R_i is the three-dimensional orientation of the sensor element i with respect to the transmitter **12**, and $B(\vec{r}_i)$ are the generated magnetic fields (transmitted at different phases or frequencies), as matrix columns, at the three-dimensional location $\vec{r}_i$ of the sensor element i with respect to the transmitter **12**. For each of the N_x sensor elements, estimated six-dimensional values of location and orientation (for example, specified as three Euler angles) may be found by minimizing an energy function E_i, that depends on the difference between the resulting modeled magnetic field X_i and the measured magnetic field X_i^{measured} by the sensor element i. For example, E_i may have the form:

$$E_i = \frac{1}{2}\left|R_i^T B(\vec{r}_i) - X_i^{\text{measured}}\right|^2$$

In some embodiments, X_i^{measured} may be a calibrated version of the raw measured fields, for example, by applying transmitter and/or receiver calibration matrices to the raw measured fields to account for static transmitter and/or receiver distortion, or to account for intrinsic non-calibrated sensor gains or for any other reason.

After the five/six-dimensional locations and orientations (five degrees of freedom in cases where the "roll" degree of freedom is not measured/solved, resulting in one less Euler angle) are found for the sensing elements **38/18**, a curve may be fit to pass through all the sensing elements. However, such a curve may be insufficiently accurate, or the solution may be noisy. First, the found locations and orientations of the sensing elements may be erroneous, because of noisy or faulty measurements by the sensing elements and/or because of magnetic field distortions, for example distortions caused by metal in the flexible shaft **15**, into which the working-channel tool **20** may be inserted, or by metals outside of the flexible shaft **15**. Second, without further constraints, the curve shapes between the sensing elements **38/18**, which may be interpolated arbitrarily and/or based on some predetermined assumptions, may be incorrect. Therefore, the fully calculated curve of the working-channel tool **20** may have illogical properties. For example, the total length of the curve may not match the known length of the working-channel tool **20** from manufacturing or from calibration of the working-channel tool **20**, or the solved curve may not be smooth enough, although it is known that the working-channel tool **20** is generally smooth due to its mechanical properties or due to the mechanical properties of the endoscopic device. Such constraints that relate to the entire curve/shape are not considered in the above calculation, since the position and orientation values for each sensor are solved separately.

In order to solve such issues, some embodiments of the present disclosure provide a method for solving the entire curve and/or location of the working-channel tool **20**, while considering various constraints that may reduce the resulting curve/shape inaccuracies.

Reference is now made to Fig. 3, which is a schematic representation **70** of a tracked portion of the working-channel tool **20**, according to some embodiments of the invention. The schematic representation **70** represents dynamic position and/or a curve of the tracked portion **72** of the working-channel tool **20**. The schematic representation **70** shows sensor points **78**, representing locations of sensing elements **18/38** along the working-channel tool **20**, and/or located in known locations and/or intervals along the tracked portion of the working-channel tool **20**. Additionally, between every two adjacent sensing elements **18/38**, represented by points **78**, there may be a pre-determined amount of virtual auxiliary curve points **76**, at predetermined locations and/or intervals along the schematic representation **70**. Curve points **76**, along with sensor representation points **78**, are used for calculation of a curve and/or position of the tracked portion of the working-channel tool **20**.

Reference is now made to Fig. 4, which is. In some embodiments, the shape and/or position of the working-channel tool **20** is tracked dynamically by fitting a curve that is the most energetically efficient, based on various constraints. As indicated in block **402**, the processor/controller **10** is configured for obtaining a plurality of pre-known points and/or intervals along a tracked portion of the working-channel tool **20**, such as sensor points **78** and curve points **76** in known intervals. In some embodiments, between every two adjacent sensor elements, represented by points **78**, there are a pre-determined amount of virtual auxiliary curve points **76**, at predetermined locations and/or intervals along the tracked portion of the working-channel tool **20**.

As indicated in block **404**, the processor/controller **10** comprises instructions for allocating, for each sensor point **78**, a local energy function dependent on the position and orientation of the working-channel tool **20** at this point, which incorporates relevant constraints for the point or for the type of point. For example, the energy function for each sensor point **78** may incorporate constraints related to the sensed magnetic field at this point, similarly to E_i discussed herein. In some embodiments, the processor/controller **10** comprises instructions for further allocating a weight for each local energy function, for example based on a certainty value, for example related to a certainty that a measurement is accurate. For example, a measurement value taken by a sensing element **18/38** may have a certain variation along time, according to which a certainty value may be determined.

As indicated in block **406**, the processor/controller **10** comprises instructions for generating a resultant unified energy function for the full shape and/or position of the entire tracked portion of the working-channel tool **20**. In some embodiments, the unified energy function is constructed based on the allocated local energy functions of sensor point **78** and energy functions that relate to constraints related to mechanical properties of the working-channel tool **20**, with respect to relative locations and orientation of curve points **76** and sensor points **78**. For example, each point **76** or **78** may have constraints related to its location and orientation relative to other points **76** and/or **78**, which may be incorporated into energy functions. For example, an energy function E for all N points **76** and **78**, may have the form:

$$E = \sum_{i=1}^{N_x} E_i(\vec{x}_i) + \sum_{j=1}^{N} \sum_{\substack{k=1 \\ k\neq j}}^{N} E_{jk}(\vec{x}_j, \vec{x}_k) + \sum_{j=1}^{N} \sum_{\substack{k=1 \\ k\neq j}}^{N} \sum_{\substack{l=1 \\ l\neq j,k}}^{N} E_{jkl}(\vec{x}_j, \vec{x}_k, \vec{x}_l) + \cdots,$$

Wherein E_i is discussed herein. E_{jk} relates, for example, to mechanical constraints between two points. E_{jkl} relates, for example, to mechanical constraints between three points, etc. $\vec{x}_i$ denote all the degrees of freedom of sensor i. For example, $(\vec{r}_i, q_i)$ in $\mathbb{R}^7$ or $(\vec{r}_i, \theta_i)$ in $\mathbb{R}^6$ for 6-DoF (degrees of freedom) sensors, where q and θ are quaternions and Euler angles representing the orientation, respectively. Examples of mechanical constraints and related energy functions can be found, for example, in provisional patent application No. 63/536,467, titled "DISTORTION MODELING AND COMPENSATION IN A CURVE-TRACKED DETECTOR ARRAY", incorporated herein by reference.

As a complete example, the total energy of the curve may be constructed as

$$E = \sum_i E_i^{\text{track}}(\vec{r}_i, q_i) + \sum_i E_i^{\text{time}}(\vec{r}_i, q_i) + \sum_{i,j} E_{i,j}^{\text{length}}(\vec{r}_i, \vec{r}_j) + \sum_{i,j,k} E_{i,j,k}^{\text{smooth}}(\vec{r}_i, \vec{r}_j, \vec{r}_k),$$

Where i runs over all the sensors, $\{i, j\}$ run over adjacent sensor pairs and the different energies are defined as

$$E_i^{\text{track}}(\vec{r}_i, q_i) = \frac{1}{2}\left|U_i R^T(q_i) B(\vec{r}_i) - X_i^{\text{measured}}\right|^2,$$

$$E_i^{\text{time}}(t) = \frac{W_r}{2}|\vec{r}_i(t) - \vec{r}_i(t - \Delta t)|^2 + \frac{W_q}{2}\left|q_i^{-1}(t) q_i(t - \Delta t) - 1\right|^2,$$

$$E_{i,j}^{\text{length}}(\vec{r}_i, \vec{r}_j) = \frac{W_{\text{length}}}{2}\left(|\vec{r}_i - \vec{r}_j| - L_{i,j}\right)^2,$$

$$E_{i,j,k}^{\text{smooth}}(\vec{r}_i, \vec{r}_j, \vec{r}_k) = \frac{W_{s,x}}{2}(x_i - 2x_j + x_k)^2 + \frac{W_{s,y}}{2}(y_i - 2y_j + y_k)^2 + \frac{W_{s,z}}{2}(z_i - 2z_j + z_k)^2.$$

Δt is the time difference between the current frame and the previous one and $L_{i,j}$ is the distance or length along the probe between sensors i and j, which is known accurately from the mechanical design of the probe and/or from a sterile calibration before the procedure. In $E_{i,j,k}^{\text{smooth}}$, $k = j + 1 = i + 2$, and it was implicitly assumed that the distances between the sensors are uniform, $L_{i,j} = L_{j,k}$, but more complex cases may require a generalization.

In the naïve case of electromagnetic tracking with no external magnetic field distortion, one could take the total energy to be $\sum_i E_i^{\text{track}}(\vec{r}_i, q_i)$ only (by setting $W_r = W_q = W_{\text{length}} = 0$) with no additional constraints and $U_i = 1$ and expect good tracking, up to the sensitivity of the magnetic sensors. This is since the measurements can be explained by the theoretical $B(\vec{r})$ for general $\vec{r}$ around the transmitter with small errors. However, in the present case of a probe inserted into a device which distorts the theoretical magnetic fields around it, it is no longer the case that

$$R_i^T(q_i) B(\vec{r}_i) \approx X_i^{\text{theoretical}}.$$

One possible solution to this problem is the addition of other types of energies ($E_{\text{time}}, E_{\text{length}}, E_{smooth}$) which keep the positions and orientations “sane” even when the measurements cannot be accurately explained by the theory, that is, they keep the solved positions and orientations within the range of plausible solutions under known mechanical constraints (such as length and smoothness constraints). For example, high values of $W_{s,x}, W_{s,y}, W_{s,z}$ tend to decrease the second derivative of $\vec{r}$ along the curve.

The more specific solution which specifically targets a distortion created close to the sensors (as in the case of a tool inserted into the working channel of a magnetic endoscope) consists of correcting the theoretical model to include possible distortions. This comes into the energy through the new term U_i. U_i is a 3×3 matrix per sensor which may, in general, depend on the specific sensor, its location with respect to the working channel and on the external endoscope (also referred to as endoscopic device). This set of matrices can be learned/calculated during a preliminary calibration phase. For example, the working-channel tool **20** may be held in place with respect to the transmitter with no distorter present, such that the “clean” theoretical magnetic field measured by each sensor is known. Then, the distorter (endoscope) is slowly introduced on top of the working-channel tool **20**, and the distorted magnetic fields are measured. The relevant U_i matrices can then be computed directly (no optimization needed) by solving the equation:

$$U_i X_i^{\text{undistorted}} = X_i^{\text{distorted}}.$$

This process is only required once. In addition to distortion immunity (also referred to as tool immunity herein), if the U_i matrices are saved with corresponding timestamps or positions of the working-channel tool **20** along the endoscopic device, working-channel tool position tracking relative to the larger outer-diameter endoscopic device is available to the algorithm. In some embodiments, the “working-channel tool position tracking” algorithm enables tracking and/or display of the working-channel tool’s position inside the endoscopic device’s working channel. In some embodiments, the working-channel tool **20** can then be displayed as it’s introduced into the endoscopic device’s working channel, for example in 3D, since its position inside the endoscopic device’s working channel can be tracked by analyzing the dynamic calibration matrices U_i and comparing them, for example, to pre-calibrated calibration matrices with assigned positions, as described above.

In some embodiments, by using tool immunity algorithms through dynamic U_i calibration matrices, accurate EM tracking of the inserted shape and/or position tracked tool is enabled, overcoming potential inaccuracies due to metals in the carrier endoscope, for example, due to the endoscope’s braid, bending section links, laser cut or other conductive or ferromagnetic metals in the endoscope which may change in position relative to the inserted working-channel tool **20** as it’s being inserted. Without compensating for those metals, the inserted working-channel tool **20** may be inaccurately curve-tracked by the EM tracking system, with an erroneous shape and/or position and/or orientation which might potentially be dependent on its position inside the endoscopic device’s working channel. It is therefore potentially beneficial to learn dynamic U_i calibration matrices (in a supervised or unsupervised manner) to enable tool immunity and potentially also tool tracking in the working-channel tool **20**.

In some embodiments, dynamic U_i calibration matrices can be learned once, for example in a factory calibration process, by inserting the working-channel tool into a larger outer-diameter endoscopic device of a certain configuration and then the learned calibration matrices can be used to compensate for the distortion caused by any endoscopic device. This is possible because endoscopic devices of different configuration generally apply similar type of distortion upon the inserted working-channel tool. This is potentially beneficial as it allows for calibrating the working-channel tool in a factory process, but then use it with any type of larger outer-diameter endoscopic devices.

As indicated in block **408**, the processor/controller **10** comprises instructions for calculating a full localized curve along the tracked portion of the working-channel tool **20**, for example relative to the transmitter **12**. For example, the energy function E may be minimized, so as to minimize the errors with respect to the various constraints incorporated in the function. Then, the resulting equations may be solved for all the locations and orientations of points **76** and **78** along the working-channel tool **20**.

It will be appreciated that in some embodiments of the present disclosure, for example in case the sensor points **78** are sufficiently close to each other, the calculations described herein may be performed based on sensor points **78** with no in-between addition of virtual curve points, or with variable number of virtual curve points in-between different pairs of sensor points **78**.

As used herein with reference to quantity or value, the term “about” means “within ± 10 % of”.

The terms “comprises”, “comprising”, “includes”, “including”, “has”, “having” and their conjugates mean “including but not limited to”.

The term “consisting of” means “including and limited to”.

The term “consisting essentially of” means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular forms “a”, “an” and “the” include plural references unless the context clearly dictates otherwise. For example, the term “a compound” or “at least one compound” may include a plurality of compounds, including mixtures thereof.

Throughout this application, embodiments of this invention may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as “from 1 to 6” should be considered to have specifically disclosed subranges such as “from 1 to 3”, “from 1 to 4”, “from 1 to 5”, “from 2 to 4”, “from 2 to 6”, “from 3 to 6”, etc.; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein (for example “10-15”, “10 to 15”, or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases “range/ranging/ranges between” a first indicate number and a second indicate number and “range/ranging/ranges from” a first indicate number “to”, “up to”, “until” or “through” (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

Unless otherwise indicated, numbers used herein and any number ranges based thereon are approximations within the accuracy of reasonable measurement and rounding errors as understood by persons skilled in the art.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

It is the intent of the applicant(s) that all publications, patents and patent applications referred to in this specification are to be incorporated in their entirety by reference into the specification, as if each individual publication, patent or patent application was specifically and individually noted when referenced that it is to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting. In addition, any priority document(s) of this application is/are hereby incorporated herein by reference in its/their entirety.

WHAT IS CLAIMED IS:

1. An endoscopic system, comprising:

a. an endoscopic device comprising a working channel;

b. a working channel tool configured to be inserted within said working channel of said endoscopic device, said working channel tool comprising:

i. an elongated body comprising a proximal end and a distal end;

ii. one or more Flexible Printed Circuits (FPCs) extending along said elongated body; and

iii. a curve/shape sensor comprising a plurality of sensor elements positioned on said one or more FPCs;

c. one or more transmitters;

d. a controller comprising a processor; said processor comprising instructions for calculating a full localized curve along a tracked portion of said working channel tool, relative to the one or more transmitters.

2. The endoscopic system according to claim 1, wherein said processor comprises further instructions for allocating energy functions dependent on sensed values by the sensor elements at respective points along said working channel tool, the sensed values incorporate relevant constraints.

3. The endoscopic system according to claim 1, wherein said processor comprises further instructions for:

a. obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working channel tool;

b. allocating energy functions dependent on the position and orientation of points along said working channel tool, that incorporate relevant constraints;

c. generating a resultant united energy function for the full shape and/or position of the entire tracked portion of said working channel tool.

4. The endoscopic system according to claim 1, wherein said one or more FPCs are twisted about a longitudinal axis of said elongated body.

5. The endoscopic system according to claim 1, wherein said plurality of sensor elements are positioned at known intervals on said one or more FPCs.

6. The endoscopic system according to claim 1, wherein at least one sensor element from said plurality of sensor elements is positioned at said distal end of said elongated body.

7. The endoscopic system according to claim 1, wherein said working channel tool further comprises at least one LED positioned at said distal end of said elongated body.

8. The endoscopic system according to claim 1, wherein said working channel tool further comprises at least one camera positioned at said distal end of said elongated body.

9. The endoscopic system according to claim 1, wherein said working channel tool further comprises at least one camera support for said at least one camera.

10. The endoscopic system according to claim 9, wherein said at least one camera support is configured to be manipulated during a manufacturing process of said working channel tool.

11. The endoscopic system according to claim 10, wherein said manipulation is folding.

12. The endoscopic system according to claim 11, wherein said folding positions said at least one camera facing distally from said distal end of said elongated body.

13. The endoscopic system according to claim 1, wherein said working channel tool further comprises a second working channel extending within said elongated body.

14. The endoscopic system according to claim 1, wherein said working channel tool further comprises a mount configured to house at least one camera and at least one LED.

15. The endoscopic system according to claim 14, wherein said mount is configured to allow directional positioning of said at least one camera and said at least one LED.

16. The endoscopic system according to claim 1, wherein said one or more FPCs further comprise at least one reinforcement material.

17. The endoscopic system according to claim 1, wherein said one or more FPCs are wrapped around a core, a mandrel or a fiber.

18. The endoscopic system according to claim 17, wherein said core is either hollow or full.

19. The endoscopic system according to claim 1, wherein said working channel tool comprises at least two FPCs, and wherein a first FPC is configured to house said plurality of sensor elements and a second FPC is configured to house at least one camera and at least one LED.

20. The endoscopic system according to claim 19, wherein said at least two FPCs are assembled one on top of another.

21. The endoscopic system according to claim 1, wherein said one or more FPCs are covered with a protective jacket.

22. The endoscopic system according to claim 21, wherein said protective jacket is configured for one or more of:

a. providing biocompatibility to said working tool channel;
b. providing protection to electronic component within said working tool channel;
c. enhancing mechanical properties of said working tool channel; and
d. providing protection to tissues and/or said endoscopic device working channel.

23. The endoscopic system according to claim 21, wherein said protective jacket provides a round shape to said distal end of said elongated body.

24. A working channel tool configured to be inserted within a working channel of an endoscopic device, said working channel tool comprising:

a. an elongated body comprising a proximal end and a distal end;

b. one or more Flexible Printed Circuits (FPCs) extending along said elongated body;

c. a curve/shape sensor comprising a plurality of sensor elements positioned on said one or more FPCs; and

d. a controller comprising a processor; said processor comprising instructions for allocating energy functions dependent on sensed values by the sensor elements at respective points along said working channel tool, the sensed values incorporate relevant constraints, and calculating a full localized curve along a tracked portion of said working channel tool, relative to one or more transmitters.

25. The working channel tool according to claim 24, wherein said processor comprises further instructions for:

a. obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working channel tool;

b. allocating energy functions dependent on the position and orientation of points along said working channel tool, that incorporate relevant constraints;

c. generating a resultant united energy function for the full shape and/or position of the entire tracked portion of said working channel tool.

26. The working channel tool according to claim 24, wherein said one or more FPCs are twisted about a longitudinal axis of said elongated body.

27. The working channel tool according to claim 24, wherein said plurality of sensor elements are positioned at known intervals on said one or more FPCs.

28. The working channel tool according to claim 24, wherein at least one sensor element from said plurality of sensor elements is positioned at said distal end of said elongated body.

29. The working channel tool according to claim 24, wherein said working channel tool further comprises at least one LED positioned at said distal end of said elongated body.

30. The working channel tool according to claim 24, wherein said working channel tool further comprises at least one camera positioned at said distal end of said elongated body.

31. The working channel tool according to claim 24, wherein said working channel tool further comprises at least one camera support for said at least one camera.

32. The working channel tool according to claim 31, wherein said at least one camera support is configured to be manipulated during a manufacturing process of said working channel tool.

33. The working channel tool according to claim 32, wherein said manipulation is folding.

34. The working channel tool according to claim 33, wherein said folding positions said at least one camera facing distally from said distal end of said elongated body.

35. The working channel tool according to claim 24, wherein said working channel tool further comprises a second working channel extending within said elongated body.

36. The working channel tool according to claim 24, wherein said working channel tool further comprises a mount configured to house at least one camera and at least one LED.

37. The working channel tool according to claim 36, wherein said mount is configured to allow directional positioning of said at least one camera and said at least one LED.

38. The working channel tool according to claim 24, wherein said one or more FPCs further comprise at least one reinforcement material.

39. The working channel tool according to claim 24, wherein said one or more FPCs are wrapped around a core, a mandrel or a fiber.

40. The working channel tool according to claim 39, wherein said core is either hollow or full.

41. The working channel tool according to claim 24, wherein said working channel tool comprises at least two FPCs, and wherein a first FPC is configured to house said plurality of sensor elements and a second FPC is configured to house at least one camera and at least one LED.

42. The working channel tool according to claim 41, wherein said at least two FPCs are assembled one on top of another.

43. The working channel tool according to claim 24, wherein said one or more FPCs are covered with a protective jacket.

44. The working channel tool according to claim 43, wherein said protective jacket is configured for one or more of:

a. providing biocompatibility to said working tool channel;

b. providing protection to electronic component within said working tool channel;

c. enhancing mechanical properties of said working tool channel; and

d. providing protection to tissues and/or said endoscopic device working channel.

45. The working channel tool according to claim 43, wherein said protective jacket provides a round shape to said distal end of said elongated body.

46. A method of manufacturing a working channel tool comprising one or more sensor arrays; said one or more sensor arrays comprising one or more Flexible Printed Circuits (FPCs) and a plurality of electronic components positioned on said one or more FPCs; the method comprising helically winding one or more sensor arrays around said working channel tool;

wherein said method comprises positioning said plurality of electronic components along said one or more FPCs so when said one or more sensor arrays are wound around said working channel tool, said plurality of electronic components are aligned in relation to a longitudinal axis of said working channel tool.

47. The method according to claim 46, wherein at least one of the FPCs has a spiral shaped FPC design, and is windable as a helix onto a working channel tool.

48. A method for curve/shape-tracking of a working-channel tool, comprising:

a. obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working-channel tool;

b. allocating energy functions dependent on a position and orientation of points along said working channel tool that incorporate relevant constraints;

c. generating a resultant united energy function for a full shape and/or position of said tracked portion of said working channel tool; and

d. calculating a full localized curve along said tracked portion of said working channel tool, relative to a transmitter.

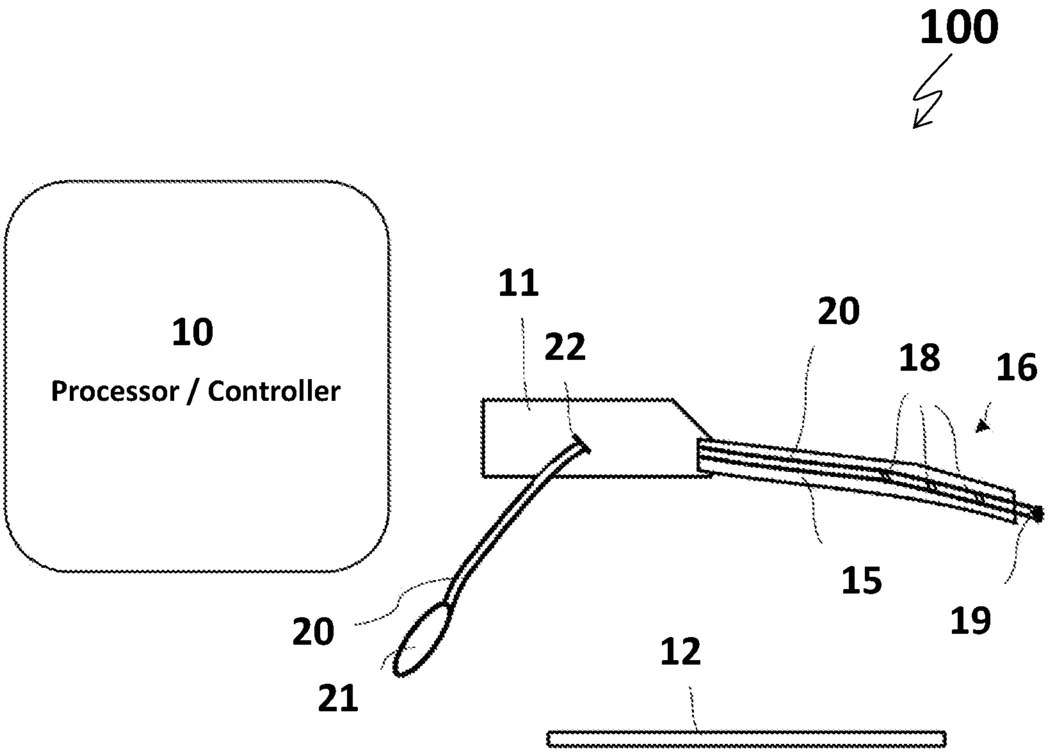

Figure 1

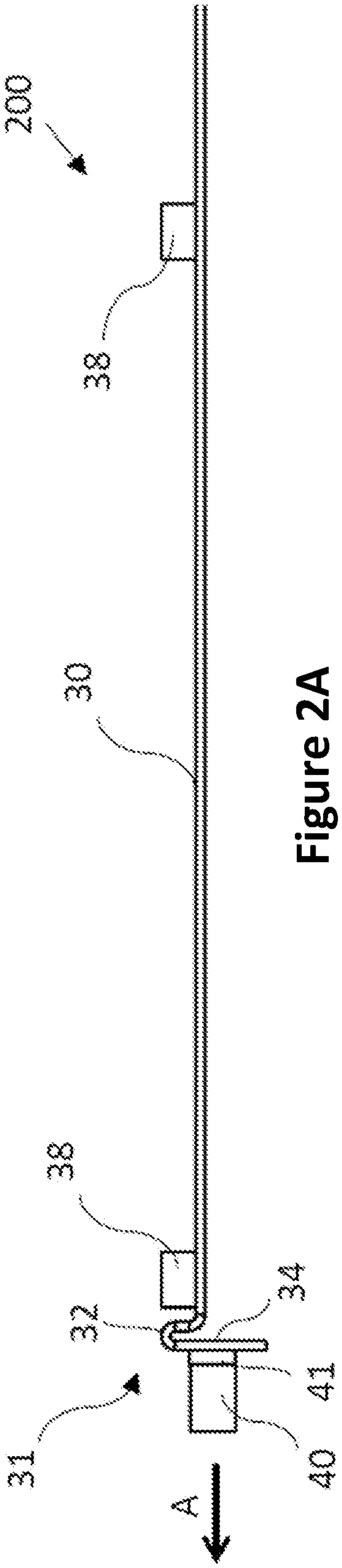

Figure 2A

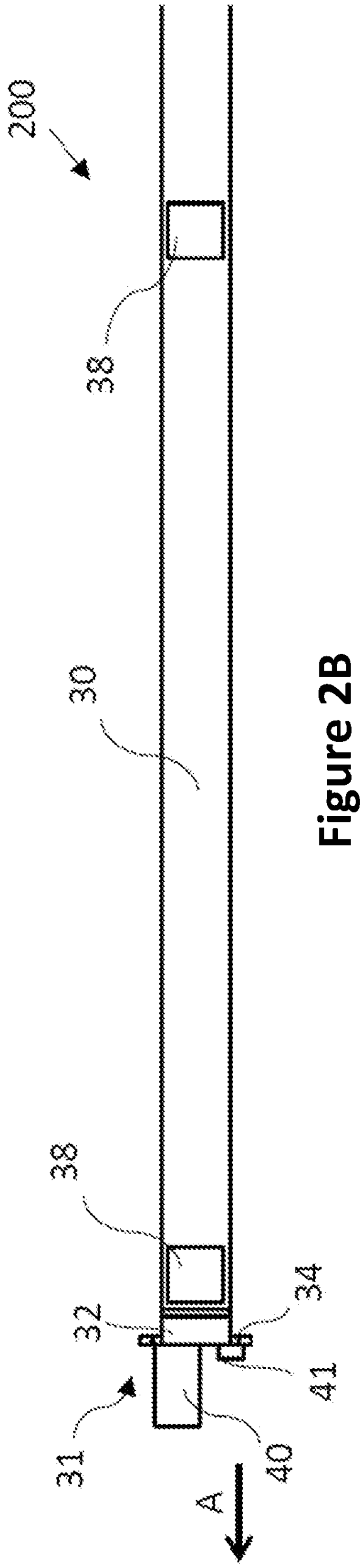

Figure 2B

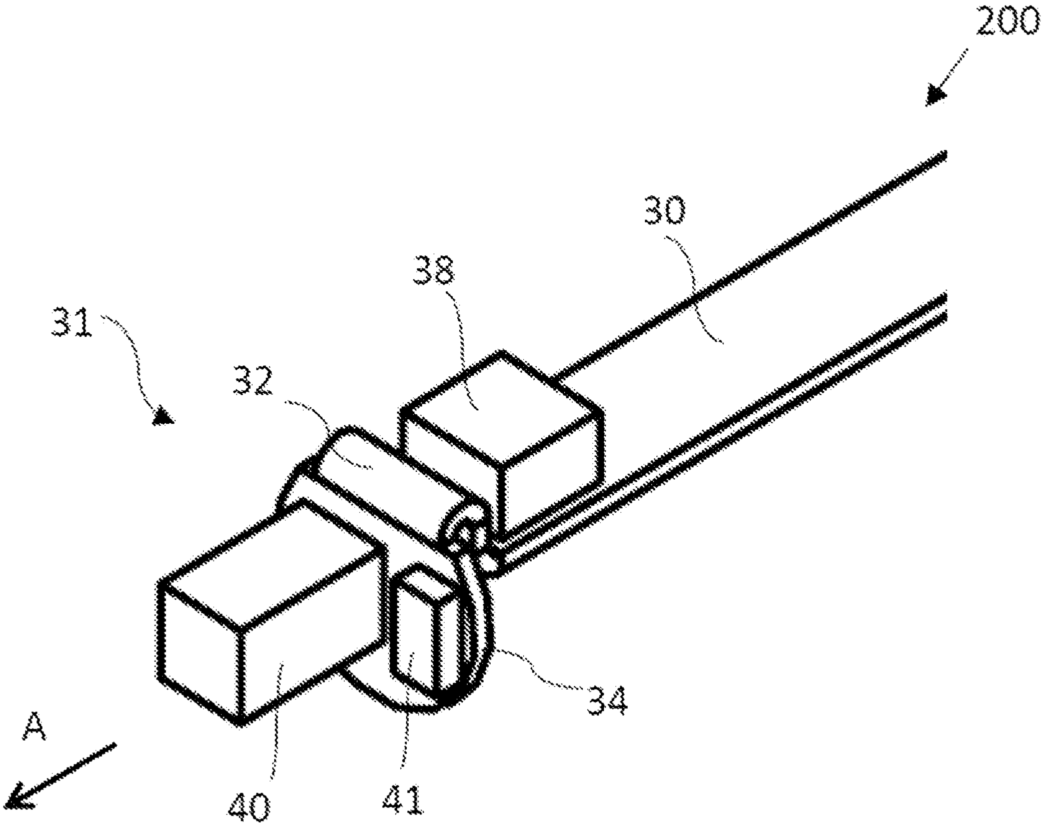

Figure 2C

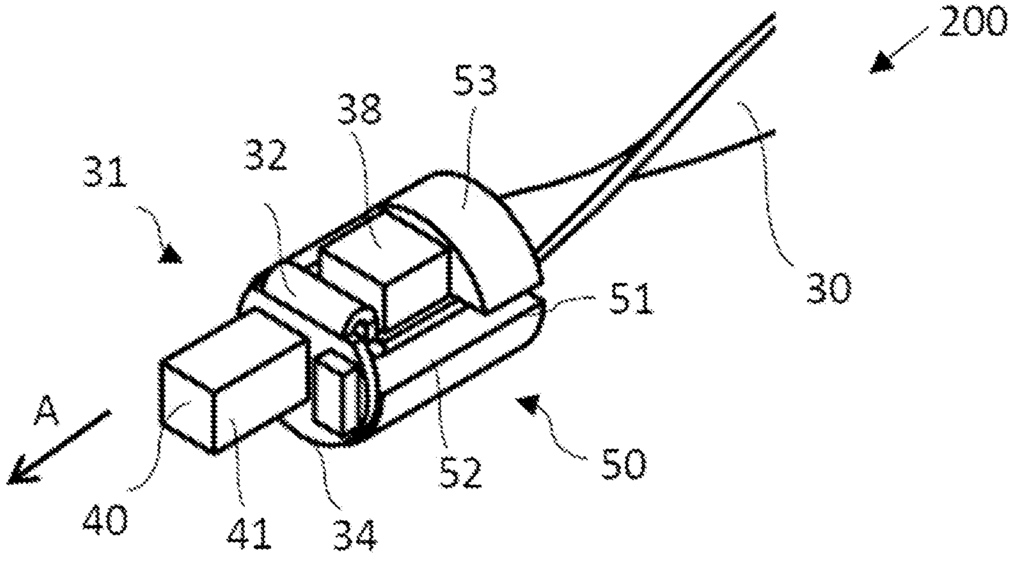

Figure 2D

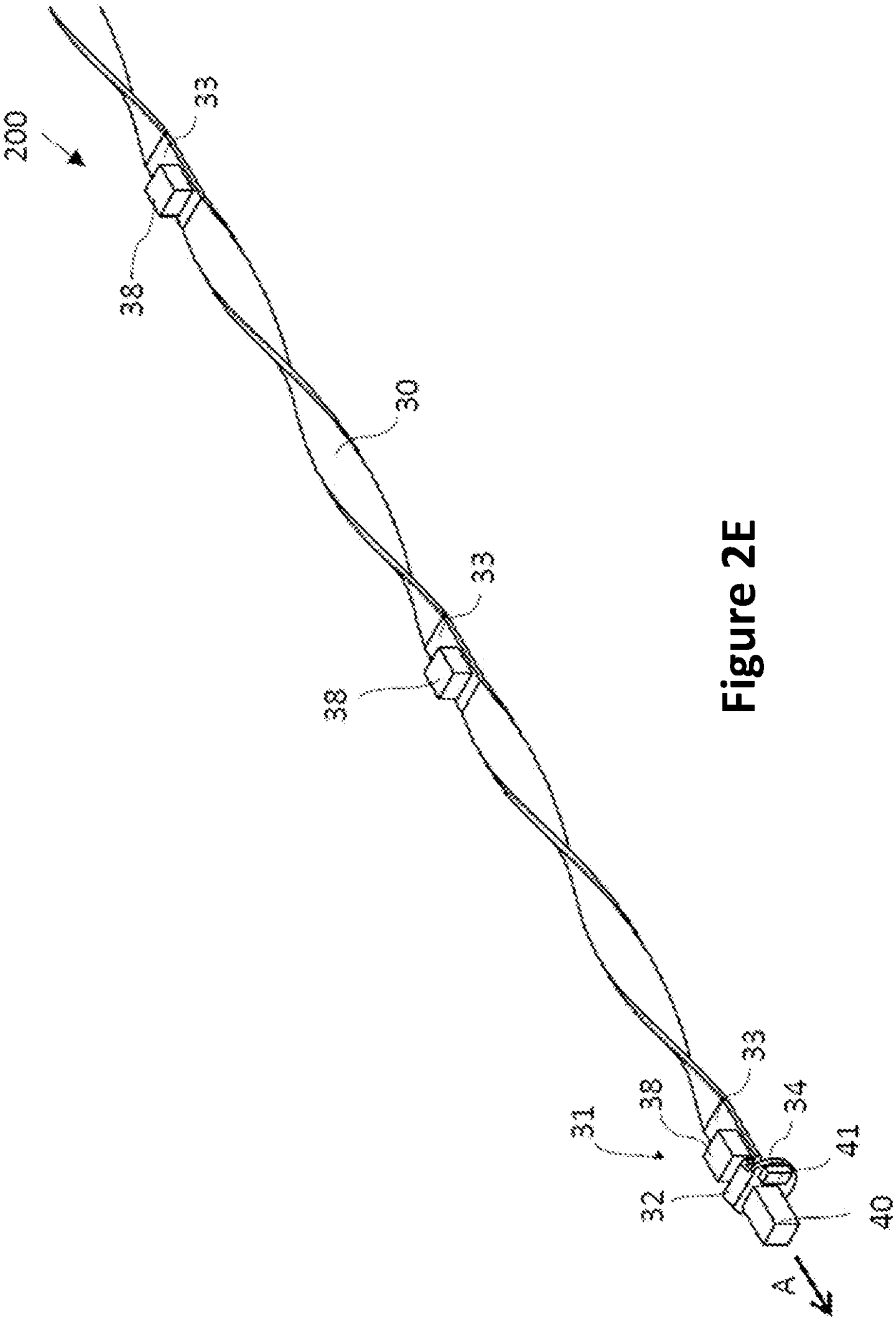

Figure 2E

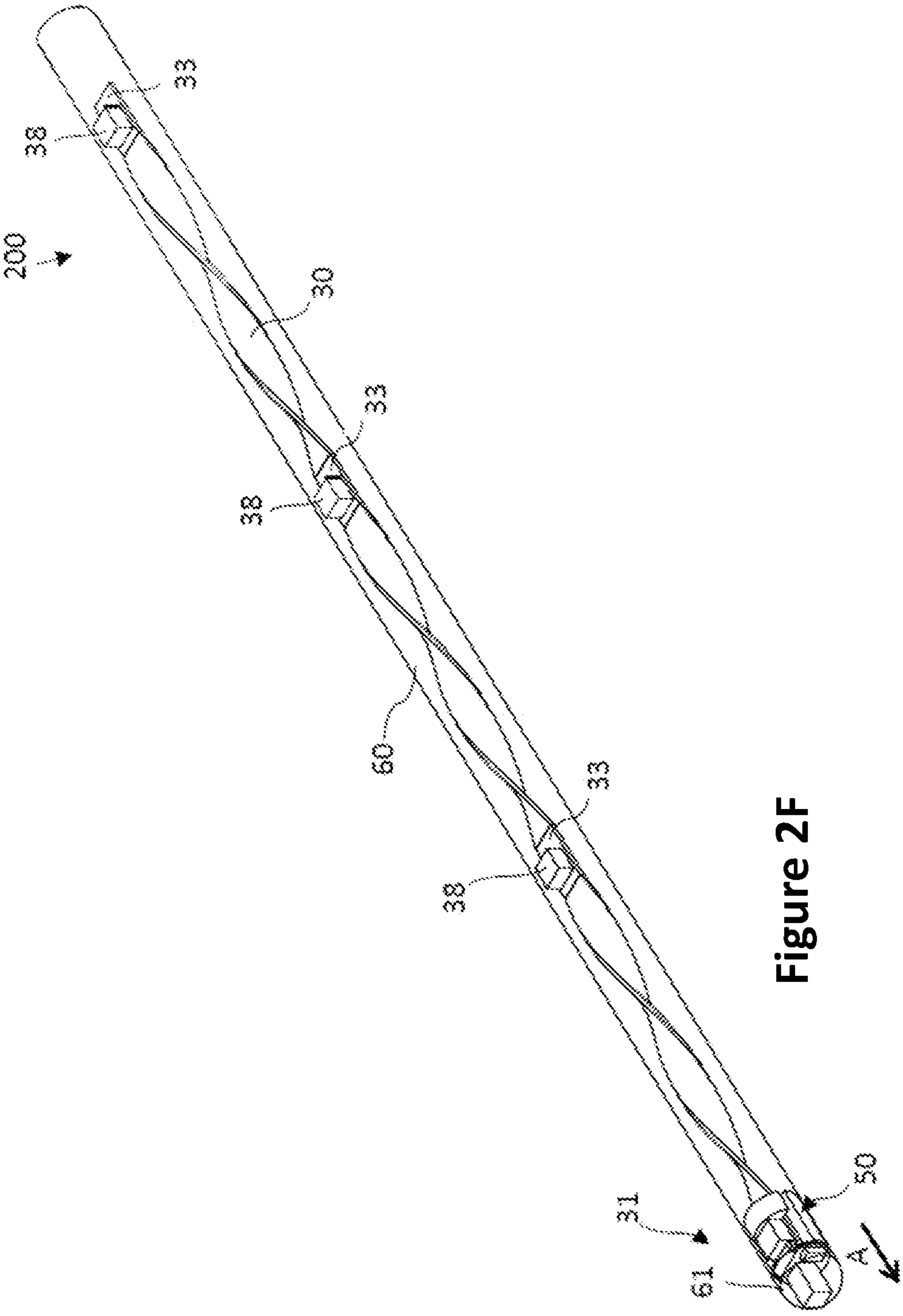

Figure 2F

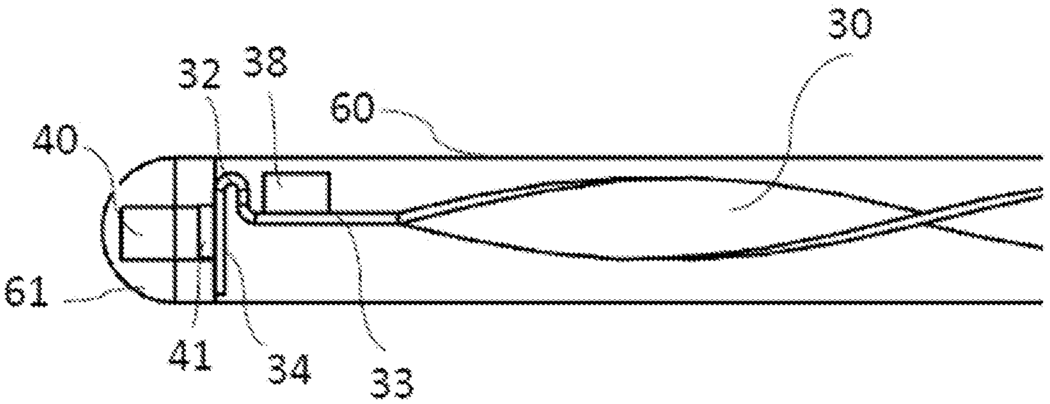

Figure 2G

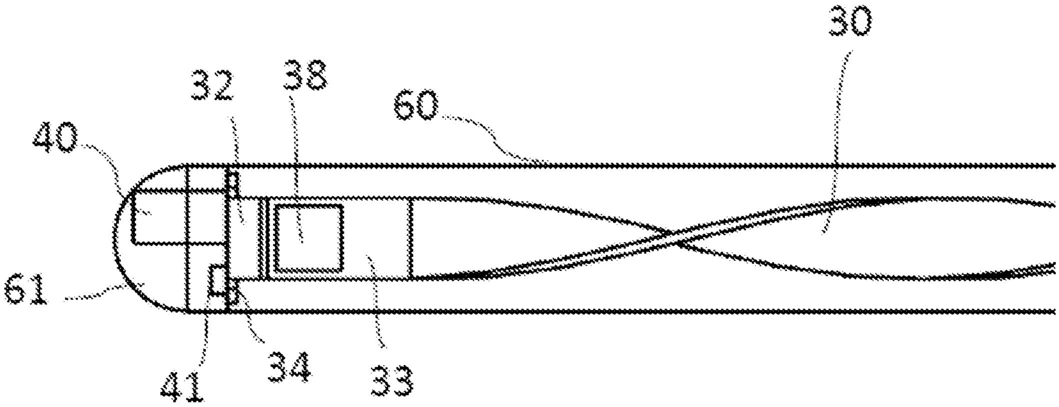

Figure 2H

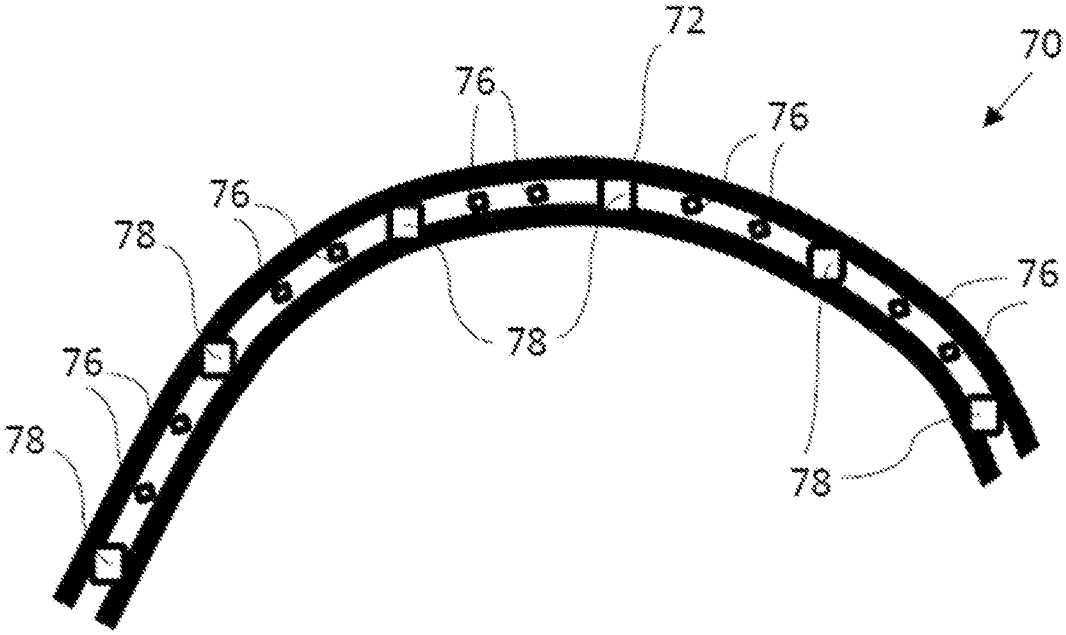

Figure 3

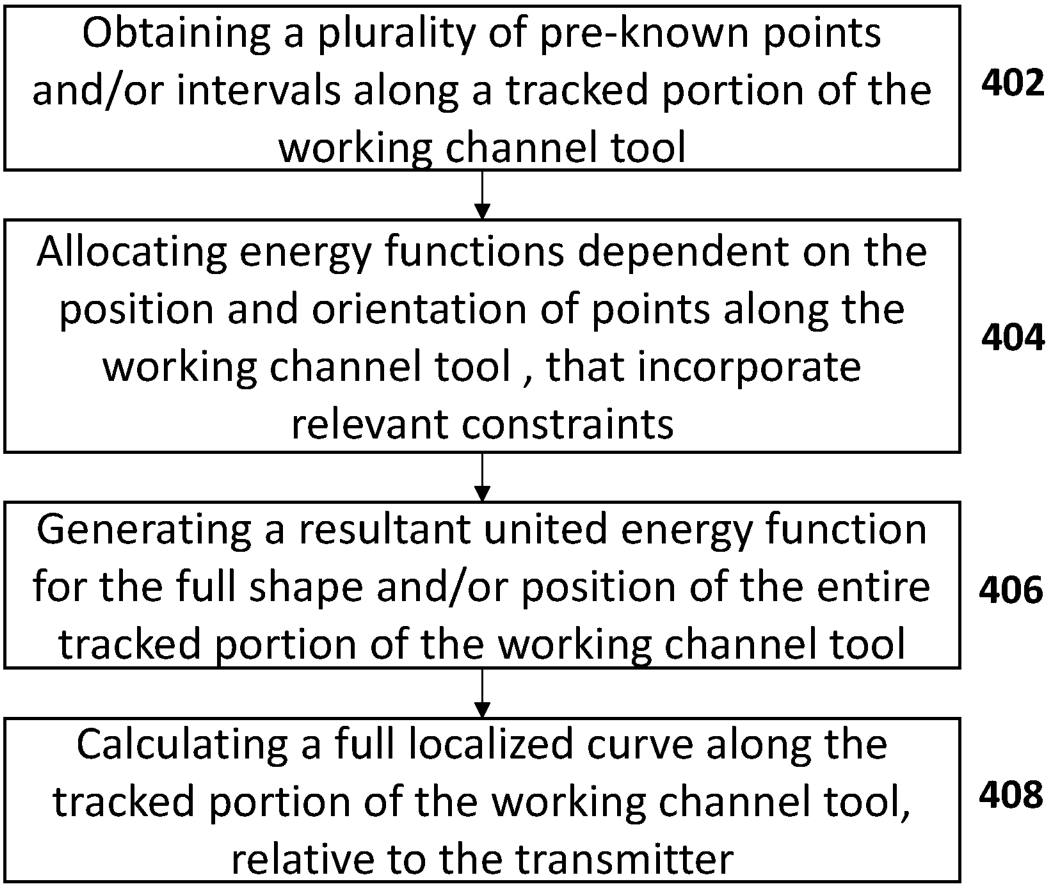
Obtaining a plurality of pre-known points and/or intervals along a tracked portion of the working channel tool
402
Allocating energy functions dependent on the position and orientation of points along the working channel tool , that incorporate relevant constraints
404
Generating a resultant united energy function for the full shape and/or position of the entire tracked portion of the working channel tool
406
Calculating a full localized curve along the tracked portion of the working channel tool, relative to the transmitter
408

Figure 4

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2024/050914

A. CLASSIFICATION OF SUBJECT MATTER

IPC: ***A61B 1/018*** (2024.01); ***A61B 1/05*** (2024.01); ***A61B 1/06*** (2024.01)

CPC: ***A61B1/018; A61B1/00087; A61B1/00098; A61B1/05; A61B1/06; A61B1/0676; A61B1/0684;*** *A61B2034/2051; A61B2034/2061; A61B2562/166*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History Document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	US 2022/0175468 A1 (MAGNISITY LTD.) 09 June 2022 (09.06.2022)	
X	Entire Document	48
Y		1-45
	WO 2001/054567 A1 (VISION SCIENCES INC.) 02 August 2001 (02.08.2001)	
Y	Entire Document	1-45
	US 2022/0160218 A1 (COOPERSURGICAL, INC.) 26 May 2022 (26.05.2022)	
Y	Entire Document	7-12, 14-16, 21-23, 29-34, 36-38, 43-45
	US 2014/0121673 A1 (GYRUS ACMI INC.) 01 May 2014 (01.05.2014)	
Y	Paragraph [0027]; Figure 5B	13, 35
	WO 2019/210227 A1 (DEKA PRODUCTS LIMITED PARTNERSHIP) 31 October 2019 (31.10.2019)	
Y	Paragraphs [0003-0005], [0029], [0060-0061], [00108], [00138]	19-20, 41-42

☑ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:
"A"	document defining the general state of the art which is not considered to be of particular relevance
"D"	document cited by the applicant in the international application
"E"	earlier application or patent but published on or after the international filing date
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O"	document referring to an oral disclosure, use, exhibition or other means
"P"	document published prior to the international filing date but later than the priority date claimed
"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&"	document member of the same patent family

Date of the actual completion of the international search **08 January 2025 (08.01.2025)**	Date of mailing of the international search report **17 January 2025 (17.01.2025)**
Name and mailing address of the ISA/US **COMMISSIONER FOR PATENTS** **MAIL STOP PCT, ATTN: ISA/US** **P.O. Box 1450** **Alexandria, VA 22313-1450** **UNITED STATES OF AMERICA**	Authorized officer **SHANE THOMAS**
Facsimile No. **571-273-8300**	Telephone No. **PCT Helpdesk: (571) 272-4300**

Box No. III **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-45 and 48 are directed toward an endoscopic system, a working channel tool configured to be inserted within a working channel of an endoscopic device, and a method for curve/shape-tracking of a working-channel tool.

Group II: Claims 46 and 47 are directed toward a method of manufacturing a working channel tool.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I include an endoscopic device comprising a working channel; an elongated body comprising a proximal end and a distal end; a curve/shape sensor comprising a plurality of sensor elements positioned on said one or more FPCs; c. one or more transmitters; d. a controller comprising a processor; said processor comprising instructions for calculating a full localized curve along a tracked portion of said working channel tool, relative to the one or more transmitters; a controller comprising a processor; said processor comprising instructions for allocating energy functions dependent on sensed values by the sensor elements at respective points along said working channel tool, the sensed values incorporate relevant constraints; obtaining a plurality of pre-known points and/or intervals along a tracked portion of said working-channel tool; b. allocating energy functions dependent on a position and orientation of points along said working channel tool that incorporate relevant constraints; c. generating a resultant united energy function for a full shape and/or position of said tracked portion of said working channel tool, which are not present in Group II.

Group II include one or more sensor arrays; a plurality of electronic components positioned on said one or more FPCs; the method comprising helically winding one or more sensor arrays around said working channel tool; wherein said method comprises positioning said plurality of electronic components along said one or more FPCs so when said one or more sensor arrays are wound around said working channel tool, said plurality of electronic components are aligned in relation to a longitudinal axis of said working channel tool, which are not present in Group I.

The common technical features of Groups I and II are a working channel tool; sensor; and one or more Flexible Printed Circuits (FPCs).

These common technical features are disclosed by US 2022/0160218 A1 to CooperSurgical, Inc. (hereinafter 'CooperSurgical'). CooperSurgical discloses a working channel tool (working tool for an endoscope; paragraph [0045]); sensor (sensor; paragraph [0056]); and one or more Flexible Printed Circuits 'FPCs' (FPC 184; paragraph [0046]).

Since the common technical features are previously disclosed by the CooperSurgical reference, the common features are not special and so Groups I and II lack unity.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL2024/050914

Box No. III **Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☑ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: **1-45, 48**

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2024/050914

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2023/0072879 A1 (NOAH MEDICAL CORPORATION) 09 March 2023 (09.03.2023) Entire Document	1-45, 48
A	US 2007/0238922 A1 (ODA, T. et al.) 11 October 2007 (11.10.2007) Entire Document	1-45, 48