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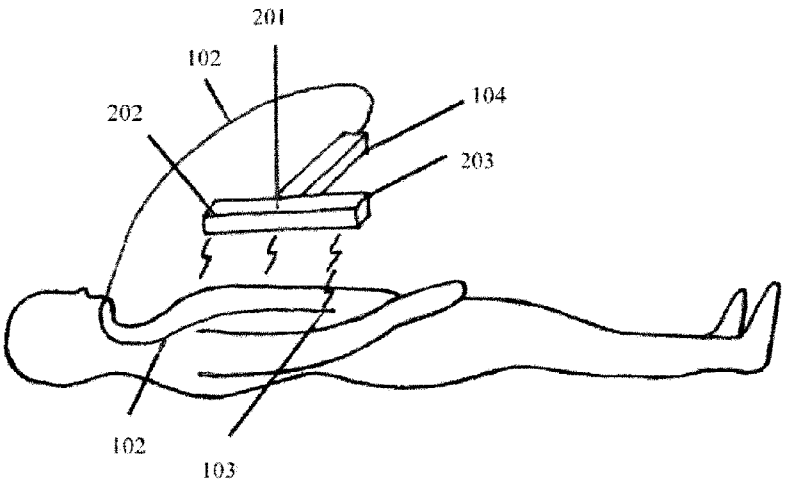

FIG. 2

(57) Abstract: The present invention includes a system and method for determining the position of a nasogastric tube inside a patient. The system includes a handheld transmitter module and a tube system. The transmitter module includes (1) a transmitter, (2) a receiver and analyzer, (3) a power source, (4) a user interface and (5) one or more transmitting antennae. The tube system includes an antenna that is attached to or imbedded in a nasogastric tube. The system can accurately determine the location of the distal end of the nasogastric tube inside the human body while minimizing the patient's exposure to electromagnetic energy.

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SYSTEM AND METHOD FOR DETERMINING THE POSITION OF INSERTED MEDICAL TUBES

The present application claims priority to United States Provisional Application Serial No.: 62/173,432, filed June 10, 2015, which is incorporated by reference herein in its entirety.

TECHNICAL FIELD

[0001] The present invention relates generally to nasogastric tubes used in medical systems, and, more specifically, to a system and method for determining the location of the distal end of a nasogastric tube in a person where the proximal end of the tube remains outside the body.

BACKGROUND

[0002] A nasogastric tube ("NG tube") is a flexible tube that is inserted through a patient's nose, past the throat and down to the stomach. It can be used to remove contents from the stomach, including air, to decompress the stomach, or to remove small solid objects and fluid, such as poison, from the stomach. An NG tube can also be used to put substances into the stomach. Nutrients can be sent directly into the stomach when a patient cannot take food or drink by mouth (i.e. enteral feeding). NG Tubes are also commonly used to administer drugs and other oral agents such as activated charcoal. Nasogastric intubation is a medical procedure wherein the end of the NG tube is inserted into the stomach.

[0003] Like most other medical procedures, NG tube intubation must be administered with utmost caution. The NG tube must be carefully passed down the nose, through the esophagus and into the stomach of the patient. Appropriate care and procedure must

be observed to ensure that the tube has not passed through the larynx into the trachea and down into the bronchi. The health care provider should also be careful to avoid folding or coiling of the tube. Serious complications can arise due to improper insertion of the NG tube. If improperly inserted, an NG tube can lead to aspiration pneumonia and death.

[0004] Because of the risk of misplacement, one or more tests are used to confirm the proper placement of the NG tube into the stomach of the patient. Moreover, if the tube is to remain in place, a tube position check is recommended before each feeding and at least once per day. There are several tests that can be performed to check the location of an NG tube.

[0005] One test entails injecting air into the tube after it is inserted. The clinician injects air into the NG tube while carefully listening for sounds in the abdomen with a stethoscope. The tube should be in the correct position if air is heard in the stomach. However, this method is unreliable and prone to error. Air sounds can be difficult to hear and interpret, particularly in a busy setting. Further, this method can be ineffective when treating obese patients.

[0006] Another test entails aspirating a sample of fluid from the tube to analyze after it is inserted. The clinician draws a sample of fluid from the tube with a syringe. The clinician can then check the pH of the sample. Because the fluid in the stomach is acidic, the sample should have a pH of 5.5 or lower to if the tube is in the correct position. However, this method can also be unreliable. The test results will vary depending on stomach contents. Moreover, acid-inhibiting drugs can cause misleading test results.

[0007] A more reliable test entails the use of an x-ray machine. The clinician takes an x-ray of the chest and abdomen of the patient after inserting the tube to confirm its location. While effective, this method is generally avoided because of risks associated

with exposure to x-rays. It is well acknowledged that any form of x-ray exposure (radiation) carries risks and the patient should be carefully monitored and controlled to minimize exposure. Further, a fetus, embryo, baby or child is more vulnerable to x-ray damage so the clinician should take extra precautions with younger patients and pregnant women. The x-ray method also requires the use of expensive, heavy equipment in a specialized clinical environment. Administering the scan and preparing images is time consuming and can require 30 minutes or more to confirm proper placement of the tube. This is particularly impractical when repeated tests are necessary for a tube that must remain in place for an extended period of time.

[0008] Alternative tests use ultrasound devices to try to visualize the position of the tube in a patient. These systems are typically designed to aid clinicians with inserting the NG tube and may not be suitable for repeated testing to verify the position of an NG tube. Moreover, these systems often require the use of tubes that have embedded or attached weights and magnets. These objects can interfere with other tests, including MRI scans that are often essential to ongoing patient care. The systems are also expensive and must be operated by a trained health care professional in a clinical environment.

[0009] Other tests use electronic transmitters that are attached to medical tubes. For example, U.S. Pat. No. 5,099,845 describes a system with a transmitter attached to a catheter and an external receiver that is tuned to the frequency of the transmitter. A battery or other internal power source must be inserted into the patient. For a tube that must remain in place, repeated testing is essential which can a problematic as batteries lose their charge. Further, the patient faces the risk of a battery leak or rupture and the battery can interfere with other medical testing.

[0010] Radio frequency identification (RFID) is used in other methods wherein a tag or chip that contains electronically stored information is attached to a medical tube. For example, U.S. Patent App. No. 11/993,218 uses an electronic system and an RFID

sensor embedded on an NG tube to determine its location. The test requires electromagnetic (EM) energy to pass from an external module (outside the human body) to a sensor module (inside the human body attached to the NG Tube) and then from the sensor module back to the external module. The system exposes the patient to a high amount of electromagnetic energy. Many recent studies have raised questions regarding the safety of exposure to electromagnetic energy. Moreover, the RFID sensor can interfere with other medical tests, including MRI scans.

[0011] Because these traditional tests have limitations, there is a need for an improved test system and method that overcomes these shortcomings. Specifically, there is a need for a test to quickly, safely and accurately determine the location of an NG tube in a patient. The system should be inexpensive, portable and suitable for use by non-medical professionals. The test should also be conducive to repeated use to verify the location of an NG tube that remains in place for an extended period of time.

SUMMARY

[0012] The invention recognizes that there exists a long felt need for a safe and effective system and method for determining and verifying the position of medical tubes, catheters, syringes and other devices that are inserted into patients. The invention enables accurate and economical bio-positioning using minimal amounts of radio-frequency electromagnetic (RF-EM) energy from an external source. This provides a safe, effective and reliable method for confirming the location of the distal end of a nasogastric tube. Further, the invention is less expensive and faster than traditional methods.

[0013] The following summary is provided to facilitate an understanding of some of the innovative features unique to the disclosed embodiment and is not intended to be a full description. A full appreciation of the various aspects of the embodiments disclosed

herein can be gained by taking into consideration the entire specification, claims, drawings and abstract as a whole.

[0014] We describe a system for determining the location of the distal end of a nasogastric tube in a person comprising a nasogastric tube having a proximal (internal) end and a distal (external) end wherein the proximal end includes one or more receiving antenna. A transmitter module is connected to the gastric tube and is composed of a power source, a transmitter, a receiver, an analyzer and a user interface. Electromagnetic (EM) energy transmitted from the transmitter is absorbed by one or more receiving antenna and analyzed to determine the location of the distal end of the medical tube. The location can be displayed to the user on an interface.

[0015] The medical tube system includes one or more receiving antenna (embedded or connected to the distal end of the NG tube) that do not transmit electromagnetic energy. A transmitter includes more than one transmitting antennae, each capable of transmitting independently of one another. The transmitter can include a plurality of transmitting antennae for determining the location of the distal end of the nasogastric tube using antennae diversity.

[0016] The analyzer of the medical tube system can use an algorithm to accurately determine the location of a nasogastric tube inside a patient. The user (e.g. health care provider or care giver) can determine the location of the distal end of a medical tube by holding the transmitter module over a person's stomach and observing a signal. The medical tube detection system uses only EM energy that is transmitted from outside a patient. That is, there is no EM energy radiated from components that are inside the patient. The amount of EM energy that is transmitted can be adjusted to accommodate for the size of a patient. For example, a stronger signal may be necessary with an obese patient.

[0017] We also describe a method of confirming the presence of a medical tube in a

patient's stomach comprising the steps of (1) placing the distal end of a medical tube in the stomach a patient, wherein the medical tube has a receiving antenna near the distal end, (2) connecting the proximal end of the medical tube to an external transmitter module, (3) placing the external transmitter module near the surface of the stomach of the patient, (4) analyzing the parameters of energy in the area near the stomach to determine the presence or absence of the distal end of the medical tube and (5) conveying information to a user through an interface. The external transmitter module can include a transmitter, a receiver, an analyzer and a user interface

[0018] According to this method, the receiving antenna (inside the patient) does not transmit EM energy. The location of the distal end of a medical tube is determined using EM energy that is transmitted from outside the patient. The external transmitter can include more than one transmitting antennae, each capable of operating independently of one another. A plurality of transmitting antennae can be used for determining the location of the distal end of said nasogastric tube using antennae diversity. The analyzer can use an algorithm to determine the location of a medical tube inside a patient.

[0019] The method can be used for a nasogastric tube, an orogastric tube, a percutaneous endoscopic gastrostomy tube, a percutaneous jejunostomy tube, an endotracheal tube, a chest tube, a urinary catheter, an intravenous catheter, an arterial catheter, a gastric decompression tube, a suction tube, a drainage tube, an intracranial pressure monitor, a catheter or a syringe.

[0020] We also describe a position-sensing medical tube for minimizing a patient's exposure to EM energy. It is comprised of (1) a medical tube having a proximal end and a distal end, wherein the distal end includes a receiving antenna and is placed inside a patient and (2) an external transmitter module connected to the proximal end of the medical tube that includes a power source, a transmitter, a receiver, an analyzer and a user interface. The transmitter radiates energy to the receiving antenna. The

receiver detects radiation patterns and the analyzer uses an algorithm to determine the presence or absence of the distal end of the medical tube.

[0021] The receiving antenna of the system does not transmit EM energy. The external transmitter can include more than one transmitting antennae, each capable of operating independently of one another. Further, the external transmitter can include a plurality of transmitting antennae for determining the location of the distal end of the nasogastric tube using antennae diversity. The distal end of a nasogastric tube can be detected by holding the external transmitter module over a person's stomach and observing a signal. The amount of EM energy transmitted can be adjusted to accommodate for the size of a patient.

INTRODUCTION

[0022] A first aspect of the invention is an improved system and method for determining the location of the distal end of an NG tube inserted into the human body where the proximal end is outside the human body.

[0023] A second aspect of the invention is an NG tube system that is portable and more economical, reliable, safe and effective than traditional methods and can be used in both surgical and bed-side settings.

[0024] A third aspect of the invention is an intelligent NG tube system that includes a transmitter module, an antenna (or antenna array) connected to a transmitter, a receiver, an analysis module and one or more tube antennae.

[0025] A fourth aspect of the invention is an NG tube system in which an external transmitter module radiates electromagnetic (EM) energy through one or more antennae to detect the location of an NG tube. The system reduces the patient's exposure to EM energy compared to traditional tests.

[0026] A fifth aspect of the invention is an intelligent NG tube system in which a receiver and analyzer module evaluate incident energy as a separate external entity (i.e. no analysis or radiated energy from the internal antenna) to determine the position of a nasogastric tube. The amount of transmitted energy can be adjusted to accommodate a patient's size.

[0027] A sixth aspect of the invention is an intelligent NG tube system that uses an algorithm with one or more transmitting antennae to accurately determine the location of a nasogastric tube while eliminating ambiguous signals.

[0028] A seventh aspect of the invention is a system and method of determining the position of an NG tube that minimizes the limitations and risks associated with electromagnetic (EM) energy travelling through the human body. The invention uses low amounts of radio-frequency electromagnetic (RF-EM) energy from an external source yet enables accurate and economical bio-positioning. The invention has greater electromagnetic compatibility than conventional systems that use EM energy.

[0029] A eighth aspect of the invention is a system and method of determining the position of an NG tube that can operate in three modes such that (1) energy is transmitted from one antenna of the transmitter module, (2) energy is transmitted from two antennae of the transmitter module and (3) energy is transmitted from all three antennae of the transmitter module.

[0030] A ninth aspect of the invention is a portable NG tube system which allows a clinician or care giver to confirm proper placement of the distal end of a nasogastric tube by holding a device over a patient's abdomen or stomach and observing a signal. The system is suitable for use outside of the clinical environment (i.e. home use) by providers or care givers with minimal training.

BRIEF DESCRIPTION OF THE FIGURES

[0031] The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

[0032] **FIG. 1** is a schematic diagram of the NG tube assembly of the system, in accordance with the invention.

[0033] **FIG. 2** is a schematic diagram the handheld module over the abdomen of a patient.

[0034] **FIG. 3** is an illustration of the handheld module.

[0035] **FIG. 4** is an illustration of the assembled NG tube.

[0036] **FIG. 5** is a schematic diagram showing the antenna radiation perpendicular to vertical orientation of body, in accordance with the invention.

[0037] **FIG. 6** is a schematic diagram showing overlapping radiation patterns that occur when the nasogastric tube is in the stomach (recording strong signals) in accordance with the invention.

[0038] **FIG. 7** is a schematic diagram showing the radiation pattern mismatch that occurs when that nasogastric tube is in lungs (recording weak signals) in accordance with the invention.

[0039] **FIG. 8** is a flow chart depicting the process of inserting and checking the location of a nasogastric tube, in accordance with the invention.

[0040] **FIG. 9** is a flow chart depicting the process of verifying the location of an NG tube, in accordance with the invention.

[0041] The following summary is provided to facilitate an understanding of some of the innovative features unique to the invention and is not intended to be a full description. A full appreciation of the various aspects of the embodiments disclosed herein can be gained by taking into consideration the entire specification, claims, drawings, and abstract as a whole.

[0042] Other aspects and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, illustrating by way of example, the principles of the invention.

DETAILED DESCRIPTION OF THE INVENTION

DEFINITIONS

[0043] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Generally, the nomenclature used herein and described below are well known and commonly employed in the art. Where a term is provided in the singular, the inventors also contemplate the plural of that term, and when a term is provided in the plural, the inventors also contemplate the singular of that term. The nomenclature used herein and the procedures described below are those well known and commonly employed in the art unless set forth otherwise. As employed throughout the disclosure, the following terms, unless otherwise indicated, shall be understood to have the following meanings:

[0044] While the invention is primarily described for the insertion and confirmation of nasogastric (NG) tube location, it is understood that the invention is not so limited and may be used to assist in properly inserting and verifying the location of other objects,

including medical tubes, orogastric tubes, nasogastric tubes, percutaneous endoscopic gastrostomy tubes, percutaneous jejunostomy tubes, endotracheal tubes, chest tubes, urinary catheters, intravenous catheters, arterial catheters, gastric decompression tubes, suction tubes, drainage tubes, intracranial pressure monitors, catheters, syringes and other objects. Other applications include, for example, but not limited to, using the invention in veterinary practices as well as outside of the medical/clinical setting.

[0045] Reference in this specification to "one embodiment/aspect" or "an embodiment/aspect" means that a particular feature, structure, or characteristic described in connection with the embodiment/aspect is included in at least one embodiment/aspect of the disclosure. The use of the phrase "in one embodiment/aspect" or "in another embodiment/aspect" in various places in the specification are not necessarily all referring to the same embodiment/aspect, nor are separate or alternative embodiments/aspects mutually exclusive of other embodiments/aspects. Moreover, various features are described which may be exhibited by some embodiments/aspects and not by others. Similarly, various requirements are described which may be requirements for some embodiments/aspects but not other embodiments/aspects. Embodiment and aspect can be in certain instances be used interchangeably.

[0046] The terms used in this specification generally have their ordinary meanings in the art, within the context of the disclosure, and in the specific context where each term is used. Certain terms that are used to describe the disclosure are discussed below, or elsewhere in the specification, to provide additional guidance to the practitioner regarding the description of the disclosure. For convenience, certain terms may be highlighted, for example using italics and/or quotation marks: The use of highlighting has no influence on the scope and meaning of a term; the scope and meaning of a term is the same, in the same context, whether or not it is highlighted. It will be appreciated that the same thing can be said in more than one way.

[0047] Consequently, alternative language and synonyms may be used for any one or more of the terms discussed herein. Nor is any special significance to be placed upon whether or not a term is elaborated or discussed herein. Synonyms for certain terms are provided. A recital of one or more synonyms does not exclude the use of other synonyms. The use of examples anywhere in this specification including examples of any terms discussed herein is illustrative only, and is not intended to further limit the scope and meaning of the disclosure or of any exemplified term. Likewise, the disclosure is not limited to various embodiments given in this specification.

[0048] Without intent to further limit the scope of the disclosure, examples of instruments, apparatus, methods and their related results according to the embodiments of the present disclosure are given below. Note that titles or subtitles may be used in the examples for convenience of a reader, which in no way should limit the scope of the disclosure. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure pertains. In the case of conflict, the present document, including definitions, will control.

[0049] The term “antenna” refers to an electrical device which converts electric power into radio waves, and vice versa. A typical antenna is an arrangement of metallic conductors (elements), electrically connected (often through a transmission line) to the receiver or transmitter. An oscillating current of electrons forced through the antenna by a transmitter will create an oscillating magnetic field around the antenna elements, while the charge of the electrons also creates an oscillating electric field along the elements.

The term “antenna array” refers to a geometrical arrangement of more than one antenna elements with a deliberate relationship between their currents, usually to achieve a desired radiation pattern

The term "aspirate" refers to the removal by suction of fluid and cells through a needle or syringe. The term may also refer to the accidental sucking in of food particles or fluids into the lungs.

The term "catheter" refers to a flexible tube inserted through a narrow opening into a body cavity, for example, the bladder.

The term "clinician" refers to a health professional, such as a physician, psychologist, or nurse, who is directly involved in patient care.

The term “coaxial cable” refers to a transmission line that includes a tube of electrically conducting material surrounding a central conductor held in place by insulators that can be used to transmit telegraph, telephone and television signals

The term “distal” refers to the portion that is situated away the point of origin or attachment, as of a limb or bone. It can also refer to the portion that is situated away from a point of reference.

The term “electrical envelope” (of a modulated carrier wave) refers to a curve connecting the peaks of a graph of the instantaneous value of the electric or magnetic component of the carrier wave as a function of time.

The term “electromagnetic” or “EM” refers to the interrelation of electric currents or fields and magnetic fields.

The term “electromagnetic compatibility” or “EMC” means that a device is compatible with (i.e., no interference is caused by) its electromagnetic (EM) environment and it does not emit levels of EM energy that cause electromagnetic interference (EMI) in other devices in the vicinity

The term “electromagnetic radiation” (EM radiation or EMR) is the radiant energy released by certain electromagnetic processes. Visible light is one type of electromagnetic radiation. Other familiar forms are invisible electromagnetic radiations, such as radio waves, infrared light and X-rays.

The term “incident energy” refers to energy that falls upon or strikes something and then transfers some or all of its power into the object.

The term “ISM band” refers industrial, scientific and medical (ISM) radio bands (portions of the radio spectrum) reserved internationally for the use of radio frequency (RF) energy for industrial, scientific and medical purposes other than telecommunications.

The term “loop antenna” refers to an antenna shaped by one or more loops that is made of electrically conductive material with its end connected to an electromagnetic source.

The term “lumen” refers to the canal, duct, or cavity of a tubular object or organ.

The term "medical tube" refers to a tube used in a medical procedure or method having one end internal and one end external to the body. Examples of medical tubes include nasogastric tubes, orogastric tubes, percutaneous endoscopic gastronomy tubes, percutaneous jejunostomy tubes, endotracheal tubes, urinary catheters, intravenous catheters, arterial catheters, suction tubes, drainage tubes and intracranial pressure monitors.

The term “nasogastric aspiration” or “nasogastric suction” refers to the process of draining the stomach's contents via a tube.

The term “peak envelope power” or “PEP” is the highest envelope power supplied to the antenna transmission line by a transmitter during any full undistorted RF cycle or series of complete radio frequency cycles. PEP is normally considered the occasional or continuously repeating crest of the modulation envelope under normal operating conditions.

The term “proximal” refers to the portion that is situated toward the point of origin or attachment, as of a limb or bone. It can also refer to the portion that is situated toward a point of reference.

The term radiation pattern (antenna pattern or far-field pattern) refers to the directional (angular) dependence of the strength of the radio waves from the antenna or other source.

The term “radio frequency” or “RF” refers to any of the electromagnetic wave frequencies that lie in the range extending from around 3 kHz to 300 GHz, which include those frequencies used for communications or radar signals. RF usually refers to electrical rather than mechanical oscillations.

The term “radio frequency identification” or “RFID” is a technology that incorporates the use of electromagnetic or electrostatic coupling in the radio frequency

(RF) portion of the electromagnetic spectrum to uniquely identify an object, animal, or person.

The term “signal diversity” or “diversity scheme” refers to a method for improving the reliability of a message signal by using two or more communication channels with different characteristics.

The term “subminiature connector” or “SMA” refers to a family of plugs or electrical connector that is commonly used in personal computers and components.

The term “transmitter diversity” refers to radio communication using signals that originate from two or more independent sources that have been modulated with identical information-bearing signals and that may vary in their transmission characteristics at any given instant.

The term “ultrasound” refers to the process of using sound waves with frequencies to create images of human tissue. Ultrasonic images also known as sonograms are made by sending pulses of ultrasound into tissue using a probe. The sound echoes off the tissue with different tissues reflecting varying degrees of sound. These echoes are recorded and displayed as an image to the operator.

The term "x-ray" or “x-radiation” refers to an electromagnetic wave of high energy and very short wavelength, which is able to pass through many materials opaque to light.

[0050] It will be appreciated that terms such as "front," "back," “top,” “bottom,” "side," "short," "long," "up," "down," and "below" used herein are merely for ease of description and refer to the orientation of the components as shown in the figures. It should be understood that any orientation of the components described herein is within the scope of the present invention.

[0051] Other technical terms used herein have their ordinary meaning in the art that they are used, as exemplified by a variety of technical dictionaries.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0052] The invention includes an "intelligent" NG tube locating system which may be referred to as the "iNGT system." It enables a clinician, health care provider or care giver to quickly and accurately confirm that the distal tip of a nasogastric tube is properly located in a patient's stomach. The invention utilizes an internal antenna that is embedded or attached to the distal end of the NG tube. The antenna does not have electronic sensors or a power supply and does not emit energy. This bio-positioning technology is safe, portable, inexpensive and does not require extensive training or expertise for proper use.

[0053] The system includes a handheld transmitter module ("iNGT Transmitter Module" or "transmitter") and an NG tube assembly. The transmitter module includes (1) a transmitter, (2) a receiver and analyzer, (3) a power source, (4) a user interface and (5) one or more transmitting antennae. The NG tube assembly includes (1) a tube antenna (receiving antenna), (2) a nasogastric tube, (3) a coaxial cable and (4) a connector.

[0054] A healthcare provider follows a standard procedure to insert the NG tube into a patient. The NG tube antenna is imbedded or attached to one end (the distal end) of the NG tube assembly. The NG tube is inserted into a patient by passing the distal end through the nose, through the esophagus and then to either the stomach or duodenum. After insertion, the clinician or caregiver can use the iNGT system to confirm that the distal end is properly placed in the patient's stomach. Because of the risk of misplacement, it is essential to use a reliable test to confirm that the distal end of the tube is placed into the stomach.

[0055] The user connects a coaxial cable from the NG tube assembly to the transmitter module. The system can then be turned on. The transmitter antennae

transmits electromagnetic energy from the transmitter. In a preferred embodiment, the transmitter has three antennae for this process. In typical use, all three will transmit electromagnetic energy which is captured by the NG tube antenna.

[0056] The user can hold or 'hover' the external hand-held device over the stomach area and observe a signal. The electromagnetic signal is transferred to the receiver and analysis module through the coaxial cable. The analysis module can use an algorithm to determine the location of the tube antenna inside the patient based on the parameters of the energy. The system provides a signal to the user to indicate whether or not the distal end is in the stomach.

[0057] In certain situations, the NG tube may remain in place for an extended period of time. This may be necessary when the tube is used for regular patient feeding. It is essential to verify the position of the tube before each feeding and at least once per day. In such circumstances, the user can repeat the test as often as deemed practical or necessary.

[0058] FIG.1 is a schematic diagram of the nasogastric (NG) tube assembly **100** which has been properly inserted into a patient. The system **100** includes an NG tube **102** and an external handheld device. The NG tube **102** has an electromagnetic antenna (NG tube antenna) **103** at its distal tip and an embedded insulated conductor **102** that runs along the length of the tube. The embedded insulated conductor **102** transmits an electromagnetic signal from the tube antenna **103** to the external receiver. A subminiature connector (SMA) **101** or similar connecting mechanism joins the NG tube antenna to the transmitter module. The transmitter module **104** transmits/radiates electromagnetic energy that is absorbed/monitored by the receiving antenna **103** in the NG tube **102**.

[0059] FIG. 2, is a schematic diagram of the handheld transmitter module **104** over the abdomen of a patient. Transmitter antennae include the center antenna **201**, the

"lungs" antenna **202** and the "stomach" antenna **203**. One or more antennae in the handheld module radiate EM energy to the NG tube antenna (receiving antenna) **103**. The NG tube antenna **103** absorbs the energy and it is converted into a binary value. The signal is passed through the coaxial cable **102** to the receiver/analysis module in the handheld transmitter **104**.

iNGT Transmitter Module

[0060] FIG. 3 is a diagram of the handheld transmitter module ("transmitter") **104**. In a preferred embodiment, the transmitter has three separate antennae. The center antenna **201** is flanked by the "lungs" antenna **202** and the "stomach" antenna **203**. In the illustrated design, the "lungs" antenna **202** and the "stomach" antenna **203** are detachable as shown. As described below, the transmitter can operate in three modes. The user can choose the mode by pressing one of three buttons **301**. The user interface **302**, a buzzer or one or more indicator lights **303** alert the user to the proper (or improper) placement of the NG tube. An audio mechanism or buzzer can be located near the lights **303**. A coaxial cable (or similar) plugs into the transmitter **304**. The modes of operation are described in detail below.

[0061] The transmitter includes a transmitter module **104.** The transmitter module can generate, amplify and transmit continuous EM radiation. Such modules are commonly used in the electrical and engineering arts. A preferred module for use in the transmitter has a multiple port output capable for transmitting three separate continuous electromagnetic radiation streams at 13.56MHz between 17dBm to 20dBm. Multiple sources can be used for antenna diversity to improve detection accuracy.

[0062] The transmitting antenna can be a small loop antenna. The use of three separate transmitting antennae ("antenna array" or "phased array") can be used to improve the accuracy of the system. The signals from the antennae can be combined or processed in order to achieve improved performance over that of a single antenna.

The antenna array can be used to increase the overall gain, provide diversity reception, cancel out interference from a particular set of directions, "steer" the array so that it is most sensitive in a particular direction, determine the direction of arrival of the incoming signals and maximize the Signal to Interference Plus Noise Ratio (SINR)

[0063] During normal use, after the NG tube is inserted, the user activates the power source and joins the SMA (or similar) connector **101** with the proximal end of the NG tube. The provider can then choose the intended mode or operation. EM radiation is transmitted from one or more transmitting antenna based on the mode. When the transmitter is held close to the patient's abdomen, the energy is absorbed by the NG tube antennae **103**.

iNGT Receiver and Analyzer Module

[0064] The electromagnetic signal received by the tube antenna **103** from the transmitter module **104** is sent into the receiver module through the coaxial cable/insulated conductor **102**. This way, the receiver and analyzer module evaluate the incident energy of the tube antenna.

[0065] The receiver module can include amplifying circuitry, rectifier circuitry, an analogue to digital converter (ADC), a microcontroller (e.g. arduino uno board) that reads the signal strength from the ADC, an LCD screen to display the signal strength and a buzzer to provide real-time audio feedback on the signal strength.

[0066] The receiver module receives input RF signal, amplifies the signal and converts the signal strength to a numerical value for data processing. The receiver module includes an analysis module that can use an algorithm to accurately locate the tip of the nasogastric tube.

[0067] In normal use, the analyzer module determines if the NG tube is in the proper

position (i.e. whether intubation was successful). In a preferred method of operation, the electrical envelope of electromagnetic energy is digitized into a digital/binary value. The digital output is analyzed and an audio/visual "pass" or "fail" is displayed on the interface to the user.

Modes of Operation

[0068] In Mode 1, energy is transmitted from a single antenna of the transmitter module. The module is held over the patient, specifically, the antenna labelled "stomach" is placed over the stomach. Based on the energy received from the antennae, the analyzer module will determine whether the NG tube is present in the stomach.

[0069] Energy is detected and analyzed then a signal is sent to a buzzer or speaker. The frequency and pitch of the buzzer audio output is proportional to the energy received by the NG tube antenna. Therefore, the user will hear the maximum output (loudest buzz) when the tip of the NG tube is properly located in the stomach.

[0070] In mode 2, energy is transmitted from two antennae of the transmitter module. The module is held over the abdomen of a patient. Specifically, the antenna labelled "stomach" is placed over the stomach and the antenna labelled "lungs" is placed over the lungs. Based on the energy received from the antennae, the analyzer module can determine whether the NG tube is present in the stomach.

[0071] Energy is detected and analyzed and a signal is sent to the user interface. The user can visualize a green light indicating that the NG tube is properly placed. In the alternative, a red light can indicate that the tube is improperly placed.

[0072] In mode 3, energy is transmitted from all three antennae of the transmitter module as illustrated in Fig. 2. The antenna labelled "lungs" is placed over the lungs. The antenna labelled "stomach" is placed over the stomach. The third antenna is

located between these two. Based on the energy received from the three antennae, the analyzer module can determine whether the NG tube is present in the stomach. The user interface will then indicate the proper (or improper) position of the NG tube to the user.

[0073] After connecting the insulted conductor **102** to the external handheld device **104**, the clinician can hold or 'hover' the external hand-held device over the stomach area. The external hand-held device can indicate whether the nasogastric tube is in the stomach by using a light, sound or text. For example, the device can display a green light. If the tube is not detected in the stomach, the device can give a signal to prompt the clinician to immediately remove or adjust the position of the tube. For example, the device can display a red light or emit a warning sound such as a beep.

iNGT Tube System

[0074] FIG. 4 is a detailed illustration of the assembled NG tube. The receiving antenna **103** is near the distal tip. A catheter tube **104** extends across a substantial length of the tube. The catheter tube is used for passing food or other substances into the stomach or aspirating material out of it. The coaxial cable **102** links the antenna to a subminiature connector (SMA) **101** or other similar connector. The SMA is connected to the transmitter unit for use.

[0075] NG tubes must have small diameters to be effective and minimize discomfort during NG tube intubation. Accordingly, the NG tube antenna must be compact. The iNGT system preferably includes a loop antenna of less than 3.0 mm with a ferrite core or similar design. The selected frequency dictates the arrangement of the coil (i.e. number of rotations). This determines the inductance and capacitance of the coil and other characteristics of the antenna. In a preferred design, the transmitter antenna operates at a frequency of 13.56 MHz.

[0076] The receiving antenna is compact and receives the signal from the transmitter

antenna. A loop antenna design is preferable because of the size constraint. The number of coils or turns is optimized for the preferred inductance, capacitance and other characteristics of the antenna. The number of loops therefore is chosen such that the antenna works well at the selected frequency. The loop/receiving antenna can be composed of ferrite. The coil antenna can be wound around a ferrite core to maximize the flux crossing through it and maximize the signal that is generated. The receiver antenna preferably has a diameter of less than 3.0 mm to fit on the distal end of the NG tube. It preferably also has a short length improve so that the system can accurately pinpoint its location.

[0077] FIG. 5 is a schematic diagram showing the antenna radiation **401** perpendicular to the vertical orientation of the body. By antenna theory, the expected radiation pattern of the nasogastric tube antenna is donut shaped with its primary gain perpendicular to the vertical axis of the human body.

[0078] When the distal end of the NG tube is in the stomach and the transmitter is placed directly over the stomach, the transmitter will detect overlapping radiation patterns. FIG. 6 shows how radiation patterns **500** overlap when the nasogastric tube is in stomach. A radiation pattern **501** from external hand-held device is shown when placed over stomach area. The radiation pattern from embedded antenna in the nasogastric tube is also shown **502**. Here, the maximum energy is detected by the receiver and analyzer module (i.e. handheld device) when placed over the stomach of the patient. The system will detect less energy if the handheld device is placed over the lungs of the patient or elsewhere.

[0079] FIG. 7 shows the mismatch in radiation patterns **600** when the nasogastric tube is in lungs. Maximum energy will be recorded by the handheld device when the tube antenna is placed above the lungs of the patient. Significantly less energy is detected when the handheld device is placed over the stomach of the patient. A radiation pattern **601** from the external hand-held device does not overlap with that of the NG tube

antenna **602**. Here, the hand-held device will alert the clinician of the misplacement and indicate that the tube should be removed or adjusted.

WORKING EXAMPLE – DETECTION OF A FEEDING TUBE

[0080] An NG tube is often used for enteral feeding. The tube is minimally invasive and relatively quick and easy to insert. It is particularly useful to avoid a surgical procedure to insert a gastrostomy device. However, because of the dangers of an improperly placed NG tube, the user must use caution in inserting and maintaining the position of the tube.

[0081] FIG. 8 is a flow chart depicting a process **800** of intubating a patient and verifying the position of a nasogastric tube using the invention. At step **801**, the clinician selects a feeding tube suitable for the patient. A clinic or hospital may have particular guidelines for choosing the appropriate type and size of NG tube. The iNGT system can include different types of tubes of various sizes. The healthcare provider selects the proper NG tube depending on considerations such as the desired procedure, patient's size and the anticipated length of time that an NG tube will remain in place. Further guidelines and considerations may be necessary when treating an infant or child.

[0082] The healthcare provider ("user") inserts the tube into the patient **802** according to an accepted protocol. He or she carefully inserts the NG tube into the patient by passing the distal end through the nose, down through the esophagus and then to the stomach. Thereafter, the proximal end of the tube may be secured with tape or held in place while checking its position.

[0083] A coaxial cable is attached to the proximal end of the NG tube. The user connects a subminiature connector (SMA) on the end of the cable to the transmitter module. The user confirms that the system has power by, for example, visualizing a "power on" button or light.

[0084] The user can confirm that the location of the distal end of the NG tube by moving the handheld apparatus ("transmitter") over the surface of the patient and watching the visual display. The transmitter is "hovered" or placed over the patient's body to allow it to detect and analyze the emitted energy. The user can guide the transmitter over the contour of the body, from the throat to the esophagus and then the stomach.

[0085] These steps are depicted in Figure 9, wherein the user places the handheld device over the stomach area of the patient **803**. At step **804**, the device detects whether the tube is in stomach area. If the device is not detected in stomach area, then the handheld device is hovered over the lungs area of the patient **805**. At step **807**, the device determines whether the tube is in the area near the lungs.

[0086] If the NG tube was properly inserted and has not been misplaced, the distal end will be in the stomach. When the transmitter is placed directly over the stomach, the detector module will sense the overlapping radiation patterns (see FIG.5). In this case, the interface on the transmitter will notify the caregiver with a signal such as a beep or icon on the screen. The user can proceed with nasograstric feeding or other patient care.

[0087] Occasionally, an NG tube will bend or form a coil when it is inserted, in which case, the distal tip may not reach the stomach. Other times, the tube may be misdirected into the lungs. If the NG tube is not properly inserted or is misplaced after insertion, the radiation patterns will not overlap (see FIG.6). The interface on the transmitter will notify the user with a signal such as a buzzer or flashing icon on the screen. In this circumstance, the NG tube should be promptly removed. The healthcare provider should return to the first step in the procedure.

[0088] By default, the system will operate in Mode 3, wherein energy is transmitted

from all three antennae of the transmitter module alternatively. The antenna labelled "lungs" is placed over the lungs. The antenna labelled "stomach" is placed over the stomach. The third antenna is located between these two. Based on the energy received from the three antennae, the analyzer module can accurately determine whether the NG tube is present in the stomach.

[0089] The clinician can feed the patient if the device detects the tube in the stomach area **806**. If the tube is in the lungs, as shown at step **809**, the clinician checks whether the tube can be readjusted. If so, then the clinician readjusts the tube and proceeds to step **803**. Otherwise, the clinician can remove and re-insert the tube **810**.

[0090] FIG. 9 is a flow chart depicting the process **900** of verifying the location of a nasogastric tube using the invention. This process is appropriate when, for example, regular testing is necessary for an NG tube that remains in place. At step **901**, the clinician checks the feeding tube and begins the process. The clinician places the handheld device over the stomach area of the patient **902**. At step **903**, the device determines whether the tube is in stomach area. If the device is not detected in the stomach area, then the clinician can place the handheld device over the lungs of the patient **905**. At step **907**, the device determines whether the tube is in lungs. If the tube is detected in the stomach or if the device is not detected in the lungs, the clinician can give food, fluid and medication as prescribed **904**. As shown at step **907**, the clinician can remove the tube and begin the process again if the tube is in the wrong location.

[0091] The system is safe, easy to use and is particularly well suited to repeated tests. Thus, it is conducive for use with an NG tube that is to remain in place for an extended period of time (e.g. a feeding tube). In such case, the position of the tube should be regularly confirmed prior to administering food and/or according to protocol.

[0092] The system is inexpensive and requires minimal training for use. It can be used in a clinical setting as well as a home environment. Mature patients and/or

parents/care givers can be trained to use the iNGT system. It is also possible for a health care provider to conduct a second test (e.g. pH test) to confirm the results of the iNGT system.

[0093] It will be appreciated that variations of the above disclosed and other features and functions, or alternatives thereof, may be desirably combined into many other different systems or applications. Also that various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art which are also intended to be encompassed by the following claims.

[0094] Although we have attempted to comprehensively describe the embodiments in detail to cover all possible aspects, those skilled in the art would recognize that other versions of the disclosure are also possible. For example, although we describe the use of the invention for inserting a nasogastric tube, the invention can be used for inserting other tubes, catheters, probes or other objects into a patient, animal or subject. Moreover, the invention can be used for detecting the presence (or absence) of objects in a patient. It can also be used to follow one or more objects as they progress through a patient (e.g. through the digestive tract or circulatory system).

What is claimed is:

1. A system for determining the location of the distal end of a nasogastric tube in a person comprising:
    a. a nasogastric tube having a proximal end and a distal end wherein said distal end is inserted into a person and includes one or more receiving antennae;
    b. an external transmitter module connected to said nasogastric tube composed of:
        i. a power source;
        ii. a transmitter;
        iii. a receiver;
        iv. an analyzer; and
        v. a user interface,

    wherein electromagnetic energy transmitted from said transmitter is absorbed by said one or more receiving antenna and analyzed to determine the location of said distal end of said medical tube and displaying the location through said user interface.

2. The system of claim 1 wherein electromagnetic energy is not emitted from a component inside the patient.

3. The system of claim 1 wherein said transmitter includes more than one transmitting antennae, each capable of operating independently of one another.

4. The system of claim 1 wherein said transmitter includes a plurality of transmitting antennae for determining the location of the distal end of said nasogastric tube using antennae diversity.

5. The system of claim 1 wherein said analyzer uses an algorithm to determine the

location of a nasogastric tube inside a patient.

6. The system of claim 1 wherein the presence of the distal end of a nasogastric tube can be determined by holding said transmitter module over a person's stomach and observing a signal.

7. The system of claim 1 wherein the location of the distal end of a nasogastric tube can be determined using electromagnetic energy that is transmitted from outside a patient.

8. The system of claim 1 wherein the level of electromagnetic energy transmitted from said transmitter can be adjusted to accommodate for the size of a patient.

9. A method of confirming the presence of the distal end of a medical tube in a patient's stomach, comprising:

placing the distal end of a medical tube in the stomach of a patient, said medical tube having a receiving antenna near the distal end;

connecting the proximal end of said medical tube to an external transmitter module, said external transmitter module comprising a transmitter, receiver, analyzer and user interface;

placing the external transmitter module near the surface of the stomach of the patient;

analyzing the parameters of energy in the area near the stomach to determine the presence or absence of the distal end of the medical tube; and

conveying information to a user through said user interface.

10. The method of claim 9 wherein electromagnetic energy is not emitted from a component inside the patient.

11. The method of claim 9 wherein said external transmitter includes more than one transmitting antennae, each capable of operating independently of one another.

12. The method of claim 9 wherein said external transmitter includes a plurality of transmitting antennae for determining the location of the distal end of said nasogastric tube using antennae diversity.

13. The method of claim 9 wherein said analyzer uses an algorithm to determine the location of a medical tube inside a patient.

14. The method of claim 9 wherein the location of the distal end of a medical tube is determined using electromagnetic energy that is transmitted from outside of a patient.

15. A position-sensing medical tube system for minimizing a patient's exposure to electromagnetic energy comprised of:
    a. a medical tube having a proximal end and a distal end, wherein said distal end includes a receiving antenna and is placed inside a patient;
    b. an external transmitter module connected to the proximal end of the medical tube that includes a power source, a transmitter, a receiver, an analyzer and a user interface,

    wherein said transmitter radiates energy to the receiving antenna, said receiver detects radiation patterns from the receiving antenna and said analyzer uses an algorithm to determine the presence or absence of the distal end of the medical tube.

16. The position-sensing medical tube system of claim 15 wherein electromagnetic energy is not emitted from a component inside the patient.

17. The position-sensing medical tube system of claim 15 wherein said transmitter includes more than one transmitting antennae, each capable of operating independently of one another.

18. The position-sensing medical tube system of claim 15 wherein said transmitter includes a plurality of transmitting antennae for determining the location of the distal end of said nasogastric tube using antennae diversity.

19. The position-sensing medical tube system of claim 15 wherein the location of the end of the medical tube can be determined by holding said external transmitter module at different locations over a person's body and observing a signal.

20. The position-sensing medical tube system of claim 15 wherein electromagnetic energy transmitted from said transmitter can be adjusted to accommodate for the size of a patient.

21. The position-sensing medical tube system of claim 15 wherein said medical tube is a nasogastric tube, an orogastric tube, a percutaneous endoscopic gastrostomy tube, a percutaneous jejunostomy tube, an endotracheal tube, a chest tube, a urinary catheter, an intravenous catheter, an arterial catheter, a gastric decompression tube, a suction tube, a drainage tube, an intracranial pressure monitor, a catheter or a syringe.

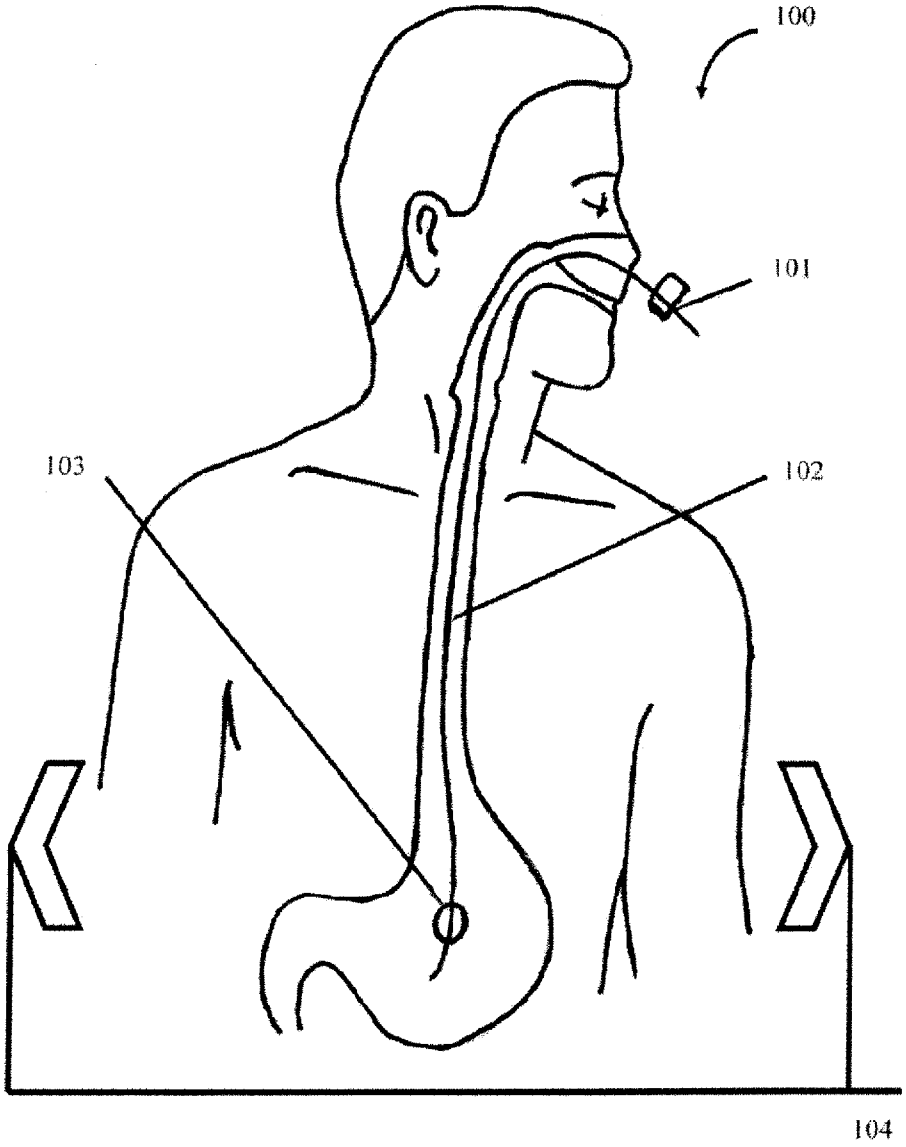

FIG. 1

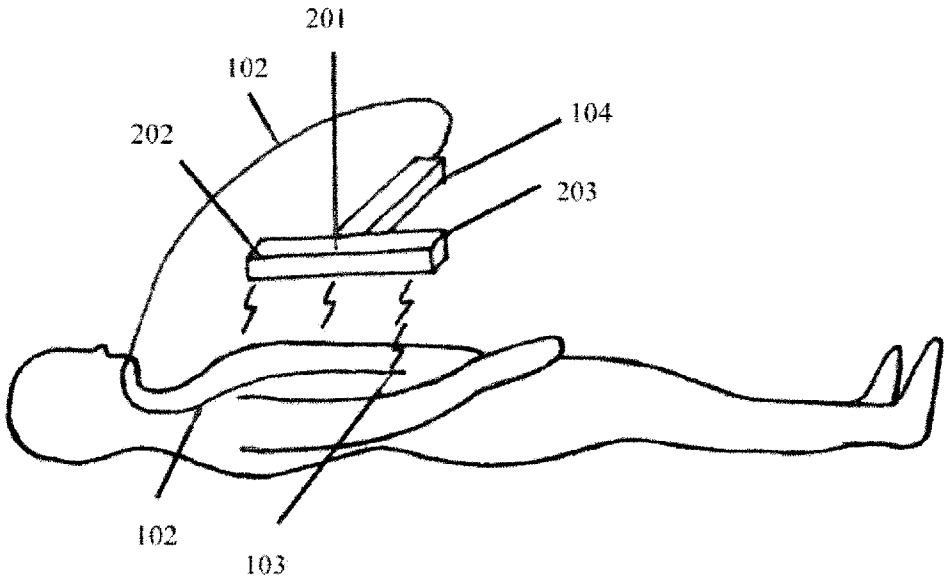

FIG. 2

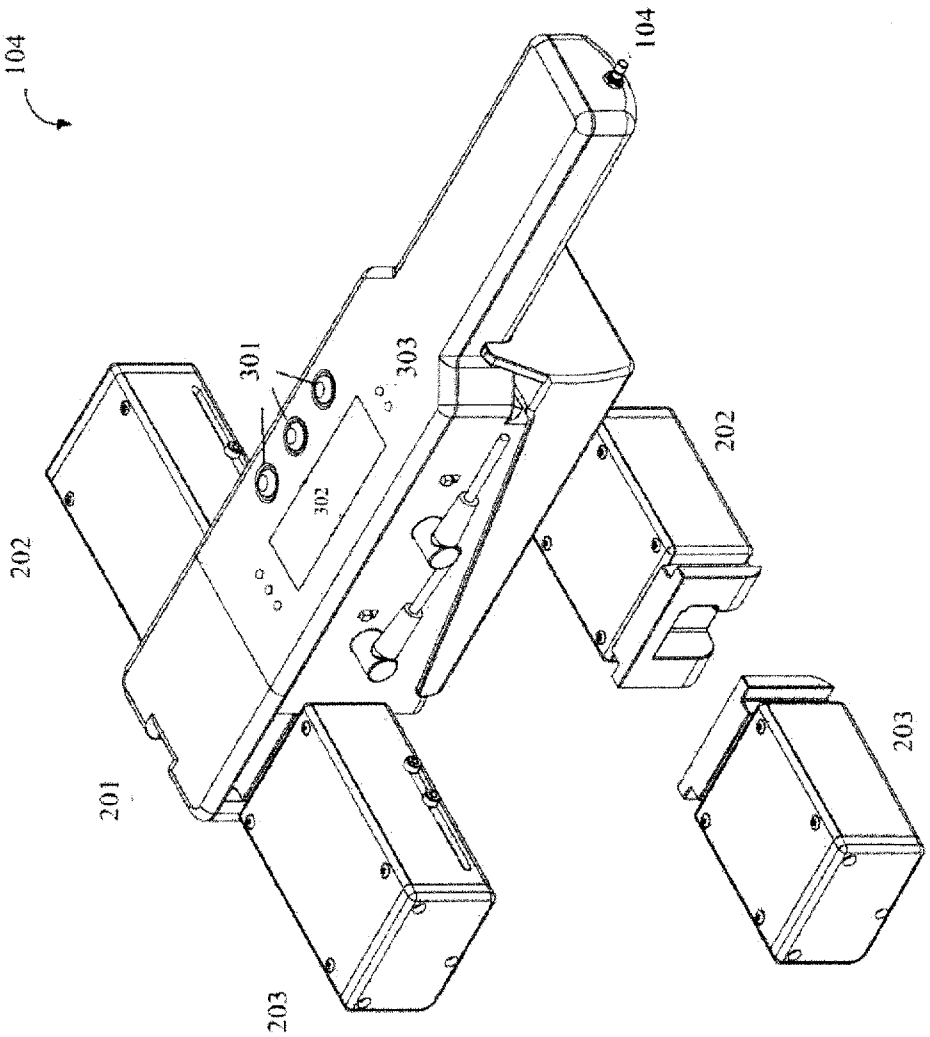

FIG. 3

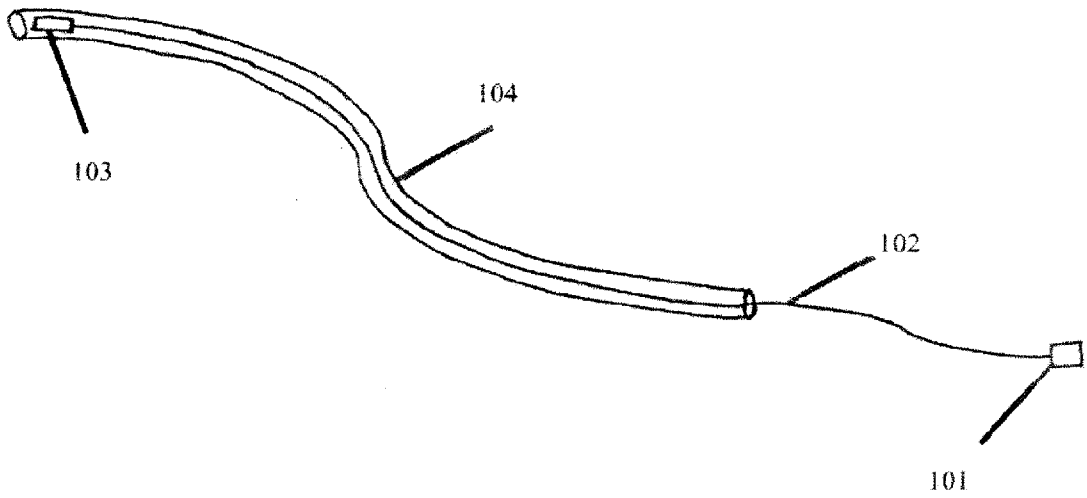

FIG. 4

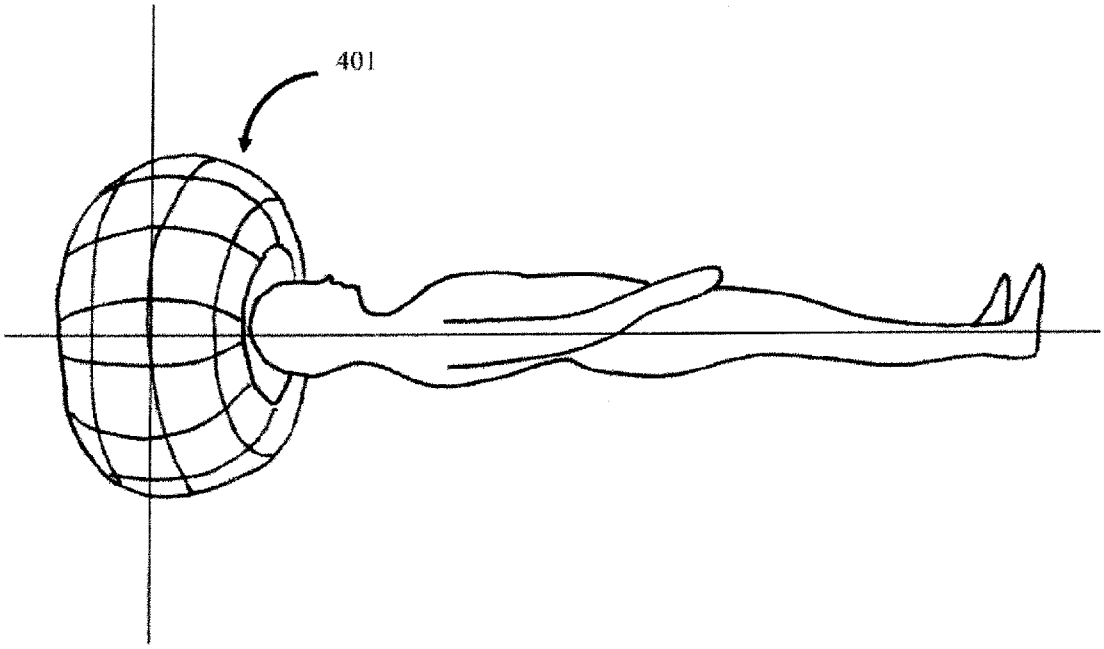

FIG. 5

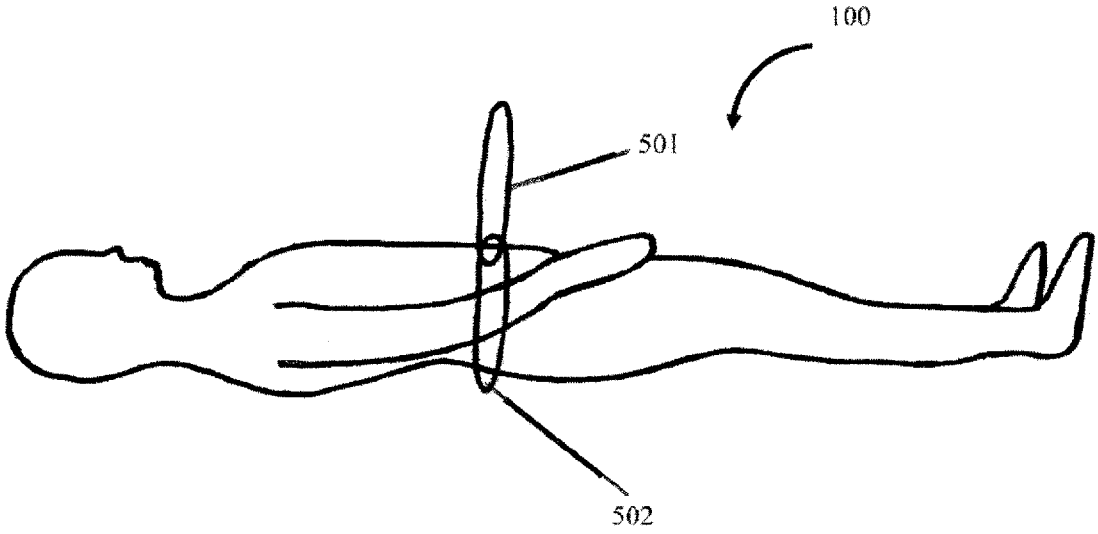

FIG. 6

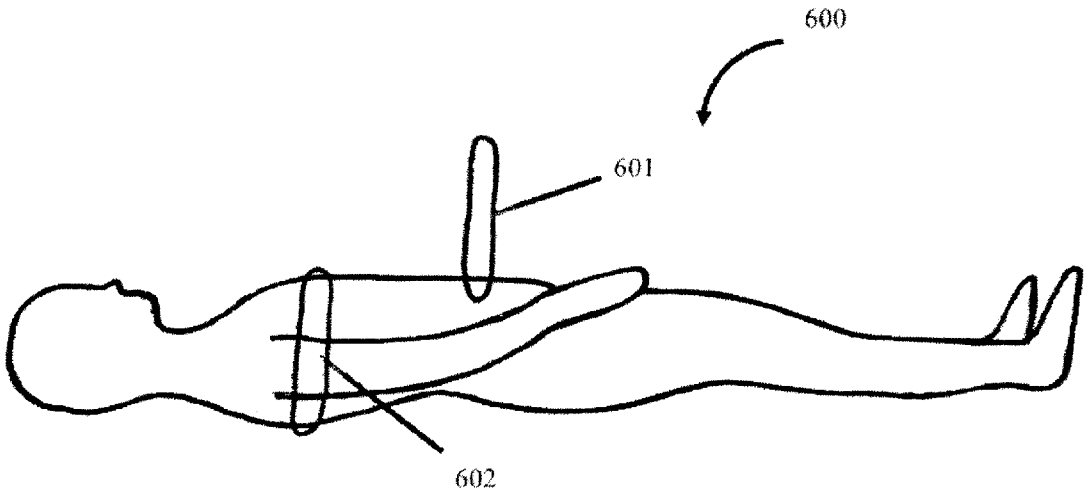

FIG. 7

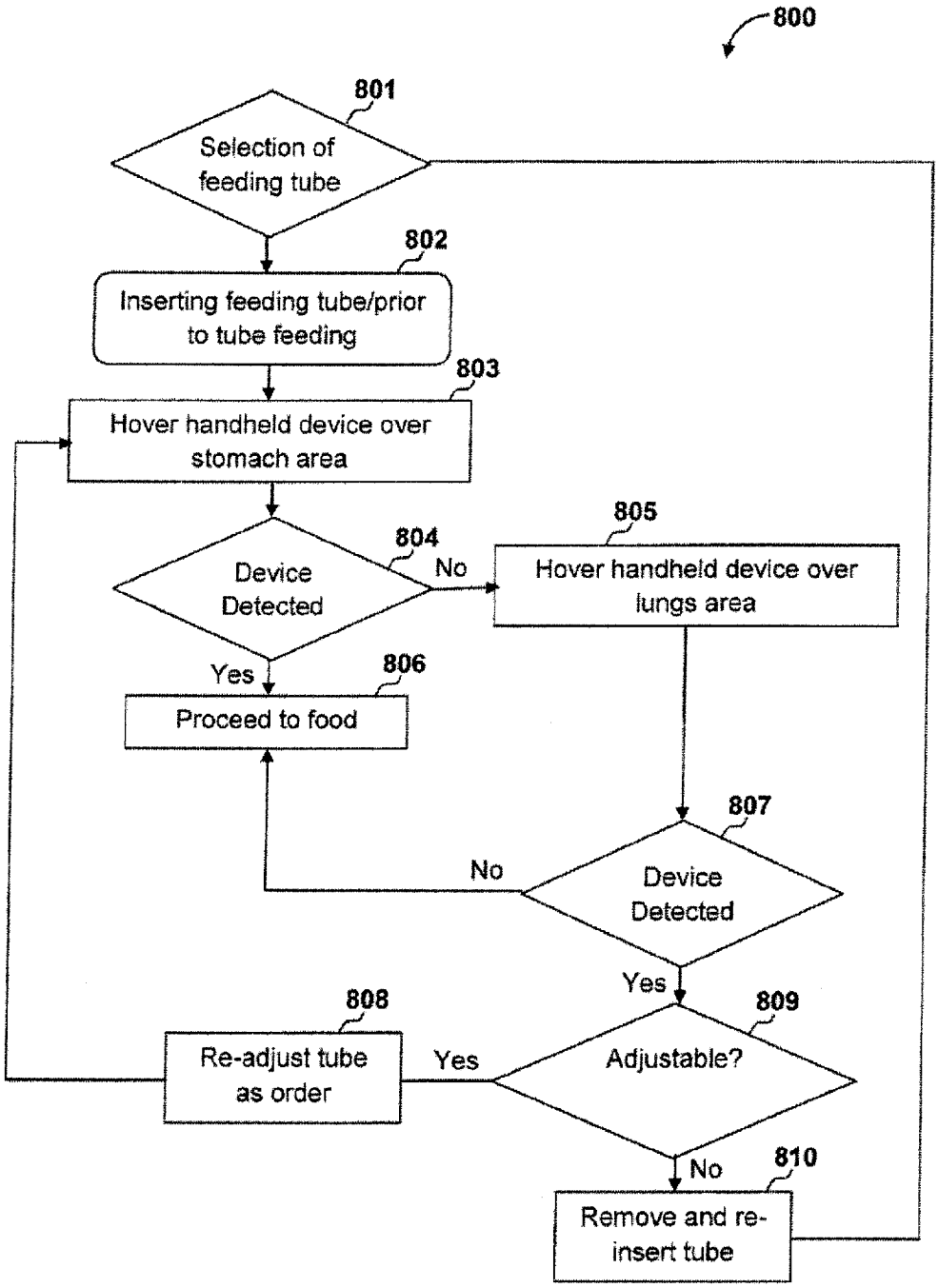
800
801
Selection of feeding tube
802
Inserting feeding tube/prior to tube feeding
803
Hover handheld device over stomach area
804
Device Detected
No
805
Hover handheld device over lungs area
Yes
806
Proceed to food
807
No
Device Detected
Yes
808
Re-adjust tube as order
Yes
809
Adjustable?
No
810
Remove and re-insert tube

FIG. 8

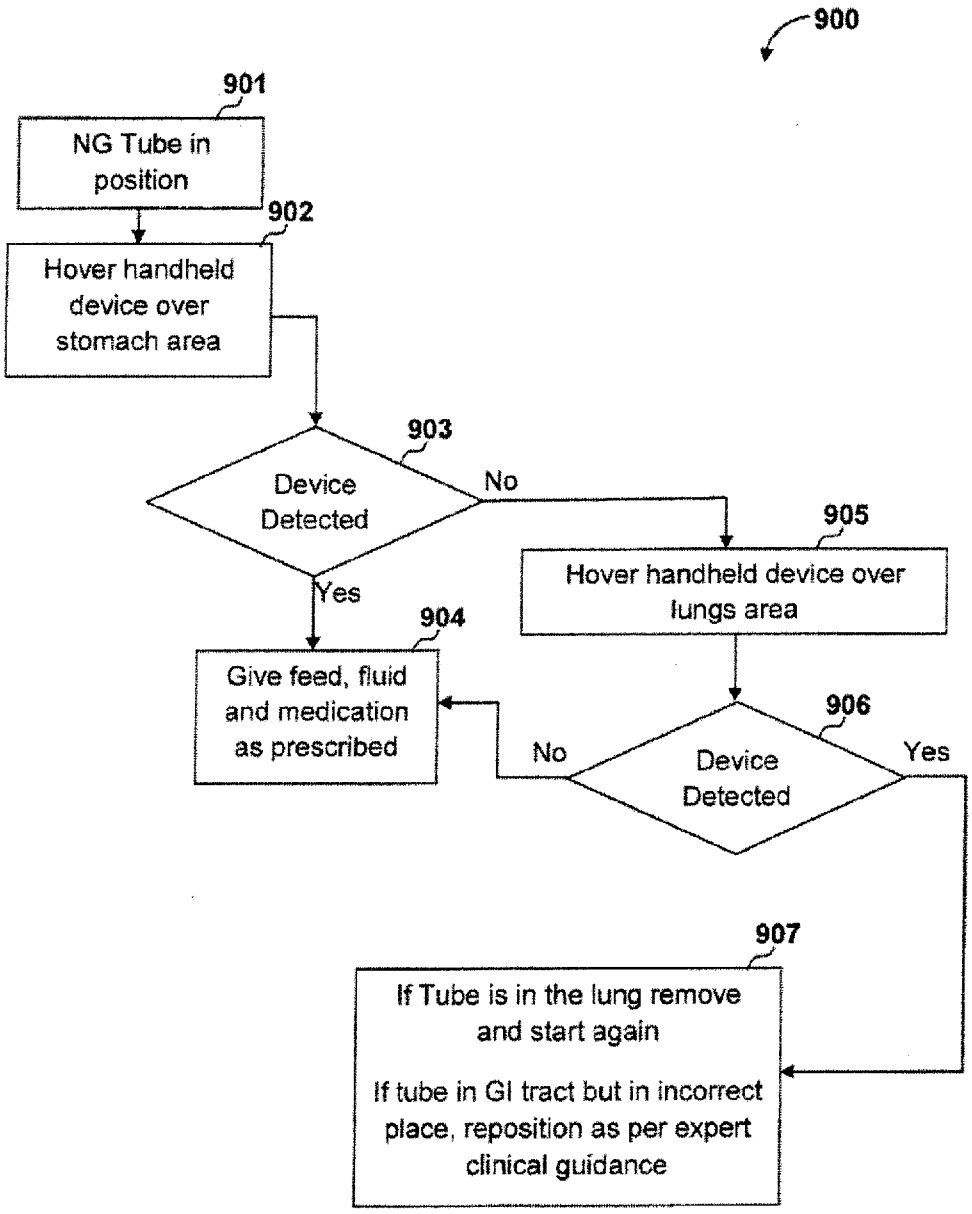
900
901
NG Tube in position
902
Hover handheld device over stomach area
903
Device Detected
No
Yes
905
Hover handheld device over lungs area
904
Give feed, fluid and medication as prescribed
906
No
Device Detected
Yes
907
If Tube is in the lung remove and start again
If tube in GI tract but in incorrect place, reposition as per expert clinical guidance

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2016/050195

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/06 (2006.01) A61B 6/12 (2006.01) A61B 34/20 (2016.01) A61J 15/00 (2006.01)

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)

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

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

Databases: EPODOC, WPIAP, TXTE; CPC/IPC Marks: A61B5/06, A61B5/062, A61B5/06/LOW, A61B6/12, A61B6/12/LOW, A61B34/20, A61B2034/2051/LOW, A61B34/20/LOW, A61J15/00, A61J15/0003/LOW, A61J15/0088; and Keywords: Antenna, Ariel, Transmit, External, Outside, Receive, Internal, Inside, Distal, End, Tip, Nasogastric, Orogastric, Oronasal, Feeding, Tube, Catheter, Track, Position, Locate, Placement, Handheld, Body, Skin, Stomach, Chest, Abdomen, Lungs and like words.

Applicant Inventor Search on ESPACENET using: "Venia" or "Tan Tock" as Applicants OR "Ogirala" or "Vaz" or "Leong" or "Singh" or "Ng" as Inventors AND/OR A61B5/06 or A61B6/12 or A61B34/20 or A61J15/00 as IPC marks.

Applicant(s)/Inventor(s) name searched in internal databases provided by IP Australia

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] 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

"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	Date of mailing of the international search report
15 July 2016	15 July 2016
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Kiran Karve AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. 0262832824

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/SG2016/050195**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5042486 A (PFEILER et al.) 27 August 1991 Figure 2; Claims; Column 4, Lines 39 – 58	1 – 7, 9 – 19 and 21
X	US 5375596 A (TWISS et al.) 27 December 1994 Column 4, Lines: 15 – 19, 47 – 52; Column 5, Line 49 – 53; Column 6, Lines: 5 – 8, 13 – 17, 50 – 58; Column 7, Lines 17 – 36; Column 8, Lines 23 – 25; Column 8, Line 66 – Column 9, Line 12.	1 – 2, 5 – 10, 13 – 16 and 19 – 21
X	US 2011/0098559 A1 (BESZ et al.) 28 April 2011 Figure 1, Paragraphs [0051] – [0055]	1 – 2, 5 – 7, 9 – 10, 13 – 16, 19 and 21

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/SG2016/050195**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 5042486 A	27 August 1991	US 5042486 A	27 Aug 1991
		EP 0419729 A1	03 Apr 1991
		JP H03133429 A	06 Jun 1991
		JP 2947908 B2	13 Sep 1999
US 5375596 A	27 December 1994	US 5375596 A	27 Dec 1994
		US 5513637 A	07 May 1996
		WO 9608998 A1	28 Mar 1996
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		AU 2006206037 A1	20 Jul 2006
		AU 2006206037 A2	02 Oct 2008
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		EP 1843810 A1	17 Oct 2007
		JP 2008526390 A	24 Jul 2008
		WO 2006074510 A1	20 Jul 2006

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.