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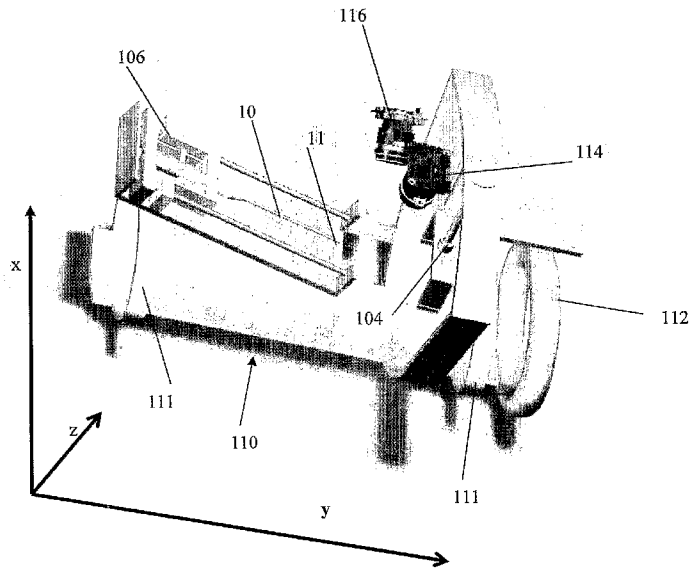
(54) **Title:** VASCULAR ACCESS SYSTEM AND METHOD



(57) **Abstract:** A puncture system for inserting a needle into a subcutaneous blood vessel comprising: (a) detection means for locating the subcutaneous blood vessel in body tissue; (b) alignment means for aligning needle into the body tissue for insertion into the blood vessel; (c) driving means for driving the needle into the body tissue for insertion into the blood vessel, and (d) means for ensuring the needle is not inserted too far, and a preferred method of inserting a needle into the blood vessel comprising the steps of: attaching a sleeve of a puncture system as described above over a distal limb; locating blood vessel; aligning the needle with the blood vessel in the plane of the skin surface; inserting the needle into the limb at a shallow angle to a depth where needle punctures outer surface of blood vessel, detecting that needle tip is within blood vessel and stopping further insertion.

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VASCULAR ACCESS SYSTEM AND METHOD

FIELD OF THE INVENTION

The present invention is directed to providing an automated system for inserting needles into veins for infusions, injections, blood sampling, blood donating, insulin injecting and the like.

BACKGROUND

Vascular access is one of the most commonly performed invasive medical procedures. It has been estimated that over 1.4 billion vascular access or venipuncture procedures are performed annually in the US alone. Inserting a needle cleanly into a vein first time around is not easy however, and it has been estimated that some 28% of needle insertions are performed badly, where the patient is an adult. Furthermore, some 23% to 28% of needle insertions result in extravasations or infiltrations.

In pediatric medicine, the problem is exasperated as the veins are smaller, making hitting a vein more difficult and not inserting the needle too far troublesome. Children have less patience than adults and typically have a low threshold to pain, making the whole venipuncture experience traumatic to all concerned.

Local anaesthetics cannot usually be used with traditional manual needle insertion techniques since the anaesthetic makes locating the vein through the skin even more difficult.

Attaching an infusion intravenously is difficult for paramedics on the battle field or at the scene of a car accident. The veins of patients in shock "sink" into the tissue, making it almost impossible to insert an IV once some minutes have elapsed since the patient was wounded. In the Vietnam was, for example, it is estimated that several thousand soldiers died from wounds to their arms or legs. Several of these could have been saved if an effective method of inserting an IV had been available. Working under stress in the dark only complicates things further.

It has been estimated that some 800,000 to 1,000,000 needle stick injuries occur in American hospitals each year. This costs some 3 billion dollars annually and sometimes results in loss of life.

Treatment of chronic diseases such as diabetes, end-stage renal failure, cancer, cardiovascular, HIV/AIDS, multiple sclerosis, obesity and the like, require recurrent

hospitalization and multiple courses of intravenous treatments. It is estimated that difficult vein access is encountered in some 25% of hospitalized patients.

To address this problem, a number of systems have been developed that use near infra red (NIR) illumination to image or map the position of subcutaneous blood vessels. For example: PCT Publication Number WO06073869 titled "System and Method for Inserting a Needle into a Blood Vessel" and incorporated herein by reference, describes a needle insertion system that includes an imaging system and a needle. The imaging system includes at least one infrared emitter an infrared detector, a computing unit, a display device, and a power source. The method includes the steps of preparing a body target area, putting on a headset, powering up the system, locating a target blood vessel, picking up the needle, aligning the needle with the target blood vessel, inserting the needle, advancing the needle until a sufficient depth of penetration has been reached, and withdrawing the needle.

PCT Publication Number WO06069066 titled "System and Method for Locating and Accessing a Blood Vessel" and incorporated herein by reference, describes an imaging system for locating subcutaneous blood vessels and a method for locating subcutaneous blood vessels using the system. The system includes at least one infrared emitter an infrared detector, a computing unit that enhances images and outputs enhanced images in substantially real time, a display device for displaying enhanced images, and a power source. The method also includes the steps of preparing a body target area, putting on a headset, powering up the system, locating a target blood vessel, inserting a needle into the target blood vessel, and performing the medical procedure.

Japanese Publication Number JP2006130201 titled "Device and Method for Presenting Positions of Blood Vessel and Syringe Needle" and incorporated herein by reference, relates to a blood vessel / needle position presentation apparatus for a doctor / nurse that comprises display of mark and blood vessel emphasis images specifying positions of needle and blood vessel simultaneously. Specifically, a device is described for presenting the positions of a blood vessel and a syringe needle, by which the position and direction of a vein which is not easily viewed are confirmed, piercing is performed with excellent precision, and relation between the point of the syringe needle after piercing and the position/direction of the vein is confirmed.

Japanese Publication Number JP2006102110 titled "Blood Vessel Position Presenting Apparatus" and incorporated herein by reference, describes a system that comprises an illumination means for radiating near-infrared light and visible light; an imaging means with high near-infrared light spectroscopic sensitivity; a means for detecting the blood vessel image of a living body through the use of an near-infrared light image imaged in radiating the near-infrared light and a visible image imaged in radiating the visible light, so as to generate a blood vessel emphasizing image; a means for detecting the image of a syringe, so as to acquire extracted syringe feature information, predicting the position of the syringe needle point which is being pieced into the living body, based on the syringe feature information, calculating the position, and generating a mark image which indicates the predicted position of the syringe needle point with respect to the blood vessel emphasizing image; and a display means for displaying a composed image of the blood vessel emphasizing image and the mark image.

Japanese Patent Publication Number JP2004329786 titled "Blood Vessel Projector and its Projecting Method" and incorporated herein by reference, provides a blood vessel projector which allegedly enables an unpracticed operator to puncture a needle infallibly and can be used not only for puncturing the needle including blood drawing but for detecting and observing a foreign body or a lesion under the skin. The blood vessel projector comprises a blood vessel detector and a blood vessel indicator. The blood vessel detector has an infrared laser generator and a reflected infrared wave measuring means, and the blood vessel indicator has a visible light laser generator.

Chinese Publication Number CN1546184 titled "Guiding Device for Venipuncture" and incorporated herein by reference, describes a directing apparatus for venous blood vessel piercing, which is a venous blood vessel image-forming system comprising a rectangular near-infrared transmitting tube, a cylindrical near infrared ray receiver, a square monitor and a DC power source. During real time operation, the image signals can be transmitted to the monitor.

United States Patent Number US 6,353,753 titled "Optical Imaging of Deep Anatomic Structures" and incorporated herein by reference, provides an apparatus and means for visualizing blood vessels and subsurface anatomic structures during surgery and in Real Time, with improved optical imaging and minimized trauma to the patient. More specifically, the technology described therein provides a method for

imaging a deep anatomic tissue of interest, comprising the steps of: emitting radiant energy to the surface of said tissue; enhancing contrast of said radiant energy; and detecting reflected radiant energy from said tissue surface, wherein the reflected radiant energy provides imaging information of the tissue.

United States Patent Number US 6,178,340 titled "Three-Dimensional Infrared Imager for Subcutaneous Puncture and Study of Vascular Network" and incorporated herein by reference, describes a novel three-dimensional infrared imager for study of the vascular network so as to cause blood vessels to be visualized for accurate subcutaneous puncture during insertion of a hypodermic needle. The technology described uses the properties of near infrared light as it is absorbed and reflected by the human body, allowing the user to visualize the tissues a few millimeters below the skin's surface. The use of infrared light permits the manipulation of the acquired information to a grade of sensed visualization, which is impossible to reach with visible light. The technology imitates the human three-dimensional perception by use of a stereoscopic infrared viewer, and is designed to be user-friendly, allowing the health care professional to work in his usual manner. A double image is superimposed on the viewer and the user wears blue-red eyeglasses to create the three-dimensional image from the double image on the viewer. With the depth perception provided by the three-dimensional image, the user can accurately penetrate the vein on the initial attempt, thereby lowering the fear of venous puncture and causing the patient to be at ease, while lowering the incidence of medical complications associated with inaccurate puncture. In a preferred embodiment, a liquid crystal display (LCD) mounted in a frame is provided on the upper surface of the apparatus. Sensitive, charge-coupled devices are provided which develop images and deliver them to a microprocessor which synchronizes the images and allows the user to manipulate the images as desired, controlling effects such as brightness, contrast, sharpness and edge enhancement. In another embodiment, the inventive imaging system incorporates the use of a contrast agent to enhance the image and allow for study of the vascular system. In yet another embodiment, the imaging system incorporates the use of a coherent source of light, such as an infrared laser.

United States Patent Number US 5,947,906 titled "Apparatus for Enhanced Visual Venous Examination" and incorporated herein by reference, relates to an apparatus for aiding in performing operations requiring location of blood vessels such

as intravenous injections or drawing blood in which a charge coupled device camera is focused on an area of the body such as the arm that is illuminated by a light source which emits light that is partly in the infrared range and partly in the ultraviolet range but from which light having a wavelength in the visible range has been substantially eliminated. The useful range of wavelengths may be provided by any one of several methods including having an infrared source and an ultra violet source or an incandescent source emitting wavelengths extending from the infrared to the ultra violet and having a filter for removing the range of visible light.

United States Patent Number US 5,608,210 titled "Infrared Aided Method and Apparatus for Venous Examination" and incorporated herein by reference, describes a device for aiding a technician to locate a vein for inserting a hypodermic needle therein in which, in one embodiment, the technician dons a headpiece supporting an infrared light source illuminating an appropriate area of the flesh so that a view is generated showing the location of a subcutaneous vein. The headpiece also supports an infrared sensitive video camera and monitor screen in front of one eye and an opaque shield over the other eye. The lines of sight of the one eye viewing the screen is coincident with the line of sight of the camera and both lines of sight are directed toward the vein of the patient. The tip of the needle is moved into the line of sight and then moved along the line of sight to the vein. In another embodiment, two cameras and screens are provided for viewing by both eyes and each camera and monitor can be positioned with line of sight coincident with the line of sight of the respective eye.

United States Patent Number US 5,519,208 titled "Infrared Aided Method and Apparatus for Venous Examination" and incorporated herein by reference, describes a method and apparatus for gaining intravenous access including a source of radiation for irradiating an area of the patient wherein the radiation has a wavelength such that the radiation is absorbed in areas containing veins and reflected in all other areas thereby forming a view which is seen through a screen to be the area where venous structure appears as dark lines thereby enabling a user to position the tip of a hypodermic needle at an appropriate location for drawing blood. In one arrangement, the apparatus is mounted on the head of the user. In another arrangement the device is mounted on a floor stand. In another embodiment, the apparatus is equipped with an image intensifier. In another embodiment, a mirror is provided that enables the user to view the selected area and the image simultaneously.

United States Patent Number US 4,817,622 titled "Infrared Imager for Viewing Subcutaneous Location of Vascular Structures and Method of Use" and incorporated herein by reference, describes an apparatus wherein a human appendage, typically the inside of the elbow, is illuminated with an infrared source, for example, at least one incandescent light bulb. A video camera for producing a video image and immediately overlying monitor for displaying the video image is utilized to look at the flesh. The camera is sensitive to infrared radiation. A video display results in which infrared absorbing or scattering contrasting portions of the flesh are highlighted, for example, hard to find veins for insertions of needles. A contrast enhancing circuit is included which discloses amplifying the video information with high contrast enhancement of the video. Adaptation of the disclosed circuit to conventional TV charge-coupled device cameras and monitors is illustrated with compensation of horizontal sweep to even image background, intensity averaging line to line for vertical image uniformity and display of image contrasts on a log amplification format.

Where systems such as those referred to hereinabove are used for venipuncture, they are used for guiding the doctor or nurse, with the actual needle insertion being performed manually, relying on the expertise of the practitioner.

Also known, are sophisticated systems for surgery that enable surgical instruments to be manipulated remotely. For example: US 6,963,792 titled "Surgical Method", incorporated herein by reference, describes a teleoperator system with telepresence which includes right and left hand controllers for control of right and left manipulators through use of a servomechanism that includes a computer. The teleoperator system comprises a surgical system suited for endoscopic surgery. The surgical system includes a surgical instrument, a servomechanism and a controller. The surgical includes an insertion section and a control section. The insertion section comprises a forearm, a wrist and an end effector in the form of a surgical instrument head selected from the group consisting of retractors, electrosurgical cutters, electrosurgical coagulators, forceps, needle holders, scissors, blades and irrigators. The control section comprises a plurality of motors and linkages which operate to insert and retract the forearm, rotate the forearm, pivot the forearm, and pivot the wrist link about the wrist joint. Here the surgeon actively manipulates the surgical tool albeit remotely.

In other systems, the relative position of surgical tool and body tissue are calculated or imaged. United States Patent Number US 6,491,702 titled "Apparatus and Method for Photogrammetric Surgical Localization" incorporated herein by reference, describes a method and apparatus for defining the location of a medical instrument relative to features of a medical workspace including a patient's body region. Pairs of two-dimensional images are obtained, preferably by means of two video cameras making images of the workspace along different sightlines which intersect. A fiducial structure is positioned in the workspace for defining a three dimensional coordinate framework, and a calibration image pair is made. The calibration image pair comprises two 2D projections from different locations of the fiducial structure. After the calibration image pair is made, the fiducial structure is removed. A standard projection algorithm is used to reconstruct the 3D framework of the fiducial structure from the calibration image pair. Appropriate image pairs can then be used to locate and track any other feature such as a medical instrument, in the workspace, so long as the cameras remain fixed in their positions relative to the workspace. The computations are desirably performed with a computer workstation including computer graphics capability, image processing capability, and providing a real-time display of the workspace as imaged by the video cameras. Also, the 3D framework of the workspace can be aligned with the 3D framework of any selected volume scan, such as MRI, CT, or PET, so that the instrument can be localized and guided to a chosen feature. No guidance arc or other apparatus need be affixed to the patient to accomplish the tracking and guiding operations.

United States Patent Number US 6,535,756 titled "Trajectory Storage Apparatus and Method for Surgical Navigation System", incorporated herein by reference, describes an apparatus and methods for use within an image-guided surgical navigation system for the storage and measurement of trajectories for surgical instruments. An icon representing the real-time trajectory of a tracked instrument is overlaid on one or more pre-acquired images of the patient. At the surgeon's command, the navigation system can store multiple trajectories of the instrument and create a static icon representing each saved trajectory for display. The surgeon may also measure a planar angle between any two trajectories. The angle is computed in the plane of the image, and therefore will be computed separately for each image

displayed. Furthermore, the surgeon has the option of computing and displaying the three-dimensional distance between two points defined by any two trajectories.

United States Patent Number US 6,491,699 titled "Instrument Guidance Method and System for Image Guided Surgery", incorporated herein by reference, is directed to a method and system for aligning surgical guide instrument over a burr hole in a patient's body. More particularly, the technology is directed to a stand-alone instrument guidance unit that is attachable to a patient's skull. Adjustments of a surgical instrument can be made in x, y, z, and angular directions using the system and method of the technology. In one aspect thereof, an instrument guide unit includes an instrument guide for guiding a surgical instrument into the body of a patient and a base unit operative to be secured to the body in an area in which surgery is to occur. The base unit is coupled to the instrument guide. An adjustment mechanism, coupled to the base unit and the instrument guide, is operative to adjust the instrument guide in lateral directions with respect the surface of the area. The adjustment mechanism is operative to adjust the instrument guide in x and y directions. The adjustment mechanism includes an x direction control mechanism for adjusting the instrument in an x direction and a y direction control mechanism for adjusting the instrument in a y direction. The y direction control mechanism may be coupled to the x direction control mechanism. The positional movement of the surgical instrument in the z direction may be tracked by sensing the location of a transducer coupled to the surgical instrument.

United States Patent Number US 6,490,467 titled "Surgical navigation systems including reference and localization frames" and incorporated herein by reference, describes a system for use during a medical or surgical procedure on a body. The system generates an image representing the position of one or more body elements during the procedure using scans generated by a scanner prior or during the procedure. The image data set has reference points for each of the body elements, the reference points of a particular body element having a fixed spatial relation to the particular body element. The system includes an apparatus for identifying, during the procedure, the relative position of each of the reference points of each of the body elements to be displayed. The system also includes a processor for modifying the image data set according to the identified relative position of each of the reference points during the procedure, as identified by the identifying apparatus, said processor

generating a displaced image data set representing the position of the body elements during the procedure. The system also includes a display utilizing the displaced image data set generated by the processor, illustrating the relative to the system are also disclosed. Also described are devices for use with a surgical navigation system having a sensor array which is in communication with the device to identify its position. The device may be a reference frame for attachment of a body part of the patient, such as a cranial reference are frame for attachment to the head or a spine reference are frame for attachment to the spine. The device may also be a localization frame for positioning an instrument relative to a body part, such as a localization biopsy guide frame for positioning a biopsy needle, a localization drill guide assembly for positioning a drill bit, a localization drill yoke assembly for positioning a drill, or a ventriculostomy probe for positioning a catheter.

United States Patent Number US 6,678,545 titled "System for Determining the Position in a Scan Image Corresponding to the Position of an Imaging Probe", incorporated herein by reference, describes a system for use in imaging a subject and determining a position relative to a body of a patient. Specifically, a base is fixed in relation to the subject. An imaging probe is configured to scan the subject and provide scan images of the subject. An array of receivers is in communication with the base and the imaging probe. A first plurality of reference points is fixed in relation to the base and in communication with the array. A second plurality of reference points is fixed in relation to the imaging probe and in communication with the array. A processor in communication with the imaging probe and the array calculates the position in the scan images corresponding to the position of the imaging probe relative to the subject.

US 7,072,704 titled "System for indicating the position of a surgical probe within a head on an image of the head", incorporated herein by reference, describes a system using imaging for controlling a probe position via a robot. The application described relates to neurosurgery rather than venipuncture.

In summary, medical imaging and three dimensional mapping appears to be well established for aiding a surgeon to navigate within the body. NIR imaging for mapping veins is also well established.

However, systems for remote manipulation of surgical tools combined with imaging systems are very costly and sophisticated and are typically only appropriate for precision brain surgery and the like. Although near infra red (NIR) imaging has been used for mapping / imaging veins, the medical practitioner wishing to inject or extract fluid into a vein has had to manually insert the needle, relying on his / her skill and experience to penetrate the needle tip into the vein, but not to exit the vein on the other side. There is a need for a simple automated system for inserting needles into accurately located veins for injecting or extracting fluids. The present invention addresses this need.

SUMMARY OF THE INVENTION

It is an aim of the invention to provide a system and method for inserting a needle into a blood vessel, typically a vein in automated fashion without relying on human skill.

It is a further aim of the invention to increase the success rate of venipuncture procedures.

It is a yet further aim of the invention to reduce pain to patient.

It is a still further aim to reduce the risk of complications.

It is a yet further aim to decrease the time that IV needle insertion takes.

It is a yet further aim to reduce the true cost of IV needle insertions.

In a first aspect a puncture system for insertion of a needle into a blood vessel is provided. The puncture system comprises: (a) detection means for locating a subcutaneous blood vessel in body tissue; (b) an alignment means for aligning a needle with the detected subcutaneous blood vessel; (c) a driving means for driving the needle into the body tissue for insertion into the detected subcutaneous blood vessel, and (d) a means for ensuring the needle is not inserted too far.

The blood vessel is typically a vein but may be an artery.

Typically, the puncture system further comprises a means of attachment for attaching to a limb.

Typically, the limb is a forearm.

Typically, the means of attachment comprises a sleeve.

Optionally, the means of attachment comprises straps.

Typically, the detection means comprises a near infra red detector for detecting near infra red emissions from the vein from above.

In one embodiment, the means for ensuring the needle is not inserted too far comprises a second near infra red detector for detecting near infra red radiation emitted sideways from the blood vessel.

In a second embodiment, the means for ensuring the needle is not inserted too far comprises a pressure sensor for detecting change of pressure as needle enters said vein.

In a second aspect, the present invention is directed to providing a method of inserting a needle into a subcutaneous blood vessel comprising the steps of: (a) attaching the puncture system of claim 1 over a distal limb by a means of attachment; (b) locating a blood vessel; (c) aligning the needle with the blood vessel in plane of skin surface; (d) inserting the needle into the limb at a shallow angle to a depth where needle punctures outer surface of blood vessel, and (e) detecting that needle tip is within blood vessel and stopping further insertion.

BRIEF DESCRIPTION OF THE FIGURES

For a better understanding of the invention and to show how it may be carried into effect, reference will now be made, purely by way of example, 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 the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention; the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice. In the accompanying drawings:

Fig. 1 is a schematic illustration of a vein map of an arm;

Fig. 2 is a near infra red image of the back of a hand, showing the blood vessels in clear contrast with surroundings;

Fig. 3 is a functional block diagram of an automated puncture system;

Fig. 4 is a schematic illustration of one embodiment of the invention consisting of a sleeve, a needle insertion apparatus and a pair of infra red cameras;

Fig. 5 shows the needle insertion apparatus and pair of NIR cameras of Fig. 3, without the sleeve;

Fig. 6 shows how needle is inserted into the needle box, and

Fig. 7 is a flowchart showing a novel automated puncture method.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to an automated puncture system, typically for venipuncture, i.e. for catheter placement, blood sampling, blood donating, infusions, injections and the like.

The system uses NIR radiation from a limb to enable mapping of blood vessels therein, for the automated insertion of a needle into a vein or artery. It can also be used to map blood vessels to ensure that a needle is inserted into tissue away from and does not puncture blood vessels.

With reference now to Fig. 1, the vein map of a typical arm is shown. It will be noted that three large diameter, straight, long peripheral veins 2A, 2B, 2C run through the flesh 4 of the anterior forearm 6. These are known as the cephalic 2A, antebrachial 2B and basilica 2C veins. In many ways, these large veins are optimal insertion locations. However, due to low vein visibility, physicians rarely use this area for venipuncture.

For purpose of the foregoing description, a set of orthogonal axes is used. The direction of blood flow along the arm is referred to henceforth as the +-Y direction. The axis across the arm as shown is known hereinafter as the X direction, and the direction into the tissue is known hereinafter as the Z direction.

With reference to Fig. 2, near infra red imaging techniques provide contrast between blood vessels and surrounding tissue. Preferred embodiments of the present invention use tried and tested near infra red imaging systems to locate veins running through the subcutaneous region selected for venipuncture.

Referring to Fig. 3, a functional block diagram of an automated puncture system 100 is shown. The puncture system 100 serves to drive a needle 10 (Fig. 4) into a blood vessel, typically a vein 2 (Fig. 1) located within the flesh 4 (Fig. 1) of a limb, such as the forearm 6 (Fig. 1), for example. The venipuncture system 100 consists of a detection means 102, an alignment means 104, a driving means 106, and a means 108 for ensuring that a needle 10 is not inserted too far. The puncture system 100 includes an attachment means 110 for attaching to the limb. The attachment means 110 may include straps, for example, and may be tied onto the limb, or a sleeve that may slid over the limb, or wrapped there around. Typically a quick closed fastening means is used, such as Velcro or pressed studs are used, for example.

Optionally an inflatable annular bladder 112 is provided that allows pressure to the veins 2A, 2B, 2C to be increased, causing them to dilate, aiding the needle 10 insertion procedure by making it more difficult for the needle 10 to be inserted too far.

The detection means 102 includes a near infra red detector 114 that detects a subcutaneous vein 2 (or artery, if preferred) and then the alignment means 104 aligns the needle 10 with the detected subcutaneous vein 2 in the XY plane. The driving means 106 drives the needle 10 into the vein 2 and the means 108 for ensuring the needle 10 is not inserted too far prevents the needle 10 from penetrating too far in the Z direction and puncturing the far side of the vein 2.

Referring to Fig. 4, a schematic illustration of one embodiment of the invention is shown. The needle 10 is situated within a needle box 12 which further comprises the driving means 106. The aligning means 104 moves the whole box in the X-X direction, thereby aligning the needle 10 with the vein 2. The means 108 for ensuring that the needle 10 is not inserted too far includes a second near infra red detector sensor 116 that maps veins in the Z direction. A sleeve 110 is shown with attachment straps 111 that may be elastic rings, or may include inflatable annular bladder 112 is provided that allows pressure to the veins 2A, 2B, 2C to be increased, causing them to dilate, aiding the needle 10 insertion procedure by making it more difficult for the needle 10 to be inserted too far.

Since the needle 10 is inserted at a very shallow angle Θ, and since large diameter veins 2A, 2B, 2C are preferably used, there is a relatively large distance and time interval between when the needle tip 11 pierces the outermost surface of the vein and when it reaches the innermost surface of the vein 2.

In a second embodiment of the invention (not shown), the means 108 for ensuring the needle 10 is not inserted too far comprises a pressure sensor such as a load cell or stress gauge that indicates that the needle 10 tip 11 has punctured the vein 2, and is forcing itself into the blood stream by a decrease in the driving force exerted by the driving means 106 indicating a decrease in resistance to the needle 10. Such a pressure sensor system essentially emulates the human operator who uses the lowered resistance to know that the needle has entered a vein. The drop in needle 10 insertion force ∂F automatically deactivates the driving means 106 and stops further motion of the needle 10, thereby preventing the needle being inserted too far.

Fig. 5 shows the needle 10 box 12, aligning means 104, driving means 106 and pair of NIR cameras 114, 116 of Fig. 3, without the sleeve 110. It will be appreciated that the basic system can be configured as particular embodiments for special applications, such as providing an epidural in a maternity ward, for example.

Fig. 6 shows how a sterilized needle 10 may be unwrapped from its packaging and inserted into the needle box 12. Since needle 10 is fully enclosed, the likelihood of accidents is minimized. For battle field applications and for use by emergency personnel at car crashes, train derailments and the like, a needle 10 can be pre-inserted into the needle box 12.

Embodiments of the equipment for the military may be designed and fabricated to meet the various applicable military specifications and will have rugged construction. Different versions may be optimized for different end users that include, inter alia, general practitioner clinics, hospital casualty units and special wards for cancer patients, pediatrics, and the like.

As shown in Fig. 7, a novel automated venipuncture method is proposed. The method comprises the steps of: (a) attaching the puncture system described above over a distal limb via the attachment means; (b) locating a vein; (c) aligning the needle with the vein in plane of skin surface; (d) inserting the needle into the limb at a shallow angle to a depth where needle punctures outer surface of vein, and (e) detecting that needle tip is within vein and stopping further insertion. In one embodiment, the Z dimensions of the vein are determined by a second NIR sensor. The needle is prevented from penetrating too far, by mapping the position of the needle onto the position of the vein. In a second embodiment, a pressure sensor in the needle driving means indicates that a vein has been punctured by a sudden, noticeable drop in the force required to drive the needle further into the tissue.

The present invention offers the following advantages over traditional manual techniques:

- The needle is inserted into the veins or arteries that are physiologically most suitable for injection, rather than those most easily seen and accessed by the physician.

- Local anesthetic can be used since the fact that anaesthetizing tends to make veins less visible to the human eye is irrelevant. This can further reduce pain to patients.
- The needle is not generally exposed, reducing accidental stabbing.
- The system can be used by non-trained personnel.
- Diabetics and other home users can inject into themselves without flinching. They can even inject themselves or do acupuncture, ensuring that arteries and veins are not punctured.
- Venipuncture can be accomplished in conditions of poor visibility, such as at night, in the field.

The system described above can be used, perhaps with application specific optimized embodiments, for insulin injection by diabetics, treating end-stage renal failure, injections and IV drips for cancer patients, treating cardiovascular illnesses, multiple sclerosis, the obese, HIV/ Aids sufferers, children, trauma victims at car crashes and on the battle field.

Thus the scope of the present invention is defined by the appended claims and includes both combinations and sub combinations of the various features described hereinabove as well as variations and modifications thereof, which would occur to persons skilled in the art upon reading the foregoing description.

In the claims, the word "comprise", and variations thereof such as "comprises", "comprising" and the like indicate that the components listed are included, but not generally to the exclusion of other components.

CLAIMS

1. A puncture system for insertion of a needle into a subcutaneous blood vessel comprising:
   (a) detection means for locating a subcutaneous blood vessel in body tissue;
   (b) an alignment means for aligning a needle with the detected subcutaneous blood vessel;
   (c) a driving means for driving the needle into the body tissue for insertion into the detected subcutaneous blood vessel, and
   (d) a means for ensuring the needle is not inserted too far.

2. The puncture system of claim 1 wherein the blood vessel is selected from the list of arteries and veins.

3. The puncture system of claim 1 further comprising a means of attachment for attaching to a limb.

4. The puncture system of claim 2, the limb being a forearm.

5. The puncture system of claim 2, the means of attachment comprising straps.

6. The puncture system of claim 2, the means of attachment comprising a sleeve.

7. The puncture system of claim 1 wherein the detection means comprises a near infra red detector for detecting near infra red emissions from the blood vessel from above.

8. The puncture system of claim 1 wherein the means for ensuring the needle is not inserted too far comprises a second near infra red detector for detecting near infra red emitted perpendicularly to puncture direction, sideways from the blood vessel.

9. The puncture system of claim 1 wherein the means for ensuring the needle is not inserted too far comprises a pressure sensor for detecting change of pressure as needle enters said blood vessel.

10. A method of inserting a needle into a subcutaneous blood vessel comprising the steps of:
    (a) attaching the puncture system of claim 1 over a distal limb via attachment

means thereof;

(b) locating a blood vessel;

(c) aligning the needle with the blood vessel in plane of skin surface;

(d) inserting the needle into the limb at a shallow angle to a depth where needle punctures outer surface of blood vessel;

(e) detecting that needle tip is within blood vessel and stopping further insertion.

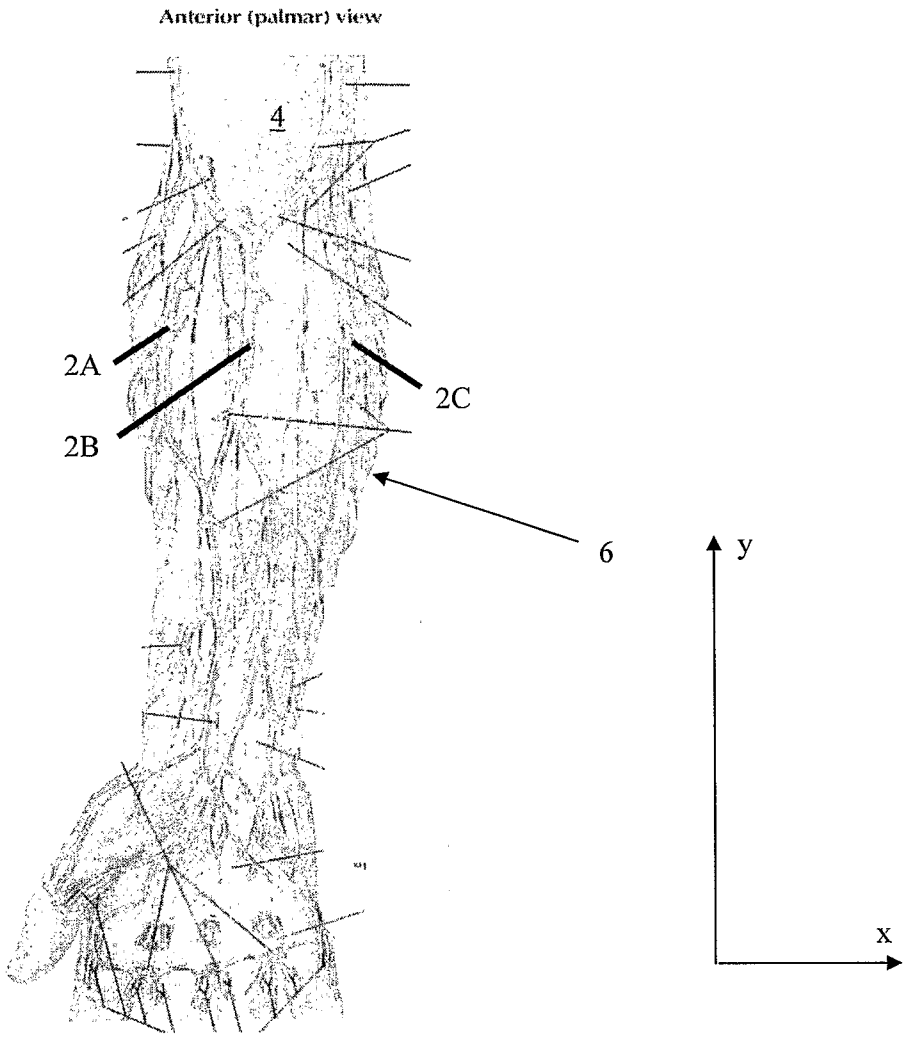

Fig. 1

Fig. 2

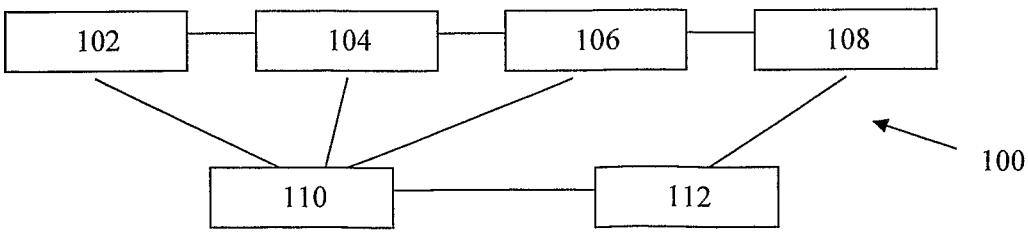

Fig. 3

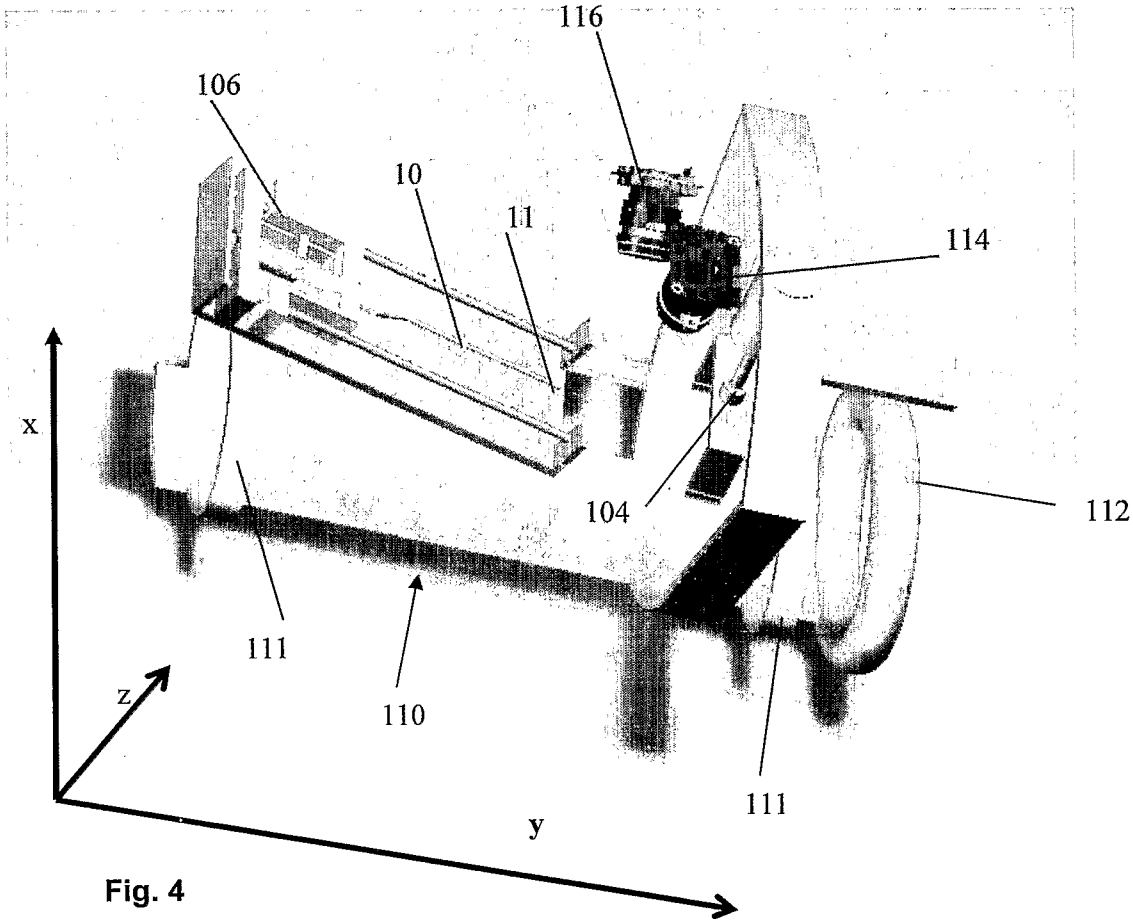

Fig. 4

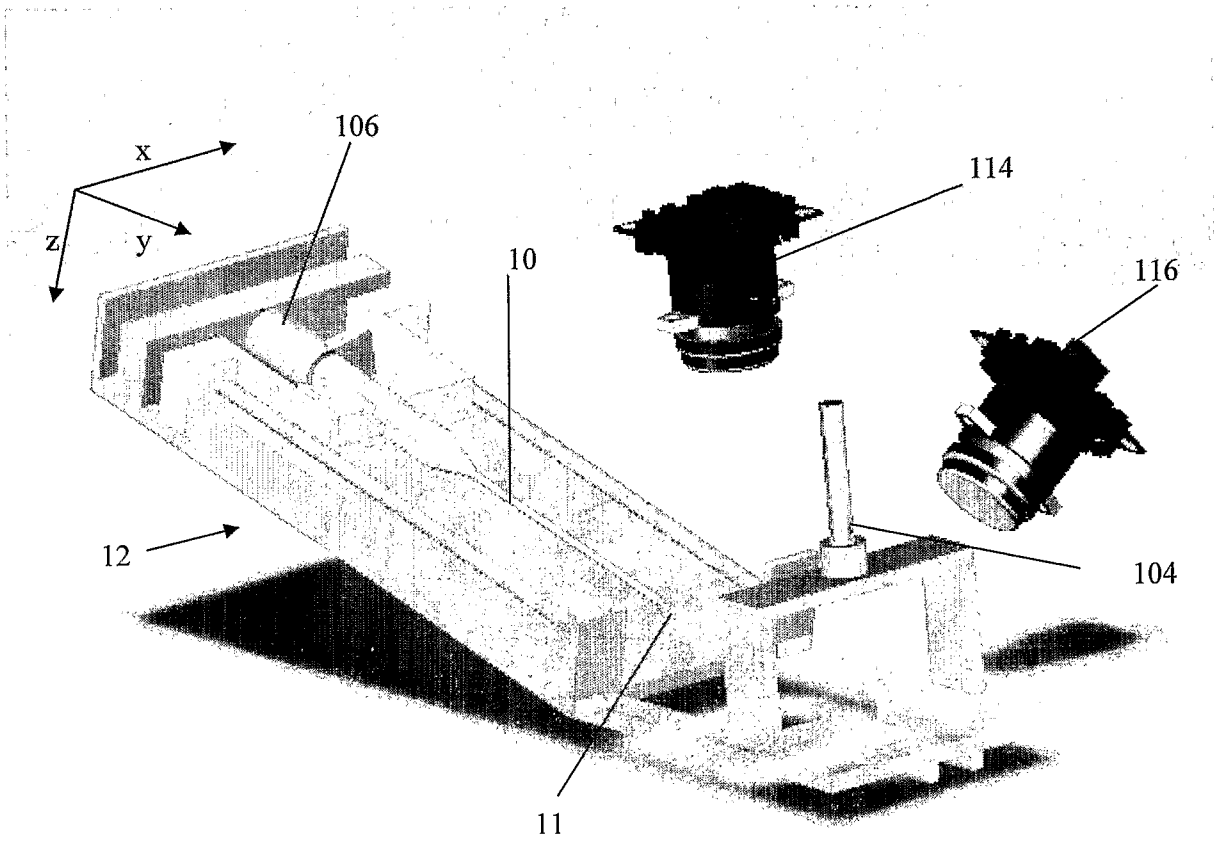

Fig. 5

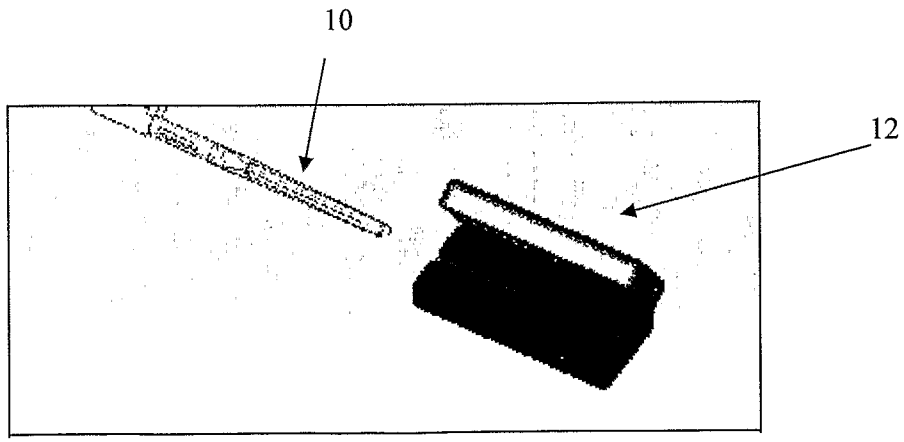

Fig. 6

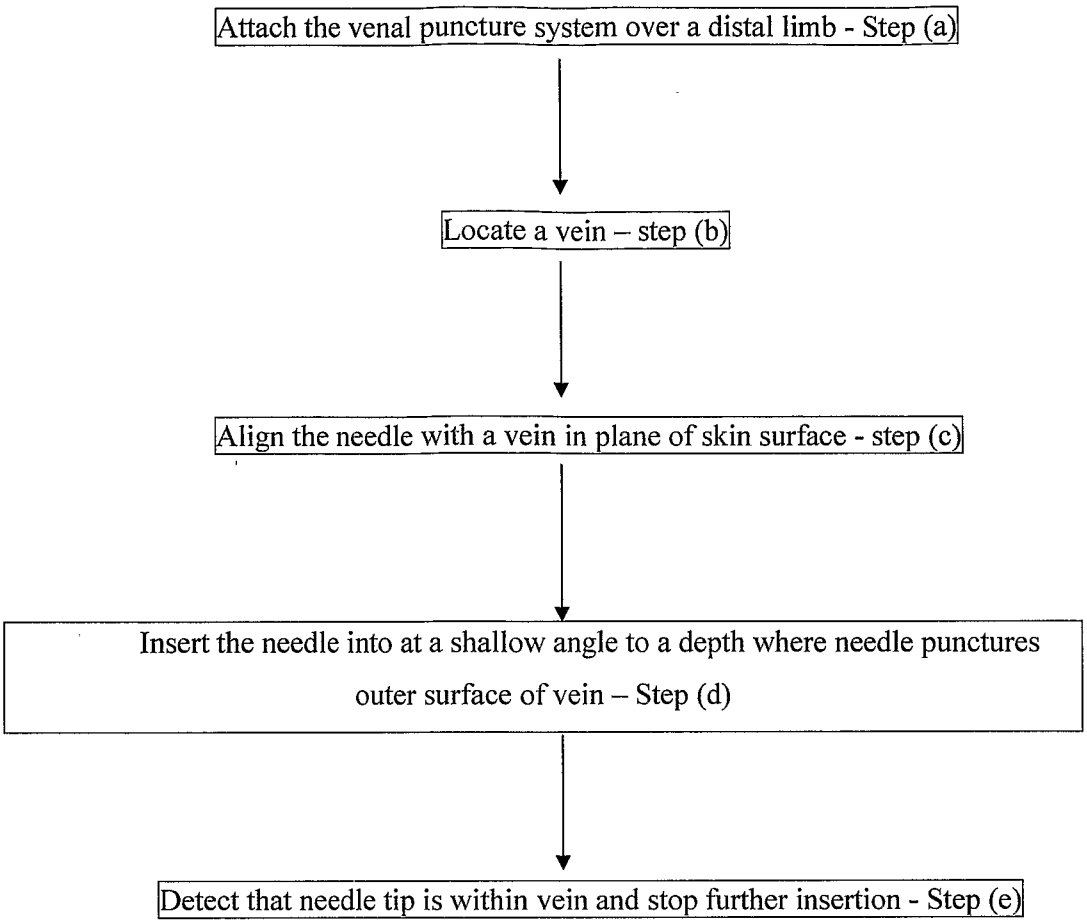
Attach the venal puncture system over a distal limb - Step (a)
Locate a vein – step (b)
Align the needle with a vein in plane of skin surface - step (c)
Insert the needle into at a shallow angle to a depth where needle punctures outer surface of vein – Step (d)
Detect that needle tip is within vein and stop further insertion - Step (e)

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2007/001627

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/42 A61B5/00 A61M5/32

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)
A61M A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/120619 A (KONINKL PHILIPS ELECTRONICS NV [NL]; SIEGLINDE NEERKEN [NL]; LUCASSEN) 16 November 2006 (2006-11-16) page 3, line 17 - line 19 page 5, line 32 - page 6, line 17 page 12, line 27 - page 13, line 15 page 14, line 11 - line 28 page 17, line 30 - page 18, line 6 page 19, line 3 - line 9 figures	1
Y		3,7,8
A		2,9

-/--

[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 document 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
22 April 2008	08/05/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Sedy, Radim

3

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2007/001627

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 733 262 A (PAUL KAMALJIT S [US]) 31 March 1998 (1998-03-31) column 4, line 31 - line 36 figure 1	3
A		4,5
Y	WO 2005/079662 A (TNO [NL]; WIERINGA FOKKO PIETER [NL]; BAKKER DIRKJAN [NL]; VAN DER STE) 1 September 2005 (2005-09-01) page 7, line 29 - page 8, line 17 figures 10,11	7,8

3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2007/001627

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 10
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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:

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

2. [ ] As all searchable claims could be searched without effort justifying an 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 reportcovers 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.:

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

Information on patent family members

International application No
PCT/IL2007/001627

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006120619 A	16-11-2006	NONE	
US 5733262 A	31-03-1998	US 6074364 A	13-06-2000
WO 2005079662 A	01-09-2005	EP 1566142 A1	24-08-2005
		JP 2007522869 T	16-08-2007