(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
31 August 2017 (31.08.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/145141 A1

(51) International Patent Classification:
A61M 5/46 (2006.01) *A61B 17/34* (2006.01)
A61M 5/48 (2006.01)

(21) International Application Number:
PCT/IL2016/050210

(22) International Filing Date:
24 February 2016 (24.02.2016)

(25) Filing Language: English

(26) Publication Language: English

(72) Inventors; and
(71) Applicants : **BRODSKY, Lea** [IL/IL]; 41 Moshe Sneh St., 49223 Petach Tikva (IL). **ZUKIER, Isaac** [IL/IL]; 25 Hazionut St., P.O.Box 3526, 4855113 Rosh Ha-Ayin (IL).

(74) Agent: **SOLOMON, Oz**; P.O. Box 6294, 4902418 Petach Tikva (IL).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

— *with information concerning one or more priority claims considered void (Rule 26bis.2(d))*

WO 2017/145141 A1

(54) Title: METHOD, SYSTEM AND DEVICE FOR DETECTING BLOOD VESSELS

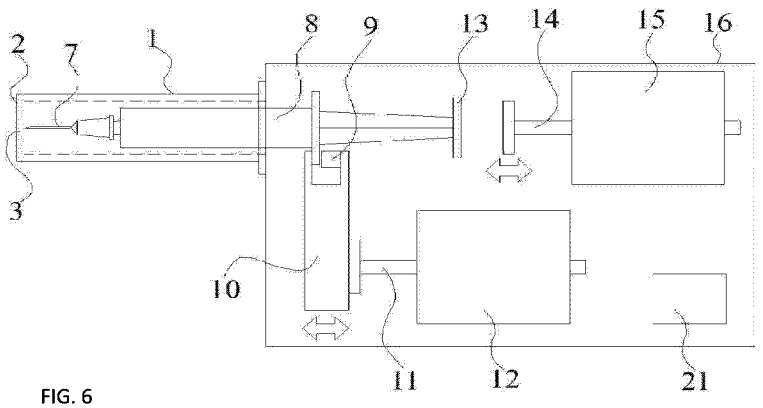

FIG. 6

(57) Abstract: Method, system and device for blood vessel penetration prevention or blood vessel penetration detection for safe injection of liquids or gels underneath the human skin surface is disclosed, either for wrinkle treatment or for other purposes. The method, system and device allow detection of needle contact with a blood vessel, detection of blood vessel penetration and detection of needle condition during its insertion into the patient's skin prior to injecting liquid or gel. The method, system and device allow prevention of blood vessel penetration by a needle, allow prevention of injection into a blood vessel and allow detection of defective needle. The device includes force sensor that measures the needle's insertion force required to overcome patient's tissues resistance to needle penetration, a controller, which performs force measurement analysis and positioning element, which stabilizes the needle in relation to the patient's skin without pressing the skin layers in the injection site.

METHOD, SYSTEM AND DEVICE FOR DETECTING BLOOD VESSELS

RELATED APPLICATIONS

The present application claims priority to US Provisional Application No. 62/088,637 filed December 7, 2014 the content of which is incorporated herein by reference.

FIELD OF THE INVENTION

This invention relates to the detection of blood vessels, as well as to the detection of blood vessels penetration during needle insertion under the skin surface.

BACKGROUND OF THE INVENTION

Many aesthetic and medical procedures involve the injection of substances into the human body. Often, it is important to avoid the injection of the substances into blood vessels, and often it is important to inject the substances into the blood vessels. For instance, when injecting hyaluronic acid dermal fillers, injection into blood vessels should be avoided since blood vessel might be obstructed due to the high viscosity injected substance, resulting in tissue necrosis. Furthermore, while injecting, it is desirable not to injure or puncture blood vessels since it may cause bruising.

It is a goal of this invention to detect blood vessels during automated injection process, avoiding injuries or puncture of blood vessels and avoiding unintentional injection of substances into blood vessels. Another goal of this invention is to detect blood vessels to ensure that the administered substance is injected within a blood vessel. Another goal of this invention is to allow medical or aesthetic treatments where blood vessels detection or blood vessels penetration detection is essential.

PCT Patent Publication No. WO 2014028285 discloses a manual device for inserting a catheter or needle into a blood vessel based on mechanically pushing forward a needle or catheter from its inside for as long as the insertion force is high. When the insertion force is low, the internal apparatus disengages due to the contraction of an element made of interlaced flexible elements and the catheter or the needle is no further introduced. This operation principle is intended for

injecting a substance into a blood vessel only, and it is therefore limited in that it cannot be used for avoiding injuring or puncturing a blood vessel, or for avoiding the undesired injection of a substance into a blood vessel.

Many catheter, needle or cannula devices have been suited with force or pressure sensors for diverse purposes. PCT Patent Publication No. WO 2006116997 and US Patent Nos. 8,603,046; 8,618,948 and 8,937,553 disclose injectors with the ability of detecting malfunctions or problems such as blockage or occlusion of the syringe or the needle, or needle disengagement.

Some patents disclose devices with integrated force or pressure sensors located within or around the needle such as US Patent No. 3,550,583, which relates to a pressure sensor embedded within a needle, enabling the blood measurement within a blood vessel. US Patent No.4,356,826 discloses a device with pressure sensors around the stabbing device tip, for sensing the tissue lateral pressure comprising: "a stabbing apparatus body having a sharp edge portion for penetrating the living body; sensor means disposed in the stabbing apparatus body for sensing a pressure to which sensor means is subjected during penetration of a living body wall, and providing a pressure signal corresponding to the pressure; accumulator means coupled to the sensor means for accumulating information corresponding to the signal level of pressure signal to provide an accumulated signal which corresponds to the depth of penetration; and indicator means coupled to an accumulator means for indicating penetration depth according to the magnitude of the accumulated signal. However, this patent's drawback is its need for sensors mounted in the needle's tip. Such needle tips are hard to manufacture and must be kept sterile prior to their utilization. Furthermore, since the sensors surround the needle, they can't sense the needle's tip contact with a blood vessel, so injury to blood vessels can't be avoided.

US Patent No. 6,221,023 teaches a device with a sensor mounted on the distal end of an intra-corporeal catheter, which detects pressure applied by surrounding tissue. The limitations and drawbacks of this patent are similar to those of patent US 3550583. However, this patent's drawback is its need for sensors mounted in the needle's tip. Such needle tips are hard to manufacture and must be kept sterile prior to their utilization. Furthermore, since the sensors surround the needle, they can't sense the needle's tip contact with a blood vessel, so injury to blood vessels can't be avoided.

US Patent No. 6,546,787 teaches a method of detecting at least one margin of a tissue structure of interest, comprising: a) providing a needle having a wall and a distal tip, a strain gage being connected to the needle wall at two spaced-apart locations, the strain gage generating a strain signal in response to strain on the wall of the needle; b) inserting the distal tip of the needle into a patient's tissue and advancing the needle distally into the tissue; c) monitoring the strain signal generated during distal advancement of the needle; and d) analyzing the strain signal to detect the margin of the tissue structure. The drawback of this patent consists on the need for sensors mounted in the needle's tip, which are hard to manufacture and must be kept sterile prior to their utilization. Furthermore, since the sensors surround the needle, they can't sense the needle's tip contact with a blood vessel, so injury to blood vessels can't be avoided.

PCT Patent Publication Nos. WO2006/120619, WO2008/081438 and US Patent Application No. 2010/0030111 all refer to automated puncture systems or injectors intended for injecting into blood vessels or for taking blood samples from blood vessels. They are based on external, non-invasive sensors, which locate the blood vessel to be punctured, and a needle is inserted accordingly. These sensors may be based on near infrared imaging, optical coherence tomography, photo acoustic Imaging or ultrasound techniques, Doppler Effect sensors, pressure sensors, sensors that operate on radar principles, or optical sensors.

The drawback of these three applications is that they require very large or expensive additional equipment, and even with this equipment it will still be very difficult to automatically locate the blood vessels.

US Patent No. 5,314,410 and US Patent Application No. 2015/0112261 teach devices based on pressure transmitted from the needle's tip through the fluid within the needle's lumen, while the fluid pressure sensing is based on a membrane. These two patents refer to devices, which are intended for manual operation. They might be able to detect or indicate the needle penetration of a blood vessel provided: (a) the needle has already penetrated the blood vessel – hence prohibiting the possibility of avoiding injury to the blood vessel, and (b) these patents do not refer to needles containing highly viscous substances such as hyaluronic acid, which would prevent pressure measurement.

US Patent Nos. 5,954,701; 7,449,008; 7,740,612; 8,608,665; 8,814,807; 8,926,525; US2011/0046477 and US2011/0202012 are based on a sensor for measuring the fluid pressure as transmitted through the needle's lumen.

These patents refer to devices which might be able to detect the needle penetration of a blood vessel provided: (a) the needle has already penetrated the blood vessel – hence prohibiting the possibility of avoiding injury to the blood vessel, and (b) the needle does not contain a highly viscous substance such as hyaluronic acid, which would prevent pressure measurement.

SUMMARY OF THE INVENTION

There is an unmet need for, and it would be highly useful to have, a device, system and a method for detecting blood vessels wherein the detection process is based on an analysis of the measured insertion force required to overcome patient's tissues resistance to the needle penetration during needle insertion under the skin surface.

There are many medical applications, treatments or tests in which this invention can be of beneficial use, such as, but not exclusively, for the prevention of injury of blood vessels or prevention of injecting liquids or gels into a blood vessel.

Embodiments of the present invention provide for detecting blood vessels during automated injection process, avoiding injuries or puncture of blood vessels and avoiding unintentional injection of substances into blood vessels.

Embodiments of the present invention provide for detecting blood vessels to ensure that an administered substance is injected within a blood vessel.

Embodiments of the present invention provide for allowing medical or aesthetic treatments where blood vessels detection or blood vessels penetration detection is essential. These goals are achieved by using at least one force sensor reactive to the needle or cannula insertion force linked to a controller, which reacts to the measured force profile.

In embodiments of the present invention there is provided a method, system and device for detection of blood vessel penetration or prevention of blood vessel penetration during needle insertion either for preventing injection of the substance within a blood vessel, or for ensuring its injection within a blood vessel or for different applications where blood vessels detection or blood vessels penetration detection is essential. Another use of the present invention is to ensure blood

vessel penetration by the needle's tip for withdrawing blood for performing blood tests.

Embodiments of the present invention provide a device that allows for detection of blood vessel penetration, thus preventing injection of liquid or gel into the blood vessel during aesthetic and/or medical procedures, for example including but not limited to wrinkle treatment or for other purposes.

Optionally the device may also ensure that the injected substance is injected into the blood vessel by detecting blood vessel penetration prior to injecting the substance.

Optionally the device allows for the detection of blood vessel and prevention of blood vessel penetration by a needle, thus preventing blood vessels injury during injection of liquid or gel under the skin surface during aesthetic and/or medical procedures, for example including but not limited to wrinkle treatment, or for other purposes.

Optionally the device may reduce the risk of injecting high viscosity substances adjacent to a blood vessel, thus avoiding its pressing and blockage by the injected substance pressure, preventing side effects for example including but not limited to necrosis or blindness.

Optionally the device allows for the detection of needle suffering from bad condition, for example dull, bent or defective needle, thus preventing patient's pain during injection of liquid or gel under the skin surface during aesthetic and/or medical procedures, for example including but not limited to wrinkle treatment or for other purposes.

The device includes a positioning element that is placed on the patient's skin. The positioning element stabilizes the device in relation to the patient's skin surface and does not press skin layers at the injection site.

The device includes a force sensor that allows the measurement of needle's insertion force required to overcome the patient's tissues resistance to the needle penetration and a controller, functionally coupled and/or linked to the force sensor which performs force measurement analysis for blood vessel penetration prevention, and/or for needle's condition detection and/or for blood vessel penetration detection.

In some embodiments, when a blood vessel penetration event is detected, the device controller may optionally prevent the injection of a substance for

example a liquid or a gel, or may optionally indicate that the substance may be injected safely into the blood vessel, according to the device application.

In some embodiments, when needle's contact with a blood vessel is detected, the device's controller may prevent the needle's penetration into the blood vessel, according to the application.

In some embodiments, when a bad needle's condition is detected, the device controller will indicate the user about this condition.

The herein disclosed method can be used by the device to detect blood vessel penetration in order to prevent injection of liquid or gel into blood vessels (which may cause blindness or necrosis in case of hyaluronic acid dermal filler injections).

The herein disclosed method can be used by the device to detect blood vessel penetration in order to prevent injection of liquid or gel outside the treated blood vessel. The herein disclosed method can be used by the device to detect needle's contact with a blood vessel and prevent blood vessel's penetration in order to prevent bruising and undesired injection of liquid or gel into blood vessels (which may cause blindness or Necrosis in case of hyaluronic acid dermal filler injections). The herein disclosed method can be used by the device to detect needle's condition and to prevent patient's pain during the injection of liquid or gel.

The method is based on measuring the needle's insertion force required to overcome the patient's tissues resistance to the needle penetration using the force sensor and a controller linked to the force sensor, which performs force measurement analysis for blood vessel detection and/or blood vessel penetration prevention. In case needle contact with a blood vessel event is detected, device's controller may prevent needle's penetration into the blood vessel prior to the injection of liquid or gel. In case needle penetration of a blood vessel event is detected, device's controller may prevent the injection of liquid or gel, or may allow the injection of a substance into the blood vessel.

The combination of the positioning element that stabilizes the device and the needle in relation to the patient's skin surface and does not press the patient's skin layers in the injection site and the force sensor measurement analysis allow precise detection of contact with the blood vessel and precise detection of blood vessel penetration.

The positioning element allows the practitioner to position the device on the patient's skin, stabilizing the device in relation to the patient's skin surface during the injection process.

The positioning element is designed in such manner that it may press the patient's skin layers in an area nearby or surrounding the injection site, but not in the injection site itself or too close to it.

The positioning element may be designed in such manner that it does not press the patient's skin layers in the treated area, allowing the practitioner to see the injection site and the treated area clearly. The positioning element may be designed in such manner that it may be placed in contact with the patient's skin, stabilizing the needle in parallel to the patient's skin surface, or perpendicular to the skin surface or at a desired angle relative to the patient's skin surface.

In one embodiment of this invention the device's purpose is to inject one of the currently available dermal fillers for wrinkle treatment avoiding penetration into the blood vessels under the patients' skin surface. In another embodiment of this invention, the device's purpose is to inject other liquids or gels avoiding penetration into the blood vessels under the patients' skin surface.

In one embodiment of this invention the device's purpose is to inject one of the currently available dermal fillers for wrinkle treatment avoiding injecting into the blood vessels under the patients' skin surface. In another embodiment of this invention, the device's purpose is to inject other liquids or gels avoiding injecting into the blood vessels under the patients' skin surface.

In one embodiment of this invention the device's purpose is to inject a substance into a blood vessel, avoiding its injection outside the blood vessel.

In one embodiment of this invention the device's purpose is to inject one of the currently available dermal fillers for wrinkle treatment while detecting needle's condition during its penetration under the patients' skin surface. In another embodiment of this invention, the device's purpose is to inject other liquids or gels while detecting needle's condition during its penetration under the patients' skin surface.

In one embodiment of this invention, the device includes a disposable transparent positioning element that is in contact with the patient's skin during the injection process. The positioning element has a hole in its tip to allow the needle to move through a hole and to penetrate the patient's skin during the injection. As

a result of the hole location (in the tip of the positioning element) and size, the patient's skin layers are not pressed in the needle penetration point, allowing precise blood vessel detection or blood vessel penetration detection.

In another embodiment of this invention, the device includes a positioning element that is in contact with the patient's skin during the injection process. Positioning element may be disposable or not, may be transparent or not, and may be made of any suitable material and may have any suitable shape, as long as it is able to stabilize the device in relation to the patient's skin surface.

In one embodiment of this invention, a needle is attached to the tip of a syringe.

In another embodiment of this invention, a flexible tube links the syringe and the needle, and the needle is displaced independently of the syringe or container.

In one embodiment of this invention, force sensor may be placed on top of the syringe barrel. In this embodiment syringe barrel is pushed by an actuator during syringe displacement. In another embodiment of this invention, force sensor may be placed on the top of the syringe's plunger, or it may be placed in any other suitable location that allows measuring the needle's insertion force required to overcome patient's tissues' resistance to needle penetration.

In one embodiment of this invention force sensor is connected to an electronic circuit, which functions as a device controller. Force sensor's output signal is measured, read and analyzed by device controller. According to the force sensor signal analysis a controller determines whether needle's tip has touched a blood vessel wall or whether a needle has penetrated a blood vessel.

Controller electronic circuit controls an actuator, which is responsible for syringe/needle displacement and it can optionally stop syringe's/needle's displacement in case of contact with blood vessel detection or in case of blood vessel penetration detection. Controller electronic circuit controls an actuator, which is responsible for syringe's plunger displacement, and in case a blood vessel has been detected or a blood vessel penetration event has been detected it may prevent plunger displacement, thus preventing the injection of liquid or gel, or may allow the plunger displacement, thus injecting the substance into the blood vessel as intended, according to the application.

In one embodiment of this invention the force sensor is connected to an electronic circuit, which functions as a device controller. Force sensor's output signal is measured, read and analyzed by the device controller. According to the force sensor signal analysis a controller may determine whether the needle is not sharp, bent or defective, and may inform the practitioner accordingly.

In one embodiment of this invention, an actuator may be an electrical motor. In another embodiment of this invention, an actuator may be a pneumatic, hydraulic or any other suitable actuator able to push and displace the syringe or the needle.

In one embodiment of this invention, the syringe displacement motor may be an electrical motor, which, using a mechanical transmission, moves the syringe in a linear path.

In one embodiment of this invention, a motor may be a step motor. In another embodiment of this invention linear motor may be a D.C. brush motor, a D.C. brushless motor, an AC motor, or any kind of electrical motor with an added motion, rotation or position detector or sensor for either directly or indirectly measuring needle's movement and for determination of needle's position. Motion, rotation or position detector may be mechanical, electrical, optical or of any suitable kind.

In one embodiment of this invention, the device may activate an audible alarm in case contact with a blood vessel event has been detected. In another embodiment of this invention, the device may activate an optical, vibratory or any kind of suitable alarm in case contact with a blood vessel event has been detected, in order to inform the practitioner of such event.

In one embodiment of this invention, the device may activate an audible alarm in case a blood vessel penetration event has been detected. In another embodiment of this invention, the device may activate an optical, vibratory or any kind of suitable alarm in case a blood vessel penetration event has been detected, in order to inform the practitioner of such event.

In another embodiment of this invention, the device may activate an optical, vibratory or any kind of suitable alarm in case a blood vessel penetration event has not been detected prior to injecting the substance, in order to inform the practitioner of such event.

In one embodiment of this invention the needle is inserted in parallel to the patient's skin surface. In another embodiment of this invention the needle is inserted perpendicularly to the patient's skin surface, or it may be inserted at any suitable angle in relation to the patient's skin.

Unless otherwise defined the various embodiment of the present invention may be provided to an end user in a plurality of formats, platforms, and may be outputted to at least one of a computer readable memory, a computer display device, a printout, a computer on a network or a user.

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 invention belongs. The materials, methods, and examples provided herein are illustrative only and not intended to be limiting.

Implementation of the method and system of the present invention involves performing or completing certain selected tasks or steps manually, automatically, or a combination thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in order to provide 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 drawings:

FIG. 1 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, showing the tip of a disposable positioning element and needle;

FIG. 2 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, shows the tip of the disposable positioning element and needle (transparent);

FIG. 3 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, shows a vertical central cutout of the disposable positioning element;

FIG. 4 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, shows a vertical central cutout of the disposable positioning element placed on patient's skin, including the needle, the skin layers and a blood vessel;

FIG. 5 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, shows the skin, the needle and a blood vessel position during six different stages of the injection process;

FIG. 6 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, shows the device configuration; and

FIG. 7 is a schematic illustrative diagram of an exemplary embodiment according to the present invention, shows an oscillogram of the force sensor measurement registered by an oscilloscope during needle penetration of the skin surface, the oscillogram showing measured voltage as a function of time.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The principles and operation of the present invention may be better understood with reference to the drawings and the accompanying description. The following figure reference labels are used throughout the description to refer to similarly functioning components are used throughout the specification hereinbelow.

1 disposable transparent positioning element;
2 disposable transparent positioning element's tip;
3 disposable transparent positioning element tip's center hole;
4 patient's skin surface;
5 pressed patient's skin layers;
6 not pressed patient's skin layers;
7 needle;
8 syringe;

9 force sensor;
10 syringe and force sensor holder;
11 piston of linear motor for syringe displacement ;
12 linear motor for syringe displacement;
13 syringe plunger;
14 piston of linear motor for pushing the plunger;
15 linear motor for pushing the plunger;
16 device enclosure;
17 moment when needle tip touches the skin surface (measured by force sensor);
18 moment when needle tip penetrates the skin (measured by force sensor);
19 epidermis;
20 dermis;
21 device controller;
22 blood vessel;
23 moment when needle tip touches the blood vessel (measured by force sensor);
24 moment when needle tip penetrates the blood vessel (measured by force sensor).

The present invention is described with reference to the accompanying drawings. According to this invention there is provided a method, system and device for detection of blood vessels or prevention of blood vessel penetration for safely injecting of liquids or gels under the skin surface .

The device allows prevention of blood vessel penetration, thus preventing blood vessels' injury (bruising) and/or allows detection of blood vessel penetration, thus preventing injection of liquid or gel into the blood vessel under the skin surface either for wrinkle treatment or for other purposes.

The drawings are schematic, not showing all the details such as the securing elements of the various items, for the sake of simplicity and clarity .

In the preferred embodiment of this invention the device enclosure 16 is designed for being hand-held by the operator, as shown in FIG. 6. The operator places the device on the patient's skin, just on top of the skin area to be treated, for

instance a wrinkle. The device should be placed on the treated skin area in such manner that the disposable transparent positioning element's tip 2 is in full contact with the area to be treated. The disposable transparent positioning element tip's center hole 3 should be placed precisely on the intended injection site.

A thin needle 7 is mounted on the tip of the syringe 8. In order to perform the injection, the linear motor for syringe displacement 12 and the syringe displacement linear motor's piston 11 are activated by the device controller 21. The activation of the linear motor for syringe displacement 12 and syringe displacement linear motor's piston 11 moves the syringe 8 and the needle 7 together either forward or backwards, allowing needle's insertion into patient's skin or its extraction from the patient's skin.

The disposable transparent positioning element 1 is shown in FIG. 1 as an opaque element, and in FIG. 2 as a transparent element. FIG.3 shows a vertical central cutout of the disposable transparent element 1. The disposable transparent element 1 houses syringe 8 with the needle 7 attached to the syringe's 8 tip. The disposable transparent positioning element 1 has a tube shape with a flat tip 2. Flat tip 2 has a round hole 3 in its center, which allows to position the device on the patient's skin surface in such a manner that the device is completely stable and the skin layers, epidermis 19 and dermis 20, are not pressed at the injection site, allowing precise measurement of the needle's insertion force required to overcome the patient's tissues resistance to the needle 7 insertion.

FIG. 4 depicts the skin layers of the patient and the blood vessel 22, showing the pressed skin layers 5 under the solid part of the disposable transparent positioning element's tip 2, and the not-pressed skin layers 6 in the central area of the disposable transparent positioning element's tip center hole 3. The external, thin skin layer is the epidermis 19, and under it the thicker dermis layer 20 as shown.

Force sensor 9 is placed on top of the syringe 8 barrel, which is pushed by the piston 11 of the linear motor for syringe displacement 12 during syringe displacement. Detection of event when needle 7 contacts blood vessel's 22 is determined by the needle's insertion force measured by the force sensor 9 during needle 7 insertion into the patient's skin. Device controller 21 receives output signal from the force sensor 9 and, accordingly, can stop the needle 7 insertion process .

Upon detection of needle's 7 contact with a blood vessel 22, device controller 21 immediately stops the operation of linear motor for syringe displacement 12, preventing any further insertion of the needle 7 into the blood vessel 22, thus preventing the blood vessel 22 penetration by the needle 7.

Device controller 21 may stop the operation of the linear motor for pushing the plunger 15, preventing the injection of liquid or gel adjacent to the blood vessel.

Detection of blood vessel penetration by the needle 7 is determined by the needle's 7 insertion force measured by the force sensor 9 during needle 7 insertion into the patient's skin. Device controller 21 receives output signal from the force sensor 9 and, accordingly, can stop the needle's 7 insertion process.

Device controller 21 stops the operation of the linear motor for pushing the plunger 15, preventing the injection of liquid or gel into the blood vessel.

FIG. 5A-F show the disposable transparent element 1, the needle 7, the patient's skin surface 4, the skin epidermis 19, the skin dermis 20 and the blood vessel 22 in six stages FIG. 5A-F showing the progression of the needle's 7 penetration prior to the injection process, including needle's 7 contact with blood vessel 22, and also needle's 7 penetration into a blood vessel 22 .

FIG. 7 shows an oscillogram of the force sensor 9 signal recorded during needle's 7 penetration into the skin and penetration into a blood vessel 22, which this method and device prevents. The vertical axis reflects the force measured by the force sensor 9 and the horizontal axis reflects the time elapsed. Since the linear motor for syringe displacement 12 operates at constant speed, the horizontal axis represents syringe's 8 and needle's 7 displacement in a linear scale.

First, the needle 7 is at a certain distance from the skin surface 4 as shown in FIG. 5A. At this stage force sensor 9 senses only the frictional force of the advancing syringe 8 and the oscillogram shows a flat line.

As the needle 7 is displaced further toward the skin surface, it touches the epidermis 19 as shown in FIG. 5B. At this stage force sensor 9 starts sensing the force required to overcome the resistance of the epidermis 19 to needle's 7 tip insertion. Accordingly, the force measurement chart shows a steep increase in the sensed force, as shown in the inflexion point 17 in FIG.7. As the needle 7 further pushes the skin layers down as depicted in FIG.5c, the force measured by the force sensor 9 increases, as shown in FIG. 7 between points 17 and 18.

The needle 7 moves further forward, until the patient's skin is pierced as shown in Fig. 5d. The patient's skin penetration by the tip of the needle 7 happens at the moment 18 in FIG. 7. At this point the needle 7 insertion force required to overcome the skin resistance measured by force sensor 9 begins to decrease.

If the force measured at point 18 is higher than it should be when operating under normal conditions, then we can conclude that the needle's 7 condition is not good, either needle 7 is not sharp, or bent, or the needle 7 is defective in some manner.

In case the force measured at the peak point 18 increases by a predetermined amount or factor after a number of injections have been carried out, the device controller 21 activates a red LED (not shown), informing the practitioner that needle 7 is not sharp.

In case the force measured at the peak point 18 is higher than a predetermined threshold, the device controller 21 activates a yellow LED (not shown) informing the practitioner that needle 7 is defective.

The needle 7 moves deeper under the skin and the needle's 7 tip touches the blood vessel 22 wall as shown in FIG. 5E, point 23 in FIG. 7. At this point the needle 7 insertion force required to overcome the tissue resistance force measured by force sensor 9 begins to increase, as shown in FIG. 7 between points 23 and 24.

In order to prevent blood vessel's 22 penetration that would happen at point 24, the needle 7 insertion is stopped by device controller 21 somewhere between points 23 and 24 as shown in FIG. 7, after it identified a raise in the force measured by force sensor 9. The syringe displacement linear motor's 12 operation is stopped by the device controller 21 when the needle's 7 tip touches and very slightly pushes the blood vessel 22 wall, thus preventing blood vessel 22 penetration.

The device controller 21 doesn't activate then the linear motor for pushing the plunger 15, preventing the injection of liquid or gel in case a blood vessel was detected. The device controller 21 activates the linear motor for syringe displacement 12 backwards, taking the syringe 8 back inside the disposable transparent positioning element 1.

The device controller 21 activates an on-board beeper (not shown), informing the practitioner that a blood vessel has been detected by the needle 7, and that the current injection process has been stopped.

In case the needle 7 has not touched a blood vessel, the syringe displacement linear motor's 12 operation is stopped by the device controller 21 when the desired penetration depth is achieved.

In order to prevent injection of liquid or gel into a blood vessel, assuming that following the stage depicted in FIG. 5E the needle 7 keeps moving forward, it penetrates the blood vessel's 22 wall, as shown in FIG. 5F. At this point the needle 7 insertion force required to overcome the blood vessel 22 resistance force measured by force sensor 9 peaks and begins to decrease, as shown in FIG. 7 point 24.

The device controller 21 detects a peak 24 shown in FIG. 7, which indicates the penetration of a blood vessel 22 by the needle 7 .

The device controller 21 doesn't activate then the linear motor for pushing the plunger 15, preventing the injection of liquid or gel inside a blood vessel. The device controller 21 activates the linear motor for syringe displacement 12 backwards, taking the syringe 8 back inside the disposable transparent positioning element 1.

The device controller 21 then activates an on-board beeper (not shown), informing the practitioner that a blood vessel penetration event has occurred, and that the current injection process has been stopped.

While the invention has been described with respect to a limited number of embodiment, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly and use, are deemed readily apparent and obvious to one skilled in the art, and all equivalent relationships to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention.

Therefore, the foregoing is considered as illustrative only of the principles of the invention. Further, since numerous modifications and changes will readily occur to those skilled in the art, it is not described to limit the invention to the exact construction and operation shown and described and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention.

While the invention has been described with respect to a limited number of embodiment, it is to be realized that the optimum dimensional relationships for the parts of the invention, to include variations in size, materials, shape, form, function and manner of operation, assembly and use, are deemed readily apparent and obvious to one skilled in the art, and all equivalent relationships to those illustrated in the drawings and described in the specification are intended to be encompassed by the present invention.

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

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

Citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the invention.

Section headings are used herein to ease understanding of the specification and should not be construed as necessarily limiting.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

CLAIMS

What is claimed is:

1. A method and device for detecting or preventing blood vessel penetration during needle insertion under the skin surface for medical or aesthetic applications, said device comprising :
   a. a container or a syringe or other needle holding element connected to a needle,
   b. a force sensor that measures said needle's insertion force required to overcome patient's tissues resistance to the needle penetration ,
   c. a controller linked to said force sensor, which performs force measurement analysis for detecting or preventing blood vessel penetration , and
   d. a positioning element, which stabilizes said needle in relation to the patient's skin.
2. The device according to claim 1, wherein a container or a syringe containing liquid or gel connected to a needle for injecting said liquid or gel under the skin's surface.
3. The device according to claim 1, wherein needle insertion is performed by a motor.
4. The device according to claim 1, wherein needle insertion is performed by a pneumatic or hydraulic drive.
5. The device according to claim 1, wherein said needle insertion is stopped when a blood vessel is detected or penetrated.
6. The device according to claim 1, wherein an alarm is activated when a blood vessel is detected or penetrated.
7. The device according to claim 1, wherein an alarm is activated when a blood vessel is not detected or penetrated prior to injecting a substance.
8. The device according to claim 1, wherein needle insertion into the patient's skin is controlled by a micro-controller or microprocessor.
9. The device according to claim 1, where needle condition is detected, based on the force measurement analysis.

10. The device according to claim 1, wherein said positioning element is disposable.
11. The device according to claim 1, wherein said positioning element is transparent.
12. The device according to claim 1, wherein said positioning element stabilizes said device in relation to patient's skin surface without pressing skin layers at the injection site.
13. The device according to claim 1, wherein said needle is attached to the tip of said container or syringe .
14. The device according to claim 1, wherein a flexible tube connects said container or syringe to said needle .
15. The device according to claim 1, wherein said needle is moved independently of said container or syringe.
16. The device according to claim 1, wherein said force sensor is placed on top of said syringe barrel.
17. The device according to claim 1, wherein said force sensor is placed on top of said syringe's plunger.
18. The device according to claim 1, wherein said force sensor is placed in suitable location which allows measurement of said needle's insertion force required to overcome patient's tissues resistance to the needle penetration.

FIG. 2

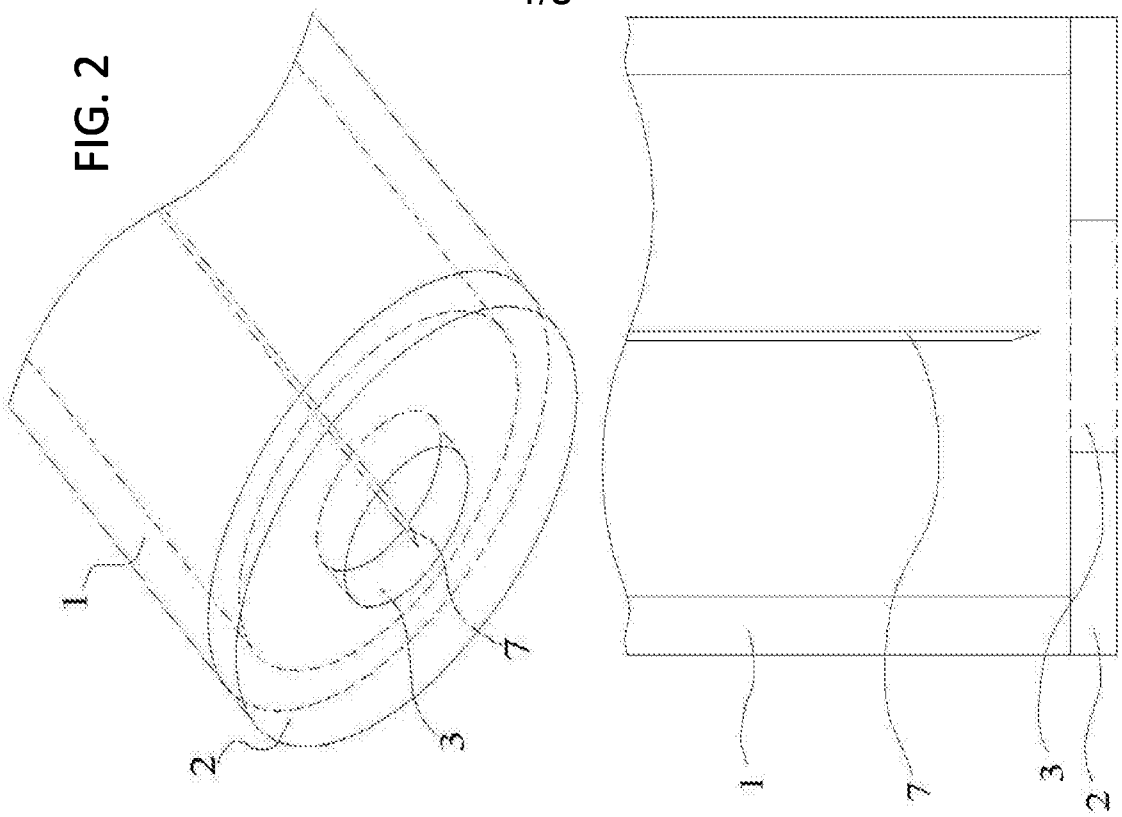

FIG. 1

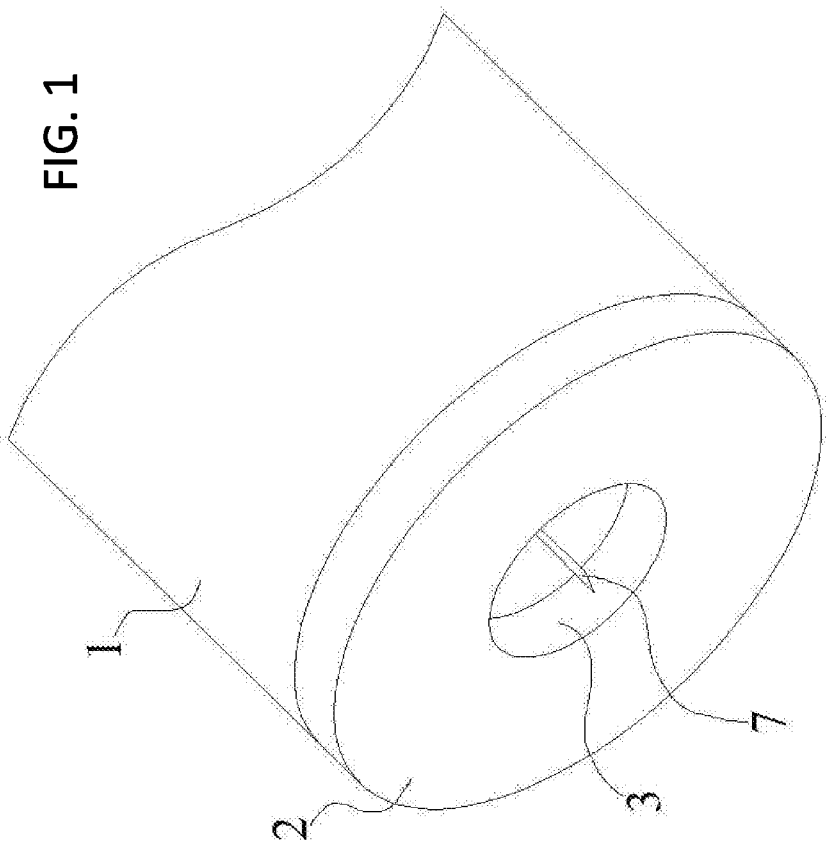

FIG. 3

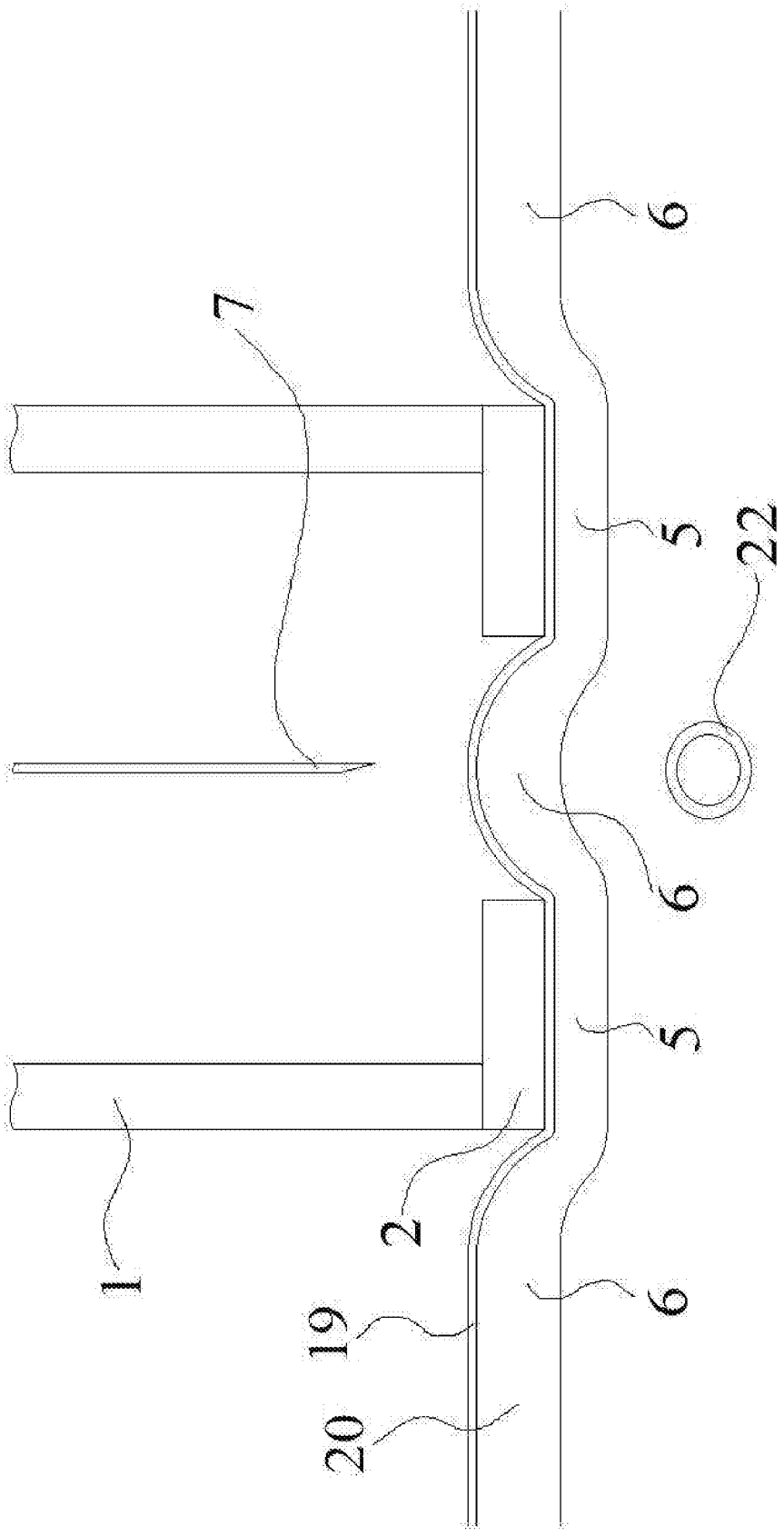

FIG. 4

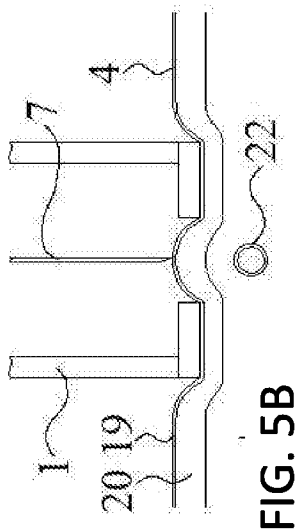

FIG. 5A

FIG. 5B

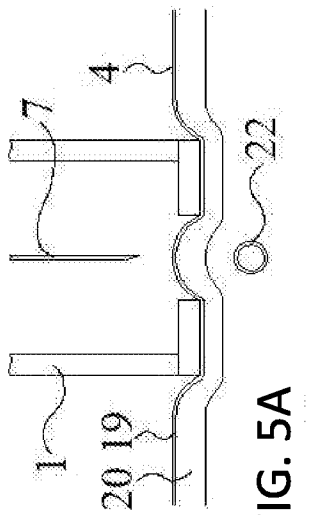

FIG. 5C

FIG. 5D

FIG. 5E

FIG. 5F

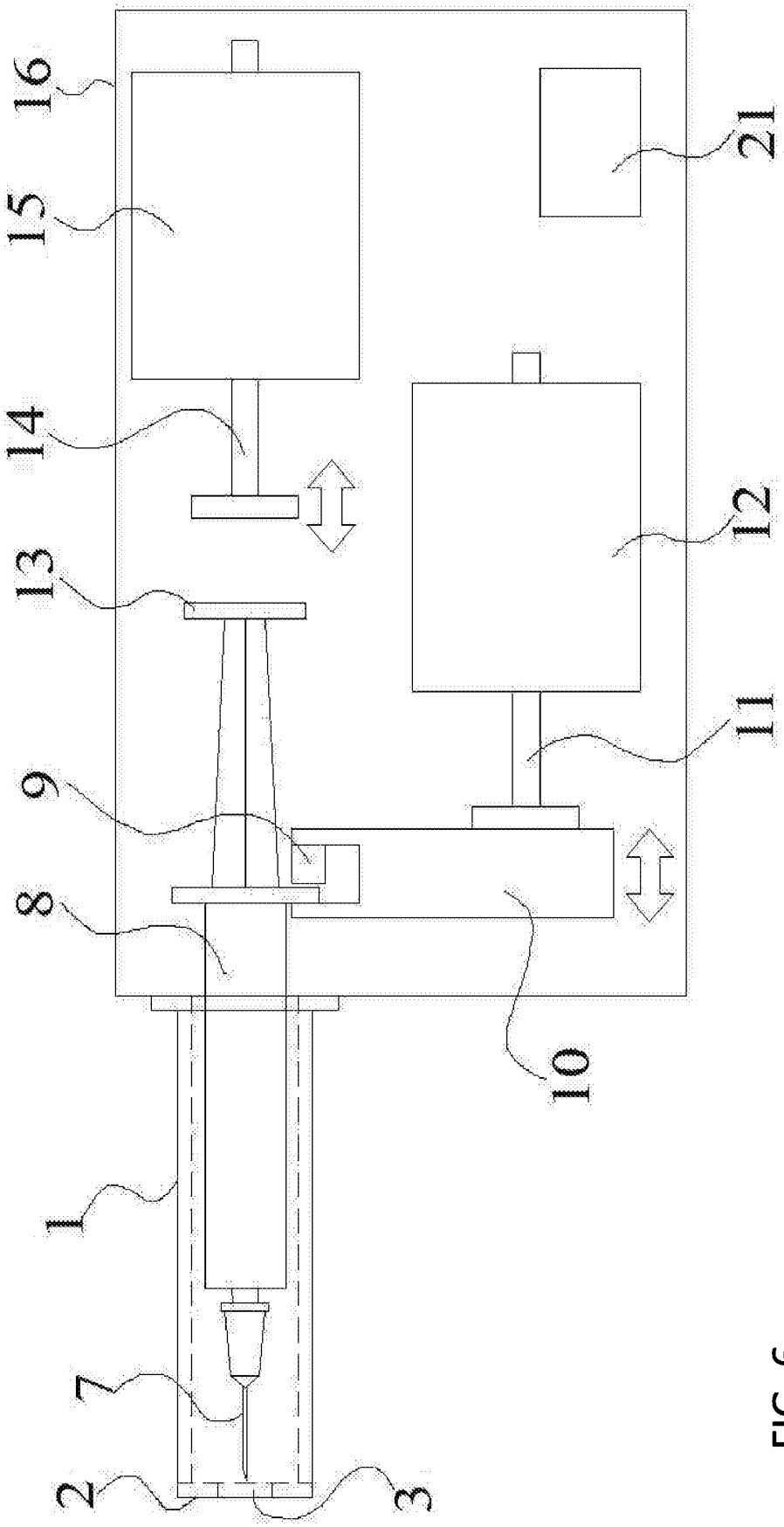

FIG. 6

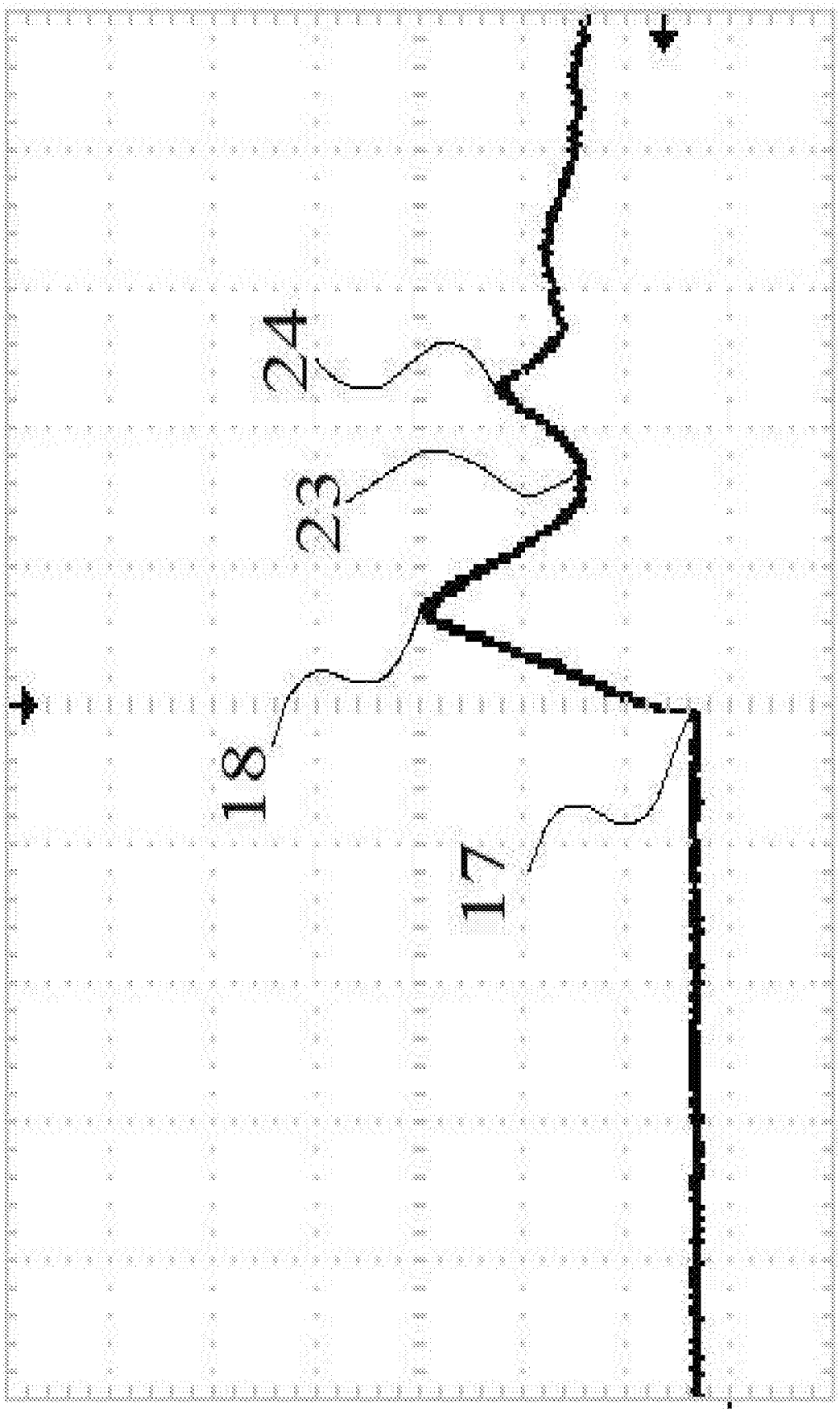

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2016/050210

A. CLASSIFICATION OF SUBJECT MATTER
IPC (2016.01) A61M 5/46, A61M 5/48, A61B 17/34

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)
IPC (2016.01) A61B 17/00, A61M

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 consulted: Esp@cenet, Google Patents, FamPat database
Search terms used: vascular, blood, vessel, detect, access, puncture, prevent, penetrate, insert, measure, inject, force, sensor, needle, stabilize, tissue, resistance, hypodermic.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 0056213 A1 IMPERIAL COLLEGE et al 28 Sep 2000 (2000/09/28) The whole document	1-18
Y	WO 2008028571 A1 ROCHE DIAGNOSTICS GMBH et al 13 Mar 2008 (2008/03/13) Fig.2b	1,12

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"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
22 Jun 2016	27 Jun 2016

Name and mailing address of the ISA:	Authorized officer
Israel Patent Office Technology Park, Bldg.5, Malcha, Jerusalem, 9695101, Israel Facsimile No. 972-2-5651616	ITIN Yulia YuliaI@justice.gov.il Telephone No. 972-2-5651680

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/IL2016/050210

Patent document cited search report	Publication date	Patent family member(s)	Publication Date
WO 0056213 A1	28 Sep 2000	WO 0056213 A1	28 Sep 2000
		AU 3444900 A	09 Oct 2000
		GB 9906759 D0	19 May 1999
WO 2008028571 A1	13 Mar 2008	WO 2008028571 A1	13 Mar 2008
		AT 486523 T	15 Nov 2010
		DE 502006008234 D1	16 Dec 2010
		EP 1897493 A1	12 Mar 2008
		EP 1897493 B1	03 Nov 2010
		EP 2314206 A1	27 Apr 2011
		EP 2314206 B1	05 Jun 2013
		ES 2421781 T3	05 Sep 2013
		US 2010063417 A1	11 Mar 2010
		US 8444574 B2	21 May 2013