-- A further deficiency of nerve stimulation technique is the inability to set the appropriate charge for a defined distance from the outer surface of the fascicle, i.e., Extra-Fascicular. It is more concerning if a high charge above 1.0mA is utilized Intra-Fascicular, as it may cause a severe response by the patient or, even worse, result in irreversible damage from an excessive electrical charge applied directly on the axon. Hence there is an inability to determine what appropriate charge should be applied for a specific distance from the fascicle.

-- A further deficiency is that confounding variables make the use of nerve stimulation a non-specific technique. These are related to anatomic variations within a given patient as well as anatomic variation between different patients. The body is comprised of a variety of tissue types which include connective tissue of mineralized and non-mineralized tissues. These tissues are composed of water and collagen, adipose tissue (fat), muscle, fluids (blood), bone, cartilage, etc. Each of these tissues types provides a different resistance and/or capacitance to a charge when it is applied at a given distance to the intended target. The variables of tissue cannot be underestimated or anticipated. Hence current devices lack the ability to quantify a specific charge to a specific location. This has lead to an inability to produce predictable response to a given electrical charge when used as the primary means of determining location or proximity to a specific nerve.

[0015] In summary, the variables of charge intensity, frequency and tissue resistance to the electric charge have made it difficult to standardize a technique to enable location of a specific nerve branch.

Summary of the Invention

[0015a] According to a first aspect of the present invention, there is provided an apparatus for administering fluid into an anatomic space, comprising: an injection system for controlling a flow of fluid from a fluid reservoir to a needle, wherein the needle is configured for subcutaneous insertion into a mammalian subject; a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously to detect the characteristic as the needle is inserted into the subject; and an electric nerve stimulation element for providing an electric nerve stimulation at or adjacent to a tip of the needle; wherein the electric nerve stimulation element provides electric nerve stimulation to a patient after the sensor detects a characteristic of the fluid pressure indicative of the fluid pressure exceeding an upper threshold.

[0015b] According to a second aspect of the present invention, there is provided a system for providing a peripheral nerve block to a patient, comprising: a needle having a sharpened tip; a fluid pump providing a flow of fluid to the needle, wherein the fluid pump comprises a microprocessor for controlling the flow of fluid to the needle; a sensor for detecting the fluid pressure in the needle; a conductive element for providing an electric nerve stimulation at the tip of the needle; and an output element configured to provide a human perceptible signal wherein in response to a signal indicative of the fluid pressure exceeding an upper limit the output element provides an alert signal to alert the operator to discontinue insertion of the needle; wherein the conductive element is configured to provide an electric nerve stimulation at or adjacent to the tip of the needle after the sensor detects a fluid pressure exceeding the upper limit.

[0016] Embodiments of the present invention provide an injection system that may improve the reliability and safety of injections particularly of those injections that are performed to identify fluid filled spaces contained within the body by narrow layers of fascia or connective tissue. By allowing information, particularly continuous pressure monitoring to be projected upon the surface of a patient at the location of needle entry, the operator can carefully and continuously monitor needle movement while obtaining critical injection parameters such as exit-pressure, flow-rate, warnings, exit-pressure threshold changes and any important information that was typically displayed elsewhere. This may allow the operator to maintain visual focus at the site of the injection at all times.

[0017] Additionally, an embodiment of the present invention provides an apparatus and method that can provide a mechanism for an operator to continuously guide the insertion of

a needle while simultaneously receiving visual information projected upon the surface of the a patient at the site of the injection, thus enabling the operator to continuous maintain the view of the needle and the injection site to enable precise eye hand coordination to be maintained continuously. This information can be provided in a variety of formats from color changes, images, numbers, words and visual changes to these formats including intensity, blinking, coordinated illumination patterns, etc.

[0018] An embodiment of the present invention provides an infusion device that continuously monitors fluid pressure of the fluid being infused to the subject. The pressure resistance measure may then be converted into a visual signal on a continuous basis. The measurements are then presented to the medical professional so that the medical professional can determine or confirm whether the injection is being delivered to the correct tissue. In addition, the measurements are also recorded for later review and documentation of the clinical event. Upper limits of pressure as well as control of flow-rate can be pre-defined to ensure that excessive pressure and/or flow-rate are not used during this process.

[0019] An embodiment of the present invention provides a method and apparatus for utilizing counter-head pressure when calculating the exit pressure. The counter-head pressure is related to the insertion rate of the needle. Therefore, the system includes a mechanism for controlling the insertion rate of the needle. In particular, the system may include markings on the needle and auditory or visual cues for prompting the appropriate insertion rate for the needle.

[0020] Additionally, an embodiment of the present invention provides a hand-piece to which a marked needle is connected that is designed to house a small display, such as an LED light or display screen that will provide a blink or visual instruction and/or speaker and/or beeps or provides an audible tone that can be intermittent to enable the coordination of the defined forward movement to the provided visual or audible signal to the advancement of the needle based upon the markers on the surface of the needle as it penetrates the skin or other part of the body. The audible and visual cadence defines the rate of advancement of the needle so that it can be coordinated to forward movement to improve the accuracy of counter head-pressure produced and provided to the calculation of the real-time exit-pressure monitoring.

[0021] An embodiment of the present invention provides a mechanism for distinguishing between intra-fascicular and extra-fascicular needle placement.

[0022] Another embodiment of the current invention is a current charge that is transmitted via an ionic solution through a disposable syringe and tubing to the tip of the needle for the purpose of nerve stimulation.

[0023] A further embodiment of the current invention is a system that provides a constant flow of fluid from the tip of the needle during the advancement of a needle movement through tissues when performing a peripheral nerve block to prevent the needle tip from entering the fascicle. The constant flow of fluid from a needle tip acts as a means to move or push dense structures away from the tip of a needle as it advances.

[0024] Yet another embodiment of the current invention is a system that provides a defined rate or pace of forward movement to the needle within the tissues to prevent a biasing counter head-pressure force applied upon a needle as one is advancing said needle into and through the tissues while simultaneously and continuously measuring a pressure at tip of the needle.

[0025] Still another embodiment of the current invention provides that when the needle is not being advanced the counter head-pressure will not be subtracted from the calculation of the exit-pressure. It is understood that the button or control on the hand-piece may also be activated to correspond with the forward movements in which the counter head-pressure is subtracted from the calculation of the head-pressure therefore providing a means to distinguish between when the needle is being advanced and when the needle remains stationary within the tissues.

[0026] An embodiment of the current invention also provides a hand-piece to which a marked needle is connected that is designed to house a small LED light or display screen and/or speaker that will blinks and/or beep in coordination to said rate to advance said needle. The hand-piece may possess input elements to control flow-rate, electrical current stimulation and communicate with the CPU of the drive unit. Additionally, the hand-piece may possess a vibratory chip or element to provide vibration of the hand-piece to communicate a command or signal from the CPU to the operator. This vibratory sensation can be discreet and represent a command warning or signal for the operator to respond to. The hand-piece may also include an output display to additional display information.

[0027] An embodiment of the present invention also provides an injection device for providing a peripheral nerve block that uses maximum back pressure range between 75 mm/Hg to 500 mm/Hg to trigger an electrical stimulation. An instantaneous discrete emission of a current may be provided when a specific pressure value is detected within the pressure range. This signal is to control an

instantaneous discreet emission of a current at a specific pressure value within stated pressure range.

[0028] According to another embodiment, the system uses a biasing head-pressure value that is set in a CPU that is determined and correlated to a rate (pace) of forward movement to the marked needle within the tissues. Biasing head-pressure value is calculated and is factored into the calculated head pressure value to eliminate pressure bias from the counter head-pressure value of a needle resulting from forward movement during simultaneously use of continuous flow and pressure monitoring.

[0029] According to a further embodiment, an injection device is provided that provides a current between 0.15mA to 2.0mA. The current is provided in response to a detected exit-pressure value. Further, the electric charge is to be emitted as for a discreet period between 1.0 to 10.0 seconds. Simultaneously, when the electric charge is emitted a control signal is transmitted to the CPU to which a response is required. An example of a response to the control signal would be:

i) verification of muscle twitch.

ii) change to higher flow-rate to dispense drug.

[0030] A further embodiment of the present invention is to have a first condition (specific exit-pressure value at a fixed-flow rate) and second condition (emitted current stimulation) requiring a response by the operator to set a third condition (positive/negative observation) to result in an output (instruction and warning signal).

[0031] Yet another embodiment of the present invention is a device that provides a means to advance the needle within the tissues at an advancement rate between 2 and 20mm/sec with constant flow of fluid at a defined flow-rate.

[0032] According to a still further embodiment, the present invention provides a method and apparatus for utilizing counter-head pressure when calculating the exit pressure. The counter-head pressure is related to the insertion rate of the needle. Therefore, the system includes a mechanism for controlling the insertion rate of the needle. In particular, the system may include markings on the needle and auditory or visual cues for prompting the appropriate insertion rate for the needle.

[0033] Additionally, another embodiment of the present invention provides a hand-piece to which a marked needle is connected that is designed to house a small display, such as an LED light or display screen that will provide a blink or visual instruction and/or speaker and/or beeps or

CLAIMS

What is claimed is:

1. An apparatus for administering fluid into an anatomic space, comprising:
   an injection system for controlling a flow of fluid from a fluid reservoir to a needle, wherein the needle is configured for subcutaneous insertion into a mammalian subject;
   a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously to detect the characteristic as the needle is inserted into the subject; and
   an electric nerve stimulation element for providing an electric nerve stimulation at or adjacent to a tip of the needle;
   wherein the electric nerve stimulation element provides electric nerve stimulation to a patient after the sensor detects a characteristic of the fluid pressure indicative of the fluid pressure exceeding an upper threshold.
2. The apparatus of claim 1 wherein the system includes an indicator operable to provide an audible, visual or tactile signal.
3. The apparatus of claim 2 wherein the indicator is operable to provide a signal when the fluid pressure exceeds the upper threshold.
4. The apparatus of claim 2 comprising an input element configured to provide a mechanism for an operator to input whether a clinically observable response was observed in response to the electric nerve stimulation.
5. The apparatus of claim 4 wherein the indicator is operable to provide a signal indicative of the needle being in an appropriate position for an injection, wherein the indicator is configured to provide the signal in response to a signal from the input element indicative of no clinically observable response being observed.
6. The apparatus of any of claims 1-5 wherein the injection system includes a fluid reservoir and an elongated flexible tube, wherein a first end of the flexible tube is connected with the fluid reservoir and a second end of the flexible tube is connected with the needle.
7. The apparatus of claim 6 wherein the sensor is located in-line between the fluid reservoir and the needle so that the sensor detects the fluid pressure in-line with the flow of fluid between the reservoir and the needle.
8. The apparatus of any of claims 1-7 wherein the injection system comprises a

microprocessor for controlling the rate of fluid flowing from the fluid reservoir.

9. A system for providing a peripheral nerve block to a patient, comprising:

a needle having a sharpened tip;

a fluid pump providing a flow of fluid to the needle, wherein the fluid pump comprises a microprocessor for controlling the flow of fluid to the needle;

a sensor for detecting the fluid pressure in the needle;

a conductive element for providing an electric nerve stimulation at the tip of the needle; and

an output element configured to provide a human perceptible signal wherein in response to a signal indicative of the fluid pressure exceeding an upper limit the output element provides an alert signal to alert the operator to discontinue insertion of the needle;

wherein the conductive element is configured to provide an electric nerve stimulation at or adjacent to the tip of the needle after the sensor detects a fluid pressure exceeding the upper limit.

10. The system of claim 9 comprising an input element configured to allow the operator to indicate whether a clinically observable response was observed in response to the electric nerve stimulation.
11. The system of claim 10 wherein the output element is configured to provide a second alert signal in response to a signal from the input element indicating that a response was observed in response to the electric nerve stimulation.
12. The system of claim 11 wherein the output element is configured to provide a third alert signal in response to a signal from the input element indicating that no response was observed in response to the electric nerve stimulation.
13. The system of any of claims 9-12 wherein the fluid reservoir comprises a syringe having a plunger and the injection system comprises a control mechanism for automatically advancing the plunger to expel fluid from the syringe.
14. The system of any of claims 9-13 wherein the sensor comprises a pressure transducer.
15. The system of claim 14 wherein the sensor detects fluid pressure and the pump controls the flow of fluid in response to the detected fluid pressure.