needle makes contact to bony vertebrae as one is attempting to find the correct trajectory to the epidural space. Any backward movement (retraction) of the needle along a path during the repositioning creates a drop in pressure in the fluid, which can result in a false-LOR further complicating the detection of a true-LOR.

[009] Various conditions can create a false-LOR. False-LORs can lead to many problems. For example, excess fluids can be indiscriminately injected while trying to determine the location of the epidural space. The additional fluid released into these tissues can further complicate the identification of epidural space. Additionally, if the doctor has difficulty discriminating between a false-LOR and a true-LOR, the Touhy needle may be moved beyond the boundary of the epidural space and inadvertently advanced into and through the dura of the spinal cord producing what is termed a wet-tap, which can have dangerous long-term consequences to the patient.

[0010] Therefore, it is desirable to provide a system that supplements or supplants the loss of resistance information to accurately guide a needle during insertion.

Summary of the invention

[0010a] According to a first aspect of the present invention, there is provided a needle-bearing apparatus for administering fluid into target location in a subject, comprising:

a fluid reservoir for storing fluid to be provided to a needle;

an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir;

a drive element configured to engage the ejection element to control displacement of the ejection element;

a controller operable to control the drive element to control the flow of fluid from the reservoir to the needle;

a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject;

a flexible conduit in fluid communication with the fluid reservoir and the sensor, wherein the conduit is substantially rigid radially;

a display including a first output section configured to display the fluid pressure at the needle as a function of time in a manner consistent with a guidance procedure;

wherein the controller is configured to periodically discontinue movement of the drive element and process data from the sensor to detect one or more characteristic indicative of a pulsatile waveform;

wherein the conduit, reservoir, ejection element and drive element are configured so that the fluid volume between the needle and the fluid reservoir is substantially constant so that the sensor is able to accurately detect the pulsatile waveform passing through residual fluid in the needle when movement of the drive element is discontinued;

wherein the controller is programmed to process data from the sensor to isolate data indicative of a pulsatile waveform;

wherein the display comprises a second output section configured to display the data indicative of a pulsatile waveform while the first section displays the fluid pressure data as a function of time in the first section.

[0010b] According to a second aspect of the present invention, there is provided an apparatus for administering fluid into target location in a subject, comprising:

a fluid reservoir for storing fluid to be provided to the needle;

an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir;

a drive element configured to engage the ejection element to control displacement of the ejection element;

a controller operable to control the drive element to control the flow of fluid from the reservoir to the needle;

a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject;

a flexible conduit in fluid communication with the fluid reservoir and the sensor;

a user interface comprising a display;

wherein the controller is programmed to display data on the user interface in a first format in which the fluid pressure sensed by the sensor is displayed as a function of time;

wherein the controller is programmed to process data from the sensor to isolate data indicative of a pulsatile waveform and wherein the controller is programmed to display the processed data on the user interface separate from the first format.

[0010c] According to a third aspect of the present invention, there is provided an apparatus for administering fluid into target location in a subject, comprising:

a fluid reservoir for storing fluid to be provided to a needle;

an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir;

a drive element configured to engage the ejection element to control displacement of the ejection element;

a controller operable to control the drive element to control the flow of fluid from the reservoir to the needle;

a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject;

a flexible conduit in fluid communication with the fluid reservoir and the sensor;

an operator interface comprising a display;

wherein the controller is programmed to analyze data from the sensor to detect one or more characteristics indicative of a loss of resistance;

wherein in response to the controller detecting the one or more characteristics the controller is programmed to discontinue movement of the drive element and process data from the sensor to isolate data indicative of a pulsatile waveform;

and wherein the controller is programmed to display the processed data on the operator interface separate from the first format.

[0010d] According to a fourth aspect of the present invention, there is provided a needle/catheter-bearing apparatus for administering fluid into target location in a patient, comprising:

a manual syringe having fluid reservoir deposed therein;

a hollow-bore structure in fluid communication with the fluid reservoir of the manual syringe, the hollow-bore structure including one or both of a needle and/or a catheter;

a pressure sensor operably connected to the hollow-bore structure for detecting a characteristic indicative of the fluid pressure in the hollow-bore structure, wherein the sensor is configured to continuously detect the characteristic as the hollow-bore structure is inserted into the patient;

a controller operable to processes data from the sensor to detect one or more characteristic indicative of a pulsatile waveform, the controller configured to provide a verification signal that the hollow-bore structure is properly placed adjacent a target tissue upon receipt of a signal indicative of a pulsatile waveform at the hollow-bore structure; and

a display including a first output section configured to display a graph of the fluid pressure at the hollow-bore structure as a function of time and including a second output section configured to display a graph of the signal indicative of a pulsatile waveform while the first section displays the fluid pressure data as a function of time in the first section.

[0011] There is provided a method and apparatus or device that enables practitioners to more easily perform the identification of anatomical target regions such as the epidural space.

[0012] There is provided a novel system for guiding a needle to an anatomical target region. The system provides a software logic and apparatus that can simplify discrimination between a false-LOR and true-LOR when performing these operations, such as detection of the epidural space, thereby improving the reliability and safety of such injections.

[0013] There is provided a needle bearing apparatus for administering fluid into an anatomic space of a mammalian subject. The apparatus includes a fluid reservoir for storing fluid to be provided to the needle, an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir and a drive element configured to engage the ejection element to control displacement of the ejection element. A controller is provided for controlling the drive

element to control the flow of fluid from the reservoir to the needle. Additionally, the apparatus includes a sensor for detecting a characteristic indicative of the fluid pressure in the needle. The sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject. A flexible conduit is in fluid communication with the fluid reservoir and the sensor; and the conduit is substantially rigid radially. The controller periodically discontinues movement of the drive element and processes data from the sensor to detect one or more characteristics indicative of a pulsatile waveform. Additionally, the conduit, reservoir, ejection element and drive element are configured so that the fluid volume between the needle and the fluid reservoir is substantially constant so that the sensor is able to accurately detect the pulsatile waveform passing through residual fluid in the needle when movement of the drive element is discontinued. Optionally, the fluid reservoir may be a syringe barrel. Additionally, the ejection element may be slidably displaceable within the fluid reservoir.

[0014] There is provided a controller configured to analyze the data from the sensor to detect one or more characteristics indicative of a loss of resistance.

[0015] There is provided a system in which in response to detecting one or more characteristics, the controller discontinues movement of the drive element and processes data from the sensor to detect one or more characteristics indicative of a pulsatile waveform. Optionally, the controller may be configured to provide a verification signal that the needle is properly placed adjacent a target tissue upon receipt of a signal indicative of a loss of resistance and upon receipt of a signal indicative of the presence of a pulsatile waveform at the needle.

[0016] There is provided a display including a first output section configured to display the fluid pressure at the needle as a function of time in a manner consistent with a loss of resistance guidance procedure. Additionally, the controller may be configured to process data from the sensor to isolate data indicative of a pulsatile waveform. The display may comprise a second output section configured to display the data indicative of a pulsatile waveform while the first section displays the fluid pressure data as a function of time in the first section.

[0017] There is provided a method for locating a target region which is situated in a body of a subject with a needle in fluid communication with a reservoir. The method includes the steps of providing a reservoir containing injection fluid, tubing in communication at one end with the reservoir and connected at the other end to the needle to be inserted into the body of the subject and the step of acquiring data about a resistance measurement of the injection fluid when the fluid is pumped into the body of the subject through the needle. The method further includes the steps of advancing the needle into the patient. Additionally, the method may include the step of pumping injection fluid into the patient during the step of advancing the needle. Still further, the method may include the step of intermittently discontinuing the step of advancing the needle and the step of pumping injection fluid. The method may also include the step of acquiring data regarding the fluid pressure in the needle during the step of intermittently discontinuing and processing the data acquired during the step of intermittently discontinuing to detect one or more characteristics indicative of a pulsatile waveform at the needle.

[0018] There is disclosed re-starting the steps of advancing the needle and pumping injection fluid after the step of intermittently discontinuing.

[0019] There is provided the step of processing the data regarding fluid pressure in the needle by removing noise related to the flow of fluid when the fluid is pumped into the body. The pump may be operable to pump fluid during the step of pumping injection fluid and the step of removing noise may include the steps of running the pump prior to inserting the needle into the body of the subject and acquiring data related to noise during the step of running the pump. Further still, the step of removing noise may comprise modifying the data regarding fluid pressure in response to the data acquired related to noise.

[0020] There is provided a method including the step of selectively varying an amplitude range for processed fluid pressure data to attempt to identify a pulsatile waveform.

[0021] There is provided a method for inserting a needle into a patient. The method includes the step of performing a loss of resistance procedure to attempt to place a needle at a target location in the patient, wherein the step of performing a loss of resistance procedure comprises the steps of:
inserting the needle into the patient, injecting fluid through the needle during the step of inserting, detecting the fluid pressure at the needle during the step of injecting, and guiding the needle in response to the step of detecting the fluid pressure. The presence of a pulsatile waveform at the needle is detected, which may include the steps of detecting the fluid pressure at the needle when the needle is substantially stationary in the patient and injecting a bolus of medication into the patient after the step of performing a loss of resistance procedure indicates that the needle is at the target location and after the step of detecting the presence of a pulsatile wave indicates the presence of a pulsatile waveform.
[0022] Optionally, the method may include the step of intermittently switching between the step of performing a loss of resistance procedure and the step of detecting the presence of a pulsatile waveform. Additionally, the step of injecting fluid comprises electronically controlling a drive unit to dispense fluid from a fluid reservoir. Further, the step of injecting comprises electronically controlling the drive unit in response to the step of detecting the fluid pressure.
[0023] There is provided an apparatus for locating a target region which is an anatomic space situated in a body of a subject. The apparatus includes a reservoir for receiving an injection fluid, a needle in fluid communication with the reservoir, and a sensor operable to detect a characteristic indicative of the fluid pressure in the needle. A pump is configured to pump fluid to the needle from the reservoir and a controller is operable to process data from the sensor regarding the fluid pressure in the needle. The controller is configured to process the data from the sensor when the needle is stationary to identify a pulsatile waveform. Additionally, the controller is configured to provide signals to guide insertion of the needle wherein the signals are provided in response to the data from the sensor. Further, wherein the

Claims

1. A needle-bearing apparatus for administering fluid into target location in a subject, comprising:

a fluid reservoir for storing fluid to be provided to a needle;

an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir;

a drive element configured to engage the ejection element to control displacement of the ejection element;

a controller operable to control the drive element to control the flow of fluid from the reservoir to the needle;

a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject;

a flexible conduit in fluid communication with the fluid reservoir and the sensor, wherein the conduit is substantially rigid radially;

a display including a first output section configured to display the fluid pressure at the needle as a function of time in a manner consistent with a guidance procedure;

wherein the controller is configured to periodically discontinue movement of the drive element and process data from the sensor to detect one or more characteristic indicative of a pulsatile waveform;

wherein the conduit, reservoir, ejection element and drive element are configured so that the fluid volume between the needle and the fluid reservoir is substantially constant so that the sensor is able to accurately detect the pulsatile waveform passing through residual fluid in the needle when movement of the drive element is discontinued;

wherein the controller is programmed to process data from the sensor to isolate data indicative of a pulsatile waveform;

wherein the display comprises a second output section configured to display the data indicative of a pulsatile waveform while the first section displays the fluid pressure data as a function of time in the first section.

2. The needle-bearing apparatus of claim 1 wherein the fluid reservoir is a syringe barrel.

3. The needle-bearing apparatus of claim 1 wherein the ejection element is slidably displaceable within the fluid reservoir.

4. The needle-bearing apparatus of claim 1 wherein the controller is configured to analyze the data from the sensor to detect one or more characteristics indicative of a loss of resistance.

5. The needle-bearing apparatus of claim 4 wherein in response to the controller detecting the one or more characteristics the controller is configured to discontinue movement of the drive element and process data from the sensor to detect one or more characteristic indicative of a pulsatile waveform.

6. The needle-bearing apparatus of claim 5 wherein the controller is configured to provide a verification signal that the needle is properly placed adjacent a target tissue upon receipt of a signal indicative of a loss of resistance and upon receipt of a signal indicative of the presence of a pulsatile waveform at the needle.

7. The needle-bearing apparatus of claim 1 comprising a display including a first output section configured to display the fluid pressure at the needle as a function of time in a manner consistent with a loss of resistance guidance procedure.

8. The needle-bearing apparatus of claim 7 wherein the controller is configured to process data from the sensor to isolate data indicative of a pulsatile waveform,

wherein the display comprises a second output section configured to display the data indicative of a pulsatile waveform while the first section displays the fluid pressure data as a function of time in the first section.

9. The needle-bearing apparatus of claim 1 wherein the controller is configured to provide signals to guide insertion of the conduit wherein the signals are provided in response to the data from the sensor.

10. The needle-bearing apparatus of claim 1 wherein the system comprises an input mechanism for selectively varying an amplitude range for the processed data to attempt to identify a pulsatile waveform.

11. The needle-bearing apparatus of claim 1 wherein the conduit is a hollow needle having a sharpened tip.

12. The needle-bearing apparatus of claim 1 wherein the conduit is a catheter form a fluid-tight connection with the sensor.

13. An apparatus for administering fluid into target location in a subject, comprising:

a fluid reservoir for storing fluid to be provided to the needle;

an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir;

a drive element configured to engage the ejection element to control displacement of the ejection element;

a controller operable to control the drive element to control the flow of fluid from the reservoir to the needle;

a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject;

a flexible conduit in fluid communication with the fluid reservoir and the sensor;

a user interface comprising a display;

wherein the controller is programmed to display data on the user interface in a first format in which the fluid pressure sensed by the sensor is displayed as a function of time;

wherein the controller is programmed to process data from the sensor to isolate data indicative of a pulsatile waveform and wherein the controller is programmed to display the processed data on the user interface separate from the first format.

14. The apparatus of claim 13 comprising an input mechanism for selectively varying an amplitude range for the processed data to attempt to identify a pulsatile waveform.

15. An apparatus for administering fluid into target location in a subject, comprising:

a fluid reservoir for storing fluid to be provided to a needle;

an ejection element displaceable relative to the fluid reservoir to expel fluid from the reservoir;

a drive element configured to engage the ejection element to control displacement of the ejection element;

a controller operable to control the drive element to control the flow of fluid from the reservoir to the needle;

a sensor for detecting a characteristic indicative of the fluid pressure in the needle, wherein the sensor is configured to continuously detect the characteristic as the needle-bearing apparatus is inserted into the subject;

a flexible conduit in fluid communication with the fluid reservoir and the sensor;

an operator interface comprising a display;

wherein the controller is programmed to analyze data from the sensor to detect one or more characteristics indicative of a loss of resistance;

wherein in response to the controller detecting the one or more characteristics the controller is programmed to discontinue movement of the drive element and process data from the sensor to isolate data indicative of a pulsatile waveform;

and wherein the controller is programmed to display the processed data on the operator interface separate from the first format.

16. The apparatus of claim 15 wherein the controller is configured to provide a verification signal that the needle is properly placed adjacent a target tissue upon receipt of a signal indicative of a loss of resistance and upon receipt of a signal indicative of the presence of a pulsatile waveform at the needle.

17. A needle/catheter-bearing apparatus for administering fluid into target location in a patient, comprising:

a manual syringe having fluid reservoir deposed therein;

a hollow-bore structure in fluid communication with the fluid reservoir of the manual syringe, the hollow-bore structure including one or both of a needle and/or a catheter;

a pressure sensor operably connected to the hollow-bore structure for detecting a characteristic indicative of the fluid pressure in the hollow-bore structure, wherein the sensor is configured to continuously detect the characteristic as the hollow-bore structure is inserted into the patient;

a controller operable to processes data from the sensor to detect one or more characteristic indicative of a pulsatile waveform, the controller configured to provide a verification signal that the hollow-bore structure is properly placed adjacent a target tissue upon receipt of a signal indicative of a pulsatile waveform at the hollow-bore structure; and

a display including a first output section configured to display a graph of the fluid pressure at the hollow-bore structure as a function of time and including a second output section configured to display a graph of the signal indicative of a pulsatile waveform while the first section displays the fluid pressure data as a function of time in the first section.

18. The apparatus of claim 17, wherein the controller is configured to identify proper placement of the hollow-bore structure relative to a target tissue using a first search criterion and to identify the proper placement of the hollow-bore structure relative to the target tissue using a second search criterion, at least one of the first and second criteria being receipt of a signal indicative of a pulsatile waveform at the hollow-bore structure.

19. The apparatus of claim 17, wherein the pressure sensor is an in-line fluid pressure sensor.

20. The apparatus of claim 17, wherein the controller is operable to generate a visual and/or audible alarm in response to the characteristic indicative of the fluid pressure exceeding a selected threshold.

21. The apparatus of claim 17, wherein the controller is operable to isolate the data from the sensor that is representative of the pulsatile waveform.

22. The apparatus of claim 17, wherein the controller includes a self-centering filter to maintain the signal indicative of a pulsatile waveform at the center of the graph thereof.