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 a 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, fluid reservoir, ejection element and drive element are configured so that a 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;

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

a sensor for detecting a characteristic indicative of a 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;

and 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 fluid 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 fluid reservoir to the needle;

a sensor for detecting a characteristic indicative of a 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 a 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 a 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 process 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 output section displays the fluid pressure data as a function of time in the first output 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

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 a 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, fluid reservoir, ejection element and drive element are configured so that a 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;

and wherein the display comprises a second output section configured to display the data indicative of a pulsatile waveform while the first output section

displays the fluid pressure data as a function of time in the first output 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, wherein the guidance procedure is a loss of resistance guidance procedure.

8. 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.

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

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

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

12. 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 fluid 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 fluid reservoir to the needle;

a sensor for detecting a characteristic indicative of a 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;

and 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.

13. The apparatus of claim 12 comprising an input mechanism for selectively varying an amplitude range for the processed data to attempt to identify a pulsatile waveform.

14. 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 fluid 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 fluid reservoir to the needle;

a sensor for detecting a characteristic indicative of a 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 a first format.

15. The apparatus of claim 14 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.

16. 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 a 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 process 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 output section displays the fluid pressure data as a function of time in the first output section.

17. The apparatus of claim 16, 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.

18. The apparatus of claim 16, wherein the pressure sensor is an in-line fluid pressure sensor.

19. The apparatus of claim 16, 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.

20. The apparatus of claim 16, wherein the controller is operable to isolate the data from the sensor that is representative of the pulsatile waveform.

21. The apparatus of claim 16, wherein the controller includes a self-centering filter to maintain the signal indicative of a pulsatile waveform at the center of the graph thereof.