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(54) **NEEDLE ASSEMBLY WITH TEMPERATURE MEASUREMENT DEVICE**

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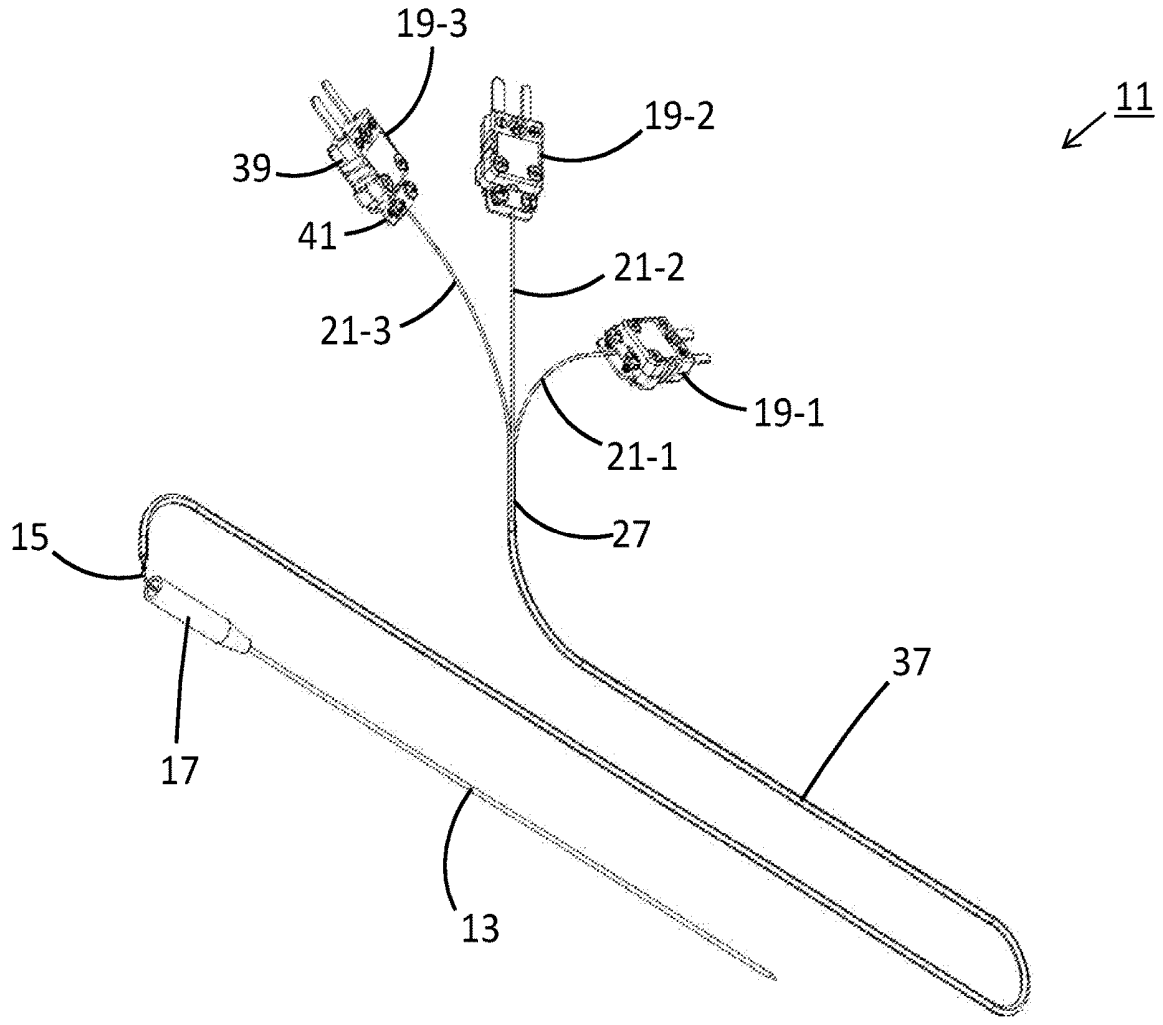
(57) **ABSTRACT**

A needle assembly includes an elongated, hollow, hypodermic needle and a temperature measurement device at least partially disposed within the needle. The temperature measurement device comprises a plurality of parallel thermal sensors collectively retained in a fixed relationship within a common dielectric sheath. Each thermal sensor includes a temperature-sensing region which is capable of generating a voltage in proportion to the sensed temperature. The temperature-sensing regions for the plurality of thermal sensors are arranged in an offset relationship within the hypodermic needle, with each temperature-sensing region located at a different position relative to the sharpened tip of the hypodermic needle. Accordingly, in use, needle assembly is designed to compile temperature measurements at multiple locations along the length of the needle, thereby yielding a comprehensive and accurate temperature profile of the body into which the hypodermic needle is inserted.



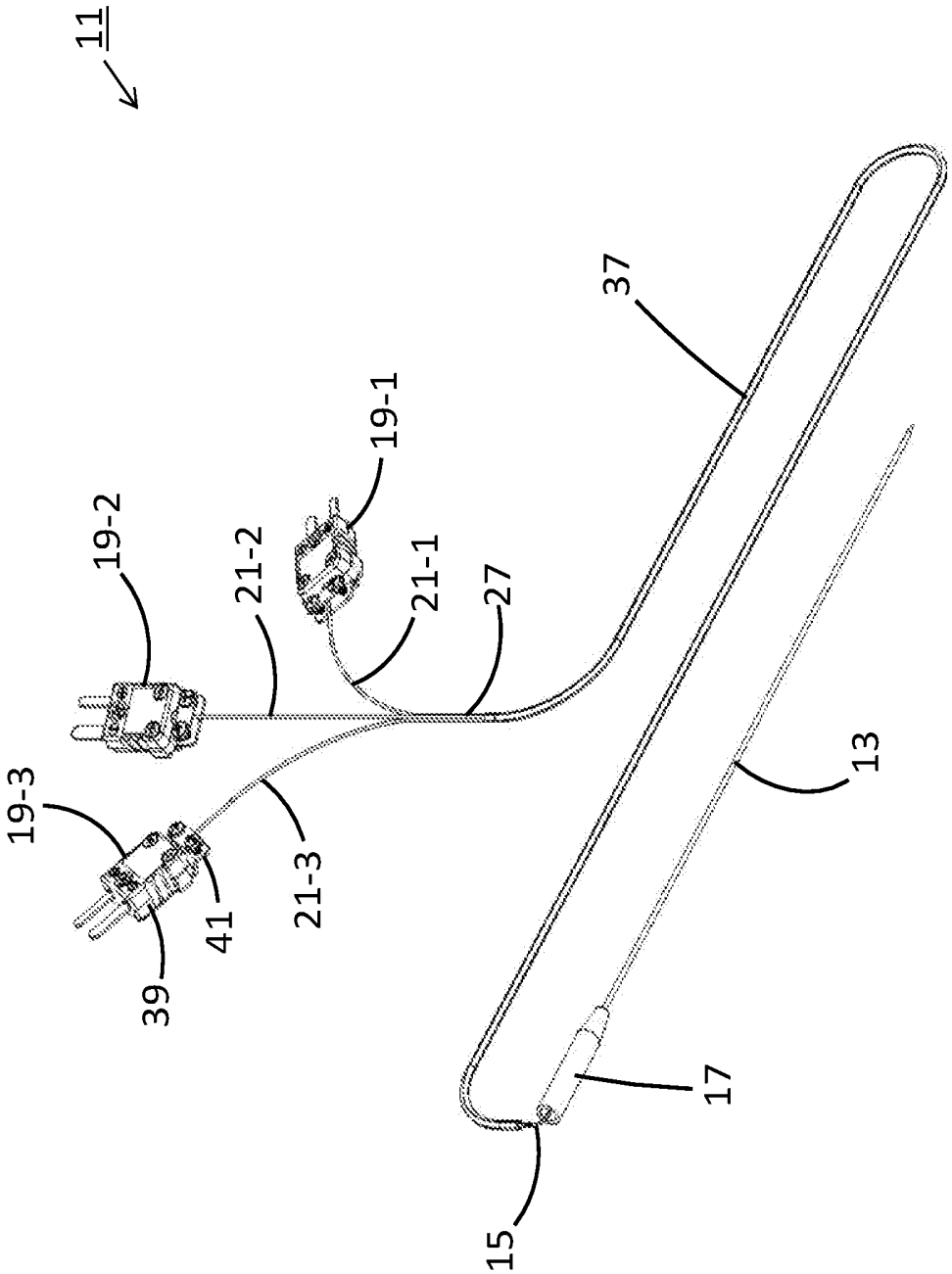


Fig. 1(a)

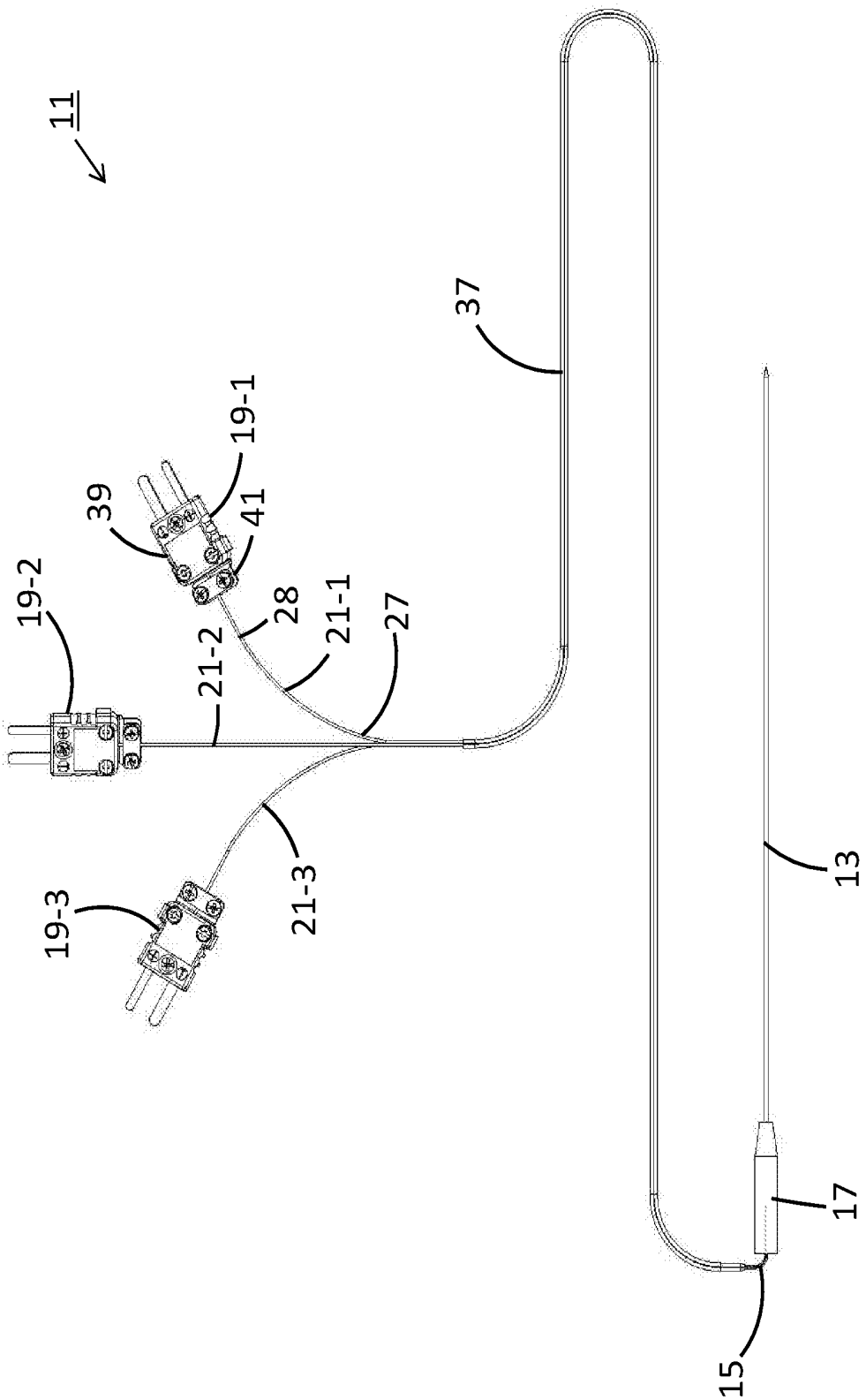


Fig. 1(b)

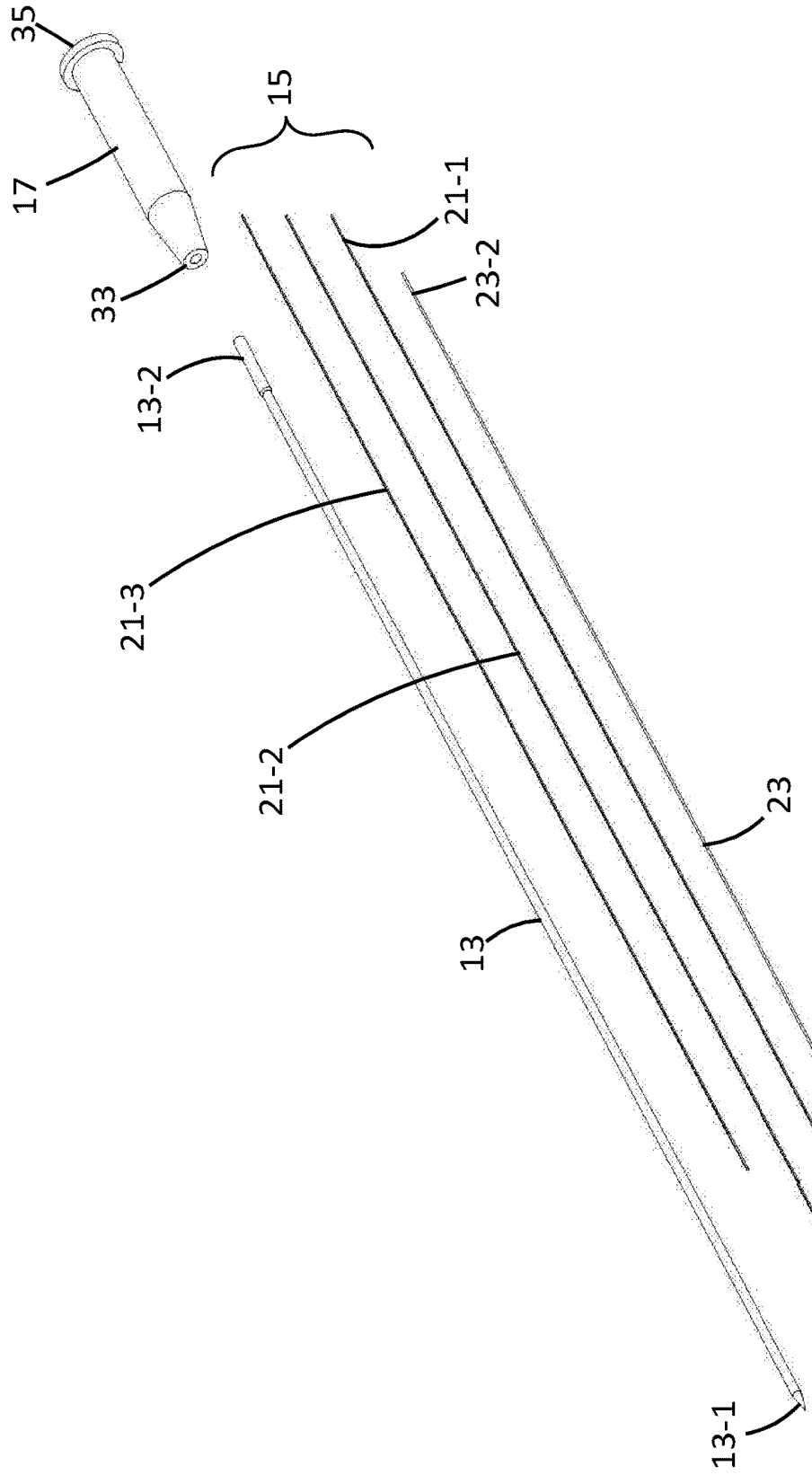


Fig. 2

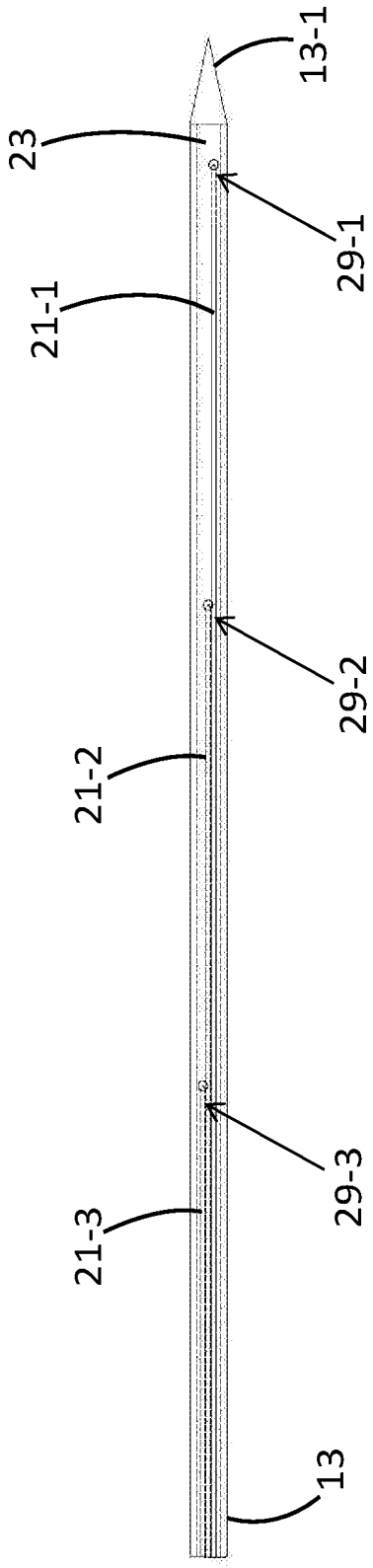


Fig. 3

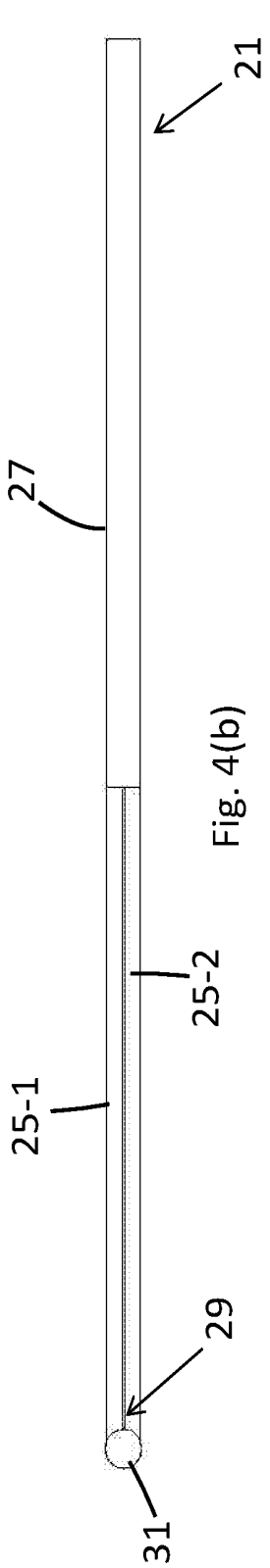


Fig. 4(b)

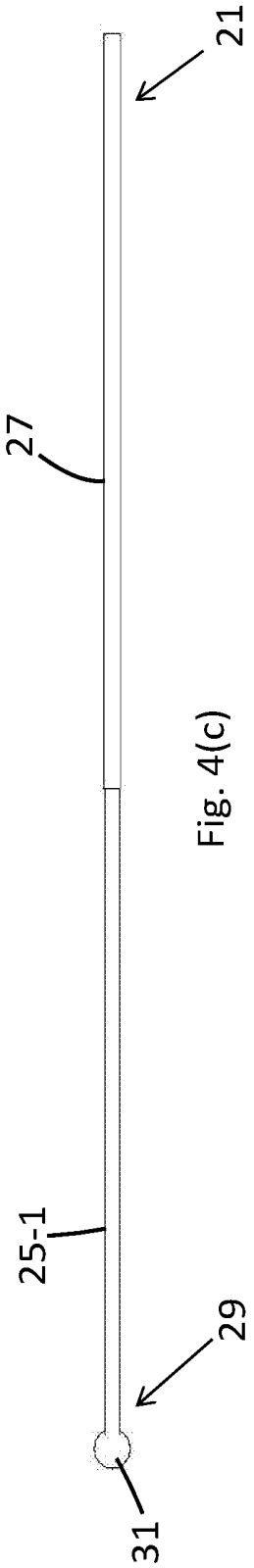


Fig. 4(c)

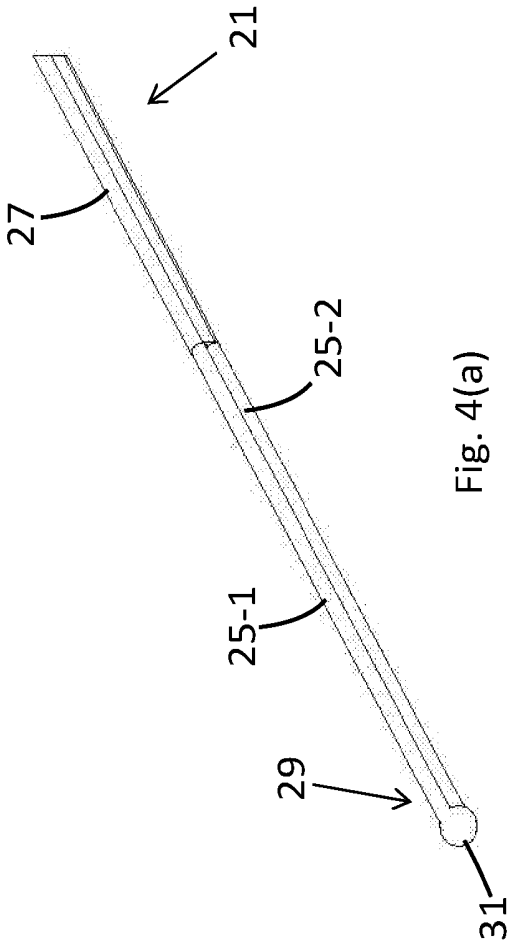


Fig. 4(a)

NEEDLE ASSEMBLY WITH TEMPERATURE MEASUREMENT DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Patent Application No. 62/696,521, which was filed on Jul. 11, 2018 in the names of Michael Pike et al., the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to hypodermic needles and, more particularly, to hypodermic needles with temperature measurement capabilities.

BACKGROUND OF THE INVENTION

[0003] Hypodermic needles are well known in the art and are used in a wide variety of applications including, but not limited to, medical research, surgery and drug delivery. A hypodermic needle, or probe, is typically constructed a thin, hollow tube with a sharpened tip at one end to facilitate insertion into the body.

[0004] In certain medical applications, it has been found that the monitoring of temperature within the surrounding insertion area is essential to the effectiveness of a particular procedure. For this reason, it is known in the art for hypodermic needles to be incorporated with a single temperature measurement device, such as a thermocouple, to monitor the temperature of the immediate needle-insertion region.

[0005] Although well known in the art, hypodermic needles with temperature measurement capabilities have been found to suffer from a notable drawback. Specifically, the temperature data accumulated by conventional hypodermic needles is limited to the insertion area surrounding the temperature sensor and is therefore largely dependent upon on the specific depth of insertion of the needle into the body. Because certain medical procedures are reliant on a high degree of temperature measurement accuracy, the imprecise collection of temperature data can have adverse consequences.

[0006] To remedy this shortcoming, multiple hypodermic needles, each with temperature measurement capabilities, are often concurrently disposed at various depths within a body to compile an array of temperature data that, in turn, is used to provide a more comprehensive temperature profile of the body into which the needles are inserted. This expansion of data is therefore utilized to provide greater temperature measurement accuracy, which often results in the greater overall success of the underlying procedure.

[0007] Although desirable for the reasons set forth above, it is to be understood that the use of multiple temperature-measuring needles introduces a number of notable drawbacks.

[0008] As a first drawback, the use of multiple temperature-measuring needles renders certain medical procedures more complex, time consuming and inefficient to perform.

[0009] As a second drawback, the use of multiple, separate, temperature-measuring needles requires acute, manual precision in the relative depth that each needle is inserted. Due to the unknown distance between adjacent temperature sensors, any imprecision in needle insertion depth introduces potential errors in the resultant temperature profile.

[0010] As a third drawback, the use of multiple, separate, temperature-measuring needles often creates considerable variance in the response time between the various temperature sensors (e.g. due to sizable discrepancies in signal travel length). Because certain medical procedures are reliant upon immediate temperature measurements, any delay in response time can potentially compromise procedure effectiveness.

[0011] As a fourth drawback, the use of multiple temperature-measuring needles directly increases the amount of disruption, and any resultant pain, to the region of the body into which they are insertion. For this reason, the amount of probing into a body is typically minimized to the greatest extent possible.

SUMMARY OF THE INVENTION

[0012] It is an object of the present invention to provide a new and improved needle assembly.

[0013] It is another object of the present invention to provide a new and improved needle assembly with temperature measurement capabilities.

[0014] It is yet another object of the present invention to provide a needle assembly of the type as described above which provides a comprehensive and highly accurate temperature profile of the body into which it is inserted.

[0015] It is still another object of the present invention to provide a needle assembly of the type as described above which has a limited number of parts, is inexpensive to manufacture and is easy to use.

[0016] Accordingly, as one feature of the present invention, there is provided a needle assembly comprising (a) an elongated, hollow needle having a first end and a second end, and (b) a temperature measurement device at least partially disposed within the needle, the temperature measurement device comprising a plurality of thermal sensors, each thermal sensor comprising a temperature-sensing region, (c) wherein the temperature-sensing regions for the plurality of thermal sensors are located within the hollow needle at different positions relative to the first end.

[0017] Various other features and advantages will appear from the description to follow. In the description, reference is made to the accompanying drawings which form a part thereof, and in which is shown by way of illustration, an embodiment for practicing the invention. The embodiment will be described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the invention. The following detailed description is therefore, not to be taken in a limiting sense, and the scope of the present invention is best defined by the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] In the drawings, wherein like reference numerals represent like parts:

[0019] FIGS. **1**(*a*) and **1**(*b*) are top perspective and top plan views, respectively, of a needle assembly constructed according to the teachings of the present invention;

[0020] FIG. **2** is an exploded perspective view of selected components of the needle assembly shown in FIG. **1**(*a*);

[0021] FIG. **3** is an enlarged, fragmentary, top view of the needle assembly shown in FIG. **1**(*b*), with selected internal components of the needle assembly being shown in dashed form to illustrate the configuration upon assembly; and

[0022] FIGS. **4**(*a*)-(*c*) are fragmentary, front perspective, front plan and top plan views, respectively, of one of the temperature sensors shown in FIG. **2**.

DETAILED DESCRIPTION OF THE INVENTION

Needle Assembly **11**

[0023] Referring now to FIGS. **1**(*a*) and **1**(*b*), there is shown a needle assembly constructed according to the teachings of the present invention, the needle assembly being identified generally by reference numeral **11**. As will be explained in detail below, needle assembly **11** is designed to measure temperatures at multiple locations along its length, thereby rendering needle assembly **11** particularly useful in connection with certain medical applications.

[0024] Although needle assembly **11** is described herein principally for use in medical applications, such as in surgical procedures, it is to be understood that needle assembly **11** need not be limited to any particular use. Rather, it is to be understood that the multi-sensor construction of needle assembly **11** could be modified, as needed, for implementation in a wide variety of different applications without departing from the spirit of the present invention.

[0025] As can be seen, needle assembly **11** comprises (i) a hypodermic needle **13**, (ii) a multi-sensor, temperature measurement device **15** incorporated into hypodermic needle **13**, (iii) a needle hub **17** mounted onto hypodermic needle **13** through which electrical leads for device **15** externally extend, and (iv) a plurality of connectors **19-1** thru **19-3** mounted on the electrical leads for device **15** in electrical communication therewith.

[0026] As seen most clearly in FIG. **2**, hypodermic needle **13** is constructed as an elongated, thin, hollow tube formed of a suitable material, such as stainless steel. Needle **13** is preferably provided with a sharpened tip **13-1** at one end to facilitate insertion into a body and an opened port **13-2** at its opposite end to provide access into its longitudinal, interior channel.

[0027] As defined herein, needle **13** represents any conventional hollowed needle, or probe, which is suitably dimensioned to axially receive temperature measurement device **15** therewithin. For example, needle **13** may be of the type commonly used in connection with various medical procedures and related applications.

[0028] A multi-sensor, temperature measurement device **15** is incorporated into hollow needle **13**, as will be explained further in detail below. The multi-sensor construction of device **15**, as well as its integration into hypodermic needle **13**, affords needle assembly **11** with the ability to compile multiple, concurrent temperature readings at various locations along its length, which serves as a principal novel feature of the present invention. As a result, needle assembly **11** is uniquely capable of providing a comprehensive and accurate temperature profile of the body into which it is inserted.

[0029] Temperature measurement device **15** comprises (i) a plurality of independent temperature sensors **21-1**, **21-2** and **21-3**, and (ii) a tubular plastic sheath **23** into which sensors **21** are fittingly, coaxially disposed. As part of the assembly process, which will be described further below, sheath **23**, with sensors **21** disposed therein, is inserted into hollow needle **13** to render needle assembly **11** a unitary device, as seen most clearly in FIG. **3**.

[0030] Referring now to FIGS. **4**(*a*)-(*c*), each temperature, or thermal, sensor **21** is represented herein as comprising a first and second sensor wires **25-1** and **25-2** of dissimilar metals which are dielectrically isolated, or separated, through the application of a layer of insulation **27** over the majority of their lengths.

[0031] In order to minimize space requirements within needle **13**, each sensor wire **25** is applied with insulation **27** through a multi-pass bath dipping process to achieve insulation thickness in the order of tens of thousandths of an inch. The provision of insulation **27** is critical to prevent the formation of electrical junctions along the intermediary region of sensor **21**, thereby improving its overall measurement robustness.

[0032] At the external, or distal, end **28** of insulation **27**, sensor wires **25** are exposed and, in turn, electrically coupled together with a corresponding connector **19**, as shown in FIG. **1**(*b*). Furthermore, as shown in FIGS. **4**(*a*)-(c), the exposed (i.e. non-insulated) section of sensor wires **25** that is located within needle **13** is, in turn, joined together at its free ends to form a primary temperature-sensing junction, or region, **29**.

[0033] In the present embodiment, a weld bead **31** is shown connecting sensor wires **25** together to form temperature-sensing junction **29**. However, alternative means for coupling sensor wires **25** to form junction **29** could be achieved (e.g. by simply twisting wire leads together) without departing from the spirit of the present invention. Preferably, once a temperature-sensing junction **29** is formed, a thin layer of UV cured adhesive (not shown) is applied to and coats junction **29** to ensure adequate structural integrity.

[0034] As can be appreciated, junction **29** serves as the primary temperature-sensing region for each sensor **21**. More specifically, in accordance with the well-known thermoelectric effect, also commonly referred to as the "Seebeck Effect," the dissimilar alloys for wires **25** form an electrical voltage in proportion to the temperature differential on each side of temperature-sensing junction **29** (i.e. the temperature within the immediate region of the needle insertion body as compared to the temperature within the thermowell defined within the interior of sheath **23**).

[0035] It should be noted that each temperature sensor **21** is not limited to the specific, above-described, thermocouple-type construction. Rather, it is to be understood that temperature sensor **21** represents any thermoelectric device that is commonly utilized to measure temperature, including thermoresistors, resistance temperature detectors (RTD) and the like, without departing from the spirit of the present invention.

[0036] Referring back to FIG. **3**, the three temperature sensors **21-1**, **21-2** and **21-3** are arranged in parallel, with temperature-sensing junctions **29-1**, **29-2** and **29-3**, respectively, offset or staggered at equidistantly spaced locations within the length of needle **13**. In this manner, temperature data can be collected at various points along the length of needle **13**, which is highly desirable.

[0037] To fix the relative position of temperature-sensing junctions **29**, an ultraviolet (UV) cured adhesive is preferably applied between insulation **27** of adjacent (i.e. succes-

sive) temperature sensors **21**. In this manner, the adhesive permanently secures together the plurality of individual sensors **21**, thereby enabling each successive temperature-sensing junction **29** to be retained within needle **13** at a fixed, specified distance from needle tip **13-1**, thereby providing greater temperature measurement accuracy.

[0038] It should be noted that needle assembly **11** is not limited to the particular number and arrangement of temperature sensors **21** shown herein. Rather, it is to be understood that the number and relative position of sensors **21** within needle **13** could be modified, as needed, without departing from the spirit of the present invention.

[0039] As seen in FIG. **2**, sheath **23** is constructed as an elongated, thin, hollow tube formed of a suitable dielectric material, such as a polymer material. Sheath **23** is preferably provided with an enclosed first end **23-1**, which is dimensioned to align fittingly within tip **13-1** of hypodermic needle, and an open second end **23-2**. Accordingly, once temperature sensors **21** are secured together with adhesive, thereby fixing the relative locations of temperature-sensing junctions **29**, the resultant assembly is axially inserted into the interior channel of sheath **23**. Thereafter, additional UV-cured adhesive is applied to open end **23-2** of sheath **23** to ensure that sensors **21** and, in particular, temperature-sensing junctions **29** do not shift within sheath **23** (as well as needle **13**) during subsequent use and handling of needle assembly **11**. In this manner, dielectric sheath **23** not only facilitates construction of needle assembly **11** but also serves as a protective layer that prevents accidental grounding of the individual thermal sensors **21** via needle **13**.

[0040] Several dimensional factors, including the total number of temperature sensors **21**, the gage of each sensor wire **25**, the thickness of insulation **27** as well as the inner and outer diameters of sheath **23** and needle **13**, are preferably calculated in order to minimize the gap, or spacing, between temperature sensors **21** and sheath **23**, as well as between sheath **23** and needle **13**. Minimizing gaps not only reduces the overall cross-section of needle **13** but also improves the response time and overall measurement accuracy of thermal sensors **21**.

[0041] As seen in FIG. **2**, a needle hub **17** is preferably constructed as an enlarged, unitary, hollow tubular component formed of a rigid and durable material, such as plastic. Hub **17** comprises a reduced-diameter proximal section **33**, which is dimensioned to fittingly receive port **13-2** of hypodermic needle **13**, and an enlarged distal section **35** through which the electrical leads for thermal sensors **21** exit. Among other functions, needle hub **17** can be used to facilitate actuation of needle **13**.

Assembly of Needle Assembly **11**

[0042] The construction of needle assembly **11** as set forth above not only provides certain functional advantages (e.g. enhanced temperature profile capabilities) but also facilitates its assembly. Most notably, for ease of assembly and optimized performance, temperature-measurement device **15** is preferably assembled in its entirety prior to insertion into hypodermic needle **13**, thereby ensuring that construction specifications are accurately met.

[0043] In other words, as referenced above, temperature sensors **21** are arranged in parallel such that the plurality of temperature-sensing junctions **29** are offset, or staggered, at predefined locations. Then, to fix the relative position of temperature-sensing junctions **29**, a UV-cured adhesive is applied between insulation **27** of adjacent temperature sensors **21**. In this manner, the adhesive permanently secures together the plurality of individual sensors **21**.

[0044] In turn, the plurality of adhesively-bonded, thermal sensors **21** is inserted into the interior channel of sheath **23**. Thereafter, additional UV-cured adhesive is applied to open end **23-2** of sheath **23**. The entire pre-assembled sheath **23** (i.e. with sensors **21** mounted therein) is inserted through hub **17** and into needle **13**, which is initially separate from hub **17**.

[0045] The pre-assembled sheath **23** is advanced into needle **13** until temperature-sensing junction **29-1** is at the desired location from needle tip **13-1**. Due to the fixed relationship between sensors **21**, each successive temperature-sensing junction **29** is therefore properly disposed at its specified position relative to needle tip **13-1**.

[0046] With the pre-assembled sheath **23** disposed at its proper position within needle **13**, UV-cured adhesive is then applied to the open end **13-2** of needle **13** to prevent the resultant assembly from moving therewithin. In this capacity, the resultant assembly effectively forms a thermal well. If required, the outer diameter of needle **13** can then be reduced through a swaging operation.

[0047] With the exposed electrical leads of sensors **21** pulled taut, end **13-2** of needle **13** is fittingly inserted into proximal end **33** of hub **17**. Thereafter, the interior of hub **17** is preferably filled with UV-cured adhesive to encapsulate and further protect the insulated pair of wires **25** for each sensor **21**. As can be appreciated, the adhesive material utilized in the manufacture of needle assembly **11** is preferably selected to ensure proper sterilization and biological compatibility with the intended medical device application.

[0048] Referring back to FIGS. **1**(*a*) and (*b*), the majority of the exposed section of insulation **27** for sensors **21** is fed into a heat shrink tube **37** to further protect wires **25** from any accidental damage as well as to simplify, or manage, the arrangement of the plurality of individual sensor cables.

[0049] Finally, the exposed, or free, ends of lead wires **25** for sensors **21-1** thru **21-3** are inserted into the appropriate receptacles of designated electrical connectors **19-1** thru **19-3**, respectively. In this manner, each connector **19** is adapted for electrical coupling, either directly or indirectly, to a device capable of converting electrical voltage measurements into corresponding temperature data.

[0050] In the present embodiment, connector **19** is represented as comprising a male-type interface, or plug, **39** and a corresponding retention cable clamp **41**. However, it is to be understood that connector **19** is not limited to the aforementioned construction and could be replaced with other known types of electrical connectors (e.g. female-type connectors) without departing from the spirit of the present invention.

[0051] The invention described in detail above is intended to be merely exemplary and those skilled in the art shall be able to make numerous variations and modifications to it without departing from the spirit of the present invention. All such variations and modifications are intended to be within the scope of the present invention as defined in the appended claims.

What is claimed is:

1. A needle assembly, comprising:

(a) an elongated, hollow needle having a first end and a second end; and

(b) a temperature measurement device at least partially disposed within the needle, the temperature measurement device comprising a plurality of thermal sensors, each thermal sensor comprising a temperature-sensing region;

(c) wherein the temperature-sensing regions for the plurality of thermal sensors are located within the hollow needle at different positions relative to the first end.

2. The needle assembly as claimed in claim **1** further comprising a tubular sheath into which the plurality of thermal sensors is coaxially disposed.

3. The needle assembly as claimed in claim **2** wherein the temperature-sensing regions for the plurality of thermal sensors is located within the tubular sheath.

4. The needle assembly as claimed in claim **3** wherein the tubular sheath is constructed of a dielectric material.

5. The needle assembly as claimed in claim **1** wherein the temperature-sensing regions for the plurality of thermal sensors are equidistantly spaced apart.

6. The needle assembly as claimed in claim **1** wherein the plurality of thermal sensors is arranged in parallel.

7. The needle assembly as claimed in claim **6** wherein the plurality of thermal sensors is secured together with an adhesive.

8. The needle assembly as claimed in claim **1** wherein each thermal sensor generates an electrical voltage in proportion to the temperature sensed within the temperature-sensing region.

9. The needle assembly as claimed in claim **8** wherein each thermal sensor comprises a pair of sensor wires of dissimilar metals.

10. The needle assembly as claimed in claim **9** wherein at least a portion of the pair of sensor wires is dielectrically separated by a layer of insulation.

11. The needle assembly as claimed in claim **10** wherein the pair of sensor wires for each thermal sensor is conductively coupled together to form the temperature-sensing region.

12. The needle assembly as claimed in claim **1** wherein the first end of the needle is in the form of a sharpened tip.

13. The needle assembly as claimed in claim **12** wherein the second end of the needle is in the form of an open port.

14. The needle assembly as claimed in claim **13** wherein the needle further includes a longitudinal, interior channel dimensioned to receive at least a portion of the temperature measurement device.

15. The needle assembly as claimed in claim **1** further comprising a plurality of electrical connectors, each of the plurality of electrical connectors being electrically coupled to one of the plurality of thermal sensors.

16. The needle assembly as claimed in claim **1** further comprising a needle hub mounted on the second end of the needle.

* * * * *

专利名称(译)	带有温度测量装置的针头组件		
公开(公告)号	US20200015750A1	公开(公告)日	2020-01-16
申请号	US16/508432	申请日	2019-07-11
发明人	PIKE, MICHAEL DWYER, HERB		
IPC分类号	A61B5/00 A61B5/01		
CPC分类号	A61B2562/0271 A61B5/6848 A61B2562/222 A61B2562/227 A61B5/01 A61B2562/043		
优先权	62/696521 2018-07-11 US		
外部链接	Espacenet USPTO		

摘要(译)

针头组件包括细长的中空皮下注射针头和至少部分地布置在该针头内的温度测量装置。 该温度测量装置包括多个平行的热传感器，其以固定的关系共同地保持在公共电介质护套内。 每个热传感器包括温度感测区域，该温度感测区域能够产生与感测到的温度成比例的电压。 用于多个热传感器的温度感测区域以偏移关系布置在皮下注射针内，其中每个温度感测区域相对于皮下注射针的尖锐尖端位于不同的位置。 因此，在使用中，针头组件被设计为汇编沿针头长度的多个位置处的温度测量值，从而产生皮下注射针头插入的身体的全面而准确的温度曲线。